

Pharmaceutical (Re)Capture

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Abstract:

This Article makes the case that pharmaceutical companies, along with other powerful corporate actors in the pharmaceutical industry, are in effect designing their own markets, often at the expense of, rather than in pursuit of, public health. The influence exerted by these corporate actors extends beyond traditional forms of regulatory capture, rising to what this Article refers to as pharmaceutical capture—a concept that encompasses the exercise of holistic and systemic control over the operation of pharmaceutical markets and their regulation.

After developing a framework for thinking about pharmaceutical capture, this Article uses the evolution of the opioid epidemic as a case study of capture at work. It argues that the patterns of corporate influence highlighted in the case study are not unique to opioids, but rather are structural features of U.S. pharmaceutical markets.

A popular political response to concerns about the power exerted by corporate actors in the pharmaceutical industry has been to pin the blame on government regulation as impeding the discipline of the “free market.” But pharmaceutical markets rely on government regulations to function, and this push for deregulation is in many cases simply an effort to substitute one governance structure for another more favorable to incumbent corporate interests. This Article concludes that it is not deregulation, but rather a redesign of regulation, that is needed to improve the public health impact of the pharmaceutical industry. Drawing lessons from pharmaceutical capture, it suggests guidelines for a regulatory recapture.

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INTRODUCTION

The United States is unique in its reliance on a market-based, “consumer”-driven approach to the delivery of health care—an approach that has continued to yield among the highest profits, the highest spending, and the poorest health outcomes of all high-income countries.¹ The United States is the only industrialized country without universal health coverage,² and one of the few industrialized countries without some kind of single-payer system, relying instead on a fragmented and incomplete mix of public and private insurance.³ Despite its limited coverage, the United States spends two or three times more the amount per capita on health care than most other industrialized countries, much of this paid by federal, state, and local governments.⁴ This high spending level correlates with high levels of profit. Biotech, generic, and major pharmaceutical companies rank among the top ten most profitable industries in the United States, competing with and even beating many industries within the financial sector, with profit margins in the 24% to 30% range.⁵ Profits have also boomed for the largest U.S. health

1 See, e.g., Roosa Tikkanen & Melinda K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?*, COMMONWEALTH FUND (Jan. 30, 2020), <https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019> (showing that the United States continues to spend more on health care as a share of the economy—nearly double that of the average OECD country—and perform worse on health care outcomes as compared to other developed economies); see also Amanda Holpuch, *Profits Over People, Costs Over Care: America’s Broken Healthcare Exposed by a Virus*, THE GUARDIAN (Apr. 16, 2020, 2:00 AM EDT), <https://www.theguardian.com/us-news/2020/apr/16/profit-over-people-cost-over-care-americas-broken-healthcare-exposed-by-virus> (“In the wealthiest country in the world, the Covid-19 pandemic has exposed the core of a healthcare system that is structurally incapable of dealing with the pandemic. . . . The pandemic crisis is being further exacerbated by the system’s devotion to profits over people.”). For an in-depth analysis of industry involvement in the U.S. health care system see, for example, ELISABETH ROSENTHAL, *AN AMERICAN SICKNESS* (2017) (exploring the myriad ways in which health care has been transformed into a business focused largely on profits, and how this focus has in turn transformed U.S. health care).

2 See, e.g., Analisa Merelli, *The Story of Why the U.S. Is the Only Rich Country Without Universal Healthcare*, QUARTZ (July 18, 2017), <https://qz.com/1022831/why-doesnt-the-united-states-have-universal-health-care>.

3 See, e.g., Luca Lorenzoni, Annalisa Belloni & Franco Sassi, *Health-Care Expenditure and Health Policy in the USA Versus Other High-Spending OECD Countries*, 384 LANCET 83 (2014), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)60571-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60571-7/fulltext); Alicia Adamczyk, *What Is Single-Payer Healthcare and Why is it So Popular?*, MONEY (Apr. 13, 2017), <https://money.com/what-is-single-payer-healthcare-system> (stating that the United States is one of the only countries in the developed world without a single-payer health care system); see also Elisabeth Rosenthal, *How an Industry Shifted from Protecting Patients to Seeking Profits*, STAN. MED. (2017), <https://stanmed.stanford.edu/2017spring/how-health-insurance-changed-from-protecting-patients-to-seeking-profit.html> (looking at the role that for-profit health insurance has played in shifting the focus from patients to profits).

4 See, e.g., Merelli, *supra* note 2.

5 See Liyan Chen, *The Most Profitable Industries in 2016*, FORBES (Dec. 21, 2015, 4:19 PM EST) <https://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016>.

insurance companies, with the top five earning \$4.5 billion dollars in net earnings in the first three months of 2017.⁶ Pharmaceutical company executives rank among the most highly compensated of any industry.⁷

While this high spending on health care has generated large profits, and may well have contributed to comparatively high rates of biomedical innovation, it has not produced better health outcomes.⁸ According to United Nations measures, the United States ranks 28th out of 188 countries in terms of health care outcomes.⁹ The Commonwealth Fund has ranked the U.S. health care system at the bottom of the eleven developed nations it analyzes.¹⁰ The U.S. system fares particularly poorly in measures of population health such as infant mortality, life expectancy, and mortality amenable to health care.¹¹ When compared to people in other advanced economies, Americans have the lowest average life expectancy and are more likely to die from preventable diseases or complications.¹² Overall, as these

6 See Bob Herman, *Profits Are Booming at Health Insurance Companies*, AXIOS (May 24, 2017), <https://www.axios.com/profits-are-booming-at-health-insurance-companies-1513302495-18f3710a-c0b4-4ce3-8b7f-894a755e6679.html>; *The Profitability of Health Insurance Companies*, COUNCIL ECON. ADVISORS (Mar. 2018), <https://trumpwhitehouse.archives.gov/wp-content/uploads/2018/03/The-Profitability-of-Health-Insurance-Companies.pdf>.

7 See, e.g., Eric Sagonowsky, *The Top 15 Highest-Paid Biopharma CEOs of 2019*, FIERCEPHARMA (June 1, 2020, 3:00 AM), <https://www.fiercepharma.com/special-report/top-15-highest-paid-biopharma-ceos-2019>; Elizabeth Whitman, *Healthcare and Pharma CEOs Paid More Than Top Execs in Any Other Industry, Analysis Finds*, INT'L BUS. TIMES, (May 25, 2016, 12:15 PM), <https://www.ibtimes.com/healthcare-pharma-ceos-paid-more-top-execs-any-other-industry-analysis-finds-2374013>.

8 See, e.g., Irene Papanicolas, Liana R. Woskie & Ashish K. Jha, *Healthcare Spending in the United States and Other High-Income Countries*, 319 JAMA 1024, 1025 (2018) (“In 2016, the United States spent nearly twice as much as 10 high-income countries on medical care and performed less well on many population health outcomes.”); David Squires & Chloe Anderson, *U.S. Health Care from a Global Perspective: Spending, Prices, and Health in 13 Countries*, COMMONWEALTH FUND (Oct. 8, 2015), <http://www.commonwealthfund.org/publications/issue-briefs/2015/oct/us-health-care-from-a-global-perspective> (arguing that higher spending is largely driven by greater use of medical technology and higher health care prices, and that despite spending more, the system covers fewer residents and produces relatively poor health outcomes).

9 See GBD 2015 SDG Collaborators, *Measuring the Health-Related Sustainable Development Goals in 188 Countries: A Baseline Analysis from the Global Burden of Disease Study 2015*, 388 LANCET 1813, 1838 (Sept. 21, 2016), [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(16\)31467-2.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31467-2.pdf).

10 See Eric C. Schneider et al., *Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care*, COMMONWEALTH FUND (2017), <https://interactives.commonwealthfund.org/2017/july/mirror-mirror> (identifying performance shortcomings in access, administrative efficiency, and equity and health care outcomes, and suggesting poor performance is attributable in particular to lack of universal coverage and barriers to accessing primary care).

11 See, e.g., Olga Khazan, *What's Actually Wrong with the U.S. Health System*, ATLANTIC (July 14, 2017), <https://www.theatlantic.com/health/archive/2017/07/us-worst-health-care-commonwealth-2017-report/533634>.

12 See Melissa Etehad & Kyle Kim, *The U.S. Spends More on Healthcare than Any Other*

metrics suggest, U.S. health care markets seem to have done a much better job of generating profits than improving health outcomes.

The persistence of the country's unique market-based approach to health care, even in the face of clear evidence that it yields comparatively poor health outcomes, reflects a seemingly unshakeable belief in the efficiency of markets.¹³ While competitive markets generally work well, albeit not perfectly, as mechanisms for satisfying some types of consumer needs, the American approach over recent decades has been to extend the reach of markets indiscriminately to ever-increasing domains of human activity.¹⁴ Even imperfectly competitive markets, of which there are many, are thought to work better than the alternatives for satisfying our daily needs and wants. Even in the midst of a pandemic.¹⁵ This expansion of market-driven activity has been accompanied by subtle, and not so subtle, limitations on mechanisms of government oversight.¹⁶ The intertwining of market forces with all aspects of life and all aspects of government decision-making has expanded the range and scope of market pressures on lawmakers and the lawmaking process in ways that, ironically, often undermine the economic health and competitiveness of these same markets. These pressures are of particular concern in those markets that depend most heavily on regulation in order to function.

The pharmaceutical industry is one of the most highly regulated industries, with government interventions playing critical roles at every stage of pharmaceutical development and distribution.¹⁷ It is also, not surprisingly, an

Country—But Not with Better Health Outcomes, L.A. TIMES (July 18, 2017, 4:25 PM PT), <http://www.latimes.com/nation/la-na-healthcare-comparison-20170715-htlstory.html>.

13 See, e.g., *Regulation and the Economy, The Relationship and How to Work to Improve It*, COMM. FOR ECON. DEV. CONF. BD. (Sept. 27, 2017), <https://www.ced.org/reports/regulation-and-the-economy>; see also Alexander Zaitchik, *How Big Pharma Was Captured by the One Percent*, NEW REPUBLIC (June 26, 2018), <https://newrepublic.com/article/149438/big-pharma-captured-one-percent> (“That narrative, that America’s drug economy represents a complicated but beneficent market system at work, is so ingrained it is usually stated as a fact, even in the media.”)

14 See, e.g., ROBERT KUTTNER, *EVERYTHING FOR SALE: THE VIRTUES AND LIMITS OF MARKETS* (1996) (discussing the expansion of market ideology in U.S. political thinking and the emphasis on market solutions for social and economic problems).

15 See, e.g., Yaniv Heled, Ana Santos Rutschman & Liza Vertinsky, *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, 7 J. L. & BIOSCIENCES 1 (2020).

16 See, e.g., COUNCIL ECON. ADVISORS, *THE ECONOMIC EFFECTS OF DEREGULATION SINCE JANUARY 2017: AN INTERIM REPORT* (2019) (examining the deregulatory approach of the Trump Administration); Dominique Tobbell, *Understanding Pharmaceutical Relations and the Limits of Regulatory Reform*, SCI. HIST. INST. (Apr. 2, 2009), <https://www.sciencehistory.org/distillations/understanding-pharmaceutical-relations-and-the-limits-of-regulatory-reform>.

17 See, e.g., Aaron S. Kesselheim et al., *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and Avenues for Improvement*, 30 STAN. L. & POL’Y REV. 421 (2019); see also *Competition and Regulation Issues in the Pharmaceutical Industry*, OECD (Feb. 6, 2001), <https://www.oecd.org/competition/sectors/1920540.pdf> (documenting extensive regulation across the product life cycle for pharmaceuticals; also documenting concentration and profitability in the

industry in which the largest companies exercise significant influence over the regulatory process.¹⁸ But the extent of pharmaceutical influence is not limited to overly friendly relationships with regulators or isolated instances of excessive influence over the design and enforcement of regulations; it extends to every aspect of the pharmaceutical marketplace. The largest corporate actors in the industry have adopted a holistic, systemic approach towards shaping the design of pharmaceutical markets and their regulation.¹⁹ The magnitude and scope of the influence exerted by the largest corporate actors in the pharmaceutical industry over all commercially important aspects of pharmaceutical markets and their regulation, and the success of this influence in changing the incentives and decision-making of key public and private stakeholders in the industry in ways that facilitate desired corporate objectives, amounts to what this Article defines as “pharmaceutical capture.”²⁰

This Article uses this concept of pharmaceutical capture to inform policy debates over how best to improve the public health impact of the pharmaceutical industry.²¹ Pharmaceutical companies, along with other large and sophisticated

pharmaceutical industry).

18 See, e.g., Kesselheim et al., *supra* note 17 (discussing aspects of the regulatory structure that significantly limit competition and the industry actions that seek to further limit it); see also Nicholas Florco & Lev Facher, *How Pharma, Under Attack from All Sides, Keeps Winning in Washington*, STAT (July 16, 2009), <https://www.statnews.com/2019/07/16/pharma-still-winning> (describing the power and influence of the pharmaceutical lobby in avoiding regulations that would increase competition).

19 While this Article limits its focus to the pharmaceutical industry, this level of holistic, systemic capture may well exist in other industries, both within and outside of health care. A good example is the financial industry. See, e.g., Lawrence G. Baxter, “Capture” in *Financial Regulation: Can We Channel It Toward the Common Good?*, 21 CORNELL J. L. & PUB. POL’Y 175 (2011) (discussing the concept of deep capture as it applies to the financial industry).

20 See, e.g., Julie Margetta Morgan & Devin Duffy, *The Cost of Capture: How the Pharmaceutical Industry Has Corrupted Policymakers and Harmed Patients*, ROOSEVELT INST. (May 2019), https://rooseveltinstitute.org/wp-content/uploads/2020/07/RI_Pharma_Cost-of-Capture_brief_201905.pdf (exploring the range of ways in which pharmaceutical companies influence policymakers). In addition to the literature on regulatory capture, this notion of pharmaceutical capture builds on concepts of institutional corruption in the pharmaceutical industry as discussed by scholars such as Lawrence Lessig, Jonathan J. Darrow, and others. See, e.g., Lawrence Lessig, Foreword, “Institutional Corruption” Defined, 41 J. L. MED. & ETHICS 553 (2013); Donald W. Light, Joel Lexchin & Jonathan J. Darrow, *Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs*, 41 J. L. MED. & ETHICS 590 (2013).

21 See *supra* note 20 and accompanying text. It also reflects recent scholarship critiquing existing concepts of regulatory capture and delving more deeply into the nature and reasons for regulatory failure. See generally PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT (Daniel Carpenter & David A. Moss eds., Cambridge Univ. Press 2014) [hereinafter PREVENTING REGULATORY CAPTURE] (reorienting discussions of regulatory capture and providing a rigorous definition of and approach to investigating different forms of regulatory capture); Michael E. Levine & Jennifer L. Forrence, *Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis*, 6 J. L. ECON. & ORG. 167 (1990) (exploring the limits of both

corporate actors in the industry such as, but not limited to, distributors, retailers, intermediaries such as pharmacy benefit managers, and insurers, exercise significant control over the construction, operation, and regulation of pharmaceutical markets from start to finish of the pharmaceutical product life cycle. The often hidden role of business interests in industry design extends to every level of government, ranging from local regulations²² to international pressures on guidelines prepared by the World Health Organization.²³ It extends from the inception of an idea to post-sale product liability, encompassing the research that shapes our understandings of health and disease in the first place and our understanding of product risks and benefits after the fact.²⁴ There is even an industry role in shaping the way that we think about regulation and deregulation,²⁵ with significant industry effort targeted at controlling health and drug policy narratives—as illustrated by recent private sector efforts to make “innovation” synonymous with an expansion of private sector incentives and a limitation of government rights over even publicly funded technology.²⁶ But industry influence

regulatory capture and public interest theories).

22 See, e.g., Jayne O’Donell, *Family Matters: EpiPens Had High-Level Help Getting Into Schools*, USA TODAY (Sept. 20, 2016, 12:46 PM ET), <https://www.usatoday.com/story/news/politics/2016/09/20/family-matters-epipens-had-help-getting-schools-manchin-bresch/90435218> (explaining how the head of the National Association of State Boards of Education, who was also the mother of Mylan’s CEO, played a significant role in encouraging states to require school boards to purchase Epi-Pens, paving the way for Mylan to develop a near monopoly in school nurses’ offices, supported by state legislation and federal legislation known as the “EpiPen Law.”).

23 See, e.g., Chris McGreal, *Purdue Pharma Accused of ‘Corrupting’ WHO to Boost Global Opioid Sales*, GUARDIAN (May 22, 2019, 1:09 PM EDT), <https://www.theguardian.com/us-news/2019/may/22/purdue-pharma-opioid-world-health-organization-painkiller-global-sales> (discussing pharmaceutical company influence over World Health Organization guidelines to relax prescription standards for opioids).

24 See, e.g., Elizabeth A. Kitsis, *The Pharmaceutical Industry’s Role in Defining Illness*, 13 VIRTUAL MENTOR 906 (2011).

25 See, e.g., Edward Nik-Khah, *Neoliberal Pharmaceutical Science and the Chicago School of Economics*, 44 SOC. STUD. SCI. 489 (2014) (exploring the role of the pharmaceutical industry in supporting institutions influential in policy debates about deregulation).

26 This control over the narrative can be seen in the NIST Special Publication 1234: Return on Investment Initiative to Advance the President’s Management Agenda, Final Green Paper, which has led to proposed rule changes that would narrow the scope of government rights over publicly funded inventions and related technology. See Nat’l Inst. of Standards & Tech., *NIST Special Publication 1234: Return on Investment Initiative to Advance the President’s Management Agenda, Final Green Paper*, U.S. DEP’T COM. (April 2019), <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf> [hereinafter *NIST Green Paper*]; see, e.g., Law Professors, Comment Letter on NIST Proposed Rule on Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 FR 35 at <https://www.regulations.gov/comment/NIST-2021-0001-13026>. For a broader discussion about notions of capture that encompass the narratives dominating policy debates, see, for example, Baxter, *supra* note 19 (discussing cultural and social dimensions of capture, including control over the “entire language of the policy debate” in the context of regulating the financial industry).

on its own is not enough to constitute pharmaceutical capture. Pharmaceutical capture occurs only when the magnitude and scope of corporate influence is significant enough to alter the incentive structures, and corresponding decisions, of a sufficient number of industry stakeholders (whether it be consumption choices, prescription choices, rulemaking, enforcement decisions, or other relevant decisions and actions) in ways that ensure that relevant markets yield the outcomes desired by the industry captors. The result of pharmaceutical capture is a pharmaceutical industry that generates excessive profits, often at the expense of health outcomes. The subsequent concentration of large profits in the hands of a small group of large health care companies, including among them the largest pharmaceutical companies, further increases the ability of these companies to influence regulatory design, deepening the capture.²⁷

After developing the concept of pharmaceutical capture, this Article develops a case study of opioids to illustrate how pharmaceutical capture works in practice. This case study provides a detailed account of how some of the largest companies in the pharmaceutical industry exercise control over the construction and regulation of the health care markets they profit from.²⁸ The opioid epidemic has its roots in the over-production, over-prescription, and abuse of prescription opioids. These are drugs that have been developed through the direct and indirect use of publicly funded research, benefited from government grants of patent protection and other regulatory exclusivities, subject to government approval and oversight, prescribed by state-licensed physicians, monitored by federal agencies, and paid for by public programs and highly regulated private insurers. The evolution of the opioid epidemic reveals the pervasive influence that opioid manufacturers and distributors exerted—and continue to exert—over the design of this regulatory system and the underlying market structure to ensure profits at the expense of public health.

Although the opioid epidemic is among the most dramatic examples of

²⁷ See, e.g., Barak Richman et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 *LOY. U. CHI. L.J.* 787 (2017) (exploring consequences of unprecedented market concentration in pharmaceutical industry); see also Daniel Carpenter & David A. Moss, *Introduction to PREVENTING REGULATORY CAPTURE*, *supra* note 21, at 1, 11 (developing a definition of capture that distinguishes between weak and strong forms of capture).

²⁸ For a thoughtful analysis of the political, legal and social context that contributed to the opioid epidemic and the need for systemic change as a policy response see, for example, Mariano-Florentino Cuéllar & Keith Humphreys, *The Political Economy of the Opioid Epidemic*, 38 *YALE L. & POL'Y REV.* 1 (2019) (“[I]nstitutional realities as well as political and economic pressures operate against the backdrop of various legal domains that can enable or exacerbate a public health crisis. Without taking those realities seriously, narrow interventions focused on a single area of law or isolated technical changes in treatment may prove largely ineffective.”). For a discussion of how the design of innovation institutions contributed to the opioid epidemic, see, for example, Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, *J. L. & BIOSCIENCES* 1 (2020).

pharmaceutical capture, the problems it exposes are by no means unique to opioids,²⁹ nor are they unique to public health emergencies.³⁰ While the structural problems that capture creates are often most visible in emergency contexts, the influence that companies with financial interests in pharmaceutical sales exert over markets relevant to their profitability, and the resulting growth of profits at the expense of public health, is endemic in pharmaceutical markets.³¹ Numerous lawsuits arising from particularly egregious misconduct have exposed myriad examples, large and small, in which pharmaceutical companies, along with other corporate actors in health care markets, exercise control over the structure and operation of their relevant markets to grow demand, control price, and extract

29 See, e.g., Katy Milani & Devin Duffy, *Profit over Patients: How the Rules of Our Economy Encourage the Pharmaceutical Industry's Extractive Behavior*, ROOSEVELT INST., (Feb. 2019), https://rooseveltinstitute.org/wp-content/uploads/2020/07/RI_Profit-Over-Patients_brief_201902.pdf (discussing how the structure of pharmaceutical markets leads companies to prioritize profits at the expense of patient health).

30 See, e.g., Stephen Buryani, *How Profit Makes the Fight for a Coronavirus Vaccine Harder*, GUARDIAN (Mar. 4, 2020, 7:29 AM EST), <https://www.theguardian.com/commentisfree/2020/mar/04/market-coronavirus-vaccine-us-health-virus-pharmaceutical-business> (“The current setup is often the worst of both worlds—too slow to pick up research on new threats because the money isn’t there, and too quick to drop it if it can’t be sure the money will be there in the future. It’s a highly market-dependent system, and the market usually fails us.”); Sarah Karlin-Smith, *How the Drug Industry Got Its Way on the Coronavirus*, POLITICO (Mar. 5, 2020, 5:28 PM EST), <https://www.politico.com/news/2020/03/05/coronavirus-drug-industry-prices-122412> (“Industry lobbyists successfully blocked attempts this week to include language in the \$8.3 billion emergency coronavirus spending bill that would have threatened intellectual property rights for any vaccines and treatments the government decides are priced unfairly.”); Sharon Lerner, *Big Pharma Prepares to Profit from the Coronavirus*, INTERCEPT (Mar. 13, 2020, 11:46 AM), <https://theintercept.com/2020/03/13/big-pharma-drug-pricing-coronavirus-profits> (“The global crisis ‘will potentially be a blockbuster for the industry in terms of sales and profits,’ [Gerald Posner] said, adding that ‘the worse the pandemic gets, the higher their eventual profit.’”); Gerald Posner, *Big Pharma May Pose an Obstacle to Vaccine Development*, N.Y. TIMES (Mar. 2, 2020), <https://www.nytimes.com/2020/03/02/opinion/contributors/pharma-vaccines.html> (“Pharmaceutical industry concerns about profits, as well as potential liability for adverse reactions to the inoculation, often keep them from moving quickly enough to develop or distribute effective vaccines when there emerges a novel virus, like the one that has set off the Covid-19 outbreak.”).

31 The life cycle description of pharmaceutical markets provided in Section II.C shows the many ways in which pharmaceutical companies influence the formal and informal rules governing the markets they operate in. See also a discussion of the structural features of pharmaceutical markets that allow companies to make decisions with profit rather than public health in mind in Yaniv Heled, Liza Vertinsky & Cass Brewer, *Why Healthcare Companies Should (Be)come Benefit Corporations*, 60 B.C. L. REV. 1 (2019). While the focus of this Article is on pharmaceutical companies, they are by no means the only participants in industry capture. Other industry players, such as HMOs and other private insurers, pharmacy benefit managers, and pharmaceutical distributors, are also involved in shaping pharmaceutical markets with profits in mind, and stories of capture can be extended to include them all. See, e.g., Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices -- Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303 (2020) (exploring ways in which the pharmacy benefit manager industry exerts systemic influence on a variety of industry stakeholders to keep prices—and profits—high).

profit.³² The pharmaceutical industry is the biggest source of False Claims Act recoveries by the Department of Justice (DOJ), for example, and the public disclosures that result from litigation and settlements reveal the complex and expansive ways in which the corporate wrongdoers seek to influence market outcomes for their pharmaceutical products.³³ A few examples make headline news. The \$3 billion settlement reached with GlaxoSmithKline to resolve fraud allegations, kickbacks, off label marketing, and failure to report safety data in the sale of well-known prescription drugs Paxil, Wellbutrin, and Avandia was widely publicized.³⁴ The settlements reached with manufacturers of antipsychotic drugs like Johnson & Johnson, maker of Risperdal,³⁵ and Eli Lilly, maker of Zyprexa,³⁶

32 See, e.g., ROSENTHAL, *supra* note 1 (offering a large number of examples of how different industry players exert influence on the creation and operation of markets for their products in order to increase profits); see also Paul D. Jorgenson, *Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda*, 14 J. L. MED. & ETHICS 553 (2013) (arguing that the pharmaceutical industry has influenced legislators to define policy problems in ways that advance their interests). For a historical perspective see, for example, Jean-Paul Gaudillière & Ulrike Thoms, *Pharmaceutical Firms and the Construction of Drug Markets: From Branding to Scientific Marketing*, 29 HIST. & TECH. 105 (2013).

33 See, e.g., Press Release, Off. of Pub. Affs., Dep't of Just., (Jan. 9, 2020), <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019>; see also *Pharma Biggest Source of DoJ False Claims Act Recoveries*, PHARMA LETTER (Jan. 15, 2021), <https://www.thepharmaletter.com/article/pharma-biggest-source-of-doj-false-claims-act-recoveries> (largest recoveries by U.S.DoJ in civil cases involving fraud and fraud claims against the government in the fiscal year 2020 came from settlements and judgements against drug companies).

34 In 2012, GlaxoSmithKline admitted guilt and agreed to pay \$3 billion to resolve fraud allegations and failure to report safety data in the sale of prescription drugs Paxil, Wellbutrin and Avandia, with practices including unlawfully promoting drugs for treatments not approved by the FDA, publishing and distributing a misleading medical journal article misreporting clinical data about efficacy while failing to disclose the results of clinical studies with negative efficacy results, and encouraging overprescribing of its drugs in ways that caused harm. See Press Release, Off. of Pub. Affs., Dep't of Just., (July 2, 2012), <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.

35 See, e.g., Jonathan D. Rockoff, *J&J Is Accused of Kickbacks to Omnicare on Drug Sales*, WALL STREET J., (Jan. 16, 2010, 12:01 AM ET), <https://www.wsj.com/articles/SB10001424052748703657604575004902853166786> (describing how the Department of Justice charged Johnson & Johnson with “paying ‘tens of millions of dollars in kickbacks’ to a nursing-home pharmacy company to boost sales of Johnson & Johnson drugs to nursing-home patients. . . . The allegations, detailed in a 34-page complaint, shed light on the workings of a lucrative marketing channel for drug makers that can help drive sales of major drugs: the middlemen like Omnicare that process prescriptions, distribute medicines and manage insurance coverage.”). In 2013 Johnson & Johnson admitted to having engaged in a variety of illegal activities related to prescription drugs Risperdal, Invega and Miretanol, including promotion for uses not approved as safe and effective by the FDA and payment of kickbacks to physicians and the nation’s largest long-term care pharmacy provider, with a settlement of more than \$2.2 billion to resolve civil and criminal liability. See Press Release, Off. of Pub. Affs., Dep't of Just., (Nov. 4, 2013), <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations>.

36 See, e.g., Eli Lilly and Company Agrees to Pay \$1.415 billion to resolve allegations of off label promotion of Zyprexa, DoJ Press Release, January 15, 2009 at <https://www.justice.gov>

for a variety of illegal activities designed to expand their markets by aggressively promoting uses of antipsychotic medications not approved as safe and effective for use in nursing homes and related markets, also received a great deal of media attention. But most corporate strategies to exert profit at the expense of health receive little attention, either remaining hidden or with details revealed only through disclosures occurring as the result of government investigations into alleged wrongdoing or through litigation.³⁷ Moreover, enforcement efforts reveal only illegal activity, but many forms of pharmaceutical capture do not involve conduct that is illegal. As discussed in Part II, there are extensive patterns of industry influence over pharmaceutical markets and their regulation that are perfectly legal, despite any negative impact on public health objectives.

In offering an extended approach to the capture of U.S. pharmaceutical markets, this Article also challenges longstanding approaches to deregulation and privatization in the pharmaceutical industry. Although popular explanations for the high cost and poor performance of the U.S. health care system vary, there is a growing public consensus that U.S. health care markets in general, and pharmaceutical markets in particular, are not working well for patients and public health.³⁸ In the context of pharmaceutical markets, public outcry has tended to focus largely on the issue of high prices, including the high price of prescription drugs.³⁹ Some of this public and policy discontent with the health care system has been channeled into political support for a “free market” response premised on market primacy and the need for deregulation.⁴⁰ Some has been focused on the

/archive/opa/pr/2009/January/09-civ-038.html.

37 See, e.g., Sammy Almashat & Timothy Waterman, *Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010*, PUB. CITIZENS (Dec. 16, 2010), <https://www.citizen.org/wpcontent/uploads/migration/rapidlyincreasingcriminalandcivilpenalties.pdf>.

38 For a reflection of public concerns, see, for example, Jim Norman, *Healthcare Once Again Tops List of Americans' Worries*, GALLUP (Apr. 1, 2019), <https://news.gallup.com/poll/248159/healthcare-once-again-tops-list-americans-worries.aspx>.

39 See, e.g., Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, ATLANTIC (Mar. 23, 2019), <https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253>.

40 The belief in “market primacy”—that markets, if just left alone by government to operate freely, will produce efficient and effective health care outcomes—plays an important role in shaping U.S. health care policy. See, e.g., Joseph White, *Markets and Medical Care: The United States 1993-2005*, 85 MILBANK Q. 395 (2007) (exploring how “the broad ideological battle over the role of markets remains a basic dividing line and dominant theme in American health policy” and how powerful these ideological arguments can be in shaping policy and public opinion regardless of actual impact on health care). Powerful political groups such as the Heritage Foundation and the America Enterprise Institute along with a variety of other political think tanks have supported market primacy as the basis for health care reform. For examples of this argument at work, see Joseph Antos, *Improve Markets, Not Government Controls, for Real Health Reform*, 42 J. AMBULATORY CARE MGMT. 173 (2019) (republished by the American Enterprise Institute, June 17, 2019) (arguing that reform should be focused on promoting consumer choice and market competition); James Capretta & Kevin

need to remove “barriers” to innovation in the form of reserved government rights over publicly funded technology and public expenditures over the resulting products.⁴¹ This Article confronts the market primacy arguments that have been gaining prominence in political circles and among some segments of the public.⁴² It argues that these efforts to change pharmaceutical regulation and to minimize the independent role of government in policing pharmaceutical markets are simply another manifestation of pharmaceutical capture. The purpose of this analysis is not to challenge the innovative power of the industry or its value as a source of technologies that reduce morbidity and mortality, but rather to expose the harms of failing to effectively regulate the industry with public health goals in mind. This Article concludes with some ideas for how to make regulations more robust to special interests and more responsive to patient and public health needs.

The rest of this Article proceeds as follows. Part II provides a brief overview of regulatory capture and the debate it has provoked over the appropriate role of regulation. It then offers a theory of pharmaceutical capture and explains why this holistic concept of capture is necessary to understand the influence that corporate actors exert over the design and operation of pharmaceutical markets. Part III uses the opioid epidemic as a case study of pharmaceutical capture at work. Part IV suggests why deregulation is not the answer to pharmaceutical industry woes and argues instead for a redesign of regulation. This Article concludes with some ideas for shifting current regulatory approaches in ways that might lead to a pharmaceutical recapture.

I. A THEORY OF PHARMACEUTICAL CAPTURE

The need to reform U.S. health care markets has been a central feature of political debate and an area of intense public interest for decades.⁴³ While there is

Dayratna, *Compelling Evidence Makes the Case for a Market-Driven Health Care System*, HERITAGE FOUND. (Dec. 20, 2013), <https://www.heritage.org/health-care-reform/report/compelling-evidence-makes-the-case-market-driven-health-care-system> (“It is primarily federal policies that are responsible for driving up costs and making health insurance unaffordable for so many Americans.”); Matthew Kandrach, *To Improve Healthcare, Look to the Free Market, Not Single-Payer*, THE HILL (Feb. 9, 2018, 12:15 PM EST), <https://thehill.com/opinion/healthcare/373119-to-improve-health-care-look-to-the-free-market-not-single-payer> (“What’s clear is that substantive health-care reform requires less government interference so that patients have more ownership and control over their health-care dollars and choices.”); and Raymond March, *Deregulation is the Only Cure for High Drug Prices*, FDAREVIEW.ORG, (Jan. 3, 2019), <https://www.fdareview.org/2019/01/03/deregulation-is-the-only-cure-for-high-drug-prices>.

41 See, e.g., *NIST Green Paper*, *supra* note 26.

42 See also Steven K. Vogel, *Rethinking Stigler’s Theory of Regulation: Regulatory Capture or Deregulatory Capture*, PROMARKET BLOG (May 15, 2018), <https://promarket.org/rethinking-stiglers-theory-regulation-regulatory-capture-deregulatory-capture> (making the argument that the push for deregulation is best understood as a form of deregulatory capture).

43 See, e.g., PAUL STARR, *REMEDY AND REACTION: THE PECULIAR AMERICAN STRUGGLE OVER*

fierce debate over what should be done to improve quality and reduce cost, political support for a private market approach towards the provision of health care has continued to dominate alternative positions. At the same time, the role of the private sector in all aspects of health care has continued to expand.⁴⁴ This leaves the current U.S. health care debate mostly confined to decisions about whether and how to regulate, and deregulate, health care markets to improve outcomes, bringing with it contested views about whether regulations can be relied upon to achieve public health goals or whether regulation is instead itself a source of market failure.

Pharmaceutical markets are heavily regulated for a variety of reasons, ranging from the need to create incentives for research and development to ensuring the quality, efficacy, and safety of pharmaceuticals.⁴⁵ Ideally, regulations are designed with the public interest in mind. But sometimes special interests come to dominate regulatory decisions, and regulations are harnessed to serve those interests instead of the public good, a phenomenon generally referred to as “regulatory capture.”⁴⁶ The idea that industry members with special interests may unduly influence regulators, resulting in regulation that favors special interests at the expense of the public interest, is far from new.⁴⁷ But the extent of involvement of the private sector in every aspect of market design in a market that is both uniquely vulnerable to industry influence and critical to public health raises new challenges that go beyond simple models of regulatory capture.⁴⁸ The financialization of pharmaceutical markets further exacerbates these challenges by increasing the pressures on pharmaceutical companies to ensure revenue growth.⁴⁹ This Part II

HEALTHCARE REFORM (2011) (providing a historical examination of the political dynamics of U.S. health care reform).

44 See, e.g., ROSENTHAL, *supra* note 1; David U. Himmelstein & Steffie Woolhandler, *Privatization in a Publicly Funded Health Care System: The U.S. Experience*, 38 INT’L J. HEALTH SERVICES 407 (2008); Heather Perlberg, *How Private Equity Is Ruining American Healthcare*, BLOOMBERG (May 20, 2020, 2:09 PM PDT), <https://www.bloomberg.com/news/features/2020-05-20/private-equity-is-ruining-health-care-covid-is-making-it-worse>.

45 See, e.g., Kesselheim et al., *supra* note 17. For a broad discussion of the evolution and nature of FDA regulation over the pharmaceutical industry, and an underlying theory of regulation, see DANIEL CARPENTER, *REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA* (2010).

46 For a standard definition see Prateek Agarwal, *Regulatory Capture Definition*, INTELLIGENT ECONOMIST (May 30, 2019), <https://www.intelligenteconomist.com/regulatory-capture>. For alternative ways of defining and understanding “regulatory capture” see PREVENTING REGULATORY CAPTURE, *supra* note 21.

47 See, e.g., William J. Novak, *A Revisionist History of Regulatory Capture*, in PREVENTING REGULATORY CAPTURE, *supra* note 21, at 25.

48 For a description of the unique characteristics of health care markets that make relying on the profit incentive for health care production problematic, see, for example, Heled, Vertinsky & Brewer, *supra* note 31.

49 See, e.g., William Lazonick et al., *US Pharma’s Financialized Business Model* (Inst. for New Econ. Thinking, Working Paper No. 60, 2017), <https://ssrn.com/abstract=3035529>; Rosie Collington,

suggests that general understandings of regulatory capture, which focus on instances in which regulatory agencies come to be dominated by the interests that they regulate, are inadequate to capture the systemic and pervasive ways in which the pharmaceutical industry has taken on the multifaceted design of its own markets.

A. Theories of Regulatory Capture

“The true forms of government, therefore, are those in which the one, or the few, or the many, govern with a view to the common interest; but governments which rule with a view to the private interest, whether of the one, the few, or the many, are perversions.” – Aristotle⁵⁰

Theories of regulatory capture have a long history, with their roots in “the general notion that democratic and republican institutions of government were prone to the corruptions of private interest.”⁵¹ Concerns with the ability of concentrated business interests to act in ways that are harmful to the public interest have been a source of policy concern and academic debate since the earliest forms of government.⁵² Indeed, concerns about the influence of powerful factions on governing bodies played a formative role in the constitutional foundations of the U.S. system of governance, with its checks and balances and separation of powers.⁵³ The literature on regulatory capture, which predates even this label of regulatory capture, contains a rich and varied discussion of ways in which special interests impact regulators and regulations, studies of different types and mechanisms of capture, as well as a variety of prescriptions in response to specific or general models of industry control over government decision-makers.⁵⁴ Modern discourse on regulatory capture, as further discussed below, spans a shift from a New Deal era belief in the public interest theory of regulation, with government acting in the public interest to limit capture of markets by concentrated private interests, to a post-New Deal pessimism about the ability of government to evade capture by special interests and a corresponding belief in the ability of “free”

Profits, Innovation and Financialization in the Insulin Industry, (Inst. for New Econ. Thinking, Working Paper No. 120, 2020), <https://ssrn.com/abstract=3593906>.

⁵⁰ ARISTOTLE, *THE POLITICS AND THE CONSTITUTION OF ATHENS* bk. III, at 71 (Stephen Everson ed., Cambridge Univ. Press 1996) (c. 325 B.C.E.).

⁵¹ Novak, *supra* note 47, at 25.

⁵² See, e.g., Alissa Ardito, *Regulatory Capture, Ancient and Modern*, REG. REV. (June 30, 2016), <https://www.theregreview.org/2016/06/30/ardito-regulatory-capture-ancient-and-modern> (examining the history of the concept of capture dating back to the classical world of Greece and Rome).

⁵³ See THE FEDERALIST NO. 10 (James Madison); see also Novak, *supra* note 47, at 25.

⁵⁴ See, e.g., Ernesto Dal Bo, *Regulatory Capture: A Review*, 22 OXFORD REV. ECON. POL’Y 203 (2006) (reviewing the empirical and theoretical economics literature on regulatory capture).

markets to promote social welfare.

In the New Deal era, regulation was seen as a way of addressing the capture of markets and consumers by concentrated business interests. The New Deal was based on views of public interest or public service theories of regulation in which regulators acted to protect the public interest.⁵⁵ Progressive reformers promoting an expansion of the administrative state saw regulation itself as a way of addressing capture:

[With regulations] designed to combat what progressives envisioned as a perennial problem in republican and democratic governance—that is, the tendency of private economic interests to capture the public political sphere. More particularly, they viewed late-nineteenth-century agglomerations of corporate wealth and power as producing a dangerous new form of the age-old threat of private interest trumping public democracy.⁵⁶

The New Deal saw an increase in the delegation of policymaking authority to executive and independent administrative bodies, reflecting a belief in the role of experts crafting policy with the public interest in mind and acting as a safeguard on markets and a counterbalance to the power of private business interests.⁵⁷

The public interest theory of regulation is based on the idea that if they are left unhindered, markets will often fail, and that governments—often acting through agency experts—can and will act in the public interest to correct these market failures through regulation.⁵⁸ This theory, which supported the rise in the administrative state that occurred during the New Deal era, subsequently came under attack from both progressive and conservative critics, although for different reasons. The idea that regulators will be motivated to protect the public interest was challenged in the 1960s by left-leaning scholars and activists who “suggested that agencies were captured by elite interests that used the administrative state to stifle competition and enrich themselves.”⁵⁹ These groups saw the expansion of

55 For examples of classic theories of public interest regulation see, for example, FELIX FRANKFURTER, *THE PUBLIC AND ITS GOVERNMENT* (Yale Univ. Press 1930); and JAMES M. LANDIS, *THE ADMINISTRATIVE PROCESS* (Yale Univ. Press 1938).

56 Novak, *supra* note 47, at 25, 38.

57 See, e.g., Philip Wallach, *The Administrative State’s Legitimacy Crisis*, BROOKINGS (Apr. 2016), <https://www.brookings.edu/research/the-administrative-states-legitimacy-crisis> (providing a brief historical overview of the academic debate over the rise of the administrative state).

58 See, e.g., Andrei Shleifer, *Understanding Regulation*, 11 EUR. FIN. MGMT. 439, 440 (2005) (exploring some of the main theories of regulation that emerged in the twentieth century).

59 Reuel Schiller, *Regulation and the Collapse of the New Deal Order, or How I Learned to Stop Worrying and Love the Market*, in BEYOND THE NEW DEAL ORDER: U.S. POLITICS FROM THE GREAT DEPRESSION TO THE GREAT RECESSION 168 (Gary Gerstle, Nelson Lichtenstein & Alice O’Connor eds., 2019) [hereinafter BEYOND THE NEW DEAL ORDER].

administrative power as being in tension with, rather than in pursuit of, the public interest, focusing instead on the role of legally protected individual rights as mechanisms for protecting public interests.

[Since] distrust of government in the 1960s extended to legislatures as well as “captured” agencies, reformers on both sides of the political spectrum searched for ways of allowing private citizens (and the “public interest” groups representing them) to wield the power of government enforcement, including by creating “private attorneys general” provisions that allowed citizens to sue to enforce the law.⁶⁰

New environmental, health, safety, civil rights, and other social regulatory programs adopted by Congress created mechanisms for asserting these individual rights in the courts.⁶¹

In the 1980s, it was the turn of right-wing scholars and activists to challenge the role of agencies, and government more generally, pointing instead to the primacy of markets. “In many ways,” historian Jefferson Cowie wrote, “the 1960s celebrations of the social individual made the 1980s celebration of the economic individual possible.”⁶² Two decades later the idea that

[the] provision of government services should be reconceptualized as a market-driven process had . . . become commonplace . . . [and] [t]hus, the most common regulatory strategy of the new millennium was based on the presumption that fully-informed consumers would make choices in the market that punished businesses that did not meet aspirational, non-enforceable regulatory goals.⁶³

Theories of regulatory capture based on a particularly pessimistic view of regulation began to gain prominence in U.S. academic and policy circles in the wake of the expansion of the administrative state in the 1950s, and were further developed through the work of George Stigler, Gary Becker, and other members of the Chicago School of Economics.⁶⁴ In 1958, in the very first volume of the *Journal of Law and Economics*, Becker raised the question of whether market

60 Wallach, *supra* note 57.

61 See, e.g., Richard Stewart, *Administrative Law in the Twenty-First Century*, 78 N.Y.U. L. REV. 437 *passim* (2003).

62 JEFFERSON COWIE, *THE GREAT EXCEPTION: THE NEW DEAL AND THE LIMITS OF AMERICAN POLITICS* 27 (2016).

63 Schiller, *supra* note 59, at 168.

64 See, e.g., Levine & Forrence, *supra* note 21.

imperfections ever justified government intervention, reflecting that in the face of pervasive imperfections in government behavior, “[i]t may be preferable not to regulate economic monopolies and to suffer their bad effects, rather than to regulate them and suffer the effects of political imperfections.”⁶⁵ In an influential paper called “The Theory of Economic Regulation,” Stigler rejects the “public interest theory of regulation,” which portrays regulation as a mechanism for protecting the public interest in otherwise unfettered markets, and lays out the view that regulators end up representing the interests of the industries they regulate and must themselves be constrained.⁶⁶ The basic idea behind this version of regulatory capture is that the concentrated and lucrative interests of industry will inevitably have more political influence than the fragmented and diffuse interests of consumers. Industry players will seek out regulation of their industry as a tool for restricting competition and increasing their control.⁶⁷ Add asymmetry of information to this mix, with the regulated industry using its own inside information to stay a step ahead of regulators, and the scope for regulatory capture—and consequent negative impact of regulation on the operations of the market—widens and deepens. For Stigler and others of a similar ideological bent, this meant that regulation was doomed to benefit the industry it regulates at the expense of the public interest; it was destined to fail and should be thrown out.⁶⁸

This Chicago School attack on the public interest theory of regulation can be understood as resting on three main assumptions.⁶⁹ The first is that the market, and private orderings, can resolve most market failures without any government intervention. The second is that private litigation can be used to address whatever conflicts market participants might have.⁷⁰ The third, and perhaps the most critical assumption, one emphasized by Stigler in his theory of regulatory capture, is that regardless of any limitations of the market, “government regulators are incompetent, corrupt, and captured, so regulation would make things even worse.”⁷¹ This approach to regulation and the role of government produced influential theories of regulatory capture grounded in the belief that “as a rule,

65 Gary S. Becker, *Competition and Democracy*, 1 J. L. & ECON. 105, 109 (1958).

66 George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971).

67 George J. Stigler, *The Pleasures and Pains of Modern Capitalism*, in EXPLORATIONS IN ECONOMIC LIBERALISM: THE WINCOTT LECTURES 126, 139 (Geoffrey E. Wood ed., 1996).

68 See, e.g., Novak, *supra* note 47, at 25; Zaitchik, *supra* note 13.

69 See, e.g., Shleifer, *supra* note 58 (identifying these three intellectual steps in the challenge to the public interest theory of regulation that are mostly attributed to the Chicago School of Law and Economics).

70 This assumption reflects the logic of efficient bargaining provided by Ronald Coase. In a Coasean world, the courts are seen as playing an important role in resolving disputes, providing an important enforcement mechanism for private orderings. See, e.g., Ronald Coase, *The Problem of Social Cost*, 31 J. L. & ECON. 1 (1960).

71 Shleifer, *supra* note 58, at 440.

regulation is acquired by the industry and is designed and operated primarily for its benefit.”⁷² The natural conclusion to draw from this line of reasoning, those promoting this view of the world suggested, was that only deregulation would be in the public interest. They turned to the pharmaceutical industry as one of the prime examples of the harms of regulatory capture, and worked closely with the pharmaceutical industry to further develop these ideas into a political and economic agenda for the pharmaceutical industry.⁷³

The theoretical development of this particular version of the regulatory capture thesis has become intertwined with growing political support for strengthening private enterprise as a countervailing force to an expanding regulatory state.⁷⁴ But while political and even academic discussions of regulatory capture have increasingly focused on the influence of special interests on regulators, and the need to limit the actions of regulators, it is important to keep in mind the broader view of market capture that informs regulatory strategies in the first place.⁷⁵ In the absence of government as a countervailing force, special interests will control the operation of markets, and indeed the structure of the industries in which they operate, through a variety of mechanisms that go beyond traditional forms of regulatory capture. The result will be an industry that pursues profits regardless of whether the public interest is served. The concept of pharmaceutical capture that is further described below is intended to encompass this broader view of industry influence over a particular segment—one of the most profitable segments—of health care markets and the dangers of such influence on health outcomes.

⁷² Stigler, *supra* note 66, at 3; see also Mark Green & Ralph Nader, *Economic Regulation vs. Competition: Uncle Sam the Monopoly Man*, 82 YALE L.J. 876 (1973) (argues that the regulatory system reflects both a failure of design and a failure of process that often results in regulatory policies that undermine competition and supports monopoly).

⁷³ See, e.g., Edward Nik-Khah, *Getting Hooked on Drugs: The Chicago School, the Pharmaceutical Project, and the Construction of the Modern Medical Marketplace* (Apr. 2009) (unpublished manuscript) (on file at <https://www.ru.nl/publish/pages/515575/nik-khak.pdf>) (discussing the influential relationship between the Chicago School of Economics and the pharmaceutical industry and its impact; with an alliance “forged for the express purpose of giving the pharmaceutical industry a voice in academic discussions about how the medical marketplace should be constructed and regulated”).

⁷⁴ For a discussion of the history of theories of regulatory capture see, for example, Novak, *supra* note 47, at 25. But for a competing view of the role of government in an increasingly privatized economy, see, for example, MARTHA MINOW, *PARTNERS, NOT RIVALS: PRIVATIZATION AND THE PUBLIC GOOD* (2002).

⁷⁵ For a discussion of evolving theories of regulation and the relationship between the state and markets, see, for example, *GOVERNMENTS AND MARKETS: TOWARD A NEW THEORY OF REGULATION* (Edward J. Balleisen & David A. Moss eds., 2009).

B. Pharmaceutical Capture

Contemporary theories of regulatory capture continue to focus primarily on the relationships between regulators and the industries that they regulate, exploring situations in which the regulators are unduly influenced by the special interests of the entities they are regulating.⁷⁶ While theories of regulatory capture have evolved well beyond Stigler's seminal contributions, discussed above, "the essential idea that policymakers are for sale, and that regulatory policy is largely purchased by those most interested and able to buy it, remains central to the literature."⁷⁷

In their comprehensive study of capture, Daniel Carpenter and David Moss begin their effort to build a more nuanced view of capture by providing a conceptual structure built around a view of regulatory capture as "the result or process by which regulation, in law or application, is consistently or repeatedly directed away from the public interest and towards the interests of the regulated industry, by the intent and action of the industry itself."⁷⁸ In this Article, I push the concept of capture even further within the context of the pharmaceutical industry, to encompass the systemic and pervasive nature of the influence exerted by the largest corporate actors in the industry over all material aspects of markets and their regulation. Pharmaceutical capture, as I define it, occurs when the magnitude and scope of corporate influence is significant enough to alter the incentive structures, and corresponding decisions, of a sufficient number of industry stakeholders (whether it be consumption choices, prescriptions by doctors, rulemaking by regulatory agencies, enforcement decisions, or some other form of decision-making or stakeholder action) in ways that ensure that relevant markets yield the outcomes desired by the industry captors.

While the pharmaceutical industry is certainly not the only industry susceptible to this type of systemic capture, I build on arguments made in prior work to suggest that U.S. pharmaceutical markets have distinctive features that make it particularly susceptible to capture of this scope and magnitude.⁷⁹ Five features in particular stand out: the pervasive role of regulation over the entire product life cycle; the belief in the private sector as the primary engine of (lifesaving) biomedical innovation and the socialization of costs but not benefits from this R&D; the fragmentation of the market and the treatment of patients as consumers for some purposes but not others; the pervasive role of industry in

⁷⁶ See generally PREVENTING REGULATORY CAPTURE, *supra* note 21 (providing a collection of ideas about what regulatory capture is, how it works and how to mitigate it; arguing for more nuanced understanding of regulatory capture).

⁷⁷ Daniel Carpenter & David A. Moss, *Introduction* to PREVENTING REGULATORY CAPTURE, *supra* note 21, at 1, 8.

⁷⁸ *Id.* at 13.

⁷⁹ See, e.g., Heled, Rutschman & Vertinsky, *supra* note 15, at 1; Heled, Vertinsky & Brewer, *supra* note 31.

shaping scientific, medical, and patient knowledge about pharmaceuticals and their use; and the extreme potential for profit due in part to the inelasticity of demand for the goods involved.

The pervasive role of regulation over the entire life cycle of pharmaceuticals, combined with regulatory fragmentation on the one hand and holistic pharmaceutical strategies on the other, is one factor facilitating pharmaceutical capture. The pharmaceutical industry is subject to a number of overlapping regulatory systems at the federal level, including the patent system administered by the U.S. Patent and Trademark Office (USPTO), the funding and licensing of biomedical research by the National Institutes of Health (NIH), Biomedical Advanced Research and Development Agency (BARDA) and other government agencies, the oversight of clinical testing and the approval of new drugs and accompanying market and data exclusivities and oversight of post-approval marketing and distribution of drugs by the U.S. Food and Drug Agency (FDA), monitoring of certain classes of drugs by the Drug Enforcement Agency (DEA) under the Controlled Substances Act, government reimbursement schemes administered by the Centers for Medicare and Medicaid Services (CMS), regulation by the Federal Trade Commission (FTC) to address anticompetitive behavior and deceptive and unfair trade practices, and for some products a requirement that they be provided only through prescription by an authorized, state-licensed professional health care worker (most often a physician). Regulating and enforcing prescription drug practices, along with other forms of regulating medical practice, are primarily left to state law.⁸⁰ There are many additional federal and state laws and regulations that impact pharmaceuticals, including without limitation rules governing manufacturing and marketing practices, reimbursement schemes, product liability, insurance practices, and the types of transactions that are permissible between physicians and pharmaceutical manufacturers. This fragmented web of regulations targeting different aspects of pharmaceuticals creates myriad opportunities for corporate influence and control over pharmaceutical markets. While regulators are confined to specific areas of regulation, and limited jurisdiction within those areas, corporate actors are able to adopt a holistic, systemic approach towards their products and business strategies.

The belief in the private sector as a driving force of biomedical innovation, with particularly high stakes when it comes to life saving technologies, is a second driving factor for pharmaceutical capture in the United States. The regulatory structure in its existing form is justified largely in terms of promoting innovation on the front end, and providing access to safe and effective drugs on the back end. Regulatory exclusivities and public funding are awarded to pharmaceutical

⁸⁰ See, e.g., State Laws on Prescription Drug Misuse and Abuse, CTRS. FOR DISEASE CONTROL & PREVENTION (June 15, 2018), <https://www.cdc.gov/php/publications/topic/prescription.html>.

companies to encourage them to develop drugs, and their subsequent monopolies and control over pricing are justified as the necessary cost of encouraging innovation. These same pharmaceutical companies are then tasked with producing their own data to show the regulators that their products are safe and effective. Although the government finances the research and even sometimes the development of drugs, and despite the fact that the government is the largest single purchaser of drugs through programs such as Medicare and Medicaid, the ability of the government to bargain with private companies over access and price are limited through regulation.⁸¹ The government also plays little role in product selection beyond prioritizing certain areas of research in government funding, relying instead on the private sector to drive product choice. The (questionable) rationale that supports these restrictions on government intervention into product and pricing decisions, and that constrains use of those government mechanisms for intervening that do exist, is that market forces will adequately discipline the behavior of companies without the chilling effect that government intervention might have on investment and innovation.⁸² This rationale is used to support current government strategies for accelerating the development of COVID-19 treatments and vaccines, for example, where public funding and other resources are being poured into private sector R&D activities to spur private innovation with few public safeguards attached.⁸³

In addition to this narrative of pharmaceutical innovation, the contours of the regulatory structure have also been influenced by shifting ideas about the rights and needs of the patient that have been shaped by the industry in ways that are conducive to commercial interests. The legal framework accords a special position to the role of the physician as expert decision maker and gatekeeper in the prescribing of drugs, limiting the liability of drug manufacturers and providing a realm of discretion to physicians. At the same time, the legal framework reflects a view of the patient as a rational, autonomous consumer of health care when it comes to determining what rights and responsibilities companies should have when marketing their products to these patient-consumers—a view that is in tension with the role of the physician as gatekeeper.⁸⁴ Industry players have been

81 See, e.g., John B. Kirkwood, *Buyer Power and Healthcare Prices*, 91 WASH. L. REV. 253 *passim* (2015) (discussing the limitations on the government's ability to negotiate price for its drug purchases under Medicare, among other limitations on government ability to negotiate on price of prescription drugs).

82 See, e.g., John F. Wasik, *Why Medicare Can't Get the Lowest Drug Prices*, FORBES (Aug. 10, 2018, 8:26 AM EDT), <https://www.forbes.com/sites/johnwasik/2018/08/10/why-medicare-cant-get-the-lowest-drug-prices>.

83 See, e.g., Mariana Mazzucato & Azzi Momenghalibaf, *Drug Companies Will Make a Killing from Coronavirus*, N.Y. TIMES (Mar. 18, 2020), <https://www.nytimes.com/2020/03/18/opinion/coronavirus-vaccine-cost.html>.

84 For a broader discussion of this tension see, for example, Liza Vertinsky, Rethinking the

quick to utilize the protections that they argue are necessary to promote innovation, as well as the role of the physician as gatekeeper and patient as consumer, for purposes of expanding their marketing while limiting their liability.

A fourth factor that contributes to industry influence over the evolution and operation of pharmaceutical markets is the pervasive role of industry in scientific and medical research and in medical education, and indeed even in “educating” patients and policymakers.⁸⁵ Pharmaceutical companies in particular exert influence over scientific research and discussions, as well as medical training and education and professional norms.⁸⁶ They also engage in efforts to orient public policy discussions and writing on the idea of patients as consumers with the right to exercise choice over health care products, and they cultivate relationships with patients and patient advocacy groups who further this message.⁸⁷ Their interactions with regulators, health care providers, patients, and payors form part of a systematic corporate strategy to control health policy narratives in ways that support industry positions.

Finally, and in part as a result of the other factors discussed above, pharmaceutical markets offer great potential for the largest and most powerful corporate actors to profit, and thus strong incentives to invest in, and resources to support, efforts at pharmaceutical capture.⁸⁸

Role of the Prescriber with the Patient in Mind (March 12, 2021) (unpublished manuscript) (on file with author).

85 For materials exploring the role of industry in medical research and education, see, for example, Resources, PHARMEDOUT, <https://sites.google.com/georgetown.edu/pharmedout/resources> (last visited July 6, 2021); see also INSTITUTE OF MEDICINE, *Conflicts of Interest in Biomedical Research*, in CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 97 (Bernard Lo & Marilyn J. Field eds., 2009) (report examining conflicts of interest in medical education, research and practice, focuses on conflicts of interest across the spectrum of medicine). For a discussion of concerns about industry funding of clinical trials, see, for example, Sameer S. Chopra, *Industry Funding of Clinical Trials: Benefit or Bias?*, 290 JAMA 113 (2003).

86 See, e.g., Charles Ornstein, *From Twitter to Treatment Guidelines, Industry Influence Permeates Medicine*, NAT’L PUB. RADIO (Jan. 17, 2017, 11:01 AM ET), <https://www.npr.org/sections/health-shots/2017/01/17/510226214/from-twitter-to-treatment-guidelines-industry-influence-permeates-medicine> (summarizing findings from a series of papers in JAMA on how “the long arm of the pharmaceutical industry continues to pervade practically every area of medicine”)

87 See, e.g., Matthew S. McCoy et al., *Conflicts of Interest for Patient Advocacy Organizations*, 376 NEW ENG. J. MED. 880 (2017) (documenting a significant level of industry funding and other forms of involvement in patient advocacy organizations); see also Sharon Batt et al., *Pharmaceutical Ethics and Grassroots Activism in the United States: A Social History Perspective*, 17 J. BIOETHICAL INQUIRY 49 (2020) (examining the dangers of expanded industry funding of patient advocacy groups since the 1990s and industry influence over patient advocacy discourse and agendas); Emily Kopp et al., *Patient Advocacy Groups Take in Millions from Drugmakers. Is There a Payback?*, KHN (Apr. 6, 2018), <https://khn.org/news/patient-advocacy-groups-take-in-millions-from-drugmakers-is-there-a-payback/> (describing trends in pharmaceutical industry influence over patient advocacy organizations and providing a database that tracks industry donations to these organizations).

88 See, e.g., Heled, Vertinsky & Brewer, *supra* note 31 (discussing private incentives to

C. Capture Across the Product Life Cycle

Pharmaceutical companies, along with other large corporate actors in the industry, adopt a holistic approach to their regulatory strategies, both across different products and across product life cycles, thinking systemically about how different regulations interact in ways that may ultimately impact product sales, and profits. Direct efforts at regulatory capture are combined with efforts to influence other aspects of market design, including the types and nature of research relevant to pharmaceutical markets, the guidelines and standards of care used by physicians, and the agendas and activities of patient advocacy groups. Pharmaceutical capture occurs when this influence is significant enough to alter the incentive structures, and corresponding decisions, of a sufficient number and range of key industry stakeholders (including patients, doctors, health care payors and regulators) in ways that systematically produce market outcomes desired by the pharmaceutical industry—often at the expense of the public interest.

Examining the opportunities for regulatory capture across the life cycle of biomedical products provides a picture of how pharmaceutical companies, as well as other powerful industry players, seek to influence every aspect of the regulatory process that might touch upon their market opportunities, ranging from before the idea for the product even emerges to post-sale liability for product harms. The following discussion offers a brief—and by no means complete—overview of capture opportunities across the product life cycle, beginning with the research preceding product discovery and development and ending in post-sale product liability.

Early Stage Biomedical Research and Development Pharmaceutical company involvement in market design begins in processes of knowledge production and in the legal structures that govern access to and control over any resulting discoveries.⁸⁹ Pharmaceutical companies play a range of different roles in the generation of scientific knowledge, as well as decisions to not generate certain kinds of scientific evidence.⁹⁰ They have some influence over the flow of government funding to support biomedical research, along with the legal structures

maximize profits and resulting impact on pharmaceutical markets).

⁸⁹ See, e.g., SERGIO SISMONDO, *GHOST-MANAGED MEDICINE: BIG PHARMA'S INVISIBLE HANDS*, (2018) (exploring the role of pharmaceutical companies in the production of medical knowledge); Kitsis, *supra* note 24 (exploring the role of pharmaceutical companies in the construction of disease, offering a case of fibromyalgia and how the search for new treatments might have influenced the definition of the illness); Marc A. Rodwin, *Five Un-Easy Pieces of Pharmaceutical Policy Reform*, 41 J. L. MED. & ETHICS 581 (2013) (exploring the improper role of drug firms in setting R&D priorities).

⁹⁰ See, e.g., Elie A. Akl & Assem M. Khamis, *The Intersection of Industry with the Health Research Enterprise*, 17 HEALTH RSCH. POL'Y & SYS. 53 (2019) (providing a framework that identifies different types of relationships between industry and researchers, particularly in pharmaceuticals).

that govern receipt of the funds and access to the results. While some funding takes the form of public-private partnerships or direct grants to the private sector, many of the drugs that pharmaceutical companies develop are based at least in part on early publicly funded research performed at universities and government labs.⁹¹

Pharmaceutical companies cultivate close relationships with the academy, often providing financial support to universities and their researchers through sponsored research and public-private collaborations, seeking in return control over publications and the option to obtain intellectual property rights to the results.⁹² As public funding for academic research has become harder to secure, financial support from pharmaceutical companies has become increasingly attractive, allowing companies to expand their influence over research activities and researchers. Despite the growing use of conflict-of-interest policies and other efforts to ensure independence of academic research, the industry's influence over research continues to grow.⁹³

Securing Rights to Publicly Funded Inventions Where promising drug candidates emerge from collaborations between public research entities and pharmaceutical companies, the companies are often able to secure rights to any inventions that emerge through the use of contracts that favor private intellectual property ownership. Where promising drug candidates arise from academic research or labs, the process for acquiring rights to commercialize publicly funded research, along with the legal strings attached to the use of such research, become the target of pharmaceutical interest. The Bayh-Dole Act (for inventions developed using federal government funding) and Stevenson-Wydler Technology Innovation Act (for inventions from federal labs) provide legal frameworks for licensing patents covering publicly funded inventions to private companies, and public-

91 See, e.g., Pierre Azoulay et al., *Public R&D Investments and Private-Sector Patenting: Evidence from NIH Funding Rules*, 86 REV. ECON. STUD. 117 (2019) (measuring the impact of NIH funding on patenting by biotech and pharmaceutical companies); Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010-2016*, 115 PROC. NAT'L ACAD. SCI. 2329 (2018)

(examining the contributions that NIH funding has made to published research associated with 210 new molecular entities that the FDA approved during the period 2010-2016); Marcela Vieira, *Research Synthesis: Public Funding of Pharmaceutical R&D*, KNOWLEDGE PORTAL (Apr. 2019), <https://www.knowledgeportalia.org/public-funding-of-r-d> (providing a comprehensive review of public funding on pharmaceutical R&D). For a critique of public-private partnerships and multistakeholder initiatives in health, see, for example, JONATHAN H. MARKS, *THE PERILS OF PARTNERSHIP: INDUSTRY INFLUENCE, INSTITUTIONAL INTEGRITY, AND PUBLIC HEALTH* (2019).

92 For a collection of papers exploring different aspects of the relationship between industry and the academic and medical community, see Publications, PHARMEDOUT, <https://sites.google.com/georgetown.edu/pharmedout/resources/publications> (last visited July 6, 2021).

93 See, e.g., Peter Whoriskey, *As Drug Industry's Influence Over Research Grows, So Does the Potential for Bias*, WASH. POST, (Nov. 24, 2012), https://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9_story.html.

private partnerships facilitate further utilization of publicly funded facilities and discoveries by private companies.⁹⁴ While this technology transfer framework provides only modest government rights and protections of the public interest, even those rights are rarely if ever exercised, compliance remains limited,⁹⁵ and efforts are now being made to weaken even these limited rights.⁹⁶ Even in the midst of a pandemic, efforts to attach reasonable pricing and access terms to federal funding of pandemic therapies and vaccines have proven unsuccessful. Indeed, the federal government has recently expanded its use of “other contracting authority” to allow funding agreements with pharmaceutical companies that are not subject even to the limited federal protections of the public interest found in traditional funding agreements.⁹⁷

Medical and Scientific Education and Discourse In addition to funding and collaborating on R&D, pharmaceutical companies also exercise considerable influence over medical and scientific discourse through relationships with academics and academic journals, publications, and educational programs.⁹⁸ A particularly insidious form of industry influence involves the practice of medical ghostwriting.⁹⁹ Pharmaceutical companies either directly or indirectly, through the use of medical education companies, hire medical writers to produce works that serve a corporate purpose and seek doctors or academics to sign on as authors or co-authors to lend legitimacy to the work, which is then published in a medical or scientific journal. “Reported examples of ghost-writing have covered up problems

94 See, e.g., PAUL W. HEISEY ET AL., *Technology Transfer by Federal Agencies*, in GOVERNMENT PATENTING AND TECHNOLOGY TRANSFER 11 (2006); see also Act to Amend the Patent and Trademark Laws (Bayh-Dole Act), Pub. L. No. 96-517, 94 Stat. 3015 (1980) (federal legislation dealing with inventions arising from federally funded research); Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (federal technology transfer law encouraging federal labs to engage in technology transfer).

95 See, e.g., Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 NATURE BIOTECHNOLOGY 953 (2012).

96 See, for example, recent proposals to “streamline” the technology transfer process and remove “barriers” to private-sector development such as those summarized in *NIST Green Paper*, supra note 26.

97 See, e.g., KEI Staff, *KEI Letter to Speaker Pelosi Regarding Use of “Other Transactions Authority” (OTA) in Coronavirus Bill to Escape Bayh-Dole Public Interest Safeguards*, Press Release, KNOWLEDGE ECOLOGY INT’L (Mar. 23, 2020), <https://www.keionline.org/32530>.

98 See supra note 92.

99 See, e.g., Chung-Lin Chen, *Assessing Potential Legal Responses to Medical Ghostwriting: Effectiveness and Constitutionality*, 5 J. LAW & BIOSCIENCES 84 (2018) (examining the extensive practices of ghostwriting by pharmaceutical companies and the challenges of legal regulation); Susan Gaidos, *Ghostwriters in the Medical Literature*, SCIENCE (Nov. 12, 2010), <https://www.sciencemag.org/careers/2010/11/ghostwriters-medical-literature> (examining the role that ghostwriters, and the medical education companies that employ them and pharmaceutical companies that fund them play in shaping medical-scientific discourse and literature); Nicola Jones, *Ghosts Still Present in the Medical Machine*, 461 NATURE 325 (2009) (discussing surveys indicating continuing problem of medical ghostwriting by pharmaceutical companies).

with drugs, sought to circumvent the Federal Food and Drug Agency's prohibition on advertising off-label indications and endeavored to create a market for a drug."¹⁰⁰ A widely publicized example of industry influence over the production and dissemination of "scientific" knowledge came to light in the extensive litigation against Merck, a well-known pharmaceutical company, after it was forced to withdraw its painkiller Vioxx from the market because of the known cardiovascular risks associated with its use.¹⁰¹ Merck's practices included the use of ghostwriters and carefully selected data in publications supporting the use of Vioxx, raising questions not just about the authorship of the studies but also about the underlying validity of the clinical trials on which the research was based.¹⁰² The Merck documents suggested that practices of this sort are widespread in the industry.¹⁰³

Using Regulatory Exclusivities to Restrict Competition Pharmaceutical companies rely upon the patent system to exclude competitors during their development and sale of a new drug.¹⁰⁴ Sometimes patents are a necessary part of the development process, given the high costs of drug discovery and development and the long period from discovery to sale. For startup biotech companies, patents secure rights to promising discoveries and make them attractive for investment and/or acquisition. Universities and government labs rely on the technology transfer provisions included in the Bayh-Dole Act and Stevenson-Wydler Technology Innovation Act to license patents to pharmaceutical companies.¹⁰⁵ Yet patents can also be used strategically by pharmaceutical companies in a wide variety of potentially anticompetitive ways to delay entry into a market well after the initial patents on a new drug have expired and well beyond the legitimate confines of their monopoly rights.¹⁰⁶ Patents work in combination with a variety

100 See, e.g., Elise Langdon-Neuner, *Medical Ghost-Writing*, 6 MENS SANA MONOGRAPH 257 (2008).

101 See, e.g., Harlan Krumholz et al., *What Have We Learnt from Vioxx?* 334 BRIT. MED. J. 120 (2007).

102 See, e.g., Janice Hopkins Tanne, *Merck Used Selective Data in Vioxx Publications*, JAMA SAYS, 336 BRIT. MED. J. 849 (2008).

103 See, e.g., Joseph S. Ross, Kevin P. Hill, David S. Egilman & Harlan M. Krumholz, *Guest Authorship and Ghostwriting in Publications Relating to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation*, 299 JAMA 1800 (2008); Stephanie Saul, *Ghostwriters Used in Vioxx Studies*, *Article Says*, N.Y. TIMES (Apr. 15, 2008), <https://www.nytimes.com/2008/04/15/business/15cnd-vioxx.html>.

104 See, e.g., Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363 (2014).

105 See, e.g., Maria Freire, *Statement of National Institutes of Health Before Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies*, NAT'L INST. OF HEALTH (Aug. 1, 2001), <https://stemcells.nih.gov/policy/statements/080101freire.htm>.

106 See, e.g., KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES (2020) (providing an overview of pharmaceutical company gaming of the patent system, including evergreening, patent thickets,

of other regulatory exclusivities, or what have been described as regulatory shelters, to significantly limit competition in pharmaceutical markets.¹⁰⁷ The pharmaceutical industry not only exploits the existing patent law framework to limit competition, but also exerts influence over patent legislation and other aspects of patent policy in order to preserve and enhance patent rights.¹⁰⁸ Anticompetitive practices such as creating patent thickets, product hopping, evergreening, and “pay for delay” arrangements, all involving the use of patents as mechanisms for restricting competition, are well documented.¹⁰⁹

Despite the fact that much of the R&D that contributes to new pharmaceuticals is not performed by pharmaceutical companies, they rely heavily on a narrative of exclusive rights fueling innovation to justify strong patent protection and resulting high prices for the products they ultimately sell.¹¹⁰ With little cost transparency, and the ready availability of data generated by an industry-funded think tank to support their arguments, this narrative is hard to attack.¹¹¹ Pharmaceutical companies are influential stakeholders in patent policy, although their power is counterbalanced by equally large and influential companies in the high tech sectors. While they tend to concentrate their lobbying and other pressures on Congress as the source of patent legislation, pharmaceutical companies also seek to influence the USPTO.¹¹² While the USPTO has limited ability to make rules, its practices can impact the availability and scope of patents as well as the costs associated with them, and the USPTO is not devoid of incentives to favor some

product hopping and pay for delay); Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), <https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive> (providing examples of how pharma uses patent strategies to delay competition). As examples of these strategies in use, see Katherine Ellen Foley, *Big Pharma Is Taking Advantage of Patent Law to Keep OxyContin from Ever Dying*, QUARTZ (Nov. 18, 2017), <https://qz.com/1125690/big-pharma-is-taking-advantage-of-patent-law-to-keep-oxycontin-from-ever-dying>; and Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG (Sep. 7, 2017, 3:00 AM PDT), <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug> (discussing the example of AbbVie's strategy of patenting multiple aspects of the research, development, and manufacturing of blockbuster drug Humira as illustrating increasing trend in biologics to find more “patentable” steps in their invention).

107 See, e.g., Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO STATE L.J. 299 (2015).

108 See, e.g., Jay P. Kesan & Andres A. Gallo, *The Political Economy of the Patent System*, 87 N.C. L. REV. 1341 (2009).

109 For a description of these different practices see, for example, RICHARDS, HICKEY & WARD, *supra* note 106. For the impact of patent practices in the context of biologics, see Greg Girvan & Avik Roy, *The Growing Power of Biotech Monopolies Threatens Affordable Care*, FOUND. FOR RSCH. ON EQUAL OPPORTUNITY (Sept. 15, 2020), <https://freopp.org/the-growing-power-of-biotech-monopolies-threatens-affordable-care-e75e36fa1529> (exploring how patents are used in anticompetitive ways to limit or even prevent competition in biologics).

110 See, e.g., Heled, Rutschman & Vertinsky, *supra* note 15.

111 See, e.g., Nik-Khah, *supra* note 73.

112 See, e.g., Kesan & Gallo, *supra* note 108.

groups, particularly large-scale patent holders and large players in pro-patent industries like the pharmaceutical industry, over others.¹¹³ While the question of whether Federal Circuit rulings are influenced by special interests is a subject of debate, pharmaceutical companies nonetheless do their best to support positions that strengthen their patent rights.¹¹⁴

Drug Approval and Industry Relationships with the FDA Regulations surrounding clinical testing and the drug approval process are of critical importance to pharmaceutical companies, and therefore also a target for industry influence. The FDA is charged with ensuring the safety, efficacy, and security of drugs, biologics, and medical devices, while also being responsible for helping to speed innovations to market where they might advance public health.¹¹⁵ This dual mandate to ensure safety and efficacy while also promoting speedy innovation brings with it conflicting pressures even before the influence of special interests is taken into account.¹¹⁶ Industry relations with the FDA remain complicated, as do determinations of the degree to which FDA decisions remain independent of these interests.¹¹⁷ FDA regulators work closely with pharmaceutical companies, and the FDA receives almost half its budget from fees paid by private industry.¹¹⁸ The FDA plays an important role in establishing guidelines and providing oversight of the design and implementation of clinical trials. The FDA then reviews applications for approvals of new drugs using evidence that pharmaceutical companies submit, including three phases of clinical trials, to determine whether the products are safe and offer some benefit over existing drugs. Pharmaceutical companies are in charge of designing and funding the generation of evidence designed to show that their products are safe and effective, and asymmetries of information and conflicts

113 See, e.g., Melissa F. Wasserman, *Deference Asymmetries: Distortions in the Evolution of Regulatory Law*, 93 TEX. L. REV. 625 (2013).

114 See, e.g., Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1 (2008).

115 See Douglas C. Throckmorton, *The Public Health Role of Drug Regulation in the U.S.*, FOOD & DRUG ADMIN. (Mar. 20, 2017), <https://www.fda.gov/media/104374/download>.

116 See, e.g., CARPENTER, *supra* note 45 (examining how the FDA has cultivated a reputation that has conferred power to regulate and the interplay between the FDA and powerful industry stakeholders).

117 See, e.g., Daniel Carpenter, *The Political Economy of FDA Drug Review: Processing, Politics and Lessons for Policy*, 23 HEALTH AFFS. 52 (2004) (arguing that the FDA drug review process involves institutional learning driven by reputational concerns but is also shaped by organized interests).

118 See, e.g., John LaMattina, *The Biopharmaceutical Industry Provides 75% of the FDA's Drug Review Budget. Is This a Problem?*, FORBES (June 28, 2018, 7:42 AM EDT), <https://www.forbes.com/sites/johnlamattina/2018/06/28/the-biopharmaceutical-industry-provides-75-of-the-fdas-drug-review-budget-is-this-a-problem>; Charles Piller & Jia You, *Hidden Conflicts? Pharma Payments to FDA Advisers After Drug Approvals Spark Ethical Concerns*, SCIENCE (July 5, 2018, 2:00 PM), <https://www.sciencemag.org/news/2018/07/hidden-conflicts-pharma-payments-fda-advisers-after-drug-approvals-spark-ethical>.

of interest abound.¹¹⁹ The FDA also reviews applications for generic versions of these drugs, based again on data provided by the applicants as well as prior data from the non-generic version of the drugs. In addition to approvals of new drugs and generic versions, the FDA can approve existing drugs for new uses. Along with approvals, the FDA provides valuable market and/or data exclusivities that augment the exclusivity conferred by existing patent protection. Pharmaceutical lobbies are constantly at work to encourage a faster, more streamlined, and less demanding review process, while also generally seeking to expand data and market exclusivities.¹²⁰

Direct and Indirect Product Marketing Marketing is a key part of the pharmaceutical business model, and pharmaceutical companies are eager to avoid rules that restrict how this marketing can take place. The product label, which is regulated by the FDA, is incredibly important to pharmaceutical marketing, since this determines the scope of what it is legally allowed to market the product as a treatment for. While physicians are able to use the drug for off-label use, direct marketing of off-label uses is illegal. Many of the lawsuits brought against pharmaceutical companies involve variations in efforts to expand off-label use of their drugs. One of the “darker side[s] of pharma marketing,” for example, “involves creating clinical trials aimed at influencing doctors and educational courses to showcase expensive drugs from non-FDA approved uses—even when there is no scientific proof of safety or efficacy.”¹²¹

Cultivating Relationships With Prescribers Building relationships between pharmaceutical companies and the physicians who prescribe their products is a key part of marketing efforts.¹²² In addition to rules against off-label marketing, there are a variety of rules governing relationships between pharmaceutical companies and physicians designed to protect against conflicts of interest, such as anti-kickback statutes that prohibit payments to physicians for prescribing drugs.¹²³ But these rules leave open substantial opportunities for pharmaceutical companies to engage in a variety of different promotional efforts that have been shown to

119 See, e.g., Light, Lexchin & Darrow, *supra* note 20.

120 See, e.g., Daniel Carpenter, *Corrosive Capture? The Dueling Forces of Autonomy and Industry Influence in FDA Pharmaceutical Regulation*, in PREVENTING REGULATORY CAPTURE, *supra* note 21, at 152 (exploring tensions between independence of the FDA and industry influence).

121 Michelle Llamas, *Selling Side Effects: Big Pharma’s Marketing Machine*, DRUGWATCH (July 17, 2016), <https://www.drugwatch.com/featured/big-pharma-marketing>.

122 See, e.g., Marc A. Rodwin, *Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform*, 40 J. L. MED. & ETHICS 511 (2012) (examining improper dependencies of physicians on pharmaceutical companies and the conflicts of interest that arise). For an exhaustive look at conflicts of interest between physicians and pharmaceutical companies see, for example, MARC A. RODWIN, *MEDICINE, MONEY, AND MORALS: PHYSICIANS’ CONFLICTS OF INTEREST* (1993).

123 See, e.g., *A Roadmap for New Physicians: Fraud and Abuse Laws*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://oig.hhs.gov/compliance/physician-education/01laws.asp> (last visited July 6, 2021).

increase prescription rates, varying from free lunches and free samples to large consulting fees and expense-paid trips to resorts. Industry influence starts early, through activities that establish relationships with medical students, and continues to build as these students leave residency and enter medical practice.¹²⁴ Much of the continuing medical education provided to physicians and other health care providers is funded, and even designed, by industry.¹²⁵ Pharmaceutical companies cultivate physicians as “key opinion leaders” to engage in speaking tours designed to augment their influence over physician education.¹²⁶ It is estimated that the pharmaceutical industry spends more than \$11 billion annually on promotion and marketing, of which approximately \$5 billion is spent on sales representatives who develop relationships with prescribers, while spending per physician is estimated to be over \$8,000.¹²⁷ Despite increasing concerns about the extent of industry influence over physician education as a pharmaceutical marketing tool, the practice continues.¹²⁸

Generating Demand From the “Consumer” Patient In addition to marketing their products to physicians, pharmaceutical companies have increasingly been marketing prescription drugs directly to patients, treating patients as consumers. Before the 1980s, pharmaceutical marketing efforts were largely focused on doctors and pharmacists. But in the 1980s, marketing strategies shifted to include, and even focus on, marketing to patients, increasingly viewed and portrayed as consumers who should be able to make their own product choices. Regulations surrounding the ability to advertise to consumers, requirements about what information industry must provide to consumers, and the role of physicians as intermediaries in that process, remain an area ripe for industry capture.¹²⁹ Direct-to-consumer (DTC) advertising is regulated by the FDA, although the FTC is charged with overseeing unfair advertising practices. The volume of DTC

124 See, e.g., Kirsten E. Austad, Jerry Avorn & Aaron S. Kesselheim, *Medical Students’ Exposure to and Attitudes About the Pharmaceutical Industry: A Systematic Review*, 8 PLOS MED. 1 (2011).

125 See, e.g., Adriane Fugh-Berman & Sharon Batt, “*This May Sting a Bit*”: Cutting CME’s Ties to Pharma, 8 VIRTUAL MENTOR 412 (2006).

126 See, e.g., Adriane Fugh-Berman, *Not in My Name: How I Was Asked to “Author” a Ghostwritten Research Paper*, GUARDIAN (Apr. 20, 2005, 9:19 PM EDT), <https://www.theguardian.com/science/2005/apr/21/science.research>.

127 See, e.g., Paul A. Komesaroff & Ian H. Kerridge, *Ethical Issues Concerning the Relationships Between Medical Practitioners and the Pharmaceutical Industry*, 176 MED. J. AUSTRALIA 118 (2002); Teri Randall, *Kennedy Hearings Say No More Free Lunch—Or Much Else—From Drug Firms*, 265 JAMA 440 (1991).

128 See, e.g., Anna Wilde Mathews, *At Medical Journals, Writers Paid by Industry Play Big Role*, WALL ST. J. (Dec. 13, 2005, 12:01 AM ET), <https://www.wsj.com/articles/SB113443606745420770>.

129 See, e.g., Michelle Llamas, *Selling Side Effects: Big Pharma’s Marketing Machine*, DRUGWATCH (July 17, 2016), <https://www.drugwatch.com/featured/big-pharma-marketing>.

pharmaceutical advertising remained fairly low until the 1980s, when a shift towards patient-centered decision-making accompanied by a political climate that was favorable to corporate interests led to greater use of consumer advertising by pharmaceutical companies. By the 1990s, earlier FDA regulations had been relaxed to accommodate the new media used for DTC advertising, and the regulations were relaxed again in 2004, each time reducing the amount and detail of the information that pharmaceutical companies were required to disclose in their advertisements. Spending on DTC advertising jumped from \$12 million in 1980 to \$47 million in 1990, \$340 million in 1995, \$1.2 billion in 1998, and more than \$5 billion in 2006 and 2007, dropping to \$4.5 billion in 2009 in response to the financial slowdown.¹³⁰ While the volume of DTC advertising has increased, the FDA's capacity to monitor the advertising has remained constant, leaving the FDA with the impossible task of monitoring a huge volume of advertising with a small team of people.¹³¹

Once patients are viewed as consumers, with the right to make choices about their health care needs, marketing becomes a form of providing consumers with information that they need to make those choices, and restrictions on advertising can be portrayed as harming consumer autonomy. The role of the physician as the gatekeeper of information about prescription drugs is inverted by this “consumerist model of health information.”¹³² In a twist of the law, pharmaceutical companies are able to market directly to consumers while at the same time relying on the learned intermediary doctrine in case law, which assumes that physicians are playing a gatekeeper role, to limit (although not remove) their duty to warn consumers of the harms attached to the products they are selling. A number of commentators have called for restrictions or even a prohibition on DTC advertising of prescription drugs to consumers, but efforts to increase restrictions on pharmaceutical advertising have been met with increasingly successful First Amendment challenges.¹³³

Limiting Legal Liabilities Pharmaceutical companies often find themselves in court in a defensive mode, defending against claims of fraud, false claims, misrepresentation, failure to warn, and—as in the case of the opioid litigation—general nuisance claims. They are among the many corporate actors seeking tort

130 C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 PHARMACY & THERAPEUTICS 681 (2011) (describing changes in FDA regulation and changes in direct-to-consumer spending over time).

131 See, e.g., Jeremy Greene & David Herzberg, *Hidden in Plain Sight: Marketing Prescription Drugs to Consumers in the Twentieth Century*, 100 AM. J. PUB. HEALTH 793 (2010); Meredith Wadman, *Drug Ads Move Online, Creating a Web of Regulatory Challenges*, 16 NATURE MED. 22 (2010).

132 See, e.g., Greene & Herzberg, *supra* note 131.

133 See, e.g., Miriam Schuchman, *Drug Risks and Free Speech—Can Congress Ban Consumer Drug Ads?*, 356 NEW ENG. J. MED. 2236 (2007).

reform and encouraging other restrictions on consumer access to the courts. But they also come to court to challenge regulations that impact their sales. Recent challenges include litigation against the Centers for Disease Control (CDC) challenging the process by which they adopted opioid guidelines, litigation against the Department of Health and Human Services (HHS) for requiring drug companies to disclose their prices, and litigation against states that engage in efforts such as ensuring emergency access to insulin stockpiles.

Pricing and Distribution The pricing and distribution systems for pharmaceuticals are complex and opaque, involving a variety of intermediaries, such as pharmacy benefit managers, and a variety of both public payors (including CMS, the Veterans Association, Tricare for military families, state Medicaid, and federal and state health insurance for its employees) and private payors (through employers or private insurers). A number of quasi-governmental actors also play a role in shaping reimbursement systems for prescription drugs, such as the compendia that influence drug use and reimbursement and formularies.¹³⁴ The fragmentation and opacity of the system, and the number of intermediaries existing between the manufacturer of drugs and the patient, makes it difficult to regulate drug pricing.

Influencing Legislators While much of the pharmaceutical capture involves industry influence outside of lawmaking, pharmaceutical companies also spend a great deal of time and money on efforts to influence legislators.¹³⁵ Industry influence on lawmaking occurs both through direct mechanisms, such as lobbying, and indirect mechanisms, such as making campaign contributions to lawmakers seeking re-election, supporting patient advocacy groups that can attract policy attention, and providing lucrative job opportunities for government actors when they retire from political roles. Beginning with direct efforts at lobbying, the pharmaceutical industry has by some accounts contributed almost \$2.5 billion to lobbying and funding members of Congress over the past decade,¹³⁶ and it remains

134 See, e.g., *Policy Primers: Prescription Drug Pricing and Consumer Costs*, HEALTH AFFS. (Sept. 14, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170914.061983/full> (“Formularies are tools used by purchasers to limit drug coverage based on favorable clinical performance and relative costs.”).

135 See, e.g., Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999-2018*, 180 JAMA INTERNAL MED. 688 (2020) (examining the magnitude of industry spending on campaign contributions and lobbying over time; identifying industry influence as a concern); Karl Evers-Hillstrom, *Big Pharma Continues to Top Lobbying Spending*, OPENSECRETS (Oct. 25, 2019, 3:42 PM), <https://www.opensecrets.org/news/2019/10/big-pharma-continues-to-top-lobbying-spending>; Lev Facher, *Pharma Is Showering Congress with Cash, Even as Drug Makers Race to Fight the Coronavirus*, STAT (August 10, 2020), <https://www.statnews.com/feature/prescription-politics/prescription-politics> (“[P]harma’s giving underscores the breadth of its influence and its efforts to curry favor through lobbying and donations to the lawmakers who regulate health care.”).

136 See, e.g., Chris McGreal, *How Big Pharma’s Money—And Its Politicians—Feed the U.S.*

the top lobbying force in Washington.¹³⁷ The pharmaceutical lobby has about two lobbyists for each member of Congress,¹³⁸ many of whom are former members of government.¹³⁹ The pattern of giving generally aligns with the power that legislators have or are likely to have, including greater giving to the party in power, greater giving to those in leadership roles, and greater attention to those with jurisdiction over issues relevant to the pharmaceutical industry.¹⁴⁰ Lobbying efforts are often successful in watering down or even preventing the passage of legislation that goes against industry interests, as can be seen by the pattern of industry pressure followed by industry-friendly modifications to legislation and even by the absence of meaningful legislation on hot-button issues such as drug pricing.¹⁴¹ The tightly organized and aligned coalitions of industry interests stand in stark contrast to a fractured and fragmented Congress, where there are many different opinions about what aspects of health care are problematic and about how best to respond to these problems.¹⁴²

Utilizing Patient Groups to Influence Regulation In addition to direct

Opioid Crisis, GUARDIAN (October 19, 2017, 6:00 AM EDT), <https://www.theguardian.com/us-news/2017/oct/19/big-pharma-money-lobbying-us-opioid-crisis> (“Nine out of 10 members of the House of Representatives and all but three of the US’s 100 senators have taken campaign contributions from pharmaceutical companies seeking to affect legislation on everything from the cost of drugs to how new medicines are approved.”).

137 See, e.g., Evers-Hillstrom, *supra* note 135; see also Elizabeth Lucas & Sydney Lupkin, *Pharma Cash to Congress*, KAISER HEALTH NEWS (May 22, 2020), <https://khn.org/news/campaign> (tracking how much pharmaceutical companies contribute to members of Congress).

138 McGreal, *supra* note 136.

139 See Sydney Lupkin, *Big Pharma Greets Hundreds of Ex-Federal Workers at the “Revolving Door,”* GUARDIAN (Jan. 25, 2018), <https://khn.org/news/big-pharma-greets-hundreds-of-ex-federal-workers-at-the-revolving-door/>.

140 See, e.g., Emmarie Huetteman & Sydney Lupkin, *Drugmakers Funnel Millions to Lawmakers: A Few Dozen Get \$100,000-Plus*, KAISER HEALTH NEWS (Oct. 16, 2018), <https://khn.org/news/drugmakers-funnel-millions-to-lawmakers-a-few-dozen-get-100000-plus>.

141 See, e.g., Jonathan H. Marks, *Lessons from Corporate Influence in the Opioid Epidemic: Toward a Norm of Separation*, 17 J. BIOETHICAL INQUIRY 173 (2020) (discussing corporate influence over legislators and policymakers); Michelle M. Mello, Sara Abiola & James Colgrove, *Pharmaceutical Companies’ Role in State Vaccination Policymaking: The Case of Human Papillomavirus Vaccination*, 102 AM. J. PUB. HEALTH 893 (2012) (documenting industry influence over legislation to support uptake of new vaccines); John Morgan, *A Bitter Pill: How Big Pharma Lobbies to Keep Prescription Drug Prices High*, CITIZENS FOR RESP. & ETHICS IN WASH. (June 18, 2018), <https://www.citizensforethics.org/reports-investigations/crew-reports/a-bitter-pill-how-big-pharma-lobbies-to-keep-prescription-drug-prices-high> (report documenting industry influence over legislation targeting prescription drug prices, includes case studies such as legislation limiting ability of government to negotiate price for drugs purchased under Medicare Part D and industry efforts to extend orphan drug designations and exclusivities); see also sources cited *supra* note 135 (exploring financial influence of pharmaceutical industry over legislators).

142 See, e.g., Florko & Facher, *supra* note 18 (“Pharma’s savvy lobbying and campaign contributions don’t account for everything—by pure luck, industry has benefited from a fractured Congress and often-chaotic White House.”).

contributions and lobbying, pharmaceutical companies engage in indirect efforts to influence legislation through charitable donations and other support for patient advocacy groups.¹⁴³ Patient advocacy organizations, nonprofit organizations that focus on combating a particular disease or disability or improving the life of a particular patient group, can and do play influential roles in health policy. The agendas of the patient advocacy organizations are often heavily influenced by their industry funders.¹⁴⁴ Some pharmaceutical companies provide millions of dollars to patient advocacy groups, many of which are comprised of patients who depend upon the products made by these companies.¹⁴⁵ In some cases pharmaceutical companies provide resources to encourage and train patients to participate in legislative advocacy, including providing testimony and exerting political pressure.¹⁴⁶ One study found that 83% of the 104 largest patient advocacy organizations receive financial support from the pharmaceutical industry, and suggested that smaller patient advocacy organizations are likely to be even more dependent on pharmaceutical funding.¹⁴⁷

Political Expenditures The pharmaceutical industry also makes often secretive contributions to organizations that themselves engage in efforts to sway legislation through carefully crafted campaigns.¹⁴⁸ This allows companies and industry groups to take a neutral policy position publicly while advancing a private agenda. As one example, the Pharmaceutical Research and Manufacturers of America (PhRMA) publicly adopted a neutral position on the Affordable Care Act

143 See, e.g., Emily Kopp et al., *PreScripton for Power: Investigating the Relationships Between Patient Advocacy Groups and Big Pharma*, KAISER HEALTH NETWORK, <https://khn.org/patient-advocacy> (“[P]atient advocacy groups [are] IRS-registered nonprofits devoted to assisting patient populations with a particular disease, disability or condition beyond simply providing services or care.” This includes groups that provide financial assistance with co-pays.)

144 See, e.g., Sarah Jane Tribble, *Drugmakers Help Turn Patients with Rare Diseases into D.C. Lobbyists*, KAISER HEALTH NEWS (Apr. 10, 2017) <https://khn.org/news/drugmakers-help-turn-patients-with-rare-diseases-into-d-c-lobbyists> (exploring conflicts of interest inherent in industry-supported patient advocacy groups that lobby for legislation that is desired by their industry supporters).

145 See, e.g., Rick Claypool, *Patients’ Groups and Big Pharma*, PUB. CITIZEN (Aug. 4, 2016) <https://www.citizen.org/wp-content/uploads/patients-groups-and-big-pharma-money-report.pdf>; Kopp et al., *supra* note 143.

146 See, e.g., Tribble, *supra* note 144.

147 See, e.g., Matthew S. McCoy et al., *Conflicts of Interest for Patient-Advocacy Organizations*, 376 NEW ENG. J. MED. 880 (2017) (seeking to quantify industry financial support for patient advocacy groups and to identify conflicts of interest)

148 See, e.g., Jay Hancock, *Drug Trade Group Quietly Spends “Dark Money” to Sway Policy and Voters*, KAISER HEALTH NEWS (July 30, 2018), <https://khn.org/news/drug-trade-group-quietly-spends-dark-money-to-sway-policy-and-voters> (discussing the role of dark money, money funneled in non-transparent ways to non-profits focused on a particular agenda designed to influence politics; arguing that such groups have thrived since the Supreme Court’s decision in *Citizens United*, which loosened rules for corporate political spending, along with limited enforcement of the remaining rules by the IRS).

while at the same time providing more than \$6 million to the American Action Network to support its efforts to put an end to the Affordable Care Act through ad campaigns and other measures.¹⁴⁹

The Revolving Door The impact of the “revolving door,” in which government employees subsequently find well-paid private employment in the industries they used to regulate, sometimes moving back and forth between the two sectors, is important but difficult to quantify.¹⁵⁰ The practice of hiring federal employees directly from agencies, particularly those involved in regulating the industry, is widespread. Although there are limitations in place designed to reduce conflicts of interest, such as a lifetime restriction on working on matters handled while in government, and a two-year ban on switching sides on a broader range of matters, in reality the practice reduces the manpower of regulators and increases industry access to the regulators still in power.¹⁵¹ Knowing this opportunity exists may impact the regulators, and once they enter private practice they bring their knowledge of enforcement strategies and their pre-existing relationships with coworkers to enhance industry-regulator relationships.

Limiting Enforcement Other parts of the regulatory strategy over the product life cycle involve capture of enforcers, such as the DEA (for controlled substances), the FTC for consumer protection and antitrust issues, and federal and state attorneys general seeking to protect consumers and the public health. The FTC is charged with protecting consumers by stopping unfair, deceptive, or fraudulent practices, such as misleading pharmaceutical advertising. The DEA is charged with enforcing U.S. controlled substance laws and regulations, including rules pertaining to the manufacture, distribution, and dispensing of legally produced controlled substances such as opioids. Federal and state attorneys general play an enforcement role through their ability to take measures such as litigating to protect the public health.

In Sum: Capture Over the Product (and Profit) Lifecycle While this product life cycle framework of pharmaceutical company influence over market structure is incomplete, it provides the outline of what a systemic view of regulation needs to encompass. As soon as a pharmaceutical company contemplates a new product,

149 *Id.*

150 See, e.g., Karen Hobert Flynn, *For Big Pharma, The Revolving Door Keeps Spinning*, HILL (July 11, 2019, 2:30 PM EDT), <https://thehill.com/blogs/congress-blog/politics/452654-for-big-pharma-the-revolving-door-keeps-spinning>; Sheila Kaplan, *From FDA Expert to Biotech Insider: The Drug Industry Thrives on the Revolving Door*, STAT (Sept. 27, 2016), <https://www.statnews.com/2016/09/27/fda-biopharma-revolving-door-study> (discussing implications of the revolving door between FDA and the biopharma industry); Morgan, *supra* note 141 (discussing how the pharmaceutical industry leverages the revolving door between government agencies and lobbying firms and the appointment of former pharmaceutical lobbyists to key government positions to influence policy and provides examples).

151 See *supra* note 150 and accompanying text.

or even before, all stages of the product life cycle become opportunities for influencing the future profit trajectory of not only the new product, but also existing and future related products and services. The sale of opioids, for example, ended up creating new opportunities for the companies selling opioids to later market drugs to treat overdosing and addiction.¹⁵² The following case study provides a concrete illustration of pharmaceutical capture across the product and market life cycle at work, highlighting the ways in which pharmaceutical companies have sought to harness every part of this framework in their pursuit of profitable drug opportunities.

II. A CASE STUDY OF CAPTURE: OPIOIDS AND THE BUSINESS OF PAIN

“It is a story of how the most ancient painkiller known to humanity has emerged to numb the agonies of the world’s most highly evolved liberal democracy And to meet that pain, America’s uniquely market-driven health-care system was more than ready.” – Andrew Sullivan¹⁵³

“There’s no question that Covid-19 is a deadly plague, with more than 90,000 deaths in the U.S. since January 2020. [But] [o]pioids are equally deadly, with approximately 450,000 lives lost to taking opioids between 1999 and 2017. In 2018 alone, there were 67,367 deaths involving opioids” – David A. Patterson Silver Wolf¹⁵⁴

Although attention has now been diverted to the pandemic caused by the rapid spread of COVID-19, the United States remains in the midst of a public health epidemic of its own creation, an opioid epidemic with its roots in the over-production, over-prescription, and abuse of prescription opioids.¹⁵⁵ These are drugs that have been developed through the direct and indirect use of publicly funded research, incentivized by government grants of patents, data and market

¹⁵² See, e.g., David Armstrong, *Facing Blame for Seeding the Opioid Crisis, Purdue Explored Its Next Profit Opportunity—Treating Addiction*, STAT (Jan. 30, 2019), <https://www.statnews.com/2019/01/30/purdue-pharma-oxycotin-maker-explored-addiction-treatment>.

¹⁵³ Andrew Sullivan, *The Poison We Pick*, N.Y. MAG. (Feb 20, 2018), <http://nymag.com/daily/intelligencer/2018/02/americas-opioid-epidemic.html>.

¹⁵⁴ David A. Patterson Silver Wolf, *Real-Time Data Are Essential for Covid-19. They’re Just as Important for the Opioid Overdose Crisis*, STAT (May 20, 2020), <https://www.statnews.com/2020/05/20/real-time-data-essential-for-opioid-overdose-crisis-as-for-covid-19> (arguing for the importance of making real time data about the opioid epidemic available).

¹⁵⁵ See, e.g., Tanya Albert Henry, *How to Reignite the Fight Against the Nation’s Opioid Epidemic*, AMA (June 23, 2020), <https://www.ama-assn.org/delivering-care/opioids/how-reignite-fight-against-nation-s-opioid-epidemic> (discussing the AMA’s concern that the already-growing opioid epidemic will be worsened by Covid-19).

exclusivities, subject to government approval and oversight, prescribed by state-licensed physicians, monitored by federal agencies, and paid for by public programs and highly regulated private insurers. The consequences of the broad availability and professionally sanctioned use of prescription opioids are widespread and the economic and social costs immense.¹⁵⁶

Although the opioid epidemic has only recently been declared a public health emergency, the epidemic is not new, and this is not even the first time that the United States has experienced a crisis of opioid overuse.¹⁵⁷ After a brief look at the earlier epidemic, this Part shows how the modern opioid epidemic emerged as the result of an intertwined evolution of medical approaches to treating pain, growth of the business of treating pain, and patient beliefs about the appropriate treatment of pain, an evolution that has been largely influenced by those with the largest financial stakes in opioid prescriptions and sales. Painkillers are one of the most widely prescribed groups of medications in the United States and a big business for industry, with opioid sales reaching \$9.6 billion in 2015.¹⁵⁸ While the profits generated by the largest distributors and manufacturers of opioids over the past few decades have been staggering, the social, economic, and human costs of the epidemic have been even more staggering. The CDC estimates “that the total ‘economic burden’ of prescription opioid misuse alone in the United States is \$78.5 billion a year,”¹⁵⁹ and studies continue to emerge documenting the devastating and far-reaching effects of the epidemic on individual lives, public health, and economic and social welfare.¹⁶⁰

Part III uses the opioid epidemic as a case study to illustrate the theory of pharmaceutical capture at work in part because of its salience and the sheer magnitude of the harms resulting from capture, and in part because of the depth of information that has been made public as a result of subsequent litigation. While the details and nuances of this story may be unique to opioids, the patterns of

156 See, e.g., Chris Christie et al., *The President’s Commission on Combatting Drug Addiction and the Opioid Crisis* (Nov. 1 2017), <https://www.doh.wa.gov/Portals/1/Documents/2300/2017/PresidentsCommissionOnCombatingDrugAddictionOpioidCrisis.pdf>.

157 See, e.g., Jessica Glenza, *America’s Opioid Epidemic Began More than a Century Ago—With the Civil War*, *GUARDIAN* (Dec. 30, 2017, 7:00 AM EST), <https://www.theguardian.com/science/2017/dec/30/americas-opioid-epidemic-began-more-than-a-century-ago-with-the-civil-war>; Sullivan, *supra* note 153.

158 See, e.g., Matthew Perone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, *ASSOCIATED PRESS NEWS* (Sept. 19, 2016), <https://apnews.com/3d257452c24a410f98e8e5a4d9d448a7>.

159 Opioid Overdose Crisis, *NAT’L INSTITUTION ON DRUG ABUSE* (Mar. 11, 2021), <https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis>.

160 See, e.g., *Deaths, Dollars, and Diverted Resources: Examining the Heavy Price of the Opioid Epidemic*, *AM. J. MANAGED CARE* (July 30, 2019), <https://www.ajmc.com/publications/supplement/deaths-dollars-diverted-resources-opioid-epidemic> (supplement that includes studies of a variety of ways in which the opioid epidemic has caused harm).

relationships, influence, and control that result in capture are far from unique, reflecting a level of industry influence and control that is endemic in the pharmaceutical industry.¹⁶¹ The following case study thus serves as a stark but useful illustration of pharmaceutical capture and its consequences.

A. Overwriting the Lessons of America's Earlier Opioid Epidemic

“Three respectable London druggists, in widely remote quarters of London, from whom I happened lately to be purchasing small quantities of opium, assured me that the number of amateur opium-eaters (as I may term them) was at this time immense; and that the difficulty of distinguishing those persons to whom habit had rendered opium necessary from such as were purchasing it with a view to suicide, occasioned them daily trouble and disputes.” – Thomas de Quincy, *Confessions of an English Opium-Eater* (1871)¹⁶²

“Opioids reach every part of society: blue collar, white collar, everybody. It’s nonstop. It’s every day. And it doesn’t seem like it’s getting any better.” – *The Opioid Diaries* (2018)¹⁶³

The United States experienced an opioid epidemic in the nineteenth century that left us with a well-documented historical record of the dangers created by the over-prescription and over-use of opioids.¹⁶⁴ This earlier epidemic also prompted a variety of government measures to restrict opioid use, including not only regulations that restricted distribution and increased liability for unauthorized sales and inappropriate prescriptions, but also efforts to alter professional education and training to discourage prescription and efforts to change public norms to discourage use. The effects of these measures persisted well into the twentieth

161 For support of this proposition, see *supra* notes 29-37 and accompanying text and *infra* notes 299-300. See also ROSENTHAL, *supra* note 1 (exploring the myriad of ways in which health care has been transformed into a business focused largely on profits, and how this focus has in turn transformed U.S. health care); Marks, *supra* note 141, at 173-74 (“Previous analyses of corporate influence in the pharmaceutical sector make clear that the opioid companies’ strategies are not entirely novel . . . These strategies are both extensive and comprehensive, involving webs or networks of relationships with government, the academy, and civil society.”).

162 Thomas de Quincy, *Confessions of an English Opium Eater*, LONDON MAG. (Sept. 1821), <https://www.gutenberg.org/files/2040/2040-h/2040-h.htm>.

163 James Nachtwey, *The Opioid Diaries*, TIME (Feb. 22, 2018), <https://time.com/james-nachtwey-opioid-addiction-america> (quoting Walter Bender, Deputy Sheriff, Montgomery County, Ohio).

164 See, e.g., Erick Trickey, *Inside the Story of America's 19th-Century Opiate Addiction*, SMITHSONIAN MAG (Jan. 4, 2018), <https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673>.

century. While the earlier epidemic shares some commonalities with the modern epidemic, however, the nineteenth century “wave of medical opioid addiction” has been described as more accidental than the current epidemic, which according to historian David Courtwright has “a more sinister commercial element to it.”¹⁶⁵ Understanding how the modern opioid epidemic emerged despite the lessons of the earlier one is an important part of the story of capture.

Opioids have been used by humans for thousands of years, with early drugs such as opium providing the foundation for later derivatives such as morphine, followed by heroin, and later prescription painkillers such as Vicodin, Percocet, and OxyContin, and finally synthetic drugs like fentanyl and methadone.¹⁶⁶ America’s first opioid epidemic dates back more than a century.¹⁶⁷ Physicians then, as now, played a central role by liberally prescribing opioids to their patients, often without a sufficient understanding and appreciation of the risks associated with their use.¹⁶⁸

Physicians first started providing morphine to their patients as a treatment for pain in the early nineteenth century, a time in which there was no criminal regulation of morphine, heroin, or opium, and opiates could be prescribed by physicians and sold by pharmacists in a largely unregulated market place.¹⁶⁹ Since physicians had few cures available they began to prescribe morphine to treat a wide variety of conditions, ranging from diarrhea to toothaches, and pharmacists were ready and waiting with a variety of morphine and other opioid-based drugs to sell over the counter to any interested customers.¹⁷⁰ While state medical licensing laws gave physicians the authority to write prescriptions, prescriptions were not required and almost any drug could be obtained without one. Two classes of drugs emerged, the first known as “patent medicines” with typically undisclosed ingredients sold under trade names and marketed heavily to consumers for self-medication, and the second group, later referred to as “ethical” drugs by the

¹⁶⁵ *Id.*

¹⁶⁶ Josh Katz, *Short Answers to Hard Questions About the Opioid Crisis*, N.Y. TIMES (Aug. 10, 2017) <https://www.nytimes.com/interactive/2017/08/03/upshot/opioid-drug-overdose-epidemic.html>.

¹⁶⁷ For a broad discussion of the history of the opioid epidemic see DAVID T. COURTWRIGHT, *DARK PARADISE: A HISTORY OF OPIATE ADDICTION IN AMERICA* (2001).

¹⁶⁸ *Id.*

¹⁶⁹ See, e.g., Jon Kelvey, *How Advertising Shaped the First Opioid Epidemic*, SMITHSONIAN MAG. (Apr. 3, 2018), <https://www.smithsonianmag.com/science-nature/how-advertising-shaped-first-opioid-epidemic-180968444>.

¹⁷⁰ See, e.g., 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, 561 (2015) (“Nineteenth-century physicians addicted patients—and, not infrequently, themselves—because they had few alternatives to symptomatic treatment.”); Kelvey, *supra* note 169; Trickey, *supra* note 164 (“Doctors then, as now, overprescribed the painkiller to patients in need, and then, as now, government policy had a distinct bias . . .”).

American Medical Association, listed in the United States Pharmacopoeia and marketed almost solely to physicians.¹⁷¹ Morphine, opium, and heroin were often used as secret ingredients in “patent medicines” marketed directly by pharmacists to consumers as solutions to common ailments, even for children.¹⁷² While no prescriptions were necessary for the more potent “ethical” opioid-based drugs, physicians nonetheless played an important role by prescribing these more potent drugs to their patients. Companies ran aggressive advertising campaigns with physicians as their target, including tactics such as placing ads for morphine in medical journals and distributing pamphlets advertising their opioid wares to physicians.¹⁷³

The commonplace, medically accepted use of morphine and opium powders by physicians in quantities sufficient to create risks of addiction, along with heavy use of opioids by the large number of veterans returning from the Civil War, contributed to an opioid epidemic in the late nineteenth century that impacted an estimated 1 in every 200 Americans.¹⁷⁴ In the wake of this epidemic, efforts were taken to change how medical providers and the public viewed the medical use of narcotics, physicians were trained to limit their use of opiates, states passed laws restricting the sale of opiates without a valid prescription, and federal legislation was enacted regulating the marketing and later pre-market approval of these drugs.

Although there was pushback from drug companies that profited from wholesale trade in narcotics and although the use of narcotics as part of medical practice persisted, a more restrictive narcotics policy and professional practice ultimately took root. Federal legislation designed to control the availability and use of opioids was passed in 1906, 1909, 1914, and 1924.¹⁷⁵ In 1908, President Roosevelt appointed as the first U.S. opium commissioner a physician, Dr. Hamilton Wright, who viewed opium and morphine as a “national curse” and saw little room for opioids as a part of legitimate medical practice.¹⁷⁶ The Harrison Narcotic Control Act was passed in 1914 as a complex compromise among competing interests, requiring anyone engaged in the sale or distribution of narcotics to register with the government, pay a tax, and keep detailed records of

171 See Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 664-665 (2006).

172 See, e.g., Kelvey, *supra* note 169.

173 See, e.g., David T. Courtwright, *Preventing and Treating Narcotic Addiction—A Century of Federal Drug Control*, 373 NEW ENG. J. MED. 2095 (2015).

174 See, e.g., Trickey, *supra* note 164.

175 See, e.g., Richard D. deShazo et al., *Backstories on the U.S. Opioid Epidemic. Good Intentions Gone Bad, an Industry Gone Rogue, and Watch Dogs Gone to Sleep*, 131 AM. J. MED. 595 (2018).

176 See, e.g., Chris McGreal, *The Making of an Opioid Epidemic*, GUARDIAN (Nov. 8, 2018, 1:00 AM EST) <https://www.theguardian.com/news/2018/nov/08/the-making-of-an-opioid-epidemic>.

transactions in narcotics open to government inspection.¹⁷⁷ Among other things, this Act made narcotics available only by prescription, turning physicians into gatekeepers of medical access to these drugs.¹⁷⁸ These changes in federal policy towards narcotics, along with efforts to change social and medical norms, acted as deterrents to opioid prescription and use.¹⁷⁹

These efforts proved successful in addressing the epidemic and curtailing opioid use for quite some time, the effects persisting well into the 1960s. But then things began to change. “American narcotic policy from the early 1920s until the middle 1960s had two key objectives: the quashing of legal maintenance and the suppression of illicit narcotic transactions through vigorous police enforcement. What has happened since then has been a qualified abandonment of the first goal, but not of the second.”¹⁸⁰ This shift in narcotic policy has its roots in the entrepreneurial efforts of companies who glimpsed the market potential for using opioids to treat pain.

B. The Co-Evolution of the Treatment of Pain and the Business of Pain

“It is hard to fathom, and bitterly ironic: the depth of the suffering caused by drugs whose ostensible purpose is to alleviate pain.” – The Opioid Diaries¹⁸¹

The market for all kinds of prescription drugs expanded in the 1950s as a combined result of new pharmaceutical products, a rise in health care consumption, and federal legislation requiring a prescription for the sale of pharmaceuticals.¹⁸² The market for prescription opioids as a treatment for acute pain also expanded, as the idea of pain as a legitimate medical condition in need of treatment became more widely accepted.¹⁸³ By 1980, acute pain was treated with opioids so often that the opioid propoxyphene was the second-most dispensed drug in the United States.¹⁸⁴ But even then, the use of prescription opioids remained limited primarily to the treatment of acute pain and to patients suffering from advanced cancer and

177 See, e.g., David T. Courtwright, *A Century of American Narcotics Policy*, in 2 TREATING DRUG PROBLEMS: COMMISSIONED PAPERS ON HISTORICAL, INSTITUTIONAL, AND ECONOMIC CONTEXTS OF DRUG TREATMENT (Dean R. Gerstein & Henrick J. Harwood eds., 1992).

178 See, e.g., Chris Elkins, *The Opioid Epidemic: What Caused the Heroin Epidemic*, DRUGREHAB (Jan. 3, 2017) <https://www.drugrehab.com/featured/opioid-epidemic-causes>.

179 See, e.g., Mark R. Jones et al., *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN THERAPY 13 (2018).

180 See, e.g., Courtwright, *supra* note 177.

181 Nachtwey, *supra* note 163.

182 See, e.g., Greene & Herzberg, *supra* note 131.

183 See, e.g., Jones et al., *supra* note 179.

184 See, e.g., Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182 (2018) (emphasizing the need to look to structural and social determinants of health framework to shape effective interventions).

other terminal conditions. Concerns about the addictive properties of opioids and fear of liability attached to overprescribing continued to limit more expansive prescribing of opioids. It took the efforts of some entrepreneurial businessmen targeting their efforts at every part of the life cycle of opioid products—from ideas about how to treat pain all the way through to post-sale strategies for limiting enforcement efforts and product liability—to overcome these concerns and fuel the market for opioid products that they were ready to provide.

1. *Commercial Construction of the Science of Pain and Addiction*

“What is the purpose of publications? . . . [The] purpose of data is to support, directly or indirectly, the marketing of our product.” – taken from a Pfizer sales document¹⁸⁵

Beginning in the 1980s, the ways in which doctors were trained and expected to treat pain and general public perceptions about what kinds of pain necessitated treatment began to shift. While the shift may have begun at least in part as a response to concerns about the undertreatment of pain, it was magnified by a small but growing number of companies that saw the opportunity to make money from the treatment of pain.¹⁸⁶ Leading the charge in this effort to transform the treatment of pain, and therefore the market for opioids, was a now infamous company called Purdue Pharma.¹⁸⁷

Purdue Pharma began a campaign to implant two ideas into the medical marketplace—the idea that health care providers were not adequately addressing the pain suffered by their patients, and the idea that opioids could be used to treat pain without causing addiction.¹⁸⁸ The claim that opioids were not that addictive was introduced into medical discourse in 1980 with the publication of a five-sentence letter to the editor in the *New England Journal of Medicine* that suggested low rates of addiction among a sample of hospitalized patients who received at least one dose of narcotics.¹⁸⁹ The letter provided no evidence to back up its claims

185 Barton Moffatt & Carl Elliott, *Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles*, 50 PERSPS. BIOLOGY & MED. 18 (2007) (examining the harmful effects of ghostwriting medical articles as a pharmaceutical marketing tool).

186 See, e.g., Sarah DeWeerd, *Tracing the U.S. Opioid Crisis to Its Roots*, NATURE (Sept. 11, 2019), <https://www.nature.com/articles/d41586-019-02686-2>.

187 See, e.g., Sari Horwitz et al., *Inside the Opioid Industry's Marketing Machine*, WASH. POST (Dec. 6, 2019), <https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing> (using evidence from unsealed court documents to show the role of Purdue Pharma in using aggressive and often misleading marketing to grow the market for opioids as a treatment for pain).

188 See, e.g., Ed. Bd., *An Opioid Crisis Foretold*, N.Y. TIMES (Apr. 21, 2018), <https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html>.

189 Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123, 123 (1980) (letter to the editor that reported that only 4 out of 11,882 hospitalized people given opioids became addicted, offered without supporting evidence, concluded that “despite

and, indeed, did not purport to be a controlled study, yet through the promotional efforts of companies like Purdue Pharma it became the basis for subsequent widespread industry claims that opioids were safe if properly managed. A bibliometric study of this letter mapped the subsequent pattern of heavy citing of the letter as “scientific” support for the broad claim that the long-term use of opioids was rarely associated with addiction.¹⁹⁰ A later paper describing the treatment of thirty-eight patients with chronic pain, also anecdotal in nature, published in the medical journal *Pain* in 1986 concluded that opioids could be safely prescribed even on a long-term basis.¹⁹¹ This study also became widely relied upon. “The scientific background for the use of opioids for non-malignant pain was therefore not based upon any demonstrable outcomes or safety studies.”¹⁹² The 1986 paper was co-authored by a leading pain authority, Dr. Russell Portenoy, who soon became one of the pharmaceutical industry’s highly compensated key “thought leaders” on the use of opioids to treat nonacute pain. Despite the lack of solid scientific foundation, these early papers became the basis for a marketing campaign by opioid producers designed to convince physicians that prescription opioids were safe and effective to treat chronic pain.

Building on this frail and faulty “scientific” foundation, companies with vested interests in growing the market for opioids played an active role in establishing additional “studies” and papers to bolster the belief among many physicians that there was little risk of addiction or even abuse associated with the use of prescription opioids to treat pain.¹⁹³ The pharmaceutical industry role in shaping medical discourse on opioids continued to evolve well beyond the use of these existing early “studies.” Pharmaceutical companies used practices such as medical ghostwriting, in which they would hire a medical writer or medical communications company to write a paper favorable to their product and then secure doctors or academics as “authors” of the articles, which would then be published in medical journals.¹⁹⁴ Ghostwriting was used to proliferate the

widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction”).

190 Pamela T.M. Leung, Erin M. Macdonald, Irfan A. Dhalla & David N. Juurlink, *A 1980 Letter on the Risk of Opioid Addiction*, 376 *NEW ENG. J. MED.* 2194 (2017).

191 See, e.g., Kolodny et al., *supra* note 170. The paper cited was Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 *PAIN* 171 (1986).

192 See, e.g., Jones, Viswanath, Peck, Kaye, Gill & Simopoulos, *supra* note 179.

193 See, e.g., William C. Becker & David A. Fiellin, *Limited Evidence, Faulty Reasoning, and Potential for a Global Opioid Crisis*, 358 *BRIT. MED. J.* 3115 (2017); Sonia Moghe, *Opioid History: From ‘Wonder Drug’ to Abuse Epidemic*, CNN (Oct. 14, 2016, 6:41 AM EDT), <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html>.

194 See, e.g., Adriane Fugh-Berman, *The Corporate Coauthor*, 20 *J. GEN. INTERNAL MED.* 546 (2005); Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, 4 *PLOS MED.* 1429 (2007).

publication of studies dismissing the addictive nature of opioids and promoting their benefits. In addition to ghostwriting, pharmaceutical companies used their control over unpublished information relevant to opioids to control medical and public understandings about opioids. This selective disclosure of information extended to clinical testing, influencing the design of clinical studies, and the selective disclosure of results.¹⁹⁵

The message that opioids were not addictive was accompanied by the promotion of work emphasizing the undertreatment of pain. By 1990, medical attention had focused on the undertreatment of chronic pain, which remains among the most common reasons for seeking medical attention.¹⁹⁶ The Institute of Medicine noted an increased prevalence of reported chronic pain, attributing it to factors such as greater patient expectations for pain relief, obesity, musculoskeletal disorders in an aging population, increased frequency and complexity of surgery, and greater survivor rates after injury and cancer.¹⁹⁷ Instead of expanding access to time-consuming and often expensive behavioral pain therapy approaches, the health care response was largely to increase the prescription of opioids for chronic pain.¹⁹⁸

The national shift towards broad prescribing of opioids thus began with the systematic marketing of the idea that opioids might be safer and less addictive than previously thought. This marketing campaign, which was driven by opioid manufacturers and distributors, involved the financial support and use of questionable research and the misinterpretation and misstatement of results to influence physician attitudes towards the prescription and use of opioids.¹⁹⁹

195 Regulatory failures by the FDA, including inadequate oversight of the approval process for opioids, have been exposed in subsequent government reports. In 2017 the President's Commission on Combatting Addiction and the Opioid Crisis found that the epidemic was caused in part by inadequate FDA oversight, including failures to obtain adequate evidence of effectiveness before approving new opioids. Christie et al., *supra* note 156; see, e.g., Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 *AMA J. ETHICS* 743 (2020).

196 See, e.g., Gery P. Guy et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015*, *CTS. FOR DISEASE CONTROL & PREVENTION* (July 7, 2017), <https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm>.

197 See, e.g., Dasgupta et al., *supra* note 184.

198 For a discussion of why alternative non-opioid treatments may have failed to emerge, see, for example, Hemel & Ouellette, *supra* note 28 (explaining how the IP incentive structures in place may have failed to facilitate investments in non-addictive treatments, and how these disincentives were compounded by other regulatory shortcomings). For suggestions of how industry may have influenced this shift away from the development of non-addictive alternative treatments, see, for example, Marks, *supra* note 141.

199 See, e.g., Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, *NEW YORKER* (Nov. 8, 2013), <https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic>.

2. Pain Associations as Corporate Partners

“Our goal is to bind these organizations more closely to us than heretofore, but also to align them with our expanded mission and to see that the fate of our product(s) are inextricably bound up with the trajectory of the pain movement.” – Purdue President Richard Sackler, in a 2001 internal email conversation about meeting with patient-advocacy groups²⁰⁰

As part of their campaign to encourage the use of opioids for long-term chronic pain, pharmaceutical companies funded and sometimes even created professional and patient pain advocacy groups, such as the American Pain Foundation and American Pain Society (APS), to serve as “fronts” for pharmaceutical lobbying and promotional efforts.²⁰¹ As documented in a recent report by former Missouri Senator Claire McCaskill, these groups became involved in issuing guidelines that minimized the risks of addiction, lobbying against laws aimed at curbing opioid abuse, and even protecting doctors sued for overprescribing painkillers.²⁰²

Professional organizations such as the APS, formed in 1977, became actively involved in encouraging more aggressive treatment of pain in the 1990s with a campaign to reduce what was seen by some physicians as the underassessment and undertreatment of pain.²⁰³ APS published guidelines that encouraged doctors to expand their use of narcotics to treat pain in 1995, and in 1996 it established the pain as the “Fifth Vital Sign” campaign to publicize its guidelines.²⁰⁴ Throughout the 1990s, APS aggressively promoted the concept of pain as a “vital sign” requiring assessment and treatment at the physician’s office or after treatment in a hospital.²⁰⁵ The Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), which controls accreditation of health facilities, followed in 2001 with pain management standards requiring hospitals to measure pain, and the Federation of State Medical Boards not only supplied prescribing guidelines, but also called on the medical boards to penalize physicians for the undertreatment of

200 See Julia Lurie, *Unsealed Documents Show How Purdue Created a “Pain Movement,”* MOTHER JONES (Aug. 29, 2019), <https://www.motherjones.com/crime-justice/2019/08/unsealed-documents-show-how-purdue-pharma-created-a-pain-movement> (quoting Richard Sackler in email obtained as part of Massachusetts litigation against Purdue).

201 *Id.*

202 See *Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement*, U.S. SENATE HOMELAND SEC. & GOVERNMENTAL AFFS. COMM. (2018).

203 See N. Levy et al., “Pain as the Fifth Vital Sign” and Dependence on the “Numerical Pain Scale” Is Being Abandoned in the U.S.: Why?, 120 BRIT. J. ANAESTHESIA 425 (2018).

204 *Id.*

205 See, e.g., Brian F. Mandell, *The Fifth Vital Sign: A Complex Story of Politics and Patient Care*, 83 CLEVELAND CLINIC J. MED. 400 (2016).

pain. The Joint Commission adopted standards that required health care organizations under its jurisdiction to “recognize the right of patients to appropriate assessment and management of pain.”²⁰⁶

The efforts of the APS to encourage the treatment of pain were closely aligned with the aggressive marketing of opioids by companies such as Purdue Pharma, Johnson & Johnson, and Endo Pharmaceuticals, and it received significant funding from opioid manufacturers to support its activities.²⁰⁷ The now-defunct American Pain Foundation received 90% of its funding in 2010 from the drug and medical device industry, and its board members included those with extensive financial relationships to drug makers.²⁰⁸ The Joint Commission received financial support for the publication of its pain guidelines, and the Federation of State Medical Boards allegedly accepted money from pharmaceutical companies to produce and distribute aggressive prescribing guidelines for narcotics.²⁰⁹

The relationships between professional organizations and industry in this process of establishing guidelines for the treatment of pain have been the subject of increasing public scrutiny as the extensive financial ties between these organizations and opioid manufacturers and distributors have been uncovered.²¹⁰ But although many of these pain associations have been discredited and even dissolved, the changes in standards of care that resulted from the activities of these associations have persisted.

3. Recruiting Prescribers

“My viewpoint is that I can have these relationships [and] they would benefit my research mission and to some extent they can benefit my own pocketbook, without producing in me any tendency to engage in undue influence or misinformation.”

²⁰⁶ See, e.g., Holcomb B. Noble, *A Shift in the Treatment of Chronic Pain*, N.Y. TIMES (Aug. 9, 1999), <https://www.nytimes.com/1999/08/09/us/a-shift-in-the-treatment-of-chronic-pain.html>.

²⁰⁷ See, e.g., Gounder, *supra* note 199; see also Francie Diep, *Did Researchers Who Seek to Relieve Pain Contribute to the Opioid Epidemic?*, PACIFIC STANDARD (May 2, 2019), <https://psmag.com/social-justice/did-researchers-who-seek-to-relieve-pain-contribute-to-the-opioid-epidemic> (“A congressional investigation has found that, between 2012 and 2017, the society received more than \$960,000 from America’s top five opioid manufacturers.”)

²⁰⁸ See, e.g., Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, PROPUBLICA (May 8, 2012, 8:57 PM EDT), <https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups>.

²⁰⁹ See, e.g., John Fauber, *Follow the Money: Pain, Policy, and Profit*, MEDPAGE TODAY (February 19, 2012), <https://www.medpagetoday.com/Neurology/PainManagement/31256>.

²¹⁰ See, e.g., HSGAC Minority Staff Report, *Fueling an Epidemic, Report 3 (referred to as the Mckaskill report)* at <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf>; Ornstein & Weber, *supra* note 208.

– Dr. Russell Portenoy²¹¹

A sharp increase in the overall number of medical prescriptions for prescription drugs written and dispensed occurred in the mid- to late-1990s, and this increase can be attributed at least in part to aggressive marketing campaigns pursued by pharmaceutical companies with physicians and others with influence over prescription decisions as their target.²¹² The relationships between physicians, professional associations representing physicians, and pharmaceutical companies that led to increased prescribing of prescription drugs in general, and of opioids in particular, are elaborate and, by now, well-documented. Looking specifically at opioids, pharmaceutical companies worked with physicians, medical researchers, medical associations, and patient groups to establish pain as a problem that required adequate treatment and opioids as safe and effective treatments.²¹³ Pharmaceutical companies responded to the business opportunities created by the chronic pain market with a proliferation of both new opioid-based therapies and marketing strategies that included downplaying addiction risks, promoting off-label use, physician kickback schemes to encourage prescriptions in high volumes, and other more indirect forms of encouraging physicians to prescribe opioids.²¹⁴

Direct marketing by pharmaceutical companies to physicians in the United States is not only widespread, but also effective: prescribing rates have been shown to increase in response to even small-scale marketing efforts such as free meals.²¹⁵ Opioid manufacturers engaged in particularly aggressive large-scale marketing of opioid products to physicians, first to overcome inhibitions about prescribing opioids outside of cancer and acute pain, and then to encourage larger volumes of prescriptions. Large staffs of sales representatives trained to carry messages about the nonaddictive nature of opioids made thousands of sales calls to physicians and were compensated based on resulting prescription volumes. Compiled data on prescribing behaviors by physicians was used to focus marketing efforts on the highest prescribers, and extra marketing efforts were targeted at states with less stringent prescription controls in place.²¹⁶ Recent research has shown that at least

211 See Arthur H. Gale, *Drug Company Compensated Physicians Role in Causing America's Deadly Opioid Epidemic: When Will We Learn?*, 113 MO. MED. 244, 248 (2016).

212 Nora D. Volkow, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, NAT'L INST. ON DRUG ABUSE (May 14, 2014), <https://archives.drugabuse.gov/testimonies/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

213 See, e.g., DeWeerd, *supra* note 186.

214 See, e.g., Dasgupta et al., *supra* note 184 (emphasizing the need to look to structural and social determinants of health framework to shape effective interventions).

215 See, e.g., Colette DeJong et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, 176 JAMA INTERNAL MED. 1114 (2016).

216 See, e.g., Austin Frakt, *Damage from OxyContin Continues to Be Revealed*, N.Y. TIMES (Apr. 13, 2020), <https://www.nytimes.com/2020/04/13/upshot/opioids-oxycotin-purdue-pharma.html>; Abby E. Alpert et al., *Origins of the Opioid Epidemic and Its Enduring Impacts* (Nat'l Bureau

one in twelve U.S. physicians, and one in five family physicians, received some form of direct marketing for opioids, and that increased industry marketing of opioid products to physicians, ranging from consulting fees and speaker fees to free meals and travel, is associated with higher rates of prescribing opioids and also elevated overdose deaths.²¹⁷

In order to encourage physicians to use opioids widely to treat pain, the pharmaceutical companies had to address concerns about the addictive nature of opioids and questions about their effectiveness as a treatment for long term chronic pain. They also had to ingrain ideas of pain as requiring treatment and opioids as a viable, indeed as the preferred, option into physician standards of patient care. One of the many ways in which they did this was to design and fund medical education for physicians and other health care providers likely to influence prescription volumes. Purdue Pharma alone provided financial support for more than 20,000 pain related educational programs between 1996 and 2002.²¹⁸ In roughly the same time period it conducted over forty national pain-management and speaker-training conferences in luxury resorts, all expenses paid, for more than 5,000 physicians, pharmacists, and nurses. From these conferences, Purdue selected and trained “thought leaders” for its speaker bureau. Part of the pharmaceutical marketing strategy involved selecting amenable medical experts as “thought leaders” to provide highly compensated presentations and articles designed to encourage expanded use of prescription opioids to treat pain. The neurologist and pain specialist Dr. Portenoy, once widely respected and known as the “King of Pain,” was one of the leading proponents in encouraging the prescription of opioids, providing other physicians with assurances that the risks of addiction were minimal and that the inadequate treatment of pain bordered on medical negligence.²¹⁹ As a young doctor, Portenoy had co-authored one of the early papers mentioned, suggesting that opioids could be used more broadly for patients not suffering from cancer. This paper, based on observations from just thirty-eight cases, opened up the door for broader opioid use. Later, Portenoy and his followers were involved in writing articles and giving lectures to the medical community about the safety and effectiveness of narcotics. Portenoy was a director of the American Pain Foundation and President of the APS, and both he and the pain associations he was involved with received millions of dollars from opioid manufacturers and distributors for the promotion of opioids to the medical

of Econ. Rsch., Working Paper No. 26500, 2019).

217 See, e.g., Scott E. Hadland et al., *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related Overdoses*, 2 JAMA NETWORK OPEN 1 (2019).

218 See, e.g., Kolodny et al., *supra* note 170.

219 See, e.g., Gale, *supra* note 211 (describing the relationships between Dr. Portenoy and the pharmaceutical industry and the role he was compensated to play as a thought leader in encouraging opioid use).

community. Many other physicians had similar relationships with opioid manufacturers, receiving various forms of compensation for providing lectures and participating in “pain education” programs. Portenoy, now discredited, admits that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.”²²⁰

In response to assurances from pharmaceutical companies and their “thought leaders” that patients would not become addicted to opioid pain relievers, and in reaction to the industry-wide adoption of pain as a “fifth vital sign” requiring greater attention, doctors began prescribing opioids at greater rates. It is estimated that the volume of opioids prescribed increased by more than 400% from 1999 to 2010, an increase matched by the increasing number of prescription-drug-related deaths over the same period. This increase occurred despite the fact that there was little change in the pain reported by patients, and was largely attributed to an increase in the use of opioids to treat non-cancer-related chronic pain.²²¹ By 2013, health care providers were writing nearly a quarter of a billion opioid prescriptions, enough for every American adult to have their own bottle of pills.²²²

Marketing efforts by pharmaceutical companies have been creative, pervasive, constantly changing, and effective. New technologies, such as novel ways of automating health records, have continued to offer the industry opportunities to further its messages. Take, for example, the case of Practice Fusion, a software company offering free ad-supported health records software, which created a health records tool at the request of opioid manufacturers as a way of increasing prescriptions of opioids. The tool, used by physicians, created a pop-up alert upon opening a health record that would ask about a patient’s level of pain, followed by a drop-down menu listing a variety of options for treating pain including prescribing opioids, followed by a treatment plan designed to encourage opioid prescriptions.²²³

4. Patents and FDA Approval as Tools to Secure the Market for “Innovative” Opioid Products

In 1987, the FDA approved MS Contin, a morphine-based drug, as the first

²²⁰ See, e.g., Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J. (Dec. 17, 2012, 11:36 AM ET), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

²²¹ See Guy et al., *supra* note 196.

²²² Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

²²³ See, e.g., Bloomberg, *In Secret Deal with Drugmaker, Health-Records Tool Pushed Opioids to Doctors*, L.A. TIMES (Jan. 30, 2020), <https://www.latimes.com/business/story/2020-01-30/health-records-company-pushed-opioids-to-doctors-in-secret-deal>.

formulation of an opioid pain medicine that could be dosed every twelve hours instead of more frequently.²²⁴ This was followed by FDA approval of OxyContin, the first formulation of oxycodone that could be dosed every twelve hours, in 1995. OxyContin was billed as an innovation that would offer the benefits of pain relief without the risks of addiction, with its slow-timed release designed to moderate the effects of the drug. The drug was marketed as nonaddictive based on support from Portenoy's study of thirty-eight subjects, with heavy reliance placed on this study to support the message that most patients would not develop addiction from even long-term treatment of pain using this and other opioid medications. Purdue emphasized this innovation of a timed release of oxycodone when securing FDA approval for OxyContin as a new and "safer" drug, an approval based on its claim that the timed release made the drug effective for 12 hours and reduced chances of abuse.²²⁵ Purdue managed to obtain FDA approval for the drug despite the absence of studies showing that the drug was an improvement over existing treatments for pain.²²⁶ The FDA's failure to obtain adequate evidence of safety and effectiveness was not limited to Oxycodone or OxyContin. Indeed, while the full role of the FDA in contributing to the opioid epidemic is still under investigation, evidence of failures in oversight includes a failure to properly enforce marketing regulations, a failure to obtain adequate evidence of long-term safety and effectiveness of opioids, and a failure to manage conflicts of interest.²²⁷

The new formulation of the drug was also used to obtain patent protection, which could then be used to limit competition.²²⁸ Purdue introduced another new (patented) formulation of the drug that allegedly reduced the risk of abuse in 2010.²²⁹ It has made a number of other slight adjustments to the drug over time, many of the changes directed at extending patent protection for the drug. Through small changes to the chemical structure of the drug to create a slow-release pill,

224 See *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, FOOD & DRUG ADMIN. (Mar. 30, 2021), <https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse> [hereinafter *FDA Opioid Timeline*].

225 See, e.g., Frakt, *supra* note 216.

226 See, e.g., Kolodny, *supra* note 195 (explaining how the FDA failed to require adequate safety and effectiveness data).

227 See, e.g., *id.*; Christie et al., *supra* note 156; *60 Minutes: Did the FDA Ignite the Opioid Epidemic?* (CBS television broadcast Feb. 24, 2019).

228 For a broader discussion of how the opioid crisis is intertwined with intellectual property law, see, for example, Hemel & Ouellette, *supra* note 28.

229 See, e.g., Associated Press, *Revamped OxyContin Was Supposed to Reduce Abuse, But Has It?*, STAT (July 22, 2019), <https://www.statnews.com/2019/07/22/revamped-oxycontin-was-supposed-to-reduce-abuse-but-has-it> (questioning whether reformulation reduced health risks, although marketing it as such helped sales, and the patent provided additional exclusivity); Amanda D'Ambrosio, *FDA Panel: Reformulated OxyContin Did not Reduce Overall Abuse*, MEDPAGE TODAY (Sept. 11, 2020), <https://www.medpagetoday.com/publichealthpolicy/opioids/88583>.

Purdue has been able to file new patents for OxyContin thirteen times with the USPTO, extending exclusive rights on the drug all the way to 2030.²³⁰

Opioid use accelerated rapidly starting with the introduction and heavy marketing of OxyContin.²³¹ After just a few years, and one of the most aggressive pharmaceutical marketing campaigns ever undertaken for a narcotic pain killer, annual sales of OxyContin reached \$1 billion.²³² When approving OxyContin, the FDA believed that this drug would be less susceptible to abuse than prior drugs because of its slow-release properties, but this proved not to be the case. Starting in the 2000s, efforts were made by the FDA and other federal agencies to engage in intra-agency coordination to address the harms from opioid abuse, but these efforts were largely ineffectual. They focused largely on patient education, stronger warnings, and public-private partnerships with pharmaceutical companies designed to establish risk management programs and consumer education programs. Public-private partnerships such as the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) Initiative, designed to improve clinical studies of pain medicines and promote the development of safer pain medicines, included the very pharmaceutical companies that were marketing (and mismarketing) existing opioids.²³³

5. Corporate Influence Over Standards of Care and Liability

The standard of patient care both influences and is influenced by general medical practices, scientific and medical understandings, legal proceedings and laws that establish or shield doctors from liability, and reimbursement guidelines. Prior to the 1990s, standards of care for the treatment of patients experiencing pain did not include the use of opioids outside of the care of terminally ill cancer patients or use for the treatment of acute pain.²³⁴ Physicians who deviated from these practices risked legal liability.

In the 1990s, as discussed above, physicians and pain advocacy groups,

230 See, e.g., Katherine Ellen-Foley, *Big Pharma Is Taking Advantage of Patent Law to Keep OxyContin from Ever Dying*, QUARTZ (Nov. 18, 2017), <https://qz.com/1125690/big-pharma-is-taking-advantage-of-patent-law-to-keep-oxycontin-from-ever-dying>.

231 See, e.g., Kolodny et al., *supra* note 170.

232 See, e.g., Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <https://www.nytimes.com/2007/05/10/business/11drug-web.html>.

233 See, e.g., NAT'L ACADS. OF SCIS., ENG'G & MED., *Public-Private Partnerships to Advance Pain and Opioid Use Disorders Research and Development*, in *ADVANCING THERAPEUTIC DEVELOPMENT FOR PAIN AND OPIOID USE DISORDERS THROUGH PUBLIC-PRIVATE PARTNERSHIPS: PROCEEDINGS OF A WORKSHOP* (2018).

234 See, e.g., Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16 *EXPERIMENTAL & CLINICAL PSYCHOPHARMACOLOGY* 405 (2008).

working closely with and often financed by pharmaceutical companies, began advocating for broader and more aggressive use of pain and pushed for the removal of barriers to the use of opioids to treat pain.²³⁵ These efforts were targeted at getting professional organizations and regulators to change the standard of care for patients experiencing pain. In 1996, the American Academy of Pain Medicine and the APS issued a joint statement that opioids should have a role in the treatment of nonacute pain. According to this statement

[t]he trend is to adopt laws or guidelines that specifically recognize the use of opioids to treat intractable pain. These statements serve as indicators of increased public awareness of the sequelae of undertreated pain and help clarify that the use of opioids for the relief of chronic pain is a legitimate medical practice.²³⁶

The HHS responded with Clinical Practice Guidelines for the management of acute pain and cancer pain that included statements that opioids are an essential part of pain management. While opioids had long been classified as controlled substances and liability attached to misuse, states began to pass intractable pain treatment acts that removed the threat of prosecution for physicians who aggressively treated pain with controlled substances.²³⁷

Thus, “[a]fter 40 years of debate among doctors, medical review boards and law-enforcement officials, state legislatures begun passing laws to shield doctors from being prosecuted for prescribing powerful medications against intractable pain.”²³⁸ This change in the law was prompted by changes in medical consensus about the appropriate use of opioids, a consensus that was formed by pharmaceutical companies working closely with pain advocacy groups and physicians who believed that opioids were the appropriate treatment for nonacute pain.²³⁹ In 1998, the Federation of State Medical Boards, also a recipient of

235 See, e.g., deShazo et al, *supra* note 175 (discussing changes in state laws to reduce liability for prescribing opioids in the 1990s).

236 See Am. Acad. of Pain Med. and the Am. Pain Soc’y, *The Use of Opioids for the Treatment of Chronic Pain, Consensus Statement*, 6 J. PHARM. CARE PAIN & SYMPTOM CONTROL 97 (1998) (“Our objective is for state policies to recognize but not interfere with the medical use of opioids for pain relief . . .”).

237 See e.g., deShazo et al., *supra* note 175; DeWeerd, *supra* note 186.

238 See, e.g., Noble, *supra* note 206.

239 See, e.g., Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221 (2009). For an overview of the ways in which the pharmaceutical companies developed and used relationships with doctors and various professional associations to alter the standard of care in ways that promoted opioid use, see, for example, Elaine Silvestrini, *Profiting from Pain*, DRUGWATCH (Dec. 15, 2017), <https://www.drugwatch.com/featured/opioid-crisis-big-pharma>.

industry funds, announced a recommended policy reassuring doctors that they would not face regulatory action for their opioid prescriptions provided it was in the course of medical treatment.²⁴⁰ In 2001, the Joint Commission on the Accreditation of Healthcare Organizations charged with accrediting U.S. hospitals issued new standards requiring hospitals to make the treatment of pain a priority. Going even further, in 2004, the Federation of State Medical Boards, with the support of the Joint Commission, proposed to reverse liability, suggesting that for the first time, state medical boards make undertreatment of pain punishable.²⁴¹ Interestingly, by 2004, OxyContin had already become one of the leading drugs of abuse in the United States.²⁴²

The campaign by pharmaceutical companies and their commercial allies to ingrain the idea of pain as a fifth vital sign and to shift accountability from the over-prescription of opioids to the undertreatment of pain was aimed not just at medical providers, but also at patients. The idea was to make the treatment of pain a part of patient care, to foster patient expectations that pain would be treated, and to evaluate the quality of care based on patient satisfaction with pain treatment. In 2001, the Institute of Medicine issued a report called *Crossing the Quality Chasm: A New Health System for the 21st Century*, which identified six ways in which the quality of medical care, and therefore the patient's experience, needed to improve, using patient satisfaction as a proxy for measuring gains in these areas.²⁴³ This was followed by the creation of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey by the CMS and the Agency for Healthcare Research and Quality, which incorporated patient satisfaction data and functioned as a measure of quality care.²⁴⁴ Hospitals were required to participate in the HCAHPS under the Deficit Reduction Act of 2005, and "the Patient Protection and Affordable Care Act of 2010 expanded the role of patient satisfaction as a payment incentive by including the HCAHPS Survey scores as a part of the Hospital Value Based Purchasing program."²⁴⁵ Given the way the scores were calculated, patient perception of pain control had a large impact on

240 See, e.g., Catan & Perez, *supra* note 220.

241 See, e.g., Silvestrini, *supra* note 239.

242 See, e.g., Zee, *supra* note 239; see also Theodore J. Cicero et al., *Trends in Abuse of OxyContin and Other Opioid Analgesics in the United States: 2002-2004*, 6 J. PAIN 662 (2005) (study of prevalence and magnitude of abuse of OxyContin and other prescription).

243 See INST. OF MED. (U.S.) COMM. ON QUALITY OF HEALTH CARE IN AM., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* (Nat'l Acads. Press 2001) [hereinafter *CROSSING THE QUALITY CHASM*].

244 See, e.g., HCAHPS Fact Sheet, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 2, 2017), https://www.hcahpsonline.org/globalassets/hcahps/facts/hcahps_fact_sheet_november_2017.pdf.

245 See T. Rummans et al., *How Good Intentions Contributed to Bad Outcomes*, 93 *Mayo Clinic Proceedings* 344, 347 (2018); see also HCAHPS: Patient's Perspectives of Care Survey, CMS Fact Sheet at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS>.

reimbursement under this purchasing program, and there is evidence that physicians who denied patient requests for opioids received lower scores.²⁴⁶

6. Patients as Consumers and The Marketing of Pain

“Convincing people they are sick and need a drug is a multi-billion dollar industry.”²⁴⁷

The notion that pain needed to be regularly assessed in all patients, and the idea that pain was subjective and thus treatment should be based on self-reporting by the patient, became accepted as part of both the provision and the administration of health care.²⁴⁸ From there, the treatment of pain became a measure of patient satisfaction, and patient satisfaction became a measure of physician and hospital performance, and that in turn became a determinant of funding.²⁴⁹ This made the patient, and the patient’s expectations about how pain should be treated, a focal point for pharmaceutical companies interested in expanding opioid sales. While early marketing efforts by opioid manufacturers had focused largely (although not exclusively) on physicians or others with prescribing authority and pharmacists, later efforts included substantial investments in marketing to patients, portrayed by the industry as “consumers,” a shift discussed at length in Part II in the context of DTC advertising and related marketing by pharmaceutical companies to patients.

C. Legislative Capture

The co-evolution of the treatment of pain and the business of pain described above has been facilitated by pharmaceutical industry influence over legislative and enforcement efforts. According to a study by the Center for Public Integrity and *Associated Press*, participants in the Pain Care Forum, a coalition of industry, professional, and patient advocacy groups that is financed largely by drug companies, spent more than \$740 million lobbying federal and state lawmakers on a variety of issues that included opioid-related measures between 2006 and 2015, with an additional \$140 million spent on political campaign contributions.²⁵⁰ “Nine out of 10 members of the House of Representatives and all but three of the US’s 100 senators have taken campaign contributions from pharmaceutical companies seeking to affect legislation on everything from the cost of drugs to how new

246 See, e.g., Anthony Jerant et al., *Association of Clinician Denial of Patient Requests with Patient Satisfaction*, 178 JAMA INTERNAL MED. 85 (2018).

247 Llamas, *supra* note 129.

248 See, e.g., Mandell, *supra* note 205.

249 *Id.*; see also Levy et al., *supra* note 203 (discusses strategies to encourage treatment of pain through measures such as a campaign to include pain as a fifth vital sign).

250 See, e.g., Perone & Wieder, *supra* note 158.

medicines are approved.”²⁵¹ The opioid industry, along with its allies, have provided support to as many as 7,100 candidates for state level offices.²⁵² In addition to campaign contributions, pharmaceutical companies and their industry organization PhRMA funded patient advocacy groups and professional pain advocacy groups that, as described above, acted as powerful advocates for legislation that would enhance the business of pain. There is evidence of states passing laws favorable to opioids based on almost identical legislative language that some legislators said was supplied by the pharmaceutical lobbyists.²⁵³ While this kind of lobbying influences medical and drug policy across the board, the effects of these efforts were particularly stark, and costly, in the case of opioids. Efforts to pass laws to curb the mass prescribing of opioids repeatedly failed over a number of years as drugmakers successfully shifted blame for the rising number of opioid deaths onto the millions who became addicted.²⁵⁴

This level of legislative capture became evident in the organized industry response to increased enforcement actions by the DEA. The following story of how the DEA’s enforcement efforts were thwarted provides a good illustration of legislative capture at work.

D. Going After the Enforcers

*“If there was a terrorist that showed up in Montgomery County today and shot 50 people or 25 or 10 for that matter, this community would be in an uproar. There would be an army here trying to stop it. That’s exactly where we are with opioids. But who’s showing up to stop it?” – The Opioid Diaries*²⁵⁵

One of the DEA’s tasks is to ensure that legally produced narcotics that are subject to controls on use are not diverted for improper use or illegal purposes.²⁵⁶ The DEA also has the authority to approve the total amounts of opioids produced each year. Federal law requires manufacturers, distributors, and pharmacies to report each narcotics transaction to the DEA, and this information is stored by the DEA in a database called the Automation of Reports and Consolidated Order

²⁵¹ See McGreal, *supra* note 136.

²⁵² See *Pharma Lobbying Held Deep Influence Over Opioid Policies*, CTR. FOR PUB. INTEGRITY (Sept. 18, 2016), <https://publicintegrity.org/politics/state-politics/pharma-lobbying-held-deep-influence-over-opioid-policies>.

²⁵³ *Id.*

²⁵⁴ See McGreal, *supra* note 136.

²⁵⁵ Nachtwey, *supra* note 163 (quoting Bruce Langos, Executive Director, Criminal Intelligence Center, Dayton, Ohio).

²⁵⁶ For an overview of the legal foundation for drug diversion laws and the role of the DEA, see, for example, John J. Mulrooney II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 MARQ. L. REV. 333 (2017).

System (ARCOS). The ARCOS database is designed to track the path of every prescription opioid pill sold in the United States and this database documented the sale of over 76 billion oxycodone and hydrocodone pills between 2006 and 2012²⁵⁷ and more than 100 billion pills between 2006 and 2014.²⁵⁸ The manufacture and distribution channels for prescription opioids remained largely concentrated in a small number of companies—with just six companies responsible for distributing three quarters of the pills sold during 2006 to 2012 and just three companies responsible for manufacturing 88% of the pills sold during that period.²⁵⁹

In the face of suspicious patterns of wholesale distribution of opioids in the early 2000s, the DEA began to target the largest wholesale companies that were distributing massive amounts of prescription opioids. Among the powers granted to the DEA is the ability to suspend or revoke the licenses of pharmaceutical companies, pharmacies, and doctors permitted to dispense opioids if they fail to comply with federal law. While there were thousands of distributors holding DEA licenses to dispense drugs, the three large distributors—McKesson, AmerisourceBergen, and Cardinal Health—controlled a lion's share of the market, collecting an annual revenue of about \$400 billion.²⁶⁰

The DEA's Office of Diversion Control responded to evidence of abusive wholesaler practices by pursuing aggressive civil enforcement actions backed by threats of immediate injunctions and financial penalties against wholesalers suspected of over-supplying corrupt pharmacies known as "pill mills" located across the country.²⁶¹ This approach was formalized with the launch of the "Distributor Initiative" by the Office of Diversion Control in 2005, a campaign that "pitted the DEA against an industry with close ties to lobbyists, lawyers and politicians."²⁶² Once this initiative started to raise its sights to the largest three pharmaceutical distributors, the industry response became aggressive. The large

257 Scott Higham et al., *76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, WASH. POST (July 16, 2019, 5:19 PM PDT), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html.

258 Steven Rich et al., *More Than 100 Billion Pain Pills Saturated the Nation Over Nine Years*, WASH. POST (Jan. 14, 2020, 4:13 PM PST), https://www.washingtonpost.com/investigations/more-than-100-billion-pain-pills-saturated-the-nation-over-nine-years/2020/01/14/fde320ba-db13-11e9-a688-303693fb4b0b_story.html.

259 See, e.g., Higham et al., *supra* note 257.

260 See, e.g., Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html.

261 See, e.g., Ed. Bd., *Locating Blame in the Opioid Epidemic*, WASH. POST (Oct. 30, 2016), https://www.washingtonpost.com/opinions/is-the-dea-partly-to-blame-for-the-opioid-epidemic/2016/10/30/2fd5dc30-9c78-11e6-b3c9-f662adaa0048_story.html.

262 See, e.g., Bernstein & Higham, *supra* note 260.

distributors and their pharmaceutical manufacturer allies increased their lobbying pressure on the DEA, the DOJ, and members of Congress, urging them to take a softer approach towards enforcement. Many of the lobbyists were former attorneys general, politicians, and even former members of the DEA. Indeed, as DEA enforcement activity increased, so did pharmaceutical industry efforts to hire some of the top DEA officials, particularly those involved in regulating the industry.²⁶³

The Deputy Attorney General pressured the DEA's diversion chief to limit actions against the industry after a case involving two large drug companies in 2012. Subsequently some DEA officials at the DEA headquarters began delaying and blocking enforcement actions, requiring higher standards of proof to move cases forward. As a result, the number of civil cases filed against wholesalers declined and the pace of enforcement actions slowed.²⁶⁴ In fiscal year 2011, civil case filings against distributors, manufacturers, pharmacies and doctors had reached 131. By 2014, they had fallen to just forty.²⁶⁵

The pharmaceutical industry also engaged in efforts to secure more industry-friendly regulation through support for a bill to limit DEA's enforcement ability by increasing the legal standard for initiating enforcement.²⁶⁶ Pharmaceutical companies were involved in every step of the legislative process, with evidence to suggest that a drug lobbyist was involved in ghostwriting the original bill, and patients' rights groups that lobbied for support for the legislation were later revealed to have extensive ties to the drug industry.²⁶⁷ Political action committees funded by the pharmaceutical industry provided the twenty-three lawmakers who supported various versions of this bill with \$1.5 million, and the industry spent \$102 million to lobby Congress to support this bill and other industry-friendly bills between 2012 and 2014.²⁶⁸

263 See, e.g., Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Cure Opioid Abuse*, WASH. POST (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (explaining how subsequent to DEA efforts to crack down on opioid distributors in 2005, pharmaceutical companies and their law firms hired at least forty-two DEA officials, of which thirty-one were directly responsible for regulating the industry.)

264 See, e.g., Bernstein & Higham, *supra* note 260.

265 See, e.g., Higham et al., *supra* note 263.

266 See, e.g., Lee Fang, *Opioid Lobbyist Left a Digital Fingerprint on Campaign by "Patient Advocates,"* INTERCEPT (Oct. 22, 2017, 5:10 AM), <https://theintercept.com/2017/10/22/opioid-lobbyist-left-a-digital-fingerprint-on-a-campaign-by-patient-advocates> (describing industry influence over the drafting of the legislation and their strong ties to patient advocacy groups that pressured lawmakers to adopt the legislation).

267 See, e.g., Scott Higham & Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST (Oct. 15, 2017), <https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress>; see also Fang, *supra* note 266 (describing political influence exerted by the pharmaceutical industry).

268 See, e.g., Higham & Bernstein, *supra* note 267.

Congress ultimately enacted a law, the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, that increased the legal standard for the DEA to initiate civil enforcement actions, further limiting the ability of the DEA to address abuses by opioid wholesalers.²⁶⁹ This Act modified the Controlled Substances Act to require that the DEA identify “imminent danger to the public health and safety” before suspending registration of a manufacturer, distributor, or dispenser for controlled substances privileges. The law was billed as a way of improving “efforts to fight prescription drug abuse without impeding legitimate patients’ access to medication.”²⁷⁰

Efforts to influence enforcers have not been limited to the DEA. Industry was quick to oppose new more conservative guidelines issued by the CDC in 2016 for prescribing opioids to treat chronic pain, for example, an attack which has continued to take various forms since the issuance of the guidelines.²⁷¹ Pharmaceutical companies have also been actively involved in managing the fallout from the state and federal litigation that has gathered steam since the early 2000s, as described below. Efforts such as this to influence legislation and enforcement activity form a core part of the pharmaceutical business model. This idea of legislation as a variable that could be altered when it interfered with sales is illustrated by a 2013 McKinsey & Company consulting report prepared for Purdue Pharma and unearthed during litigation.²⁷² In this report, McKinsey recommended that “Purdue fight back against efforts by a major pharmacy chain, the Drug Enforcement Agency, and the Department of Justice to stop illegal opioid prescribing These new rules were cutting into sales of the highest doses, which were also the most profitable”²⁷³

269 Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, 130 Stat. 353 (to be codified at 21 U.S.C. §§ 823(j), 824(c), (d)).

270 For an example of the industry spin on the “Ensuring Patient Access and Effective Drug Enforcement Act” see, for example, *Prescription Drug Abuse Bill Ready to Be Signed into Law*, CHAIN DRUG REV. (Apr. 13, 2016), <http://www.chaindrugreview.com/prescription-drug-abuse-bill-ready-to-be-signed-into-law>.

271 See, e.g., Ben Goodwin, Judy Butler & Adriane Fugh-Berman, *Industry-Funded Attacks on the CDC’s Prescribing Guidelines Are Eroding Public Health*, STAT (June 11, 2019), <https://www.statnews.com/2019/06/11/attacks-cdc-opioids-prescribing-guideline>.

272 See e.g. M. Forsythe and W. Bogdanich, *McKinsey Advised Purdue on How to “Turbocharge” Opioid Sales, Lawsuit Says*, New York Times, Feb. 1, 2019 (discusses role of McKinsey in working with Purdue Pharma to promote opioid sales and profits); First Amended Complaint, Commonwealth of Massachusetts vs. Purdue at <https://s3.documentcloud.org/documents/5715954/Massachusetts-AGO-Amended-Complaint-2019-01-31.pdf> (includes description of McKinsey’s role in aggressive efforts to expand sales of opioids).

273 Armstrong, *supra* note 152 (describes Purdue’s strategies for expanding opioid sales as revealed in court documents, including role of McKinsey in helping Purdue to shape its misleading message for marketing opioids). See also M. Forsythe and W. Bogdanich, *McKinsey Settles for Nearly \$600 Million Over Role in Opioids Crisis*, New York Times, Feb. 3, 2021 at <https://www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html> (describes

E. Limiting Liability and Profiting from Addiction

“Company documents recommended becoming an ‘end-to-end pain provider.’”²⁷⁴

Efforts by state and local governments to hold pharmaceutical companies accountable through litigation began as early as 2001, when West Virginia filed a lawsuit against Purdue for its marketing and sales taxes, but Purdue simply paid \$10 million to settle the case and moved on.²⁷⁵ Facing growing controversy as the harms of opioid abuse became evident, Purdue enlisted the help of former New York mayor Rudy Giuliani and his consulting firm in 2002 to help manage these concerns.²⁷⁶ The FDA issued a warning letter to Purdue for misleading advertising in 2003, but sales of OxyContin continued and a new formulation was approved by the FDA in 2010.²⁷⁷ Purdue was charged in federal court in 2007 for failing to disclose the risks of addiction that OxyContin posed, and in what would become a string of settlements by opioid manufacturers and distributors, Purdue Pharma and three of its top executives admitted that they had misled the FDA clinicians and patients about the risks of OxyContin by aggressively marketing the drug as a safe alternative to short-acting narcotics to physicians and to patients.²⁷⁸ This time the company paid \$600 million and added warning labels, but sales of opioids continued unabated.²⁷⁹ Around the same time, a twenty-six-state lawsuit against Purdue led to a settlement of \$19.5 million and an agreement by Purdue to limit some of its more controversial sales practices, like paying bonuses to sales representatives based on the volume of OxyContin prescribed. While the total dollar amount may seem high, the penalties are small in comparison to the profits that the companies generated from opioid sales, and can thus be regarded almost like licenses to break the law. It is estimated, for example, that by 2016 Purdue had

McKinsey role in advising Purdue Pharma on how to increase opioid sales and profits). Details of McKinsey’s role are included in a complaint filed by the Commonwealth of Massachusetts against McKinsey at <https://www.mass.gov/doc/massachusetts-mckinsey-complaint/download>

²⁷⁴ Armstrong, *supra* note 152.

²⁷⁵ See, e.g., Sam Dekin, *The Maker of OxyContin Has a New Way to Profit from the Opioid Crisis*, MISSION HARBOR BEHAV. HEALTH (Oct. 24, 2019), <https://sbtreatment.com/blog/oxycontin-maker-update>.

²⁷⁶ See, e.g., Erik Ofgang, *Purdue Pharma and OxyContin: A Timeline*, CONN. MAG. (Oct. 24, 2019), https://www.connecticutmag.com/health-and-science/purdue-pharma-and-oxycontin-a-timeline/article_e140534a-f50f-11e9-96ab-8bb2725250e0.html.

²⁷⁷ See *FDA Opioid Timeline*, *supra* note 224.

²⁷⁸ See, e.g., Gounder, *supra* note 199.

²⁷⁹ See Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies’ Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2305 (2017) (“Notwithstanding the \$600 million federal settlement with Purdue in 2007—one of the largest in history with a drug company—opioid litigation has yet to financially dent the \$13-billion-a-year opioid industry. Moreover, opioid litigation victories have all taken the form of settlements, in which companies usually have not admitted any fault.”).

earned more than \$36 billion in revenue from OxyContin.²⁸⁰

Since that time there has been a growing volume of lawsuits brought against pharmaceutical manufacturers like Purdue Pharma and pharmaceutical distributors like McKesson by local and state governments, as well as by the federal government. Hundreds of lawsuits have been filed, with almost every state and many local governments following suit.²⁸¹ As the lawsuits accumulated, many were consolidated into one massive multidistrict litigation in the U.S. District Court for the Northern District of Ohio, the largest U.S. civil case in history.²⁸² Many of these lawsuits continue to wind their way through court in varying forms of consolidation and with varying impact. These cases have demonstrated that the largest distributors of opioids were aware of the volume and distribution patterns of the pills they were selling and that they allowed sales to continue despite persistent indications that the pills were being sold in apparent violation of federal laws and diverted to the black market.²⁸³ Apart from Purdue Pharma, which filed for bankruptcy in 2019 and emerged as a new company promising to devote its profits to addiction treatments and settlement payouts, the pharmaceutical companies and distributors implicated in opioid lawsuits continue to operate.²⁸⁴

In addition to limiting their losses and (for the most part) preserving the right to continue to operate, the industry defendants have been able to exercise control over the proceedings in ways that limit public access to important information. One of the key battles that has taken place in civil suits filed by state and local governments against opioid manufacturers and distributors has been the fight over public access to distribution and sales data.²⁸⁵ The pharmaceutical company defendants, along with the DEA and the DOJ, argued against the public release of

280 See, e.g., Ofgang, *supra* note 276.

281 See, e.g., Higham et al., *supra* note 257 (“America’s largest drug companies saturated the country with 76 billion oxycodone and hydrocodone pills from 2006 through 2012 as the nation’s deadliest drug epidemic spun out of control, according to previously undisclosed company data released as part of the largest civil action in U.S. history.”)

282 See, e.g., Lenny Bernstein & Christopher Rowland, *As Lawyers Zero in on Drug Companies, a Reckoning May Be Coming*, WASH. POST (July 17, 2019, 4:45 PM PDT), https://www.washingtonpost.com/health/as-lawyers-zero-in-on-drug-companies-a-reckoning-may-be-coming/2019/07/17/c634a1bc-a89a-11e9-86dd-d7f0e60391e9_story.html; Scott Higham & Lenny Bernstein, *Drug Makers and Distributors Face Barrage of Lawsuits Over Opioid Epidemic*, WASH. POST (July 4, 2017), https://www.washingtonpost.com/investigations/drugmakers-and-distributors-face-barrage-of-lawsuits-over-opioid-epidemic/2017/07/04/3fc33c64-5794-11e7-b38e-35fd8e0c288f_story.html (stating how dozens of state, county and city governments have brought or have contemplated bringing legal actions against the small number of firms responsible for the largest distributions and sales of opioids.).

283 See, e.g., Higham et al., *supra* note 257 (describing a consolidated civil action that includes nearly 2,000 cities, towns, and counties arguing that approximately twenty drug companies saturated their communities with opioids).

284 See, e.g., Ofgang, *supra* note 276.

285 See, e.g., Rich et al. *supra* note 258.

the DEA database ARCOS, based on company rationales of unfair competitive advantage and DOJ rationales of protecting DEA investigations.²⁸⁶ The ARCOS database provides what some have characterized as a “virtual road map to the nation’s opioid epidemic,” with detailed information about every transaction, raising the question of why the DEA and DOJ did not act sooner to intervene.

At the same time that companies involved in the manufacture and distribution of opioids were starting to face liability for the harms arising from the opioid epidemic, some were already exploring new profit opportunities both abroad and in markets to treat addiction. Purdue, for example, began in earnest to pursue the market for addiction in 2014, creating a secret program with the codename Project Tango to explore the business opportunities in the growing market for addiction treatments that the company had helped to create.²⁸⁷ Starting with one product, Suboxone, Purdue quickly turned its attention to the overdose-reversing agent Narcan as another possible strategic fit. Ultimately, Purdue decided not to acquire the rights to sell either product, although an international affiliate did. In 2018, Richard Sackler, the former chairman and president of Purdue, received a patent for another drug to treat addiction.²⁸⁸

Purdue filed for bankruptcy in September 2019, likely at least in part to freeze the thousands of lawsuits filed against the company and to shift the resolution of claims, as well as discussions about limiting future liability, into bankruptcy court.²⁸⁹ The bankruptcy plan that has emerged more than a year later includes a \$10 billion plan to transform the company into a new company with its profits devoted to combatting the opioid crisis, including the creation of trusts to disburse funds to state and local governments and a division to produce treatments for both addiction and overdosing.²⁹⁰ The proposed plan also includes sweeping releases of the company and Sackler family members from future liability, and while the

286 See, e.g., Higham, Horwitz & Rich, *supra* note 257 (“America’s largest drug companies saturated the country with 76 billion oxycodone and hydrocodone pills from 2006 through 2012 as the nation’s deadliest drug epidemic spun out of control, according to previously undisclosed company data released as part of the largest civil action in U.S. history.”)

287 See, e.g., Armstrong, *supra* note 152.

288 See, e.g., Andrew Joseph, *Richard Sackler, Member of Family Behind OxyContin, Was Granted Patent for Addiction Treatment*, STAT (Sept. 7, 2018), <https://www.statnews.com/2018/09/07/richard-sackler-member-of-family-behind-oxycontin-was-granted-patent-for-addiction-treatment>.

289 See, e.g., Andrew Joseph, *Purdue Pharma Filed for Bankruptcy*, STAT (Sept. 16, 2019), <https://www.statnews.com/2019/09/16/if-purdue-pharma-declares-bankruptcy-what-would-it-mean-for-lawsuits-against-the-opioid-manufacturer>.

290 See e.g. A. Katersky and M. Deliso, *Purdue Pharma Bankruptcy Plan, Which Would Give Sackler Family Immunity, Moves Ahead as Planned*, ABC News, June 3, 2021 at <https://abcnews.go.com/Business/purdue-pharma-bankruptcy-plan-give-sackler-family-immunity/story?id=78072454>. A copy of the Disclosure Statement for the Chapter 11 Plan for Purdue Pharma filed with the bankruptcy court on March 15, 2021 can be found here: <https://www.statnews.com/wp-content/uploads/2021/03/purdue-reorg-plan-full-version.pdf>

Sackler family has provided almost half of the funds for the new company, they retain billions derived from opioid sales by Purdue and are still faced with the risk of individual civil and criminal liability.²⁹¹ The story playing out in the bankruptcy courts for Purdue reflects broader concerns with the ways in which bankruptcy courts have become ways to resolve mass tort liability in a manner favorable to the corporate wrongdoers.²⁹² Although Purdue, along with two other opioid companies—Mallinkrodt and Insys—are no longer in the business of manufacturing opioids, many other companies continue to engage in the manufacture and sale of opioids. While the settlement amounts that many of these companies have paid to settle opioid litigation may seem large, the amounts pale in comparison with the profits earned, and some of the largest opioid companies have subsequently sought tax breaks for the legal costs they incurred to further soften the financial hit.²⁹³

F. In Sum: Opioids as An Illustration of Pharmaceutical Capture

When the full extent of corporate influence over all of the key stakeholder groups involved in opioid markets is exposed, it will be hard to understand the evolution of the opioid epidemic as anything other than the result of pharmaceutical capture by companies who saw an opportunity to profit from cultivating the business of pain and growing the market for opioids to treat pain. Companies operating with patent, market, and other forms of regulatory exclusivities over the marketing, distribution and/or sale of opioid products approved by the FDA found ways to ensure the sale of millions of pills via prescriptions from licensed physicians, building their sales pitches upon medical and scientific records they helped to create and satisfying a demand for pain treatment that they helped to grow. Rules governing the use of opioids were either

291 See, e.g., Renae Merle & Lenny Bernstein, *Purdue Pharma's Bankruptcy Plan Includes Special Protection for the Sackler Family Fortune*, WASH. POST (Sept. 18, 2019, 1:38 PM PDT) (detailing the diversion of funds from Purdue to Sackler family accounts and the implications for the bankruptcy plan).

292 Libby Lewis, *The Sackler Family's Bankruptcy Scheme*, AM. PROSPECT (Mar. 31, 2021), <https://prospect.org/justice/sackler-family-bankruptcy-scheme> (arguing that the Sacklers are using the bankruptcy plan as a way to evade personal liability, and that this signals a bigger problem with the bankruptcy system—"a sign of how bankruptcy has become the haven for dispensing with the mass torts that come out of mass corporate wrongdoing"); see also Jason Mast, *Drowning in Litigation: Mallinkrodt Becomes Third Opioid Producer to File for Bankruptcy*, ENDPOINTS NEWS (Oct. 12, 2020, 8:56 AM EDT), <https://endpts.com/drowning-in-litigation-mallinkrodt-becomes-third-opioid-producer-to-file-for-bankruptcy> (discusses use of bankruptcy by companies that profited from the opioid epidemic as a tactic to freeze litigation and leave litigants competing with creditors for payouts).

293 See, e.g., Douglas MacMillan & Kevin Schaul, *Drug Companies Seek Billion-Dollar Tax Deductions from Opioid Settlement*, N.Y. TIMES (Feb. 12, 2021), <https://www.washingtonpost.com/business/2021/02/12/opioid-settlement-tax-refund>.

attacked or turned to advantage, with efforts to transform legal standards and professional guidelines limiting opioid prescriptions into de facto rules to prescribe opioids. Standards of care evolved in response to industry prodding to encourage opioid use, and overuse. Legislative capture was used to tone down enforcement efforts and ramp up prescriptions. The pharmaceutical companies that had helped to create the opioid epidemic were even invited to the table by the NIH to discuss new ideas for public-private partnerships to address the epidemic and develop new treatments for addiction. Companies in the wake of legal battles investigated opportunities to turn their settlement liabilities into tax breaks.

While the case study described above features now infamous actors like Purdue Pharma, many pharmaceutical manufacturers—including not just well-known companies like Johnson & Johnson but also some relatively unknown generic manufacturers, played (and continue to play) active roles in fueling the opioid epidemic.²⁹⁴ Moreover, pharmaceutical manufacturers were by no means the only actors in this process of pharmaceutical capture—many other corporate actors standing to benefit from growing sales of opioids, either directly or indirectly, also played important roles in fueling opioid prescriptions.²⁹⁵ These actors, including but not limited to large wholesalers, distributors, and retailers of opioids, also exerted an extensive web of influence over decision makers in the industry in order to obtain their desired outcomes.²⁹⁶ Professional advisors, such as the management consulting firm McKinsey & Company, recently implicated in the Purdue litigation, assisted with strategies for obtaining desired regulatory environments.²⁹⁷ Over time the web of stakeholders with commercial interests in growing the opioid market expanded, as described in the case study, to include professional medical associations, patient advocacy groups, and physicians. As lawsuits began to proliferate, the defense bar also benefited.²⁹⁸

294 See, e.g., Aaron C. Davis et al., *Little Known Makers of Generic Drugs Played Central Role in Opioid Crisis, Records Show*, WASH. POST (July 27, 2019, 9:25 AM PDT), https://www.washingtonpost.com/investigations/little-known-generic-drug-companies-played-central-role-in-opioid-crisis-documents-reveal/2019/07/26/95e08b46-ac5c-11e9-a0c9-6d2d7818f3da_story.html (“[R]ecords show that by 2006, as the death rate accelerated, a handful of obscure generic-drug manufacturers were selling the bulk of opioid pills flooding the country.”).

295 See, e.g., Marks, *supra* note 141 (describing the multiple industry players implicated in the opioid epidemic).

296 For a discussion of the lawsuits brought against opioid distributors, see, for example, German Lopez, *The Thousands of Lawsuits Against Opioid Companies, Explained*, Vox (Oct. 17, 2019, 6:10 PM EDT), <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-epidemic-lawsuits-purdue-oxycontin>.

297 See, e.g., Michael Forsythe & Walt Bogdanich, *McKinsey Settles for Nearly \$600 Million Over Role in Opioid Crisis*, N.Y. TIMES (Feb. 3, 2021), <https://www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html> (explaining how McKinsey reached settlement agreements with forty-nine states over its role in providing sales advice to Purdue and other drug makers, including advice about how to avoid “strict treatment” by the FDA.).

298 See, e.g., H. Nelson, *The Opioid Litigation: Settlements, Winners and Losers*, Forbes

In addition, while there are features of this case study that are unique to opioids, and to companies like Purdue Pharma that were the initial drivers of the epidemic, the general patterns of industry influence and control that are deployed in pharmaceutical capture are far from unique.²⁹⁹ As described in Part I, and as further illustrated by other compelling case studies of corporate power in markets for other drugs, the holistic and systemic control that companies with the largest financial interests in pharmaceutical sales exert over markets relevant to their profitability, and the resulting growth of profits at the expense of public health, is endemic in pharmaceutical markets.³⁰⁰

Indeed, pharmaceutical capture, along with other forms of industry capture, have extended to include the policy narratives used to characterize the very problems they have helped to create.³⁰¹ The solution to problems of high prices and harmful products, they suggest, is to reduce the burden of regulation and the

Magazine, July 26, 2019 (describes the massive litigation costs and the large fees generated for lawyers from the opioid litigation).

299 For support of this proposition, see *supra* notes 29-37 and 177 and *infra* note 300, providing support for the claim that pharmaceutical capture is widespread and not limited to opioids. See also Marks, *supra* note 141 (arguing that previous analysis of the pharmaceutical industry reveal similar strategies, and that the strategies employed by opioid companies were not entirely novel). For broad discussions of how corporate actors in the pharmaceutical industry create a web of influence over a wide variety of stakeholders in order to secure desired industry outcomes, see, for example, MARKS, *supra* note 91. For industry-wide examples of how business interests impact health care quality and price, with examples that include and go beyond the pharmaceutical industry to other health care markets, see, for example, STEVEN BRILL, *AMERICA'S BITTER PILL: MONEY, POLITICS, BACKROOM DEALS, AND THE FIGHT TO FIX OUR BROKEN HEALTHCARE SYSTEM* (Random House 2015); ROSENTHAL, *supra* note 1.

300 For case studies of corporate power in different markets, see, for example, Kalman Applbaum, *Getting to Yes: Corporate Power and the Creation of a Psychopharmaceutical Blockbuster*, 33 *CULTURE, MED. & PSYCHIATRY* 185 (2009) (case study analyzing documentary evidence of Eli Lilly's far reaching strategy of influence over the distribution chain to expand the sale of its antipsychotic medication Zyprexa beyond its conventional market, showing how this is typical of contemporary pharmaceutical marketing strategies); Ross et al., *supra* note 103 (illustrating Merck's role in ghostwriting clinical trial manuscripts and other materials relevant to approval and sale of its product Rofecoxib); Michael A. Steinman et al., *Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents*, 145 *ANNALS INTERNAL MED.* 284 (2006) (discussing how litigation and congressional inquiry have exposed expansive marketing practices used to promote drugs, including for unauthorized uses; provides case study exposing overall structure of promotion of gabapentin). For other case studies of industry influence over pharmaceutical markets, particularly through influence over medical and scientific research and medical education, see journal articles and whitepapers at Publications, PHARMEDOUT, <https://sites.google.com/georgetown.edu/pharmedout/resources/publications>.

301 See, e.g., *2019 Profile: Biopharmaceutical Research Industry*, PHRMA (2019), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2019-Profile-Booklet_FINAL_NoBleeds.pdf (pharmaceutical industry organization reports framing narrative of pharmaceutical industry role in promoting innovation and improving patient health); *2020 Profile: Biopharmaceutical Research Industry*, PHRMA (2020), <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Industry-Profile-2020.pdf> (same).

inefficiencies of government oversight, while at the same time protecting the incentives (including patent and market exclusivities) that allow them to innovate. These industry narratives, and the support they lend to arguments for at least selective deregulation—in the form of restrictions on the exercise of government rights—have gained public and policy traction in the wake of a rapid industry roll out of vaccines for COVID-19.³⁰² Part IV begins by responding to these politically popular arguments in support of deregulation,³⁰³ and then advocates for an alternative approach based on regulatory redesign as the best way to reorient the industry around public health goals.

III. PHARMACEUTICAL RECAPTURE

“[W]hat other and more effective [instrument] is there within the reach of the American people?” - Charles Francis Adams, Jr. (1871)³⁰⁴

302 See, e.g., Drew Armstrong, *The World’s Most Loathed Industry Gave Us a Vaccine in Record Time*, BLOOMBERG (Dec. 23, 2020, 2:00 AM PST), <https://www.bloomberg.com/news/features/2020-12-23/covid-vaccine-how-big-pharma-saved-the-world-in-2020>; Alexandra Bruell, *Pharma Giants Market Their Value as Pandemic Bolsters Reputation*, WALL ST. J. (Nov. 9, 2020, 5:30 AM ET), <https://www.wsj.com/articles/pharma-giants-market-their-value-as-pandemic-bolsters-reputation-11604917802>; Ed. Bd., *Watch Out for a Vaccine Patent Heist*, WALL ST. J. (Mar. 28, 2021, 3:29 PM ET), <https://www.wsj.com/articles/watch-out-for-a-vaccine-patent-heist-11616959785>; Jared S. Hopkins, *How Pfizer Developed a Covid Vaccine in Record Time: Crazy Deadlines, a Pushy CEO*, WALL ST. J. (Dec. 11, 2020, 9:34 PM ET), <https://www.wsj.com/articles/how-pfizer-delivered-a-covid-vaccine-in-record-time-crazy-deadlines-a-pushy-ceo-11607740483>.

303 For a sampling of different approaches to market-based health care policy, see, for example, Joseph R. Antos et al., *Improving Health and Health Care: An Agenda for Reform*, HEALTH AFFS. (Dec. 9, 2015), <https://www.healthaffairs.org/doi/10.1377/hblog20151209.052181/full> (arguing for a reorienting of health care away from government regulation and towards the preferences of consumers and patients); *Improving Health Care: A Dose of Competition*, FED. TRADE COMM’N & DEP’T OF JUST. (July 2004), <https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf> (suggesting the importance of competition as a mechanism for addressing health care costs); and Michael E. Porter & Thomas H. Lee, *The Strategy That Will Fix Healthcare*, HARV. BUS. REV. (Oct. 2013), <https://hbr.org/2013/10/the-strategy-that-will-fix-healthcare> (offering a market driven “value based” approach to health care reform). For a discussion of the pharmaceutical policy positions that emphasize the importance of protecting incentives for the private sector to innovate, see, for example, Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFS. 302 (Feb. 1, 2015) (summarizing the role of patent and other exclusivities in promoting pharmaceutical R&D); and Lazonick et al., *supra* note 49 (providing a critique of the pharma arguments that they require stronger incentives to engage in drug R&D).

304 CHARLES FRANCIS ADAMS, *The Railroad System*, in *CHAPTERS OF ERIE AND OTHER ESSAYS* 333, 414 (Applewood Books 1956) (1871); see also Novak, *supra* note 47, at 25 (discusses how Charles Frances Adams approached the problem of railroad monopolies, dismissing prior efforts at competition and legislation and arguing for an alternative approach that would address the problem of capture).

“The regulation of these various and interfering interests forms the principal task of modern legislation” – James Madison (1787)³⁰⁵

The opioid case study provides a powerful illustration of pharmaceutical capture and its costs. A new story of the effects of pharmaceutical capture on pandemic preparedness and response is playing out before our eyes in response to COVID-19.³⁰⁶ But the effects of pharmaceutical capture extend far beyond opioids, and far beyond the rush to develop COVID-19 treatments and vaccines. The effects of capture can be seen in the high price of EpiPens and insulin, the over-prescribing of drugs to treat attention deficit disorders, the promotion of aspirin as a way of preventing heart disease, unaddressed promotion of off-label use of risky anti-psychotic drugs—the list could go on.³⁰⁷ This final Part begins to tackle the question of what regulators can do to “recapture” the pharmaceutical industry with the goal of reorienting the industry around public health goals. It begins by challenging one of the largest hurdles to improved regulatory design—the political dominance of beliefs in market primacy and an accompanying, albeit selective, deregulatory agenda, and then provides guidelines for regulatory change designed to “recapture” pharmaceuticals.

A. *The Limits of Deregulation*

“[T]he capture thesis has so pervaded recent assessments of regulation that it has assumed something of the status of a ground norm—a taken-for-granted term of art and an all-purpose social-scientific explanation—that itself frequently escapes critical scrutiny or serious scholarly interrogation.” - William Novak³⁰⁸

*“Market economies need clear rules to function efficiently. Without a legal framework establishing and enforcing property rights and the ‘rules of the game,’ our free enterprise system could not exist.”*³⁰⁹

In early arguments for deregulation, such as those fueled by the influential ideas of Stigler and other members of the Chicago School of Economics in the 1970s and 1980s, regulation writ large is seen as unavoidably compromised by

305 THE FEDERALIST NO. 10 (James Madison).

306 See, e.g., Heled, Rutschman & Vertinsky, *supra* note 15.

307 See *supra* notes 29-37, 177, 299-300 and accompanying text.

308 Novak, *supra* note 47, at 25.

309 *Regulation & the Economy: The Relationship and How to Improve It: A Policy Statement*, COMM. FOR ECON. DEV. OF THE CONF. BD. (Sept. 27, 2017), <https://www.ced.org/reports/regulation-and-the-economy>.

special interests, something that will simply interfere with the competitive discipline and consumer protections that emerge from an idealized laissez-faire market system. Markets, not government, will be best at protecting the public interest, according to this view, and therefore the role of government should be curtailed and its interference with the operation of the market limited.³¹⁰

Since that time, arguments in support of deregulation have become more nuanced, reflecting a focus on market primacy rather than deregulation per se.³¹¹ Market primacy, in general terms, is the idea that public needs can be best satisfied through the operation of free markets, and that private market competition is the best engine for innovation.³¹² Industry incumbents focus their arguments for market primacy on the importance of preserving private sector incentives to innovate through strong intellectual property rights and limited government rights over publicly funded technology.³¹³ Broader arguments for deregulation focus on the need to increase market competition by addressing regulatory barriers that restrict competition, some of which are—it is argued—the result of regulatory capture.³¹⁴

While these different approaches to deregulation—one favoring entry and competition, one more focused on incentives to encourage innovation by incumbents—are in tension, they reflect a shared pessimism about the ability of government regulation to improve market outcomes.³¹⁵ Instead, the role of the

310 See *supra* Part I.

311 See Carpenter & Moss, *supra* note 77, at 1, 4 n.4, 8 (exploring relationship between evolving notions of and argument for deregulation and understandings of regulatory capture, includes references in footnote 4 to recent work on regulation and deregulation). For an example of approaches that move beyond traditional arguments for deregulation see, for example, IAN AYERS & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* (1992) (emphasizing the importance of industry self-regulation and the use of persuasion in addition to sanctions to guide private decision making).

312 See, e.g., Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* (Brookings Hutchings Ctr. Working Paper No. 30, 2017), https://www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf (reflecting the view that private sector competition will yield the best outcomes in the pharmaceutical industry and skepticism about the ability of government regulation to improve market outcomes).

313 See, for example, the arguments for limiting government rights over publicly funded technology to encourage private sector innovation in *NIST Green Paper*, *supra* note 26.

314 See, e.g., Morton & Boller, *supra* note 312 (arguing that industry incumbents such as pharmaceutical manufacturers have influenced regulators and stymied regulations with the goal of limiting competition).

315 To illustrate the variety of arguments in support of a market-based approach to pharmaceutical innovation, with government regulation limited to strengthening private market incentives and/or increasing competition, see, for example Henry G. Grabowski, *Public Policy and Pharmaceutical Innovation*, 4 HEALTH CARE FIN. REV. 75 (1982) (arguing that regulation is impeding pharmaceutical innovation); David R. Henderson & Charles L. Hooper, *To Increase Innovation and Make Drugs More Affordable, Deregulate*, 2 J. CLINICAL PATHWAYS 23 (2016); Morton & Boller, *supra* note 312 (arguing that it is difficult to design regulations that encourage innovation; arguing

government is largely relegated to one of subsidizing the costs of R&D, protecting intellectual property, and procuring resulting health care products, all to a varying degree, leaving the private sector to control the development, distribution, and pricing of products. Markets, not government, will be best at serving the public interest, according to this view, and therefore the role of government should be curtailed and its interference with the operation of the market limited.

Pharmaceutical industry groups interested in removing those forms of government interference that are likely to impede the interests of their most powerful members have played an active role in the policy debate.³¹⁶ They are quick to point to the need for strong incentives in the form of patent and market exclusivity to promote costly and risky pharmaceutical R&D, even when this lies in tension with increasing market competition.³¹⁷ Their form of deregulation focuses on limiting government rights over government-funded technologies and limiting government power over the terms of product sales. Health care has also been a site of particular focus for a variety of different special-interest groups who coalesce around the idea that private sector innovation and the power of “free markets” will address the inefficiencies that characterize current U.S. health care markets.³¹⁸ The narrative of market primacy, with the private sector as an engine of innovation, is a powerful one in U.S. political circles.³¹⁹ The power of this

for policies that remove barriers to competition as the best way to promote pharmaceutical innovation and reduce drug cost); Tom Coburn, *Free Market, Better Medicine: The Solution to Our Drug Pricing Problem Involves Less Government, More Transparency*, U.S. NEWS (Feb. 15, 2018, 3:31 PM), <https://www.usnews.com/opinion/articles/2018-02-15/rely-on-the-free-market-to-address-drug-prices-and-foster-innovation>; and Daniel Hempel & Lisa Larrimore Ouellette, *Pharmaceutical Profits and Public Health are Not Incompatible*, N.Y. TIMES (Apr. 8, 2020), <https://www.nytimes.com/2020/04/08/opinion/coronavirus-drug-company-profits.html> (arguing for government policy focusing on strengthening private sector incentives to promote innovation).

316 See, e.g., Wouters, *supra* note 135; Morgan, *supra* note 141; *Pharma Lobbying Held Deep Influence Over Policies on Opioids*, ASSOCIATED PRESS (Sept. 17, 2016) <https://apnews.com/article/9b72ea1408f845eaa26638a652df2912>.

317 See, e.g., PhRMA Report, 2020 Profile Biopharmaceutical Research Industry at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Industry-Profile-2020_1.pdf; PhRMA, IP Incentives Fuel Biopharmaceutical Innovation and Competition at <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/6--67416-Intellectual.pdf>.

318 See, e.g., Antos, *supra* note 40; John C. Goodman, *Why Not Try Free Market Healthcare?*, FORBES (Oct. 17, 2019, 7:51 AM EDT), <https://www.forbes.com/sites/johngoodman/2019/10/17/why-not-try-free-market-health-care>; Max Gulker, *Are We Really Ready for Free-Market Healthcare?*, AM. INST. FOR ECON. RSCH. (Nov. 20, 2019), <https://www.aier.org/article/are-we-really-ready-for-free-market-healthcare>; *Issue: Health Care Reform*, HERITAGE FOUND., <https://www.heritage.org/health-care-reform> (“Health care reform should be a patient-centered, market-based alternative . . .”).

319 See, e.g., Mike Hennessy, Sr., *How Pharmaceutical Innovation Is Saving the World*, PHARMTECH (Feb. 2, 2021), <https://www.pharmtech.com/view/how-pharmaceutical-innovation-is-saving-the-world>; John Stanford, Price Controls Would Throttle Biomedical Innovation, WALL ST. J. (July 1, 2020, 1:51 PM ET), <https://www.wsj.com/articles/price-controls-would-throttle>

market-based approach is evident even now, in the midst of a pandemic, as U.S. government policies focus largely on increasing the incentives of the private sector to produce therapies and vaccines to combat COVID-19.³²⁰

But what many of these views neglect is the fact that markets are themselves legal, political, and social constructs that are highly dependent upon regulation. Markets rely on regulation to operate; they are institutions constructed out of rules, and so the choice is never regulation versus the absence of regulation, but rather the trading of one governance structure for another.³²¹ This idea has been taken one step further in recent work on “deregulatory capture,” a situation in which regulators are captured by special interest groups bent on deregulation.³²² The debate over deregulation is really a debate over alternative governance models, and the question of regulatory capture becomes one of how different governance models may favor different actors.³²³

Moreover, the arguments for deregulation that are being advanced by a powerful coalition of free enterprise groups, many of which are backed by corporate interests, often adopt an overly simplified and idealized view of the laissez-faire market.³²⁴ Yet the pharmaceutical market is anything but a free market—it is heavily regulated and includes a variety of government-created incentives and subsidies that support private enterprise.³²⁵ And the market is anything but competitive, with large barriers to entry and restrictions on competition. In addition, health care markets have unique features that do not lend themselves to the model of perfect competition upon which many of the

biomedical-innovation-11593625880; Thomas Sullivan, *Pharmaceutical Companies Need Longer Patents to Fund Innovation*, POL’Y & MED. (May 6, 2018), <https://www.policymed.com/2012/04/pharmaceutical-companies-need-longer-patents-to-fund-innovation.html>.

320 See, for example, a discussion of current reliance on private sector to produce pandemic drugs in Heled, Rutschman & Vertinsky, *supra* note 15.

321 See, e.g., Robert I. Field, *Government as the Crucible for Free Market Health Care: Regulation, Reimbursement, and Reform*, 159 U. PA. L. REV. 1669 (2011) (arguing that government regulation is essential in creating markets and helping them to function).

322 See, e.g., STEVEN K. VOGEL, *MARKETCRAFT: HOW GOVERNMENTS MAKE MARKETS WORK* (2018).

323 See Vogel, *supra* note 42.

324 See e.g. Nicholas Skala, *Right-Wing “Think” Tanks and Health Policy*, PHYSICIANS FOR A NAT’L HEALTH PROGRAM (July 2010), <https://pnhp.org/news/right-wing-think-tanks-and-health-policy>. See also E. Lipton and B. Williams, *How Think Tanks Amplify Corporate America’s Influence*, New York Times, August 7, 2016 (describes the role of industry funding and influence on think tanks); J. Judis, *The Credible Think Tank is Dead*, The New Republic, Sept. 15, 2017 at (describes the politicization and expansion of corporate influence over think tanks) at <https://newrepublic.com/article/144818/credible-think-tank-dead>. For a description of the role of corporate funding in different think tanks see Source Watch, run by the Center for Media and Democracy, at <https://www.sourcewatch.org/index.php?title=SourceWatch>.

325 See, e.g., Field, *supra* note 321 (arguing that government programs have created the health care system that the private sector operates in).

deregulatory arguments rest.³²⁶ When more carefully scrutinized, the arguments for deregulation generally reduce to arguments for the unencumbered pursuit of profits by industry incumbents, an agenda that relies on certain forms of regulation while attacking others.

The advocates for deregulation as a response to regulatory capture also invariably ignore an important alternative response to regulatory capture, one focused on striving to make the regulatory process more robust to capture.³²⁷

B. A Starting Point for Regulatory Redesign

“All health care organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States.” – Institute of Medicine³²⁸

Drawing lessons from the industry strategies that have resulted in pharmaceutical capture, this concluding section offers three guiding principles for redesigning the regulatory approach to pharmaceuticals. The first is the need for a holistic, systemic approach to regulation. The second is the need to recalibrate key underlying policy assumptions about pharmaceutical markets and their appropriate regulation. The third is the need to make regulation more robust to corporate interests through strategies that narrow the divergence of private interests from the public interest, make capture more costly, and/or provide greater resources and rewards for regulating in the public interest.

1. The Need for a Holistic, Systemic Approach to Regulation

As a first step in addressing pharmaceutical capture, we need a regulatory system that is more holistic and systemic in approach, one that can respond in a comprehensive and flexible way to the complex and changing strategies of the most sophisticated companies in the pharmaceutical industry.

The opioid case study provides a detailed description of the multifaceted approach that the opioid manufacturers and distributors took towards influencing the design and operation of opioid markets. These large and sophisticated companies think in systemic terms about the entire commercial life cycle of their

³²⁶ See, e.g., Heled, Vertinsky & Brewer, *supra* note 31.

³²⁷ In this Article, I take it as a given that the United States will at least for the foreseeable future continue to rely on a market-driven approach to health care in general and pharmaceuticals in particular, and I focus proposals for reform on ways of shifting the regulatory approach towards these markets. An alternative approach, one that is beyond the scope of this Article, would be to expand the role of the government as a more active participant in health care markets.

³²⁸ See, e.g., CROSSING THE QUALITY CHASM, *supra* note 243.

products and services, including not just current, but also future product and service opportunities. They also think comprehensively about all of the stakeholders that will influence product development, approval, and terms of sale now and in the future. They seek to incorporate all of the factors that will or may contribute to total revenues over the life cycle of the product, including sales volume and pricing and ways of limiting competition. Regulators and regulations become variables in a system of industry influence that can be used to advantage in some cases, and the negative effects on industry interests neutralized in others.

As illustrated at length in the case study, pharmaceutical companies, along with other industry stakeholders, influence professional association guidelines, treatment protocols, physician norms, “scientific” understandings of the risks and benefits of drugs, consumer expectations and understandings, regulatory approaches towards the marketing and control of drugs, and the standards of care used to assign liability for product harm. In the context of opioids, it was the combined impact of articles in medical journals, lectures by thought leaders, physician education, professional guidelines, insurance reimbursement procedures, and changes in hard and soft law surrounding standards of care and liability for treatment of pain, for example, that made the strategy of encouraging opioid prescription and use so successful. The fact that physicians heard consistent messages from multiple sources impacted their beliefs, and their prescribing behavior, much more than the effects of more fragmented messaging.³²⁹ Influence over enforcers, such as the DEA, allowed the strategy to continue for decades.

While the most profitable companies in the pharmaceutical industry rely not on any one individual intervention, but rather on the systemic use of multiple different strategies and their interaction, regulators are generally confined in their operations to fragmented and often unconnected parts of the pharmaceutical market. Their approach to the regulation of pharmaceutical markets is siloed, dictated by the scope of their regulatory authority and jurisdiction, and limited by the resources and information they have available. Rather than working together on a common objective, such as improving health outcomes, regulators are divided by law and institutional structure into a variety of different enclaves, and assigned pieces of the market system, such as monitoring the distribution of controlled substances or approving a new drug for the stated approved use. Often the regulators are dependent on industry members for data about industry practices, and they may end up working closely with their industry counterparts—a prime example being the relationship between the FDA and pharmaceutical companies seeking drug approval.

When thinking about regulatory reform, we too often think about regulations within a narrow context, and without a system-wide analysis of the role of the

³²⁹ See, e.g., Cuéllar & Humphreys, *supra* note 28.

regulations, the ways they are formulated, applied, revised, and enforced. We think about a specific regulatory problem without taking time to consider whether the individuals making the enforcement decisions are compensated adequately for their work, whether they are likely to work for industry in the future, whether their decisions are based on information that is industry generated, and/or whether the proposed regulations are tested and evaluated by industry-funded studies.³³⁰ We often fail to think about the ways in which alternative regulations intersect, compounding the impact of each individually (such as with cumulative regulatory exclusivities), or alternatively neglecting important aspects of a multifaceted problem.³³¹ And we do not invest the resources in regulatory design and implementation needed to combat well-funded and sophisticated corporate strategies designed to counteract any reform efforts that might privilege the public interest over their own corporate interests.

In sum, pharmaceutical companies are interested in how the entire set of relevant existing and potential regulations, taken as a whole, along with other formal and informal rules governing relevant stakeholders, impacts their business models, and ultimately their ability to ensure stock price and revenue growth. They invest time and money in a holistic and systemic strategy that they continue to update and refine in response to shifting economic, legal and institutional constraints. They have large budgets and significant resources devoted to their systems of industry influence. Regulators, in contrast, are focused largely on their particular fragmented piece of the regulatory system—be it product approval, monitoring sales of controlled substances, assessing liability for illegal behavior, whatever piece of the regulatory process falls within their particular jurisdiction. Layer on top of this other constraints—limited resources, revolving doors, hostility of the administration towards enforcement actions, and regulators operate at a tremendous disadvantage in comparison to the entities they must regulate. Thus, as a first step in addressing pharmaceutical capture, regulatory strategies need to be holistic and systemic in the same way that corporate strategies are—with a comprehensive view of the roles that different stakeholders play and the ways in which one realm of regulation impacts others.³³²

330 Take, for instance, the widely cited numbers provided by the Tufts Center as estimates of the astronomical cost of developing new drugs. These numbers play important roles in debates over the need for longer patent terms and other forms of pharmaceutical protection to incentivize R&D. This Center was formed with industry money, in partnership with industry, and continues to be funded by industry, and it is hard to argue that this is anything other than a way of creating its own data for policy purposes. *See, e.g.,* Nik-Khah, *supra* note 25.

331 *See, e.g.,* Erin C. Fuse Brown, *Resurrecting Health Care Regulation*, 67 HASTINGS L.J. 85 (2015) (providing a framework for mapping policy solutions onto the health care market failure they are designed to address, shows the limitations of current à la carte policy options in attacking the problem of high drug prices).

332 *See, e.g.,* Benjamin & Rai, *supra* note 114 (arguing for the creation of an entity with a trans-

2. *Challenging Key Assumptions About Pharmaceutical Markets and Their Regulation*

A combination of features unique to U.S. health care and to the process of discovering and manufacturing pharmaceutical products makes the pharmaceutical industry particularly vulnerable to capture by the interests of pharmaceutical companies.³³³ As discussed in Part I, the factors most relevant to understanding pharmaceutical markets include: (a) the pervasive role of regulation over the entire product life cycle, including restrictions on competition intended to promote innovation at the expense of competition; (b) the belief in the private sector as the primary engine of biomedical innovation, and the asymmetric role of government as funder of R&D and purchaser of end products but with limited control over product and pricing decisions; (c) the fragmentation of the market, including but not limited to the separation between the parties who make the products, pay for the products, select the products (prescribing physicians), and consume the products (patients); (d) the pervasive role of industry in shaping scientific, medical, and patient knowledge about pharmaceuticals and their use; and the extreme potential for profit due in part to the inelasticity of demand for the goods involved.³³⁴ This approach to pharmaceutical markets is justified and sustained by certain key assumptions about the relevant stakeholders and what their roles should be, and those assumptions in turn limit the reach of regulators and regulations. A second step in the redesign of regulation involves challenging some of these key assumptions and the ways in which they are used to limit the reach of regulation and support capture.

These key assumptions about pharmaceutical markets include the following: (a) that patients should be treated as consumers, pharmaceuticals as products, and “informed consent” as assumption of the risk; (b) that doctors are “independent” learned intermediaries and not subject to industry influence; (c) that the private sector is the driver of innovation, and that limiting the role (or at least the rights) of government is essential to promote innovation; and (d) that the combination of disclosure and informed consent coupled with the operation of market forces is adequate to discipline pharmaceutical companies.

One of the most foundational of these assumptions, one that informs the others, is the industry-cultivated idea that we can treat patients as consumers for purposes of fashioning pharmaceutical regulation. Once patients are seen as consumers, the idea of facilitating product choice through reductions in regulation

agency focus to support innovation).

³³³ For an in depth discussion of what makes healthcare markets unique, and particularly vulnerable to corporate influence, see, for example, Heled, Rutschman & Vertinsky, *supra* note 15; and Heled, Vertinsky & Brewer, *supra* note 31.

³³⁴ See *supra* note 333 and accompanying text.

becomes more compelling. Consumers can be provided with information about products and given choice, and when they make their product selections with ample disclosure, and through use of the concept of informed consent, they have assumed the risk of any negative consequences. This was the argument that pervaded industry defenses to tobacco litigation claims. The market can be relied upon, or so the story goes, to ensure product quality and to limit price to reflect consumer demand. To push this story further, information about products can and should be generated through consumer use rather than relying too heavily on pre-market testing and approvals. Finally, the pharmaceutical industry argues, any efforts to restrict their marketing are restrictions on commercial speech that violate the First Amendment rights of the pharmaceutical companies.³³⁵

There are many reasons that patients should not be treated simply as consumers, and that pharmaceutical markets—at least in their current form—do not adequately protect patients when they are allowed to rest on models of consumer choice and informed consent. Any system of regulation that is going to prioritize patient and public health needs to address the limitations of a simple consumer model of health care. Once we stop seeing patients simply as consumers and the purchase of health care as equivalent to the purchase of a television, the demands on regulators and regulations and the available avenues for regulation change. Reinvigorating the regulatory position that patients are not simply consumers, and need additional protection, could fuel more expansive regulation of a variety of corporate practices, such as DTC marketing and requirements to fully investigate and disclose the potential harms of any product.

A second fundamental, and also problematic, assumption underpinning current regulatory approaches is the independence of doctors from industry influence. Doctors are treated as gatekeepers under the law. They have the expertise to determine the needs of the patient and to evaluate treatment options, and they have a professional obligation and a code of ethics that—in an ideal world—ensure that the interests of the patients come first. This gatekeeper role includes the ability to prescribe drugs, and under the learned intermediary doctrine it shields pharmaceutical companies from certain duties to warn patients about potential harms from their drugs. Given the importance of physician decision-making for prescription drug sales, and even those offered without prescription, it is no surprise that pharmaceutical marketing has for decades focused heavily on promotional strategies targeted at physicians. A cornerstone of pharmaceutical strategy is devoted to industry influence over physician decision-making and over the standards of care that guide physician choice. The opioid epidemic illustrates the dangers of relying on this gatekeeper model without adequate safeguards for

335 See, e.g., Caroline Poplin, *The First Amendment: Not One Size Fits All*, 3 EMORY CORP. GOVERNANCE & ACCOUNTABILITY REV. 30 (2016).

the independence not just of physicians, but also of the information that they are using to make their treatment decisions. When scientific papers, physician continuing education, professional conferences and medical thought leaders are influenced by pharmaceutical companies, this compromises the gatekeeping role of the physician.

The final two assumptions are based on the idea of market primacy—that if left unhindered, market forces will discipline pharmaceutical companies and ensure that they produce the goods and services that consumers want at competitive prices. One has only to look at the performance of U.S. health care markets to find ample empirical evidence that markets have not achieved socially efficient outcomes, and seminal work by economists such as Kenneth Arrow provide the theoretical justifications for why these failures might emerge.³³⁶

Thus, this second step in the redesign of regulation involves re-evaluating some of the key assumptions used to limit the reach of regulation and support capture and replacing them with a more accurate model of how the industry actually works. With this refined model in place, regulations can be better targeted to areas where private interests diverge from public health needs.

3. Making Regulations More Robust to Special Interests

Part of making regulations more robust to capture is to start with a critical examination of assumptions made at the ground level—revisiting the consequences of thinking about patients as consumers, doctors as learned intermediaries, government as doomed to fail, markets as some *laissez-faire* ideal. Changes in these assumptions will change the scope and nature of regulation needed. But even with improvements in regulatory design, the system may remain susceptible to capture by special interest groups. This final section explores ways of making regulation more robust to pharmaceutical capture by increasing the costs of and reducing the benefits from capture.

There are at least three different avenues for making regulation more robust to capture.³³⁷ One is to reduce the market pressure on regulators by narrowing the divergence of profit incentives from public health needs.³³⁸ Arguments for

336 See, e.g., Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963).

337 See, e.g., Levine & Forrence, *supra* note 21 (decomposing models of public-interest regulation into models of motivation and of monitoring; making motivation a variable subject to the constraint of monitoring; examining the role of monitoring costs and motivations in developing a model of regulatory behavior; distinguishing between private versus public interest to reflect motivation and general versus special interests to reflect political dominance).

338 See, e.g., Heled, Vertinsky & Brewer, *supra* note 31 (exploring the consequences of the divergence of private incentives from public health in the pharmaceutical industry and proposing ways of narrowing this divergence); see also Marc-André Gagnon, *Corruption of Pharmaceutical*

delinking price of drugs from returns on R&D offer one example of this approach.³³⁹ Carefully structured public-private partnerships that involve a sharing of costs, risk, and control between public and private actors offer another, albeit imperfect, alternative.³⁴⁰ A second avenue is to create barriers to industry influence that either make it harder and more costly to sway the decisions of regulators, or simply remove pathways of influence. This approach can involve measures that make it more difficult to hide industry influence, such as requirements of transparency.³⁴¹ It could include measures that make regulators more accountable for regulatory results, such as improved metrics to measure good performance and independent oversight of agency decisions and outcomes.³⁴² It could also include measures that make it more costly to exert industry influence in ways that are considered improper, such as strengthening the scope of and penalties associated with anti-kickback statutes or restricting the ability of companies to make campaign contributions or engage in lobbying.³⁴³ Greater restrictions could also be placed on the ability to work in industry after holding important regulatory roles.

Markets: Addressing the Misalignment of Financial Incentives and Public Health, 41 J. L. MED. & ETHICS 571 (2013) (exploring how the current architecture of pharmaceutical markets has caused a misalignment of private incentives and public health; exploring alternatives such as taxes, increased financial penalties, and drug pricing based on value to narrow divergence).

339 See, e.g., James Love, *Inside Views: Delinkage of R&D Costs from Product Prices*, INTELL. PROP. WATCH (Sept. 15, 2016) <https://www.ip-watch.org/2016/09/15/delinkage-of-rd-costs-from-product-prices>; Brian Till, *How Drug Companies Keep Medicine Out of Reach*, ATLANTIC (May 15, 2013), <https://www.theatlantic.com/health/archive/2013/05/how-drug-companies-keep-medicine-out-of-reach/275853>.

340 See, e.g., Liza S. Vertinsky, *Patents, Partnerships, and the Pre-Competitive Collaboration Myth in Pharmaceutical Innovation*, 48 U.C. DAVIS L. REV. 1509 (2015) (exploring the role and limits of public-private partnerships in pharmaceutical R&D).

341 Transparency is frequently mentioned in proposals for reform in many different aspects of the product life cycle. It appears most frequently in proposals for more transparency in pricing. See, e.g., Nisarg A. Patel, *Fee-for-Value in the Pharmaceutical Industry: A Policy Framework Applying Data Science to Negotiate Drug Prices*, J. L. & BIOSCIENCES 205 (2017) (proposal for addressing lack of price transparency through the use of an independent review board to provide a value based reimbursement system); Martha S. Ryan & Neeraj Sood, *Analysis of State-Level Drug Pricing Transparency Laws in the United States*, 2 JAMA Network Open 1 (2019). For a view about how transparency might improve conduct through market forces, see, for example, Jennifer E. Miller, *From Bad Pharma to Good Pharma: Aligning Market Forces with Good and Trustworthy Practices Through Accreditation, Certification and Rating*, 41 J. L. MED. & ETHICS 601 (2013) (arguing that metrics that force companies to reveal ethical performance to investors, customers and regulators will allow market forces to improve conduct). For arguments about the benefits of increasing transparency in regulatory decision making, see, for example, Ana Santos Rutschman, Yaniv Heled & Liza S. Vertinsky, *Regulatory Reactivity: FDA and the Response to Covid-19*, Food and Drug Law Journal (forthcoming 2021).

342 See, e.g., Light, Lexchin & Darrow, *supra* note 20 (proposing measures to increase independence of agencies like the FDA with gatekeeping roles over drugs).

343 See, e.g., Gagnon, *supra* note 338 (considering the role of increased financial penalties in addressing divergence of private incentives from public health).

A third avenue is to increase the support and rewards for public interest regulation. The gap between private sector marketing salaries and the much lower government regulator compensation is also worth considering, since making regulation a more lucrative job might reduce interests in cultivating future industry ties.

Taken together, the adoption of systemic strategies, increasing the resources devoted to regulation, altering the grounding assumptions to refocus on patients and health, and limiting the divergence of private incentives from public health needs, could provide a regulatory approach strong enough to put regulators and the public interest they are charged to protect, back in control of writing the rules for how pharmaceutical markets operate and whose interests they serve.

CONCLUSION

This Article has offered a theory of pharmaceutical capture that ties together the myriad ways in which pharmaceutical companies exert influence over the construction and regulation of pharmaceutical markets. The pharmaceutical industry is, in effect, now writing its own rules for how pharmaceutical markets operate. The result of pharmaceutical capture is a pharmaceutical industry that is driven largely by profits, often at the expense of health outcomes. The opioid epidemic provides a stark example of the tensions that can emerge between private incentives and public health needs and the harms that can result when corporate actors gain too much influence over health care markets. Rather than seeing the opioid epidemic as an outlier, this Article argues that the opioid epidemic is simply a particularly salient example of pharmaceutical capture at work and a warning of the magnitude of public health harms that can occur as a result.

A popular political response to concerns about the economic and political power exerted by pharmaceutical companies has been to pin the blame on government regulation as impeding the efficiency and innovative power of the “free market.” The clarion calls for selective deregulation and/or privatization of the pharmaceutical industry, calls fueled by private sector interests, have become louder and more politically enticing in the wake of what is portrayed as the private sector triumph in producing COVID-19 vaccines. But as this Article has argued, markets—particularly pharmaceutical markets—rely on government regulations to operate, and this push for limiting government control over industry decisions is in many cases simply an effort to substitute one governance structure for another that is more favorable to corporate interests.

This Article concludes with some guidelines for regulatory redesign with the goal of “recapturing” pharmaceutical markets to serve public health needs. Drawing lessons from the industry strategies that have resulted in pharmaceutical capture, it proposes a shift away from existing fragmented regulatory approaches

and towards a regulatory strategy that is holistic and systemic, recalibrated to respond to contemporary market realities, and more robust to special interests. The pharmaceutical industry, working in partnership with public actors, has vast potential to meet even the most daunting of public health challenges, but realizing this potential depends upon the success of this recapture.