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Why Healthcare Companies Should Be(come) Benefit Corporations

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WHY HEALTHCARE COMPANIES SHOULD BE(COME) BENEFIT CORPORATIONS

YANIV HELED, LIZA VERTINSKY & CASS BREWER

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WHY HEALTHCARE COMPANIES SHOULD BE(COME) BENEFIT CORPORATIONS

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Abstract: Our healthcare system is broken. Despite spending far more on healthcare per capita than any other country, health outcomes in the United States are relatively poor. There is a pervasive disconnect within the healthcare system between private incentives to develop and provide healthcare products and services and public health needs. Mainstream proposals for how to fix the system have focused on changes in regulation, incentive schemes, consumer behavior, and competition in healthcare markets. All of these proposals share the assumption that the development and provision of healthcare products and services will remain primarily in the hands of traditional corporations and, to a lesser extent, non-profit organizations operating within a market-based healthcare system. Yet, as this Article demonstrates, there is an inherent problem with relying on profit-focused corporations to drive healthcare innovation and provide healthcare products and services. Traditional corporations are structured to focus on profits rather than to tend to the public need, a focus that is reinforced by the legal framework that governs them. Even though this profit focus is not unusual nor considered undesirable in most markets, healthcare markets are different in ways that create a divergence between the private incentives to which corporations respond and public health needs. In this Article, we suggest that a change in corporate form can be used to more closely align private incentives with public need by changing corporate incentives from the inside. We propose that companies involved in the provision of healthcare products and services should be encouraged or even required to assume alternative business forms that would both enable and require them to consider the needs of a broader range of stakeholders and the public interest in addition to shareholder value. We identify benefit corporations, broadly defined, as one preferred mechanism for achieving this. We conclude that this approach could help to change corporate behavior in ways that improve healthcare outcomes.

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INTRODUCTION

The U.S. healthcare system is failing us in many ways.¹ We spend more on healthcare both in terms of percentage of gross domestic product (GDP) and per capita than any other industrialized nation.² We consume more healthcare technology than any of these nations.³ Yet, our healthcare outcomes are almost uniformly among the worst of all Organization for Economic Cooperation and Development (OECD) countries.⁴ Healthcare products and services are excessively priced,⁵ leaving many healthcare consumers with limited or no

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¹ See, e.g., ELISABETH ROSENTHAL, *AN AMERICAN SICKNESS: HOW HEALTHCARE BECAME BIG BUSINESS AND HOW YOU CAN TAKE IT BACK* (2017) (analyzing the destructive outcomes for patients in a profit focused healthcare industry); Steven Brill, *Bitter Pill: Why Medical Bills Are Killing Us*, TIME (Mar. 4, 2013), <http://content.time.com/time/subscriber/printout/0,8816,2136864,00.html> [<https://perma.cc/ED8Q-Y5CU>] (reporting on the myriad problems that are leading to high costs and poor outcomes in the U.S. healthcare system).

² See *National Health Expenditure Fact Sheet 2015*, CTRS. FOR MEDICARE & MEDICAID SERVS. (last updated Apr. 17, 2018), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html> [<https://perma.cc/DFC8-C9EF>] [hereinafter *National Health Expenditure Fact Sheet 2015*] (providing an overview of national health spending); see also ORG. FOR ECON. CO-OPERATION & DEV., *COUNTRY NOTE: HOW DOES HEALTH SPENDING IN THE UNITED STATES COMPARE? 1* (2015), <https://www.oecd.org/unitedstates/Country-Note-UNITED-STATES-OECD-Health-Statistics-2015.pdf> [<https://perma.cc/B5PW-9CXF>] [hereinafter *OECD HEALTH STATISTICS 2015*] (showing that the United States is spending more than any other nation on healthcare in terms of GDP); ORG. FOR ECON. CO-OPERATION & DEV., *HEALTH AT A GLANCE 2015: OECD INDICATORS 164* (2015) [hereinafter *HEALTH AT A GLANCE 2015*] (providing a statistical analysis of healthcare systems performance in OECD countries).

³ See, e.g., *HEALTH AT A GLANCE 2015*, *supra* note 2, at 30 (finding that in 2013 the United States spent twice as much on pharmaceuticals than the “OECD average, and more than 35% higher than . . . Japan, the next highest spender”); see also *id.* at 102 (finding “[t]he number of CT exams per capita is highest in the U.S.” and the “number of MRI exams more than doubled between 2000 and 2013”); *National Health Expenditure Fact Sheet 2015*, *supra* note 2 (finding the national health expenditure reached \$3.0 trillion).

⁴ See, e.g., *HEALTH AT A GLANCE 2015*, *supra* note 2, at 26 (reporting the United States has a relatively low life expectancy when compared to its high spending on healthcare, and that the United States is a “bottom third performer” for quality of care as measured by hospital admissions associated with asthma, chronic obstructive pulmonary disease, and diabetes); see also ORG. FOR ECON. CO-OPERATION & DEV., *HEALTH AT A GLANCE 2017: HOW DOES THE UNITED STATES COMPARE?* (2017), <https://www.oecd.org/unitedstates/Health-at-a-Glance-2017-Key-Findings-UNITED-STATES.pdf> [<https://perma.cc/7VQ6-UX5X>] (finding that life expectancy in 2015 in the United States was 78.8 years, 2 years less than the OECD average).

⁵ By “excessively” we mean two things: (a) significantly—i.e., by orders of magnitude—more expensive than the marginal or even the average cost of making the product or rendering the service;

access to the products and services that they need.⁶ For those who can pay for healthcare, either directly or through healthcare insurance, prices often bear little relationship to health need or benefit, leading to ineffective and unsustainable healthcare spending.⁷ In stark contrast to the poor health outcomes for patient-consumers, financial outcomes for many of the healthcare companies in U.S. markets are extremely good.⁸ Many sectors of the healthcare industry

and (b) significantly more than what is being paid for the same products and services in other countries. See ORG. FOR ECON. CO-OPERATION & DEV., OECD HEALTH DATA 2012: U.S. HEALTH CARE SYSTEM FROM AN INTERNATIONAL PERSPECTIVE 6, 7–14 (2012) (comparing the United States' hefty spending on healthcare to other countries throughout the world); INT'L FED'N OF HEALTH PLANS, 2011 COMPARATIVE PRICE REPORT: MEDICAL AND HOSPITAL FEES BY COUNTRY 7–8, 24–25 (2011) (reporting significant discrepancies in the average cost of a variety of medical products between the United States and other countries); Erin C. Fuse Brown, *Resurrecting Health Care Rate Regulation*, 67 HASTINGS L.J. 85, 92–103 (2015) (discussing the reasons and causes for the “excessive and inexplicable” prices of healthcare in the United States in general and in the hospital industry in particular); Daniel A. Goldstein et al., *Global Differences in Cancer Drug Prices: A Comparative Analysis*, 34 J. CLINICAL ONCOLOGY (Suppl. Abstr. LBA6500) (2016), http://ascopubs.org/doi/abs/10.1200/JCO.2016.34.18_suppl.LBA6500 (documenting high drug prices in the United States compared to other countries); Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the U.S.: Origins and Prospects of Reform*, 316 JAMA 858, 859 (2016), <https://phhp-bahealthscience-new.sites.medinfo.ufl.edu/files/2016/09/jsc1600151.pdf> [<https://perma.cc/A9A5-RFF6>] (finding that per capita prescription drug spending in the United States exceeds all other countries and that this increased expenditure is driven mostly by high brand-name drug prices); Miriam J. Laugesen & Sherry A. Glied, *Higher Fees Paid to U.S. Physicians Drive Higher Spending for Physician Services Compared to Other Countries*, 30 HEALTH AFF. 1647, 1654 (2011) (finding higher fees for primary care and orthopedic physicians responsible for higher spending on physician services).

⁶ See, e.g., MURRAY AITKEN & SILVIA VALKOVA, IMS INST. FOR HEALTHCARE INFORMATICS, AVOIDABLE COSTS IN U.S. HEALTHCARE 7–8 (2013), http://offers.premierinc.com/rs/381-NBB-525/images/Avoidable_Costs_in%20US_Healthcare-IHII_AvoidableCosts_2013%5B1%5D.pdf [<https://perma.cc/6CDF-UTZ9>] (estimating that the cost of medical non-adherence—namely, when patients do not take their medicines appropriately or at all, including due to cost—in 2013 in the United States reached \$105 billion); Emily R. Cox et al., *Medicare Beneficiaries' Management of Capped Prescription Benefits*, 39 MED. CARE 296, 296 (2001) (finding Medicare beneficiaries exposed to health risks due to efforts aimed at minimizing out-of-pocket drug costs); Kathryn E. Weaver et al., *Forgoing Medical Care Because of Cost*, 116 CANCER 3493, 3495 (2010) (reporting on cancer survivors forfeiting medical services because of cost).

⁷ See M. Gregg Bloche, *The Emergent Logic of Health Law*, 82 S. CAL. L. REV. 389, 391–92 (2009) (describing the unsustainable increase in medical spending, particularly for treatments with “unproven value,” and estimating that medical spending will increase to 30% of GDP in the next quarter century); Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363, 364 (2014) (describing “the lawful sale of medicines that have little or no therapeutic effect” and referring to “the surprising absence of substantial efficacy or advantage exhibited by many of today’s most celebrated pharmaceuticals”).

⁸ For purposes of this Article, we define “healthcare companies” as for-profit business entities involved in the commercial development, manufacture, or distribution of healthcare products and services. Healthcare companies may include pharmaceutical companies and other developers of biomedical technology, distributors and retailers of medical supplies (including retail pharmacies), medical insurance companies, pharmacy benefit management companies, laboratories, and so forth. We acknowledge that healthcare markets are complex and operate in different ways, subject to different constraints, and that these markets are constantly changing, but we argue that private profit incentives

rank among the most profitable sectors in the U.S. economy, some even on par with the banking sector.⁹ The pharmaceutical industry in particular has enjoyed a median return on assets that exceeds the median return for all Fortune 500 companies by two or three times.¹⁰ More recently, health insurance companies have been outperforming the market, with the growth of the six largest health insurance companies far exceeding the growth of the overall S&P 500 healthcare sector and with record profits expected to continue.¹¹

There are many factors that contribute to the broken state of the healthcare system. Current proposals for how to fix our healthcare system have focused primarily on changes to healthcare regulation,¹² alternative incentive

largely explain choices made by healthcare companies and that a divergence of private and public interests persists across different parts of the market. Even though we largely focus on for-profit organizations, in Part III we suggest why in many cases benefit corporations may also be preferable to non-profit organizations, although we leave a more detailed comparison and analysis for a separate article.

⁹ According to Forbes, the average net profit margin of the top ten drug companies in 2014 was 19%, which was the highest of all five industries surveyed and the same as the average profit margin of the ten biggest banks surveyed. Liyan Chen, *Best of The Biggest: How Profitable Are the World's Largest Companies?*, FORBES (May 13, 2014), <http://www.forbes.com/sites/liyanchen/2014/05/13/best-of-the-biggest-how-profitable-are-the-worlds-largest-companies/#505104be4c33> [https://perma.cc/M4MT-E83Q]; see Marc-André Gagnon, *Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health*, 41 J.L. MED. & ETHICS 571, 577 fig.1 (2013) (comparing the net return on revenues of average U.S. major pharmaceutical companies with that of an average Fortune 500 company); see also, e.g., Phillip Mattera, *Taking the Profit Out of Health Insurance: A Response to Jacob Hacker and Andrew Stern*, 16 NEW LAB. F. 47, 50–51 (2007) (highlighting increasing profits for healthcare companies); Press Release, Hospital Corporation of America, HCA Reports Second Quarter 2015 Results 1 (Aug. 5, 2015), <http://investor.hcahealthcare.com/press-release/hca-reports-second-quarter-2015-results> [https://perma.cc/EU33-9YLD] (reporting second quarter financial and operating data for Hospital Corporation of America).

¹⁰ See, e.g., Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), <http://www.bbc.com/news/business-28212223> [https://perma.cc/9GJY-XNCU] (reporting on revenue outcomes for the world's largest pharmaceutical companies); Alfred B. Engelberg, *How Government Policy Promotes High Drug Prices*, HEALTH AFF. (Oct. 29, 2015), <http://healthaffairs.org/blog/2015/10/29/how-government-policy-promotes-high-drug-prices/> [https://perma.cc/MCR3-8T57] (analyzing the outcomes of U.S. laws which curb innovation and competition in the pharmaceutical industry).

¹¹ See Bertha Coombs, *As Obamacare Twists in Political Winds, Top Insurers Made \$6 Billion (Not That There Is Anything Wrong with That)*, CNBC HEALTH & SCI. (Aug. 5, 2017), <https://www.cnbc.com/2017/08/05/top-health-insurers-profit-surge-29-percent-to-6-billion-dollars.html> [https://perma.cc/CP9M-Q834] (highlighting increasing revenues for the nation's top health insurers).

¹² See, e.g., THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS 15 (Einer R. Elhauge ed., 2010) (exploring regulatory responses to problem of fragmentation); Fuse Brown, *supra* note 5, at 128–37 (calling for the imposition of government controls on prices for healthcare products and services); Bruce C. Vladeck & Thomas Rice, *Market Failure and the Failure of Discourse: Facing up to the Power of Sellers*, 28 HEALTH AFF. 1305, 1312–13 (2009) (suggesting an “all-payer system” where every player’s behavior is highly regulated and “payments are uniform across insurers”).

schemes for healthcare companies,¹³ changes in healthcare purchaser and consumer behavior,¹⁴ and efforts to increase competition in healthcare markets.¹⁵ Almost all of these proposals, including those currently being debated at the federal and the state level, share the assumption that the provision of healthcare products and services will remain largely in the hands of traditional corporations and, to a lesser extent, non-profit organizations, operating within a market-based healthcare system. The proposed interventions are targeted at changing the market environment in which these entities operate rather than replacing the market altogether or changing the entities themselves. By failing to directly target the limitations of the corporate form as a mechanism for healthcare provision, however, these approaches neglect another important and largely underexplored avenue for market-driven change. This mechanism is particularly important in a political environment where alternative regulatory or public-provision solutions remain unlikely and conversions of non-profit to for-profit entities are increasing. We suggest that it is time to include the corporate form itself in discussions about healthcare reform.

¹³ See Constance E. Bagley & Christina D. Tvarnoe, *Pharmaceutical Public-Private Partnerships: Moving from the Bench to the Bedside*, 4 HARV. BUS. L. REV. 373, 373 (2014) (proposing to “enhance the likelihood of successful commercialization of pharmacological discoveries” changing the incentive schemes of parties involved in for-profit pharmaceutical public-private partnerships). See generally Segundo Mariz et al., *Worldwide Collaboration for Orphan Drug Designation*, 15 NATURE REV. DRUG DISCOVERY 440, 440–41 (2016) (providing a comparison across countries of alternative mechanisms, including tax breaks and regulatory exclusivities, to incentivize production of orphan drugs).

¹⁴ See Amy Kapczynski & Aaron S. Kesselheim, ‘Government Patent Use’: *A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFF. 791, 792–96 (2016) (advocating for the use of 28 U.S.C. § 1498 by the government in order to lower the cost of expensive prescription medicines); Kesselheim et al., *supra* note 5, at 866 (proposing “Physician- and Patient-Level Solutions” to the problem of high drug prices); Paul J. Zwier, *High Prices in the U.S. for Life-Saving Drugs: Collective Bargaining Through Tort Law?*, 17 MARQ. BENEFITS & SOC. WELFARE L. REV. 203, 209–14 (2016) (proposing to use the tort causes of action of intentional infliction of emotional distress and negligent infliction of emotional distress to curb exorbitant pricing of lifesaving drugs).

¹⁵ See, e.g., Jonathan D. Alpern et al., *High-Cost Generic Drugs—Implications for Patients and Policymakers*, 371 NEW ENG. J. MED. 1859, 1861 (2014) (advocating for the creation of a special pathway for approval of off-patent, already-approved medicines so as “to promote competition and permit the private market to function more efficiently”); Rena M. Conti & Meredith B. Rosenthal, *Pharmaceutical Policy Reform—Balancing Affordability with Incentives for Innovation*, 374 NEW ENG. J. MED. 703, 704 (2016) (analyzing reforms that could catalyze to competition in the healthcare market); Clark C. Havighurst & Barak D. Richman, *The Provider Monopoly Problem in Health Care*, 89 OR. L. REV. 847, 876 (2011) (“As a strategy to restore competition in health care markets, antitrust enforcers might focus their efforts on requiring hospitals and other provider entities to unbundle, at a purchaser’s request, their competitive and monopolized services for purposes of negotiating prices.”); Elisabeth Rosenthal, *Lawmakers Look for Ways to Provide Relief for High Cost of Drugs.*, N.Y. TIMES, Nov. 25, 2014, at A17 (describing legislative initiatives meant to increase competition in pharmaceutical markets by allowing parallel imports of drugs).

In this Article, we argue that many of the problems besetting the healthcare system have a common foundation in the pervasive disconnect between the private incentives of the companies that develop and provide healthcare products and services and public health needs.¹⁶ We suggest that, for so long as we continue to rely on a market-based system of healthcare, changing the internal incentives of the companies themselves can be an effective way of reducing this disconnect. This approach is advocated not as a substitute for but as a complement to public-interest centered regulation, seeking to alter the decision-making of private actors from the inside in ways that can be reinforced by regulation to further public health objectives.¹⁷

Currently, the development and provision of many healthcare products and services to meet public health needs remains, with the exception of hospital services, largely in the hands of traditional corporations.¹⁸ Traditional corporations are primarily incentivized to pursue the maximization of value for their shareholders,¹⁹ making stock value and profits from the sale of products and services the primary focus of corporate decisions.²⁰ This profit-driven ap-

¹⁶ See Gagnon, *supra* note 9, at 571–80 (documenting negative healthcare outcomes as a result of profit-focused healthcare corporations).

¹⁷ We are not arguing that a change in corporate structure can, by itself, solve the myriad of problems with the healthcare system, but rather that changes in corporate form can and should be an important part of broader government-driven reforms to the system. See generally Joel Bakan, *The Invisible Hand of Law: Private Regulation and the Rule of Law*, 48 CORNELL INT'L L.J. 279 (2015) (warning of reliance on private regulation norms as replacements for state action and responsibility).

¹⁸ Moreover, even though many hospitals are non-profit organizations, this does not guarantee a focus on the public need. See Rick Cohen, *Nonprofit Hospitals No Better Than For-Profits on Charity Care*, NONPROFIT Q. (Aug. 7, 2015), <https://nonprofitquarterly.org/2015/08/07/nonprofit-hospitals-no-better-than-for-profits-on-charity-care/> [<https://perma.cc/2F97-6XG7>] (“The real question is just how ‘nonprofit’ nonprofit hospitals actually are. . . . The nonprofit sector has to live up to a legitimate debate about whether some—or many—nonprofit hospitals are not living up to mandates of service to people in need.”); see also *infra* notes 150, and 203–266.

¹⁹ See *Dodge v. Ford Motor Co.*, 170 N.W. 668, 684 (Mich. 1919) (“A business corporation is organized and carried on primarily for the profit of the stockholders. The powers of the directors are to be employed for that end.”); JOEL BAKAN, *THE CORPORATION: THE PATHOLOGICAL PURSUIT OF PROFIT AND POWER* 36 (2004) (“*Dodge v. Ford* still stands for the legal principle that managers and directors have a legal duty to put shareholders’ interests above all others and no legal authority to serve any other interests.”); Henry Hansmann & Reinier Kraakman, *The End of History for Corporate Law*, 89 GEO. L.J. 439, 439 (2001) (“There is no longer any serious competitor to the view that corporate law should principally strive to increase long-term shareholder value.”).

²⁰ See BAKAN, *supra* note 19, at 37 (“The law forbids any other motivation for [corporate] action, whether to assist workers, improve the environment, or help consumers save money. [Corporate managers] can do these things with their own money, as private citizens. As corporate officials, however, stewards of other people’s money, they have no legal authority to pursue such goals as ends in themselves—only as means to serve the corporation’s own interests, which generally means to maximize the wealth of its shareholders.”); Frank H. Easterbrook & Daniel R. Fischel, *Antitrust Suits by Targets of Tender Offers*, 80 MICH. L. REV. 1155, 1177 (1982) (“[A] corporation is no more than a convenient name for a nexus of contractual relationships among people. Only people have moral obligations; corporations can no more be said to have moral obligations than does a building, an organization

proach is not unusual, nor is it considered undesirable or unwarranted in many markets.²¹ But, notwithstanding their variety and complexity, the markets in many, if not most, sectors of the healthcare industry share three distinctive characteristics, the combination of which leads to the failure of the traditional corporate model to effectively meet public needs.²² These three characteristics are: (1) the failure of price to serve as a good indicator of public health value; (2) the public sharing of costs but not benefits; and (3) regulation and market structure that limit competition. When traditional corporations are left to make their own decisions about the provision of healthcare products and services in these types of markets, their actions are often socially sub-optimal and sometimes in direct conflict with public health needs, resulting in high social costs and poor public health outcomes.

We address the disconnect between private incentives and public needs head on, proposing an approach to healthcare reform that seeks to more closely align private incentives with public need by changing the business form of companies selling healthcare products and services in these types of markets (referred to herein as healthcare companies and healthcare markets).²³ We argue that healthcare companies should be strongly incentivized or even required to assume alternative business forms that both enable and oblige them to take broader stakeholder and public interests into account in corporate decision-

chart, or a contract.”); Robert C. Hinkley, *How Corporate Law Inhibits Social Responsibility*, HUMANIST, Mar.–Apr. 2002, at 27 (arguing that corporations are structured by law to pursue only the interests of the corporation and its shareholders and give such interests precedence over the public interest). For a more detailed discussion of the degree to which corporations focus on shareholder value, see *infra* notes 203–266.

²¹ See BAKAN, *supra* note 19, at 34–35 (citing agreement among thought leaders from different ends of the political and ideological spectrum that, ultimately, “corporations must be concerned only for their stockholders and . . . not the community or the workforce or whatever”); see also PRINCIPLES OF CORPORATE GOVERNANCE: ANALYSIS AND RECOMMENDATIONS § 2.01 (AM. LAW. INST. 1994) (“[A] corporation should have as its objective the conduct of business activities with a view to enhancing corporate profit and shareholder gain.”).

²² Although we rely for our examples primarily on pharmaceutical markets where the problems with relying on the market to serve public health needs are at their most severe, the arguments that we make about the disconnect between public health and private corporate incentives apply to other healthcare markets that share the three characteristics described in this Part. Where price does not reflect value, costs are socialized but benefits are not, and competition is limited, companies are free to set prices and make other product decisions without the constraint of pursuing public health value.

²³ This idea of using alternative company structures, while not new in other contexts, is starting to gather steam in the healthcare context. The precise reasons for doing so have not been sufficiently fleshed out. See generally Arnold Eiser & Robert Field, *Can Benefit Corporations Redeem the Pharmaceutical Industry*, 129 AM. J. MED. 651 (2016) (suggesting benefit corporations could heal numerous issues plaguing the healthcare industry); Katherine R. Lofft et al., *Is a Hybrid Just What the Doctor Ordered? Evaluating the Potential Use of Alternative Company Structures by Healthcare Enterprises*, THE HEALTH LAW., Apr. 2013, at 9–16 (analyzing the numerous factors facilitating change to corporate models in the healthcare industry).

making. We propose the collection of business forms generally referred to as “benefit corporations” as desirable business forms for these healthcare companies.²⁴

This Article proceeds in three parts. Part I examines the nature and scope of the disconnect between current private market incentives and public need in healthcare markets, using the pharmaceutical industry as the most salient example of the disconnect. It provides representative examples from across the product lifecycle to illustrate how pharmaceutical companies, simply by operating in accordance with their mandate to pursue shareholder value, make decisions at every stage of the product and service lifecycle that fail to align with public health needs. Part II analyzes the source of this disconnect, showing why it is that traditional corporations are ill-suited to healthcare markets from a public health perspective. Although the argument is anchored in examples drawn from pharmaceutical markets, where the source of the disconnect is easy to identify, it extends to other markets in the healthcare industry that share the same characteristics, and it is these markets on which we base our analysis. Part III proposes the use of alternative business forms in healthcare markets as a way of reducing the disconnect between private incentives and public health needs both by altering incentives from the inside and improving the ability to regulate from the outside. We conclude that healthcare outcomes could be improved by requiring, or at least strongly incentivizing, healthcare companies to incorporate or re-incorporate as one of these alternative forms, proposing benefit corporations as one such choice.

I. ILLUSTRATING THE MARKET/PUBLIC-HEALTH DISCONNECT IN PHARMACEUTICALS

Although there are a variety of ways in which the public interest in health can be defined, few would dispute that the public has a shared interest in reducing their general morbidity and mortality.²⁵ The goals of reducing morbidity and mortality underlie virtually every public health policy and inform gen-

²⁴ We recognize that this approach is not sufficient, on its own, to address the myriad of problems with the healthcare system, but we argue that for so long as the United States continues to rely on a market-based approach to healthcare, changing the internal incentives of the market actors is a critical part of efforts to improve public health outcomes.

²⁵ See Christian Munthe, *The Goals of Public Health: An Integrated, Multidimensional Model*, 1 PUB. HEALTH ETHICS 39, 39–41 (2008) (exploring goals driving public health policies and the tensions between individual and population-based health); Gabriel N. Stover & Mary T. Bassett, Editorial, *Practice Is the Purpose of Public Health*, 93 AM. J. PUB. HEALTH 1799, 1799 (2003) (“All who work in public health share this common goal: to prevent disease and promote health.”).

erally accepted measures of public health benefits.²⁶ The U.S. healthcare system relies largely on a market-based system to produce the goods and services needed to meet these public health objectives and on a fragmented mix of public and private entities and end users to pay for them. Yet when traditional corporations are left to make their own decisions about matters that involve human health—for example, what products and services to produce and at what prices—their decisions are based on financial goals. Thus, where the financial incentives facing healthcare companies, as well as the top-level corporate executives that run them, do not adequately reflect public health needs, it should be no surprise that this system fails to produce good public health outcomes.

The disconnect between private incentives and public health needs in healthcare markets is perhaps most stark in the pharmaceutical industry, and in this Part, we use examples drawn from that industry to illustrate the nature and magnitude of the harm that can arise from the market disconnect.²⁷ We draw examples from four different decision-making points in the discovery, development, and sale of pharmaceutical products to illustrate the pervasive and continuous disconnect between private incentives and public health needs at every stage of the pharmaceutical product lifecycle. These decision points are not unique, and there are many other types of decisions that also impact the gap between what the market provides and what the public needs. We exclude from our consideration corporate decisions that are considered to be illegal, focusing only on decisions made by companies acting (mostly) within the boundaries of the law to maximize shareholder value in accordance with corporate law requirements and market expectations.²⁸ The examples illustrate how pharmaceutical companies, simply by doing what they are designed to do, contribute to the problems besetting the healthcare system.²⁹ We suggest that a

²⁶ See, e.g., Stephen B. Thacker et al., *Measuring the Public's Health*, 121 PUB. HEALTH REP. 14, 15–16 (2006) (discussing the continued focus on measures of morbidity, mortality, and disability as measures of public health).

²⁷ In the context of this Article, “pharmaceutical industry” and “pharmaceutical companies” are defined as companies engaged in the discovery, research and development, and production of pharmaceutical products, whereas “pharmaceutical products” and “drugs,” for short, are defined broadly as including small-molecule drugs, biologics, vaccines, and any other medicinal compounds made to diagnose, treat, cure, or prevent a disease.

²⁸ In many cases, the high profits earned—often at the sacrifice of public health benefits—are rewarded through high returns and premium payments to top executives. See Matt Krantz, *Drug Prices Are High. So Are the CEOs' Pay*, USA TODAY (Aug. 26, 2016), <https://www.usatoday.com/story/money/markets/2016/08/26/drug-money-pharma-ceos-paid-71-more/89369152/> [<https://perma.cc/XJ4Y-AG64>] (stating that “CEOs of the 14 biotech and pharmaceutical companies in the Standard & Poor’s 500 that served all of 2015 pulled down median compensation packages valued at \$18.5 million in 2015 . . .” which “was 71% greater than the median \$10.8 million hauled in by S&P 500 executives in all industries in 2015 . . .”).

²⁹ This argument can be taken even further to suggest that the legal structures that govern pharmaceutical industry behavior have themselves become subordinated to corporate interests. See Eugene

similar approach can be used in other healthcare markets (those sharing the same three characteristics identified) for other healthcare products and services where similar disconnects between private profit-driven incentives and public needs result in high costs and poor health outcomes.³⁰

A. First Example: Decisions About Which Products to Develop

Decisions about which disease area(s) to focus on, and within a disease area, which potential drugs to investigate and pursue through further investments in research and development (R&D) are among the most critical decisions that pharmaceutical companies must make. The decisions about which disease areas and which projects within these areas to pursue are driven in part by scientific opportunity, but even more by considerations of the potential profitability and level of risk associated with available drug candidates. Although many new ideas are pursued by smaller venture-backed start-up companies, pharmaceutical companies enter at later stages to select among available ideas and identify those they will move into development, and anticipation of this exit strategy impacts earlier project and investment choices. Companies look for projects that are likely to yield the largest expected net profits at the lowest risk, seeking promises of high profits to offset the large costs and uncertainties of drug discovery and development. Federal legislation reinforces this profit-focused approach by providing additional financial incentives for developers of drugs for certain types of patient populations and medical conditions in areas where the market returns are perceived as being too small to attract desired investment.³¹

McCarthy, *The Pharma Barons: Corporate Law's Dangerous New "Race to the Bottom" in the Pharmaceutical Industry*, MICH. BUS. & ENTREPRENEURIAL L. REV. (forthcoming 2019) (arguing that industry players have transformed the legal structure "to allow them to profit with legal impunity at the public's expense").

³⁰ See, e.g., Irene Papanicolas et al., *Health Care Spending in the United States and Other High-Income Countries*, 319 JAMA 1024, 1024 (2018), <https://www.ncbi.nlm.nih.gov/pubmed/29536101> [<https://perma.cc/HB6U-8X6X>] (study showing that the US spent nearly twice as much as ten high income countries on medical care while performing less well on outcomes, points to high prices for healthcare products and services); Yoni Blumberg, *Here's the Real Reason Health Care Cost Much More in the US*, CNBC MONEY (Mar. 22, 2018), <https://www.cnbc.com/2018/03/22/the-real-reason-medical-care-costs-so-much-more-in-the-us.html> [<https://perma.cc/7AQE-LPJA>] (pointing to high prices of healthcare products and services as contributing to high cost of healthcare and problems with access); Jessica Glenza, *Sky-High Prices of Everything Make U.S. Healthcare the World's Most Expensive*, THE GUARDIAN (Mar. 13, 2018), <https://www.theguardian.com/us-news/2018/mar/13/us-healthcare-costs-causes-drug-prices-salaries> [<https://perma.cc/HNX9-TA2L>] (noting high spending across the board in comparison with other OECD countries, with often worse outcomes and less coverage).

³¹ See, e.g., 21st Century Cures Act, Pub. L. No. 114-255, §§ 3012–3013, 3038, 130 Stat. 1033, 1091–93, 1105–11 (2016) (providing additional incentives, including priority review vouchers and exclusivity periods, for the development of drugs for rare pediatric conditions and combination prod-

This mode of decision-making might work well in a world in which prices accurately reflect public health benefits, excess profits are competed away, and people can rationally evaluate and afford to pay for the drugs that they need. But, for a variety of reasons that are further explored in Part II below, the relationship between expected profits and actual (or even expected) public health benefits is often weak.³² As a result, even diseases that seriously harm large populations may be ignored by the pharmaceutical industry simply because the areas or the potential drug candidates within those areas are regarded as too risky or insufficiently profitable. Instead, an increasing number of pharmaceutical companies pursue R&D projects aimed at developing therapies for “lucrative” medical conditions, many of which are not considered severe or which already have effective therapies available (“me-too drugs”).³³

The disconnect between private incentives and public health need is most starkly illustrated by the disproportionate amount of investment in diseases of the rich and the neglect of diseases affecting primarily poorer populations—the latter commonly referred to as neglected diseases.³⁴ Notable examples of ne-

ucts); Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049, 2053–56 (1983) (codified as amended at 21 U.S.C. §§ 360aa–ee and scattered sections of 25, 35, and 42 U.S.C. (2012)) (providing additional tax benefits and exclusivities to developers of drugs designated for rare diseases).

³² See MÉDECINS SANS FRONTIÈRES, LIVES ON THE EDGE: TIME TO ALIGN MEDICAL RESEARCH AND DEVELOPMENT WITH PEOPLE’S HEALTH NEEDS 2 (2016) [hereinafter LIVES ON THE EDGE] (“With current incentive mechanisms, the biomedical innovation system concentrates investment on products that will sell well, and not necessarily on existing public health priorities.”).

³³ According to the former Congressional Office of Technology Assessment:

Me-too drugs are introduced after the pioneer and are similar but not identical to pioneer compounds in molecular structure and mechanism of action. Many me-too drugs are developed through deliberate imitation of the pioneer compound and have a shorter and more certain discovery period.

. . . .

The pursuit of “me-too” drugs is an attempt by rival firms to shave off part of the monopoly profits enjoyed by the maker of the pioneer drug in a therapeutic class. The higher the initial monopoly profits, the more incentive rivals have to develop a similar competing drug.

U.S. CONGRESS, OFFICE OF TECH. ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS & REWARDS 7, 45–46 (1993), ota.fas.org/reports/9336.pdf [https://perma.cc/CNG7-33P3]; see also LIVES ON THE EDGE, *supra* note 32, at 11 (“[M]e-too’ drugs . . . have only small clinical advantages over existing drugs, but . . . can be patented and bring substantial profits.”).

³⁴ See LIVES ON THE EDGE, *supra* note 32, at 45 (defining neglected diseases as “[a] diverse group of diseases and conditions affecting more than a billion people worldwide, but few in wealthy markets”); see also Margaret Chan, Dir.-Gen. of the World Health Org., Keynote Address to the Regional Committee for the Western Pacific (Oct. 13, 2014), transcript available at <http://www.who.int/dg/speeches/2014/regional-committee-western-pacific/en/> [https://perma.cc/WB3E-QUXQ] (“A profit-driven industry does not invest in products for markets that cannot pay.”).

glected diseases include: malaria,³⁵ which kills hundreds of thousands of people in developing countries each year; tuberculosis, which was responsible for the death of 1.5 million people in 2014 alone;³⁶ Ebola, which during the 2014 outbreak in West Africa caused the death of 11,310 people;³⁷ and Chagas disease, a parasitic disease impacting the heart and nervous system that is endemic to South and Central America that causes damage to the heart and central nervous system (“CNS”).³⁸ Even though neglected diseases may seem to fall outside of the purview of the U.S. healthcare system because the disease burden falls predominately outside of the United States, the potential negative impact of neglected diseases on both the health of the U.S. population and the health of the U.S. economy cannot be ignored—as was recently illustrated by the Ebola and Zika outbreaks.³⁹ Despite the tremendous financial and public health costs of these diseases, however, including potential health and economic costs within the United States, expected low-market returns deter private sector activity.⁴⁰ As a result, even though tuberculosis and tropical diseases accounted for 11.4% of the global disease burden between 1975–1999, only 1.1% of new chemical entities (“NCEs”) approved during those years were for the treatment of such diseases and with limited impact on the disease burden; and although 336 NCEs were approved during the years 2000–2011, only four

³⁵ See Eduardo Porter, *Patents’ Rewards Are Also a Barrier*, N.Y. TIMES, Apr. 13, 2016, at B1 (finding the non-existence of a malaria vaccine tied directly to the inability of the at-risk population’s ability to pay for medicine).

³⁶ See LIVES ON THE EDGE, *supra* note 32, at 2 (noting the absence of incentives to develop drugs such as tuberculosis). Drug-resistant tuberculosis has also appeared in increasing numbers among mostly poor populations in industrialized countries. *Id.* at 9.

³⁷ *Id.* at 2, 8; see also *Ebola (Ebola Virus Disease): Case Counts*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html> [<https://perma.cc/YTL8-8CM9>] (reporting on the number of cases and fatalities from Ebola disease during 2014–2016 in West Africa).

³⁸ LIVES ON THE EDGE, *supra* note 32, at 2, 6.

³⁹ See Chris Collins, *Global Health is Good Business—Trump Should Get in the Prosperity*, THE HILL (Jan. 5, 2017), <https://thehill.com/blogs/pundits-blog/healthcare/312923-the-business-case-for-global-health-in-the-trump-administration> [<https://perma.cc/397B-7B3G>] (noting outbreaks of many neglected diseases have no borders and must be considered transnational diseases).

⁴⁰ See LIVES ON THE EDGE, *supra* note 32, at 2 (“The current biomedical innovation system is overwhelmingly driven by financial interests; pharmaceutical companies develop drugs based on the likely return that a product will offer through sales. The result is a lack of investment in drugs, diagnostics and vaccines to meet the needs of people who can’t afford to pay high prices, or who don’t constitute a sizeable or lucrative market.”); Porter, *supra* note 35 (“Considering the market’s size [for malaria treatments], why haven’t pharmaceutical companies rushed to develop a vaccine against the deadly parasite that causes it? The answer is easy: There is no money to be made from a vaccine for poor children who could not possibly pay for inoculation.”). For a discussion of metrics used to define and measure global disease burdens, see generally The Global Burden of Disease Project, IHME, <http://www.healthdata.org/gbd/> [<https://perma.cc/6F5K-MRMM>] (describing the data collecting methodology for neglected diseases).

(1.2%) were for neglected diseases.⁴¹ The newest treatment for tuberculosis came to the market nearly 50 years ago.⁴² These problems of private sector neglect are further exacerbated in pediatric populations.⁴³

The disconnect between private incentives and public benefit is not limited to neglected populations and diseases, however—indeed, far from it. The misalignment of project choice and public need is amply demonstrated by the simultaneous increase in public health concern over growing antibiotic resistance and the continued exit of pharmaceutical companies from that market.⁴⁴ Despite antibiotics' immense and ever-growing importance in public health, and an already severe and growing public health threat from antibiotic-resistant bacteria,⁴⁵ the number of new antibiotic products being developed over the past few decades has been decreasing.⁴⁶ Competition from older antibiotic products, the cost and uncertainty of antibiotics R&D, and insufficiency of reimbursement incentives lower the financial attractiveness of this market.⁴⁷ Hence, the lack of expected profitability has been largely responsible for the dearth of antibiotics production by pharmaceutical companies.⁴⁸ Although a

⁴¹ LIVES ON THE EDGE, *supra* note 32, at 5.

⁴² *Id.* at 9.

⁴³ *See id.* (highlighting the deadly disparity between medicine developed for children and adults).

⁴⁴ *See* Kevin Outterson et al., *Repairing the Broken Market for Antibiotic Innovation*, 34 HEALTH AFF. 277, 277 (2015) (“Multidrug-resistant bacterial diseases pose serious and growing threats to human health. . . . But investment is declining in antibiotics. . . .”). Note that the information provided herein does not take into account any effects that may have occurred since the passage of the Generating Antibiotics Incentives Now (“GAIN”) Act in 2012. *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, §§ 801–806, 126 Stat. 993, 1077–82 (2012) (codified at 21 U.S.C. §§ 355E, 356, 524A) (providing further incentives for the development of antibiotics, including an additional period of five years of market exclusivity for products designated for the treatment of qualified infectious diseases).

⁴⁵ According to conservative estimates, as of 2013, in the United States, more than two million people are sickened every year with antibiotic-resistant infections, with at least 23,000 dying as a result of these infections. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2013, at 6 (2013), <https://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf> [<https://perma.cc/K4N2-UAZ2>] (describing the threat of antibiotic resistance in the United States as potentially having “catastrophic consequences”). The problem of antibiotic resistance is, of course, not a local issue of the United States. *See* LIVES ON THE EDGE, *supra* note 32, at 10–11 (addressing the problem of antibiotics-resistance from a global perspective).

⁴⁶ *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 45, at 44 (showing a clear decline in the number antibacterial New Drug Applications approved between 1980 and 2012); Outterson et al., *supra* note 44, at 277 (noting a decline in antibiotic development in the United States); *see also* Exec. Order No. 13,676, 184 Fed. Reg. 56,931 (Sept. 18, 2014) (announcing executive measures to address the issue of growing antibiotic resistance).

⁴⁷ *See* Outterson et al., *supra* note 44, at 278–79 (noting that pharmaceutical companies find that “the return on investment is relatively low for antibiotics as a result of low prices, limited market uptake, and modest government financial support”).

⁴⁸ *See id.* at 284 (“The existing price/volume business model for antibiotics is not working and is a key barrier to achieving more rapid progress on resistance.”).

host of incentive schemes have been proposed to make antibiotics more profitable, including price hikes, patent extensions, prizes, and upfront payments, trying to replicate the kinds of profits that pharmaceutical companies have come to expect through such measures is difficult or even impossible under existing innovation schemes.⁴⁹

The problems inherent in relying on private project choice to meet public health needs are not limited to markets with peculiar features, like those for antibiotics or vaccines. Pharmaceutical companies have also been shying away from R&D in disease areas where the risks are high, even when the potential size of the market is large. Pharmaceutical companies have been reducing their efforts to find treatments for health conditions affecting the CNS,⁵⁰ for example, despite the prevalence and enormous societal economic toll of such conditions.⁵¹ This is largely because CNS drug research has become comparatively more risky and financially less attractive than other disease areas of R&D.⁵² Similarly, while Alzheimer's disease is quickly becoming one of the world's biggest public health problems, many pharmaceutical companies have decided not to continue their efforts in this disease area, again, largely because of the high costs, risks, and the potential to earn more certain profits in other disease areas.⁵³

⁴⁹ See, e.g., Maryn McKenna, *We Need Antibiotics. They're Not Profitable to Make. Who Pays?*, NAT'L GEOGRAPHIC (May 23, 2015), <https://www.nationalgeographic.com/science/phenomena/2015/05/23/oneill-amr-3/> [<https://perma.cc/NZ42-9JU4>] (reporting on numerous studies analyzing the economic disincentives for creating antibiotics and the health threat it poses).

⁵⁰ Such conditions include mood disorders, psychotic disorders, anxiety disorders, addiction, stroke, dementia, and more. See generally Dennis W. Choi et al., *Medicines for the Mind: Policy-Based "Pull" Incentives for Creating Breakthrough CNS Drugs*, 84 NEURON 554 (2014) (analyzing the underdevelopment of drugs for CNS diseases and possible avenues for creating incentives for pharmaceutical companies). Notably, this does not mean that *all* pharmaceutical companies have been withdrawing from *all* CNS-related research projects. *Id.* at 555 (“[F]unding for CNS biotechnology companies from venture capital and other seed investors continues to be healthy.”); see SOEREN MATTKE ET AL., RAND PERSPECTIVES, THE NEW NEGLECTED DISEASES? POLICY INTERVENTIONS ARE NEEDED TO ENCOURAGE CNS DRUG DEVELOPMENT 1 (2013), http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE117/RAND_PE117.pdf [<https://perma.cc/6ZFK-2Q6Z>] (arguing that common CNS disorders, such as Alzheimer's disease, schizophrenia, and depression, are becoming “neglected” diseases, since drug R&D is not proportionate to their untreated disease burden and calling it a “disconnect between unmet need and investment”).

⁵¹ See MATTKE ET AL., *supra* note 50, at 1–2 (highlighting the health impacts from CNS disease); Choi et al., *supra* note 50, at 554 (describing “the stunning” economic impact of CNS diseases).

⁵² See Choi et al., *supra* note 50, at 555–56 (hypothesizing that “the main driver of the specific departures of companies from neuroscience research is [that] . . . [t]he neuroscience sector is now widely considered to be less attractive than most other therapeutic sectors for research investment”); see also MATTKE ET AL., *supra* note 50, at 2–5 (analyzing the numerous financial disincentives that dissuade CNS drug development by private entities).

⁵³ See Tom Blackwell, *Why Some Pharma Companies Have Given up on Finding Alzheimer's Treatments, Even as the Need Rises*, NAT'L POST (Mar. 28, 2016), <http://news.nationalpost.com/health/why-some-pharma-companies-have-given-up-on-finding-an-alzheimers-treatment-even-as-the->

Instead of confronting these major complex diseases with their massive public health burdens, the focus on profitability and the reluctance to assume risk has led many pharmaceutical companies to focus instead on niche markets for orphan diseases, where risks are lower and potential profits are high.⁵⁴ Markets for many non-lethal conditions that impair lifestyles in affluent economies have also proven to be lucrative. In the year 2000, for example, pharmaceutical companies were not engaged in a single R&D project aimed at tuberculosis—the leading lethal infectious disease globally—but there were eight R&D projects aimed at developing products for the treatment of erectile dysfunction and seven projects for baldness.⁵⁵

The prevalence of research projects intended to develop me-too drugs⁵⁶—or, as a top-manager in a major pharmaceutical company once called them: “me-slightly-different-marketed-like-hell” drugs—is yet another indication of the disconnect between private incentives and public healthcare needs.⁵⁷ These me-too drugs are typically not clinically superior to earlier-developed already-approved drugs, but their R&D costs are often lower than they would be for pioneer drugs, and are therefore developed with the hope of capturing a portion of the market from the earlier drug(s).⁵⁸ Notable examples of areas characterized by a proliferation of me-too drugs include certain cholesterol lowering medication (“statins”), blood pressure lowering medication (“ACE inhibitors”), and antidepressants (“SSRIs”).⁵⁹ Although no pharmaceutical company

need-rises?_lisa=bc1e-1b90 [https://perma.cc/7MNR-V245] (reporting on cases of investment and substantial financial loss resulting from CNS drug development by pharmaceutical companies).

⁵⁴ See Matthew Herder, *What Is the Purpose of the Orphan Drug Act?*, PLOS MED., Jan. 2017, at 2 (highlighting the economic issues surrounding drug development and ways to reform the Orphan Drug Act).

⁵⁵ See, e.g., BAKAN, *supra* note 19, at 49 (citing the statistics provided by Rachel Cohen).

⁵⁶ See *supra* note 33 and accompanying text (discussing me-too drugs). But see Aidan Hollis, *Me-Too Drugs: Is There a Problem?*, WORLD HEALTH ORG., at 1 (Dec. 13, 2004), www.who.int/intellectual-property/topics/ip/Me-tooDrugs_Hollis1.pdf [https://perma.cc/Y988-TKUW] (reviewing the policy dispute regarding the pros and cons of me-too drugs and distinguishing between follow-on drugs that are clinically superior and/or were developed in parallel to earlier approved drugs and those that are true me-too drugs); Joshua J. Gagne & Niteesh K. Choudhry, *How Many “Me-Too” Drugs Is Too Many?*, 305 JAMA 711, 711 (2011), https://www.ncbi.nlm.nih.gov/pubmed/21325189 [https://perma.cc/P9KQ-UUU3] (discussing possible potential advantages of me-too drugs).

⁵⁷ See Bill Alpert, *Roche’s Revolution*, BARRON’S (Apr. 4, 2005), https://www.barrons.com/articles/SB111239981733195958 [https://perma.cc/8NSP-EWC8] (quoting Bill Burns, the then chief of the pharmaceutical company Roche’s pharmaceutical division, arguing that the industry was trying to turn away from that business model).

⁵⁸ This definition of me-too drugs, for purposes of the present discussion, is consistent with the one proposed by Aidan Hollis. See Hollis, *supra* note 56, at 1 (“I would suggest that a me-too drug is one that is approved after a pioneering drug and which is the ‘same,’ in the sense of the U.S. Orphan Drug Act, and is not clinically superior.”).

⁵⁹ See, e.g., Gagne & Choudhry, *supra* note 56, at 711 (referring to the drug Pitavastatin (Livalo) as a me-too drug, being the eighth statin molecule approved in the United States and mentioning the

would claim to be pursuing a me-too drug, data published by regulatory authorities regarding clinical superiority and scope of testing of approved new drug products makes it possible to estimate the proportion of drugs developed under a me-too business model.⁶⁰ One 2003 estimate suggests that only 20% of the pharmaceutical companies' R&D budget spent on clinical trials goes toward the development of drugs that the Food and Drug Administration (FDA) views as offering "significant improvement" over products already on the market at the time of approval.⁶¹ The remaining 80% of that budget is left for the testing of products that do not offer significant clinical improvement.⁶² Another analysis of new drugs and new indications of older drugs approved between 1996 and 2006 found that most of them—at least 52.8% and, possibly, up to 85.1%—did not represent any significant therapeutic advantage over already-approved drugs.⁶³ Comparable surveys of drugs approved in other countries had similar findings.⁶⁴ Even conservative evaluation of this data indicates that me-too drugs comprise a majority of drugs approved.

As the above examples illustrate, pharmaceutical companies prioritize their R&D efforts in a manner consistent with their mandate to maximize profits, but expected profits are often not commensurate with the prevalence and severity of the underlying health conditions in need of treatments. As a result, choice of R&D projects by pharmaceutical companies often stands in stark, even macabre,⁶⁵ contrast to public healthcare priorities and needs.⁶⁶

classes of ACE inhibitors and SSRIs as other classes of drugs in which me-too products are common); Rosanne Spector, *Me-Too Drugs: Sometimes They're Just the Same Old, Same Old*, STAN. MED. MAG., Summer 2005, <http://sm.stanford.edu/archive/stanmed/2005summer/drugs-metoo.html> [<https://perma.cc/G6XW-GBR4>] (referring to AstraZeneca's drug, Nexium, for the treatment of stomach and esophagus problems, as a me-too version of AstraZeneca's own earlier stomach acid drug, Prilosec).

⁶⁰ See HOLLIS, *supra* note 56, at 5 (discussing how data analytics helps to shed light on research spending regarding me-too drugs).

⁶¹ *Id.*

⁶² *Id.*

⁶³ Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 34, 46 tbl.3 (2011).

⁶⁴ See Derek J. Ward et al., *How Innovative Are New Drugs Launched in the UK? A Retrospective Study of New Drugs Listed in the British National Formulary (BNF) 2001–2012*, 4 BMJ OPEN, Sept. 2014, at 1, <https://bmjopen.bmj.com/content/bmjopen/4/10/e006235.full.pdf> [<https://perma.cc/ERL8-3G67>] (finding that only up to 26% of newly-launched drugs in the U.K. between 2001–2012 were "highly innovative"); *New Drugs and Indications in 2014*, 24 PRESCRIBER INT'L 107, 109 (2015) (finding that out of 1,032 new drugs and indications approved in France in 2005–2014 only fifty-five had a clinical advantage over already-approved drugs and only nine could be considered breakthrough or as offering a real advantage over earlier drugs).

⁶⁵ See, e.g., BAKAN, *supra* note 19, at 49 ("Pfizer and its shareholders make more money from drugs that treat baldness and impotence than they would from drugs to treat diseases, such as malaria and tuberculosis, that are leading causes of death in the developing world.").

⁶⁶ Some commentators argue that this reality is further evident in a dissociation between innovation and profit in the pharmaceutical industry. See, e.g., Gagnon, *supra* note 9, at 573–74 (highlighting

B. Second Example: Non-Disclosure of Clinical Trials Information

In order to bring a new drug to the market, pharmaceutical companies must undertake extensive clinical testing to prove that the drug is safe and effective. These clinical trials yield valuable information about the nature and properties of the drug, its effectiveness or lack thereof, and its side effects. Clinical trials, in which the safety and efficacy of drug products are tested, are time consuming, expensive, and extensive, and they often include hundreds, sometimes thousands, of human subjects. The data collected in these trials, typically spanning many thousands of pages, is selectively provided to regulators solely for the purpose of trying to get the drug approved for sale.⁶⁷ Yet, even though the societal value of this data—especially the data not shared with regulators—far exceeds its utility as a mere means of regulatory evaluation of drug products, the private incentives of companies drive them to limit the disclosure, publication, and use of this data.⁶⁸ Again, the private incentives of companies stand in stark contrast to the public interest in complete and widespread dissemination of all the data collected.

One source of divergence between the private incentives and the public interest as they pertain to the disclosure of clinical data lies in the tension between private interests in providing information that will support drug approval and the public interest in a full understanding of not only the benefits, but also the risks, of the drug. Commentators have explained that:

Systematic reviews of published randomized clinical trials . . . are considered the gold standard source of synthesized evidence for interventions, but their conclusions are vulnerable to distortion when trial sponsors have strong interests that might benefit from suppressing or promoting selected data. More reliable evidence synthesis would result from systematic reviewing of clinical study reports—standardized documents representing the most complete record of

the disconnect between financial incentives for pharmaceutical companies and the health of the public).

⁶⁷ See, e.g., Peter Doshi et al., *The Imperative to Share Clinical Study Reports: Recommendations from the Tamiflu Experience*, 9 PLOS MED., Apr. 2012, at 1–2, <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001201&type=printable> [<https://perma.cc/L8ZY-HKPV>] (highlighting the issue of bias in clinical data provided for drug development and approval by analyzing the case of Tamiflu).

⁶⁸ See Editorial, *Bring Out Your Dead*, 33 NATURE BIOTECHNOLOGY, Jan. 2015, at 1 (calling for disclosure of information regarding failed compounds so as to enable their repurposing); Joshua M. Sharfstein et al., *Blueprint for Transparency at the U.S. Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products*, 45 J.L. MED. & ETHICS (SUPP.) 11–12 (2017) (listing additional constituencies who would be interested in disclosure of additional clinical information).

the planning, execution, and results of clinical trials, which are submitted by industry to government drug regulators.⁶⁹

These commentators have further warned that “[e]vidence-based medicine is valuable to the extent that the evidence base is complete and unbiased. Selective publication of clinical trials—and the outcomes within those trials—can lead to unrealistic estimates of drug effectiveness and alter the apparent risk-benefit ratio.”⁷⁰ For these reasons, scientists, doctors, and policymakers have uniformly been calling for the full disclosure of clinical trials information.⁷¹

As a general rule, however, pharmaceutical companies are not required to share much of this information with each other or with the public.⁷² Thus, despite the recognized value of independent evaluation of clinical trials information, pharmaceutical companies have not been sharing their clinical trials data and reports with third-party researchers.⁷³ Furthermore, pharmaceutical

⁶⁹ See, e.g., Doshi et al., *supra* note 67, at 2 box 1 (illustrating by listing numerous findings and understandings that would not have been available without access to Tamiflu clinical study reports and mentioning other drugs for which previously unpublished clinical trials data “radically changed public knowledge of safety and efficacy,” including Avandia, Neurontin, and Vioxx).

⁷⁰ Erick H. Turner et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 252 (2008).

⁷¹ See, e.g., High-Level Panel on Access to Health Technologies, *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicine*, at 36 (Sept. 2016), <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> [<https://perma.cc/2D85-KJJ2>] (arguing for disclosure of assessments regarding health technologies); WHO *Statement on Public Disclosure of Clinical Trial Results*, WORLD HEALTH ORG., at 1–3 (2015), http://www.who.int/ictrp/results/WHO_Statement_results_reporting_clinical_trials.pdf?ua=1 [<https://perma.cc/Z46J-AXNA>] (suggesting public access to information for clinical trials through a registry); Doshi et al., *supra* note 67, at 5 (calling also for pharmaceutical companies’ sharing of information not submitted to regulators). See generally INST. OF MED. ET AL., *SHARING CLINICAL TRIAL DATA: MAXIMIZING BENEFITS, MINIMIZING RISK* (2015) (arguing for greater access to clinical trial information to increase effective treatments); Harlan M. Krumholz et al., *Data Acquisition, Curation, and Use for a Continuously Learning Health System*, (Nat’l Acad. of Med. Vital Directions for Health and Health Care Series, Discussion Paper, Sept. 19, 2016), <https://nam.edu/wp-content/uploads/2016/09/Data-Acquisition-Curation-and-Use-for-a-Continuously-Learning-Health-System.pdf> [<https://perma.cc/TP6V-SRSL>] (arguing that increased transparency and access to health information would lead to better, and more efficient, patient outcomes).

⁷² See Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 51–57 (2009) (arguing that clinical trial data should be treated as a public good).

⁷³ See, e.g., Doshi et al., *supra* note 67, at 2 (noting there are only three such regulatory researchers); Vasee S. Moorthy et al., *Rationale for WHO’s New Position Calling for Prompt Reporting and Public Disclosure of Interventional Clinical Trial Results*, 12 PLOS MED., Apr. 2015, at 1, <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001819&type=printable> [<https://perma.cc/298P-VK8R>] (reviewing literature on partial disclosure of clinical trial information). Notably, some pharmaceutical companies, namely GlaxoSmithKline and Johnson & Johnson, have taken steps to make some of their clinical trials information available to independent researchers under certain conditions. Sharfstein et al., *supra* note 68, at 18.

companies have been known to provide only some of their clinical trials data to regulatory authorities.⁷⁴ Where pharmaceutical companies publish clinical trials results in scientific literature, they do so highly selectively and are significantly more inclined to publicize trial results favorable to their products while avoiding publishing unfavorable results (and, where publishing, avoiding the characterization as unfavorable results).⁷⁵

Pundits have decried pharmaceutical companies' nondisclosure of clinical trials information, arguing that they "waste resources and the contributions of investigators and study participants, and they hinder the advancement of medical knowledge"⁷⁶ and that making clinical studies information inaccessible to the public is unethical.⁷⁷ Commentators have been especially wary of partial disclosure and mischaracterization of clinical trials information in publications sponsored by pharmaceutical companies as overly complementary, which might "alter[] the apparent risk-benefit ratio of drugs . . . lead[ing] doctors to make inappropriate prescribing decisions that may not be in the best interest of their patients and, thus, the public health."⁷⁸

Pharmaceutical companies have, in turn, responded with the following defenses of their practices, arguing that clinical study reports and results: (1) are confidential commercial information, because they potentially have substantial economic value for generic manufacturers and other competitors;⁷⁹ (2) might deter participation in early-stage clinical trials;⁸⁰ (3) might compromise patient anonymity;⁸¹ (4) are properly and sufficiently reviewed by regulatory

⁷⁴ See, e.g., Doshi et al., *supra* note 67, at 2, 4 (referring to at least fifteen trials for which Roche did not provide regulators with full study reports).

⁷⁵ See Turner et al., *supra* note 70, at 252, 254–56 (finding that "whether the studies were published and, if so, how the results were reported were strongly related to their overall outcomes"); see also *WHO Statement on Public Disclosure of Clinical Trial Results*, *supra* note 71, at 1 ("Multiple analyses have confirmed that a substantial number of clinical trials remain unreported several years after study completion, even in the case of large randomized clinical trials.")

⁷⁶ Turner et al., *supra* note 70, at 259 (stating in the context of selective publication of antidepressants' clinical trial results).

⁷⁷ See Doshi et al., *supra* note 67, at 5 (noting that there are compelling arguments for making clinical data available).

⁷⁸ Turner et al., *supra* note 70, at 259; see Ben Goldacre, *How to Get All Trials Reported: Audit, Better Data, and Individual Accountability*, 12 PLOS MED., Apr. 2015, at 1–2, <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001821&type=printable> [<https://perma.cc/EUF8-Z57K>] (discussing issues with clinical result disclosure).

⁷⁹ See Aaron S. Kesselheim & Michelle M. Mello, *Confidentiality Laws and Secrecy in Medical Research: Improving Public Access to Data on Drug Safety*, 26 HEALTH AFF. 483, 489 (2007) (arguing this rationale has been used over broadly).

⁸⁰ See *id.* (critiquing and debunking this claim).

⁸¹ See Doshi et al., *supra* note 67, at 4 tbl.2 (contesting Roche's claim that patient information would be compromised by suggesting data anonymization).

authorities worldwide;⁸² (5) are being sufficiently reported in the scientific literature;⁸³ and more.⁸⁴ These concerns and responses have been largely addressed and discredited by commentators and regulators alike, but it has had a limited impact on the disclosure practices of pharmaceutical companies.⁸⁵

Dissatisfaction with industry information sharing and disclosure practices has led to a regulatory change in European requirements. In 2014, the European Medicines Agency (“EMA”) announced that it intended to start publishing clinical data, including clinical reports and individual patient data, submitted by pharmaceutical companies under EMA’s Centralised Marketing Authorisation procedure.⁸⁶ EMA currently makes such data available through its website.⁸⁷ In the United States, in contrast, although pharmaceutical companies are required to make public certain information regarding clinical trials,⁸⁸ the FDA and NIH do not currently require disclosure of full clinical datasets or clinical study reports.⁸⁹ Accordingly, a lot of clinical information from studies conducted prior to 2015 in the EU and virtually all clinical data submitted to the

⁸² See *id.* (quoting Roche’s assertion that the information is made available to an extensive list of members of the scientific community).

⁸³ *Id.* at 5 tbl.3.

⁸⁴ Sharfstein et al., *supra* note 68, at 19–20 (describing, explaining, and responding to industry objections).

⁸⁵ As described by one group of commentators: “If drug companies have legitimate reasons for maintaining the status quo of treating all of their data as trade secret, we have yet to hear them. We are all ears.” Doshi et al., *supra* note 67, at 3 tbls.2, 5 (describing and responding to reasons given by the pharmaceutical company Roche for not providing clinical trials data for Tamiflu); see Sharfstein et al., *supra* note 68, at 19–20 (responding to potential objections).

⁸⁶ *European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use*, at 1–3, EMA/240810/2013 (Oct. 2, 2014), https://www.ema.europa.eu/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf [<https://perma.cc/C7QW-RY43>]. Notably, this EMA policy is currently subject to an ongoing legal challenge. See Case C-513/16 P(R), *European Meds. Agency v. PTC Therapeutics Int’l Ltd.*, 2017 EUR-Lex CELEX LEXIS 148 (Mar. 1, 2017) (appellate court order dismissing the EMA’s appeal of the interim injunction); Case T-718/15 R, *PTC Therapeutics Int’l Ltd. v. European Meds. Agency*, 2016 EUR-Lex CELEX LEXIS 326 (July 20, 2016) (interim injunction issued by lower court).

⁸⁷ *Clinical Data*, EUROPEAN MEDS. AGENCY, <https://clinicaldata.ema.europa.eu/web/cdp/home> [<https://perma.cc/HA8T-WQ9R>].

⁸⁸ *FDA’s Role: ClinicalTrials.gov Information*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/fdasroleclinicaltrials.govinformation/default.htm> [<https://perma.cc/Y5WN-QN9P>]. The information is published on the website www.ClinicalTrials.gov. See Gagnon, *supra* note 9, at 574 (“In the U.S. . . . all clinical trials are required to disclose their protocols and results in a national registry in order to reduce the systematic selective reporting of clinical trial results.”).

⁸⁹ 21 C.F.R. § 314.430(c), (e)(2) (2017); see Kesselheim & Mello, *supra* note 79, at 483 (“[E]vidence suggests that such registries remain incomplete.”); Sharfstein et al., *supra* note 68, at 15 (highlighting the need for increased transparency and disclosure regulation). Since 2010, the Food and Drug Administration (FDA) has been reevaluating its own transparency policies. See Sharfstein et al., *supra* note 68, at 12–18 (recommending measures for increasing the transparency of FDA work in general and sharing of clinical information, in particular recommendations 5, 9, 10, 15, 16, and 18).

FDA⁹⁰ remain unpublished and, for the most part, inaccessible to the scientific community and the public. Further, it is estimated that the results of about half of all clinical studies ever carried out have never been reported.⁹¹ The societal cost of this non-disclosure and selective-disclosure of clinical information cannot be overstated.⁹²

The sharing of clinical trials data and publication of trial outcomes thus illustrate a second example of the disconnect between the public interest (in full disclosure) and the private interests of pharmaceutical companies (in limited, selective, commercially-oriented disclosure of such data).

C. Third Example: Drug Pricing

Once pharmaceutical products are approved for marketing, the companies that make them must decide how to price them. In explaining such pricing decisions, pharmaceutical companies have traditionally referred to the high costs and large risks involved in the R&D of pharmaceutical products,⁹³ which, despite being the subject of much controversy,⁹⁴ are widely agreed to be very

⁹⁰ The FDA, has persistently held that clinical data submitted to the agency is proprietary information and, as such, is not subject to disclosure through the Freedom of Information Act (“FOIA”) requests. See Doshi et al., *supra* note 67, at 2 (chronicling the FDA’s response to FOIA requests).

⁹¹ Carolina Riveros et al., *Timing and Completeness of Trial Results Posted at ClinicalTrials.gov and Published in Journals*, 10 PLOS MED., Dec. 2013, at 6, <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001566&type=printable> [<https://perma.cc/R9YS-ZG6Z>] (citing a previous study showing that less than half of all completed trials registered at ClinicalTrials.gov were published).

⁹² See LIVES ON THE EDGE, *supra* note 32, at 19 (“[Non-disclosure of clinical information] leads to adverse patient outcomes with tremendous financial, social and health consequences.”).

⁹³ See Jonathan D. Rockoff, *5 Things to Know About How Drug Prices Are Set*, WALL ST. J. (Dec. 8, 2015), <http://blogs.wsj.com/briefly/2015/12/08/5-things-to-know-about-how-drug-prices-are-set/> [<https://perma.cc/5SVE-6D24>] (depicting Pfizer’s process for price-setting a cancer drug).

⁹⁴ See High-Level Panel on Access to Health Technologies, *supra* note 71, at 35–36 (analyzing the myriad issues resulting from the lack of transparency concerning pharmaceutical drug development); Jerry Avorn, *The \$2.6 Billion Pill—Methodologic and Policy Considerations*, 372 NEW ENG. J. MED. 1877, 1877–79 (2015) (describing the lack of transparency in pharmaceutical companies’ formulas for price setting); Amy Maxmen, *Big Pharma’s Cost-Cutting Challenger*, 536 NATURE 388, 390 (2016) (asserting that the development of a new drug costs between \$110–170 million and challenging the alleged myth that such costs run as high as \$1.4 billion); Ben Hirschler, *GlaxoSmithKline Boss Says New Drugs Can Be Cheaper*, REUTERS (Mar. 14, 2013), <http://www.reuters.com/article/us-glaxosmithkline-prices/glaxosmithkline-boss-says-new-drugs-can-be-cheaper-idUSBRE92D0RM20130314> [<https://perma.cc/C5BX-MBUH>] (noting the uncertainty surrounding a pharmaceutical drug’s price tag); see also Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 426 (2014) (arguing that the figure of over \$1 billion as the average cost of the development of a new drug is a schema which serves to propagate cognitive biases regarding the kind of incentives necessary for the continued development of new drugs). Pharmaceutical companies, however, have been vehemently resistant to disclosure of the costs of their R&D efforts. See Light & Warburton, *supra* note 63, at 35 (discussing the gray formulas by which pharmaceutical companies calculate research and development costs); Ed Silverman, *Angry Over Drug Prices, More*

high.⁹⁵ The need to recoup investment costs and incentivize the continued investment of capital in subsequent R&D projects has been used to justify high drug prices.

The reality of determining drug prices, however, is more nuanced than this return on investment and incentives story would suggest. Although pharmaceutical companies no doubt consider their costs of development in drug pricing, drug price determinations are more often guided by market considerations such as the cost of competing or alternative treatments, the likelihood that physicians would prescribe a certain drug at a certain price-point, and restrictions that health insurers might impose that could limit physicians from prescribing the drug.⁹⁶ Pharmaceutical companies themselves have acknowledged that their drug pricing decisions are the result of a “holistic” assessment, over a longer timeframe, of therapies’ benefits not only to patients but also to payers and health systems in general.⁹⁷ In other words, pricing depends a great deal on what the market will pay.

This should come as no surprise. Indeed, setting drug prices based on the ability of the company to extract profits is exactly what we would expect from traditional corporations with their focus on shareholder value. From a corporate-governance point of view, pharmaceutical companies have been doing commendably well for their shareholders⁹⁸ and should be praised for good economic performance.⁹⁹

States Push Bills for Pharma to Disclose Costs, WALL ST. J. (Apr. 24, 2015), <https://blogs.wsj.com/pharmalot/2015/04/24/angry-over-drug-prices-more-states-push-bills-for-pharma-to-disclose-costs/> [<https://perma.cc/7824-2RVT>] (reporting on drug-makers efforts to halt legislative proposals which would make price-setting for pharmaceutical drugs more transparent).

⁹⁵ Even the lowest estimates of drug development costs speak of many tens or even a few hundreds of millions of dollars per successful development project. See, e.g., Maxmen, *supra* note 94, at 390 (documenting the hundreds of millions of dollars the Drugs for Neglected Disease Initiative, a non-profit, estimates to incur in developing a new drug, even though it has economic advantages that for-profit organizations do not).

⁹⁶ See Rockoff, *supra* note 93 (documenting Pfizer’s considerations when setting a cancer drug’s price). See generally Robert Langreth, *How Gilead Priced Its \$20 Billion Blockbuster*, BLOOMBERG (Dec. 10, 2015), <https://www.bloomberg.com/news/articles/2015-12-10/behind-the-1-000-pill-a-formula-for-profits-inside-gilead> [<https://perma.cc/63Q7-BQ6P>] (describing how Gilead came to price a pharmaceutical drug); Jonathan D. Rockoff, *The Anatomy of a Drug Price: How Pfizer Chose to Set the Cost of Its Breast-Cancer Drug at \$9,850 a Month*, WALL ST. J., Dec. 9, 2015, at A1 (analyzing Pfizer’s process for price-setting a new cancer drug).

⁹⁷ See Bronwyn Mixter, *Greater Transparency on Drug Prices Needed, Lawmakers Told*, BNA NEWS (Mar. 15, 2016), <https://www.bna.com/greater-transparency-drug-n57982068539/> [<https://perma.cc/TN57-7TW8>] (reporting responses by PhRMA and BIO to calls for further transparency on drug pricing).

⁹⁸ According to Aaron Kesselheim and Ameet Sarpatwari, “The top eleven drug manufacturers made \$711 billion from 2003 to 2012, including \$68 billion in 2012 alone, translating to an industry profit margin on par with the banking sector.” Aaron S. Kesselheim & Ameet Sarpatwari, *To Spur Medical Innovation, Make Corporate Cheaters Pay*, HEALTH AFFAIRS BLOG (Apr. 30, 2015), <http://>

Yet, high drug prices have been met with anything but praise in the public arena. Critics of the pharmaceutical industry, of which there are many, have characterized pricing decisions as dictated by “what the market would bear,”¹⁰⁰ as opposed to the more palatable criteria such as the cost of manufacturing¹⁰¹ and the drugs’ therapeutic value.¹⁰² Media reports of high prices charged by pharmaceutical companies for their products¹⁰³ and pharmaceutical price hikes¹⁰⁴ are met with public outcry and angered reactions from pundits and

healthaffairs.org/blog/2015/04/30/to-spur-medical-innovation-make-corporate-cheaters-pay/ [https://perma.cc/F3GB-QU7U].

⁹⁹ This, at least, is the sentiment within the industry, or as aptly put by a pharmaceutical company’s spokesperson: “Our duty is to our shareholders and to maximize the value [of our products]. . . . Sometimes pricing comes into it, sometimes volume comes into it.” Jonathan Rockoff & Ed Silverman, *Pharmaceutical Companies Buy Rivals’ Drugs, Then Jack up the Prices*, WALL ST. J. (Apr. 26, 2015), <http://www.wsj.com/articles/pharmaceutical-companies-buy-rivals-drugs-then-jack-up-the-prices-1430096431> [https://perma.cc/ZD2C-3DFF].

¹⁰⁰ See Editorial, *Costly Hepatitis C Drugs for Everyone?*, N.Y. TIMES (Sept. 2, 2015), <https://www.nytimes.com/2015/09/02/opinion/costly-hepatitis-c-drugs-for-everyone.html> [https://perma.cc/97DC-HQ6X] (reporting on the public need for Hepatitis C medication and the factors regarding its expensive price-tag); see also Alpern et al., *supra* note 15, at 1859–61 (explaining sharp and rapid increases in the prices of off-patent and generic medicines as resulting from low levels of competition in markets for such medicines); Jack Scannell, *Four Reasons Drugs Are Expensive, of Which Two Are False*, FORBES (Oct. 13, 2015), <https://www.forbes.com/sites/matthewherper/2015/10/13/four-reasons-drugs-are-expensive-of-which-two-are-false/#4aa024164c3b> [https://perma.cc/9MK2-VC47] (suggesting that drugs are priced based on numerous factors not associated with actual cost or value); Silverman, *supra* note 94 (quoting an industry-backed research institute saying that “[p]ricing strategies are based on therapeutic value, market size, usage, patent life, competition and other factors”).

¹⁰¹ See Light & Warburton, *supra* note 63, at 34–35 (noting the drug industry’s frequently reiterated rationale for high drug prices, high development costs); see, e.g., *The Pharmafocus Debate: Is the Price of New Hepatitis C Treatments Fair?*, PHARMAFILE (Apr. 27, 2015), <http://www.pharmafile.com/news/396162/pharmafocus-debate-price-new-hepatitis-c-treatments-fair> [https://perma.cc/2QQV-3T8Y] (“The high price [of hepatitis C drug, Sovaldi] is completely unrelated to the cost of manufacture . . .”).

¹⁰² See David H. Howard et al., *Pricing in the Market for Anticancer Drugs*, 29 J. ECON. PERSP. 139, 140, 148–49 (2015) (reviewing literature making the argument that “[t]he launch prices of new anticancer drugs and other drugs in the so-called ‘specialty’ pharmaceutical market have been increasing over time and . . . are unrelated to the magnitude of the expected health benefits,” and calculating the average cancer drug to cost \$65,900 in 2013, for which the average survival benefit was 0.46 years and the price per life-year to be \$207,000, as compared to \$139,100 in 2005 and \$54,100 in 1995).

¹⁰³ See, e.g., Tracy Staton, *Amgen Slaps \$178K Price on Rare New Leukemia Drug Blincyto*, FIERCEPHARMA (Nov. 30, 2015), <http://www.fiercepharma.com/marketing/amgen-slaps-178k-price-on-rare-new-leukemia-drug-blincyto> [https://perma.cc/7PBY-EGYJ] (reporting Amgen’s pricing of their leukemia treatment drug, Blincyto, at \$178,000, Merck & Co.’s skin cancer drug, Keytruda, at about \$150,000/year, and Bristol-Myers Squibb Co.’s skin cancer drug, Yervoy, at \$120,000 per course); Editorial, *Another Drug Pricing Ripoff*, N.Y. TIMES, Aug. 25, 2016, at A18 (criticizing the surge in cost for EpiPen devices, which was fueled seemingly by a thirst for increased profits); Editorial, *Runaway Drug Prices*, N.Y. TIMES, May 5, 2015, at A22 (documenting the fight to harness sky-high drug prices through Congress).

¹⁰⁴ See Llewellyn Hinkes-Jones, *Competition, Generics Not Always Limiting Drug Costs*, BNA NEWS (Sept. 23, 2016), <https://www.bna.com/competition-generics-not-n57982077535/> [https://

politicians alike.¹⁰⁵ These reactions are equally unsurprising given that the high prices of drugs have resulted in diminished access to therapies (often due to insufficient insurance coverage), leading to increased morbidity and mortality among patients as well as increases in both public expenditures on healthcare and in the cost of health insurance.¹⁰⁶

A highly publicized case-in-point is the old, little-known antibiotic drug, Daraprim (pyrimethamine), which is used for the treatment of certain very specific infections,¹⁰⁷ and which has been on the market since 1953.¹⁰⁸ In August 2015, the pharmaceutical company, Turing Pharmaceuticals,¹⁰⁹ bought the

perma.cc/34EX-D5ZC] (reporting price hikes of some old drugs that used to be sold at very low prices, subsequent to consolidations in the markets for these drugs).

¹⁰⁵ See, e.g., Letter from Senator Bernard Sanders and Representative Elijah Cummings to Sylvia Burwell, Sec’y of Health & Human Servs. (Oct. 16, 2014), <https://www.sanders.senate.gov/download/joint-letter-to-hhs?inline=file> [<https://perma.cc/AA6-DUYJ>] [hereinafter Letter from Sanders and Cummings] (calling for the federal government to regulate staggering generic drug costs); see also *Another Drug Pricing Ripoff*, *supra* note 103 (“The rapid increase in the price of the EpiPen . . . has shocked consumers and lawmakers.”); Katherine Greifeld, *Sanders, Cummings Blast Marathon for \$89,000 Price on Old Drug*, BLOOMBERG (Feb. 13, 2017), <https://www.bloomberg.com/news/articles/2017-02-13/sanders-cummings-blast-marathon-for-89-000-price-on-old-drug> [<https://perma.cc/6EQJ-CN3F>] (reporting on Senator Sanders and Representative Cummings’ letter to Marathon’s CEO criticizing the company’s drug prices).

¹⁰⁶ See, e.g., OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING & EVALUATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS 4–5, 12–13 (2016) (reporting that about 9.7% of adults ages 18–64 who participated in government healthcare programs in 2011–2014 did not take drugs as prescribed because of high out-of-pocket costs); Kesselheim et al., *supra* note 5, at 863 (reviewing scientific literature establishing connections between pharmaceutical price increases and increased patient nonadherence); Ayalew Tefferi et al., *In Support of a Patient-Driven Initiative and Petition to Lower the High Price of Cancer Drugs*, 90 MAYO CLINIC PROC. 996, 997 (2015) (tracing the health consequences of unaffordable cancer drugs); *Costly Hepatitis C Drugs for Everyone?*, *supra* note 100 (highlighting the enormous costs associated with new drugs treating Hepatitis C); Kasia Lipska, Opinion, *Break Up the Insulin Racket*, N.Y. TIMES (Feb. 20, 2016), <https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket.html> [<https://perma.cc/8XTG-VMQD>] (describing how rapid increases in the price of insulin products has been lowering their affordability and, consequently, increasing morbidity of diabetes patients); Letter from Sanders and Cummings, *supra* note 105 (describing how increases in drug prices lower patient access to such drugs); Letter from the Nat’l Assoc. of Medicaid Dirs. to Chairmen and Ranking Members of Cong. Comms. (Oct. 28, 2014), http://www.medicaidirectors.org/wp-content/uploads/2015/08/namd_sovaldi_letter_to_congress_10-28-14.pdf [<https://perma.cc/5EF9-9TRZ>] (addressing the significant risks and burdens associated with exorbitantly priced Hepatitis C medication).

¹⁰⁷ *Prescribing Information: DARAPRIM® (pyrimethamine) 25-mg Scored Tablets*, GLAXO SMITHKLINE (2003), http://www.accessdata.fda.gov/drugsatfda_docs/label/2003/08578slr016_daraprim_lbl.pdf [<https://perma.cc/VY3X-J6F3>].

¹⁰⁸ According to the FDA Approved Drug Products database, Daraprim was originally approved for marketing on January 23, 1953. *Drugs@FDA: FDA Approved Drug Products, New Drug Application (NDA): 008578*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&AppNo=008578> [<https://perma.cc/C8GB-R96F>].

¹⁰⁹ Notably, commentators have rejected the characterization of Turing Pharmaceuticals as a pharmaceutical company and argued that it was, essentially, an investment vehicle “masquerading as

rights to Daraprim and became the sole manufacturer of Daraprim at that time.¹¹⁰ Turing used its market power to raise the price of Daraprim from \$13.50 to \$750 per tablet practically overnight, bringing the cost of treatment for some patients to hundreds of thousands of dollars annually.¹¹¹ Although Daraprim is indicated for a relatively narrow range of rather uncommon diseases (at least in the United States), patients who tend to need Daraprim belong to an especially vulnerable group of patients, many of whom are immunocompromised and suffer from other underlying serious medical conditions such as HIV, AIDS, and cancer.¹¹² Daraprim's price hike was met with an unprecedented public uproar, and Turing's CEO was dubbed "the most hated man in America."¹¹³ The company initially attempted to deflect the criticism and justify the price hike on the grounds that it was necessary for Turing to remain in business, that the increased earnings would be used for R&D, that the financial burden for patients and the healthcare system was not as great as was being argued, that the new price of Daraprim was not unusual for a drug for rare diseases, and, finally, that "it [was] business" and that the company was "supposed to make as much money as possible."¹¹⁴ These explanations, acceptable

[a] pharmaceutical company[]." Editorial, *No Justification for High Drug Prices*, N.Y. TIMES, Dec. 20, 2015, at SR10. Setting aside questions of whether R&D activity is indeed a staple of a pharmaceutical company, as observed by the editors of the New York Times, Turing's conduct was not uncharacteristic of other companies generally viewed as part of the "pharmaceutical industry." See, e.g., Cynthia Koons, *Pfizer Raises Prices on 133 Drugs This Year, and It's Not Alone*, BLOOMBERG (Oct. 2, 2015), <https://www.bloomberg.com/news/articles/2015-10-02/pfizer-raised-prices-on-133-drugs-this-year-and-it-s-not-alone> [<https://perma.cc/3UVP-7MM3>] (showing that Turing Pharmaceuticals' price hike, although significant, was not unusual among pharmaceutical companies). Nor was Turing's business model or conduct unique in other ways. See Robert Langreth & Rebecca Spalding, *Shkreli Was Right: Everyone's Hiking Drug Prices*, BLOOMBERG (Feb. 2, 2016), <http://www.bloomberg.com/news/articles/2016-02-02/shkreli-not-alone-in-drug-price-spikes-as-skin-gel-soars-1-860> [<https://perma.cc/J7QV-479J>] (discussing Turing's purchase of Diaprim and subsequent sharp price increase); see also Rockoff & Silverman, *supra* note 99 (documenting a pharmaceutical company's arbitrary price increase of crucial heart medication shortly after purchasing the rights).

¹¹⁰ Andrew Pollack, *Once a Neglected Treatment, Now an Expensive Specialty Drug*, N.Y. TIMES, Sept. 21, 2015, at B1.

¹¹¹ *Id.* Notably, Daraprim's original cost was about \$1 per tablet and rose to \$13.50 per tablet subsequent to increases starting in 2010 with Daraprim's sale by its original owner and manufacturer, GlaxoSmithKline, and ending with the sale to Turing in August 2015. These price increases were accompanied by a marked drop in the prescription of Daraprim. *Id.* at B2.

¹¹² *Id.*

¹¹³ See, e.g., Samantha Allen, *Martin Shkreli Is Big Pharma's Biggest A**hole*, DAILY BEAST (Sept. 21, 2015), <http://www.thedailybeast.com/martin-shkreli-is-big-pharmas-biggest-ahole> [<https://perma.cc/PWP3-L5V6>] (chronicling the nation's response to Martin Shkreli's astronomical price increase of the life-saving drug, Daraprim); see also Joel Gallant, *Get Rich Quick with Old Generic Drugs! The Pyrimethamine Pricing Scandal*, 2 OPEN F. INFECTIOUS DISEASES, Nov. 2015, at 1, 2, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4685150/> [<https://perma.cc/66DY-DHZS>] (condemning Martin Shkreli for his price-hike of Daraprim and attacking his responses to public criticism).

¹¹⁴ Clyde Haberman, *Lives and Profits in the Balance: The High Stakes of Medical Patents*, N.Y. TIMES (Dec. 11, 2016), <https://www.nytimes.com/2016/12/11/us/retro-report-medical-patents-profits>.

as they may have been from a corporate governance standpoint, did not quell the public outrage, and Turing's CEO was subpoenaed to appear before Congress to explain the Daraprim price hike.¹¹⁵ As could be expected, the Daraprim price hike had an immediate negative effect on patient access and public expenditures on prescriptions.¹¹⁶ Turing eventually lowered the price of Daraprim to \$375 per pill, which it held out as a 50% reduction in price, but which doctors have characterized as "criminal" and "an immense financial burden for a drug that should be \$1 a pill."¹¹⁷

The substantial increase in the price of EpiPen provides another well-publicized example of the incongruity between pharmaceutical company decisions about pricing and the public interest in sustainable access. EpiPen, which was approved in the late 1980s,¹¹⁸ is used to rapidly inject epinephrine to treat patients experiencing severe allergic reactions (anaphylaxis).¹¹⁹ In 2007, thirty years after EpiPen's original marketing approval, the pharmaceutical company Mylan—a well-established global pharmaceutical company—acquired the right to make and sell EpiPen, which was then sold to pharmacies for less than \$100 for a two-pen set.¹²⁰ Leveraging its market power in this ubiquitous¹²¹

html [<https://perma.cc/WP88-JGA3>]; see Allen, *supra* note 113 (reporting on Martin Shkreli's defense of the price-hike); Gallant, *supra* note 113, at 2 (criticizing Martin Shkreli's justifications for the price increase).

¹¹⁵ Carolyn Y. Johnson, *Shkreli Silent Before Panel, Far from Quiet on Twitter*, WASH. POST, Feb. 5, 2016, at A14.

¹¹⁶ See Letter from Stephen B. Calderwood, President, Infectious Diseases Soc'y of America, and Adaora Adimora, Chair, HIV Med. Assoc., to Tom Evigan and Kevin Bernier, Turing Pharmaceuticals (Sept. 8, 2015), https://sc.cnbcfm.com/applications/cnbc.com/resources/editorialfiles/2018/02/23/HIVMA.IDSA_Letter.pdf [<https://perma.cc/JJM4-UKD8>] (discussing the negative patient impact the price-hike would have); see also Heather Long, *Here's What Happened to AIDS Drug That Spiked 5,000%*, CNN BUS. (Aug. 25, 2016), <http://money.cnn.com/2016/08/25/news/economy/daraprim-aids-drug-high-price/index.html> [<https://perma.cc/N8DE-UWER>] ("As hospitals try to keep costs down[sic], doctors have been discouraged from using Daraprim . . . They have turned to alternatives that aren't nearly as well tested with unknown side effects."); Meg Tirrell & Dan Mangan, *Clinton Calls Drug Price Hike 'Outrageous,' Vows Plan*, CNBC (Sept. 21, 2015), <http://www.cnn.com/2015/09/21/clinton-calls-drug-price-hike-outrageous-vows-plan.html> [<https://perma.cc/E2B4-DDCW>] (quoting the Infectious Diseases Society of America, which criticized the price increase as unjustifiable and jeopardizing the health of patients in need of the drug).

¹¹⁷ See Long, *supra* note 116 (quoting Dr. Wendy Armstrong, medical professor at Emory University and head of the Infectious Diseases Program at Grady Health System in Atlanta, Georgia).

¹¹⁸ EpiPen was originally approved for marketing on December 22, 1987. See *Drugs@FDA: FDA Approved Drug Products, New Drug Application (NDA): 019430*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&AppNo=019430> [<https://perma.cc/EM9S-G6C9>].

¹¹⁹ See *EPIPEN[®], Full Prescribing Information, Indications and Usage*, MYLAN SPECIALTY, L.P. (2018), <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=7560c201-9246-487c-a13b-6295db04274a&type=display> [<https://perma.cc/7J32-6CPZ>].

¹²⁰ Tara Parker-Pope & Rachel Rabkin Peachman, *A Surge in the Price of EpiPens Is a Worry to Severe Allergy Sufferers*, N.Y. TIMES, Aug. 23, 2016, at B1.

medical product,¹²² Mylan began to rapidly increase the price of EpiPens such that by May 2016, the cost for a two-pen set exceeded \$600, raising Mylan's sales from \$200 million annually to over \$1 billion.¹²³ As a result, the cost of EpiPen for patients without insurance or with high-deductible insurance plans rose to up to \$640 for a two-pen set, and even patients with relatively broad coverage saw significant increases in their copayments.¹²⁴ This was also the case for educational institutions, which are often required to stock EpiPens as part of their first-aid provisions.¹²⁵ Given that EpiPens expire after a year, the price increases put a strain on patients' (and schools') ability to afford what is essentially a lifesaving medicine.¹²⁶ As with Daraprim, the price increases drew the ire of numerous lawmakers, including then-presidential-candidate, Hillary Clinton, who called it the "latest troubling example of a company taking advantage of its consumers."¹²⁷ Congress called upon the CEO of Mylan to provide explanations for the price increase.¹²⁸ Mylan's CEO, Heather Bresch, explained that Mylan had invested heavily in increasing awareness for EpiPen, that it was working on extending the product's shelf life (so it would not have to be replaced annually), that Mylan's profits were actually just \$50 per pen out of the \$600 or so per set, and that she "wish[ed] [Mylan] had better anticipated the . . . financial issues for a growing minority of patients who may have ended up paying the full . . . price or more."¹²⁹ She further announced several initiatives that were meant to make EpiPen more affordable, including launch-

¹²¹ *Id.*; see also Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen into a Billion-Dollar Business*, BLOOMBERG (Sept. 23, 2015), <https://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business> [<https://perma.cc/KV4Q-Q4FQ>] (documenting EpiPen's revitalization and growth as a result of marketing).

¹²² According to the Drugs@FDA database, NDA 019430 does not have any therapeutic equivalents. *EPIPEN*[®], *Full Prescribing Information, Indications and Usage*, *supra* note 119.

¹²³ Koons & Langreth, *supra* note 121.

¹²⁴ Parker-Pope & Rabkin Peachman, *supra* note 120, at B1.

¹²⁵ *Id.* at B4.

¹²⁶ See *id.* (highlighting a mother's struggle in being able to afford to supply her child with an EpiPen).

¹²⁷ Anna Edney, *Clinton's Attacks on Drug Prices Leave Health Stocks Reeling*, BLOOMBERG (Aug. 26, 2016), <https://www.bloomberg.com/news/articles/2016-08-24/clinton-s-attacks-on-drug-pricing-leave-health-stocks-reeling> [<https://perma.cc/7S3G-R3NL>]; see *Another Drug Pricing Ripoff*, *supra* note 103, at A18 (reporting on members of Congress who called for an investigation into Mylan); Hillary Clinton (@HillaryClinton), TWITTER (Sept. 2, 2016), <https://twitter.com/hillaryclinton/status/771775910278291456> [<https://perma.cc/N8QU-JF2R>] (criticizing Mylan for the price-hike and proposing a plan to stop such activities in the future).

¹²⁸ Heather Bresch, Chief Exec. Off., Mylan, Testimony Before the U.S. House of Representatives Committee on Oversight and Government Reform (Sept. 21, 2016), <https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-21-Mylan-CEO-Bresch-Testimony.pdf> [<https://perma.cc/YKT2-5LAF>].

¹²⁹ *Id.*

ing an “authorized generic” version of EpiPen that would cost \$300, about 50% less than the \$600 price tag.¹³⁰

These examples illustrate the tensions between a corporate mandate to maximize profits—in this case by raising prices—and public healthcare needs. Negotiation power imbalances, a staple of pharmaceutical markets,¹³¹ dictate that the scales are almost always tilted in favor of the pharmaceutical industry’s interests in critical decisions throughout the drug discovery, development, and marketing lifecycle, with the interests of healthcare consumers in lowering morbidity and mortality coming in second.¹³²

D. Fourth Example: Delay of Entry of Competition into Product Markets

Upon their approval and entry into the market, new pharmaceutical products typically benefit from one or more forms of protection from competition, including market, data, and other exclusivities available (often uniquely) to drug products.¹³³ These exclusivity provisions are designed to allow pharma-

¹³⁰ *Id.* Notably, the announcement of these plans was met with much skepticism and critique and did not entirely quell the ongoing public outcry. See, e.g., James Paton & Naomi Kresge, *Why the \$600 EpiPen Costs \$69 in Britain*, BLOOMBERG (Sept. 29, 2016), <https://www.bloomberg.com/news/articles/2016-09-29/epipen-s-69-cost-in-britain-shows-other-extreme-of-drug-pricing-itnvgvam> [<https://perma.cc/J83U-Y9NY>] (reporting on unrest regarding the price hikes of EpiPen in the United States and its hefty price tag); Lydia Ramsey, *Here’s What to Expect When the CEO of EpiPen-Maker Mylan Testifies Before Congress*, BUS. INSIDER (Sept. 21, 2016), <http://www.businessinsider.com/mylan-ceo-heather-bresch-hearing-on-epipen-2016-9> [<https://perma.cc/VBH2-CPGB>] (reporting on prospective pressing questions for Mylan’s CEO by members of Congress and her likely response to them).

¹³¹ Negotiation power imbalances in pharmaceutical markets are typically the result of the accumulation of market power by pharmaceutical companies. This, in turn, is a result of a variety of factors, primary among which are (1) robust government exclusivity regimes (such as patents and a variety of other exclusivities), (2) high market entry barriers (mostly in the form of FDA regulations), and (3) other government-imposed limitations on negotiation powers (for example, by disallowing Medicare to negotiate the price of pharmaceuticals). See, e.g., Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 330–52 (2015) (discussing the numerous exclusivities available in pharmaceutical products); Chuck Shih et al., *How Would Government Negotiation of Medicare Part D Drug Prices Work?*, HEALTH AFF. BLOG (Feb. 1, 2016), <http://healthaffairs.org/blog/2016/02/01/how-would-government-negotiation-of-medicare-part-d-drug-prices-work/> [<https://perma.cc/79LZ-F2JX>] (dissecting the scenarios and likely outcomes from hypothetical government negotiations regarding Medicare Part D drug prices).

¹³² See Michael E. Miller, *‘Pharma Bro’ Martin Shkreli and the Very American Debate Over Maximizing Profit*, WASH. POST (Sept. 23, 2015), https://www.washingtonpost.com/news/morning-mix/wp/2015/09/23/pharma-bro-martin-shkreli-and-the-very-american-debate-over-maximizing-profit/?utm_term=.f306413d07c1 [<https://perma.cc/7V6Y-KCPR>] (“[W]hen companies are in the position to ask the highest possible price, and there is no opposition or measures against it, that’s what they’ll do. We’ve seen that with HIV, we’ve seen it with Hepatitis C, and we see it now with [Dara-prim],” quoting Ellen ‘tHoen).

¹³³ See, e.g., 21 U.S.C. § 355(c)(3)(E)(ii) (2018) (creating five-year new chemical entity exclusivity); 21 U.S.C. § 360cc(a)(2) (2018) (providing for seven-year orphan drug exclusivity); 35 U.S.C.

ceutical companies to recoup their R&D costs and earn sufficient profits to incentivize further investment in future R&D projects. The provisions are often highly successful in achieving these goals, enabling a highly profitable pharmaceutical industry and spurring the emergence and development of whole new sectors within that industry dedicated to orphan products, biologics, generic products, and others.¹³⁴

Over the years, however, these exclusivity regimes and certain procedures of the regulatory agencies administering them have facilitated a range of pharmaceutical company practices often referred to as “product life cycle management” by the industry and “evergreening” by its critics.¹³⁵ Despite significant controversy surrounding the purpose and legitimacy of these practices, there is little dispute that they delay and sometimes even prevent competition in drug markets.¹³⁶ These competition-limiting practices result in the imposition or prolongation of limits on patient access to pharmaceutical products, while at the same time serve to increase the revenue of pharmaceutical companies. The legal and economic literature is replete with accounts of such competition-limiting practices. Notable examples include reverse-payment settlement (“pay-for-delay”) agreements,¹³⁷ product-hopping,¹³⁸ abuse of the FDA’s Citi-

§ 156 (2015) (covering patents and creating a unique term extension available to pharmaceutical products); 42 U.S.C. § 262 (2017) (providing twelve-year exclusivity for newly approved biologics).

¹³⁴ See, e.g., Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation*, 18 INT’L J. ECON. BUS. 177, 198 (2011) (documenting over two decades of trends in market exclusivity following the passage of the Hatch-Waxman Act, which was aimed at balancing incentives for drug development while lowering costs); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1993 (2007) (documenting the success of the Hatch-Waxman Amendments in generating an expansive generic drug market); Frank R. Lichtenberg & Joel Waldfoegel, *Does Misery Love Company? Evidence from Pharmaceutical Markets Before and After the Orphan Drug Act*, 15 MICH. TELECOMM. & TECH. L. REV. 335, 348 (2009) (analyzing the market outcomes and impact on patients from the Orphan Drug Act); *Developing Products for Rare Diseases & Conditions*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/forindustry/developingproductsforrareconditions/default.htm> [<https://perma.cc/4QZX-4XA7>] (chronicling the success of the Orphan Drug Designation Program in catalyzing the development of the orphan drug industry).

¹³⁵ See Heled, *supra* note 131, at 341 n.177 (“Evergreening . . . is a term typically referring to a variety of practices of brand-name pharmaceutical manufacturers aimed at extending exclusivity periods for their products to maintain their revenue streams.”).

¹³⁶ See generally Yaniv Heled, *Follow-On Biologics Are Set up to Fail*, 2018 ILL. L. REV. 113 (noting wide-ranging efforts on behalf of the brand-name pharmaceutical companies to halt the development of follow on biologic medicines); Gregory H. Jones et al., *Strategies That Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD 11 (2016), <http://www.bloodjournal.org/content/bloodjournal/127/11/1398.full.pdf> [<https://perma.cc/Q6QV-QSZ5>].

¹³⁷ Under reverse-payment settlement agreements, branded pharmaceutical manufacturers pay generic drug companies to delay entry of a generic drug into the market. See Jeannie Baumann, *Bill Takes Aim at Branded Rx Companies’ Efforts to Stall Generics*, BNA NEWS (June 16, 2016), <https://www.bna.com/bill-takes-aim-n57982074280/> [<https://perma.cc/J635-AF4N>] (discussing the Creating

zens Petition procedure,¹³⁹ and refusal to sell drug samples to generic companies for bioequivalence studies.¹⁴⁰

The merits and legitimacy of specific instances of competition-limiting practices may be subject to debate, but, their ubiquity and effect on access¹⁴¹ make competition-limiting practices yet another example of industry practices that are at odds with public health needs.

E. Application Beyond Pharma: The Pervasive Disconnect Between Shareholder Value and Public Health Value

Pharmaceutical companies are increasingly portrayed as “heartless” and cynical, even evil. Indeed, it was telling that the conduct of pharmaceutical

and Restoring Equal Access to Equivalent Samples (“CREATES”) Act (S. 3056), which sought to tackle such conduct by branded drug-makers); Bronwyn Mixter, *No Dearth of Legislation on Tackling High Drug Costs*, BNA NEWS (Feb. 6, 2017), [https://www.bna.com/no-dearth-legislation-n57982083458/\[https://perma.cc/SDU9-A9J9\]](https://www.bna.com/no-dearth-legislation-n57982083458/[https://perma.cc/SDU9-A9J9]) (discussing the Preserve Access to Affordable Generics Act (S. 124)).

¹³⁸ Product hopping occurs when a drug manufacturer seeks to shift patients from a drug that is nearing expiration of its exclusivity term to a successor drug with more exclusivity remaining whereas the successor drug typically includes minor non-therapeutic changes to the original, earlier drug, such as in dosage or dosage form. Upon approval of its successor drug for use by the relevant patient population, the manufacturer then removes the original product from the market before generic rivals can enter the market for the original drug. CHIEMI SUZUKI ET AL., BLOOMBERG PHARM. L. & INDUS. REP., THE LONG AND WINDING ROAD FOR BIOSIMILARS: CHARTING A PATHWAY THROUGH PATENT, FDA, ANTI-TRUST, PRESCRIPTION FILLING, REIMBURSEMENT AND LIABILITY LAW 10 (2015); see e.g., Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421, 438 (3d Cir. 2016) (affirming the district court’s finding of “product hopping,” but holding that it did not rise to the level of anticompetitive behavior under Section 2 of the Sherman Act); Vincent C. Capati & Aaron S. Kesselheim, *Drug Product Life-Cycle Management as Anticompetitive Behavior: The Case of Memantine*, 22 J. MANAGED CARE & SPECIALTY PHARMACY 339, 339 (2016) (describing the process of a “product hop”); Dmitry Karshedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, IOWA L. REV. (forthcoming 2019) (proposing a novel way of addressing product hopping and related problems).

¹³⁹ See Matthew Avery et al., *The Antitrust Implications of Filing “Sham” Citizen Petitions with the FDA*, 65 HASTINGS L.J. 113, 118 (2013) (analyzing how the citizen petition process is utilized by pharmaceutical drug manufacturers to stall generic competitors); Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 307–08 (2016) (finding that citizen petitions, in some circumstances, raise serious anticompetitive issues).

¹⁴⁰ Some branded manufacturers have been accused of abusing certain distribution restrictions placed on their products by refusing to provide samples of such products to generic manufacturers for bioequivalence testing, thereby impeding generic manufacturers’ ability to establish equivalence of their generic versions of such drug products. Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential Generic Competitors*, 67 FLA. L. REV. 977, 985 (2015); Press Release, Fed. Trade Comm’n, FTC Amicus Brief: Improper Use of Restricted Drug Distribution Programs May Impede Generic Competition (June 19, 2014), <https://www.ftc.gov/news-events/press-releases/2014/06/ftc-amicus-brief-improper-use-restricted-drug-distribution> [<https://perma.cc/4FF6-PKK9>].

¹⁴¹ As mentioned above, by definition, competition-limiting practices inevitably lead to decreased patient access to pharmaceutical products (and therefore increased patient morbidity and/or mortality) and increases in pharmaceutical companies’ revenues.

companies was one of the only issues on which both candidates in the recent 2016 presidential election agreed.¹⁴² Pharmaceutical companies are, however, reaching their decisions based on their goal of maximizing shareholder value, a goal that is supported by U.S. corporate law along with well-established norms of corporate behavior. Their executives, moreover, are routinely rewarded for reaching profit goals even at the expense of public health.

Although we use the pharmaceutical industry as an illustration of just how pervasive and costly the market disconnect can be for public health, even very different types of markets, such as markets for health services, nursing homes, and markets for medical devices, share common characteristics (as further discussed in Part II) that allow for the divergence of private profit-driven decisions and public health needs.

Recent studies focus on the role of sky-high prices for everything from prescriptions to physicians' services as an explanation for why the United States spends twice as much on healthcare with worse results.¹⁴³ Private companies focused on profit have little interest in reducing the price they charge and also little interest in reducing the prices they pay where the cost can be shifted to consumers or taxpayers and competition is limited. Private health insurers, for instance, earn record profits by shifting to high-cost deductible plans and limiting their coverage of those patients requiring the most healthcare. The high cost of health insurance recently drove Amazon, Berkshire Hathaway, and JP Morgan to try their own experiment at providing healthcare for their employees with a company that will be "free from profit-making incentives and constraints."¹⁴⁴ The increasing shift of formerly not-for-profit companies in certain markets, such as the market for health insurance, to become for-profit corporations, and the active role of private investment in hospitals and physician ser-

¹⁴² Then President-elect Donald Trump said that pharmaceutical companies are "getting away with murder" and Democratic presidential candidate Hillary Clinton said, "It's wrong when drug companies put profits ahead of patients." Sy Mukherjee, *Biotech Stocks Plunge After Trump Says Pharma Is 'Getting Away With Murder' on Drug Prices*, FORTUNE (Jan. 11, 2017), <http://fortune.com/2017/01/11/trump-drug-prices-biotech-stocks/> [<https://perma.cc/V7QA-W73Q>]; see Nick Fletcher, *Pharmaceutical Shares Fall on Clinton Comments on Excessive Drug Prices*, THE GUARDIAN (Aug. 25, 2016), <https://www.theguardian.com/business/marketforceslive/2016/aug/25/pharmaceutical-shares-fall-on-clinton-comments-on-excessive-drug-prices> [<https://perma.cc/6726-DBW9>].

¹⁴³ See Jay Hancock & Shefali Luthra, *High Deductibles Are Forcing Employees to Pay More Out of Pocket*, TIME (Sept. 15, 2016), <http://time.com/money/4494938/high-deductible-health-plans-employee-costs/> [<https://perma.cc/UUC3-XJKW>] (reporting on rising deductibles for employees' health insurance). See generally Papanicolas et al., *supra* note 30 (summarizing excessive U.S. spending on healthcare and its mediocre health outcomes).

¹⁴⁴ Richard Master, *Amazon's Health Care Experiment Shows Exactly Why We Need Medicare for All*, USA TODAY (Feb. 7, 2018), <https://www.usatoday.com/story/opinion/2018/02/07/amazon-health-care-experiment-shows-why-we-need-medicare-all-richard-master-column/309251002/> [<https://perma.cc/A2DB-T7ES>] (arguing that the profit focus of insurance companies leads to higher premiums and large out of pocket expenses and expenditures on sales, marketing, and administrative overhead).

vices, suggest that the profit incentive and the potential for disconnect are only growing.

The corporate practices discussed above highlight the disconnect that arises when healthcare decisions are made by private companies focused on profit maximization. Expecting for-profit healthcare companies to voluntarily put the interests of patients before those of their own shareholders is, in effect, expecting them to act in ways that are both inconsistent with well-established norms of corporate behavior and possibly even risky in light of legal duties and the possibility of corporate takeover. In Part II, we examine the market conditions that allow for this disconnect.

II. WHY TRADITIONAL CORPORATIONS ARE ILL-SUITED FOR HEALTHCARE MARKETS

Healthcare markets are different from other markets as a practical matter and they should be treated differently as a policy matter. The distinctive characteristics of these markets, as described below, produce sub-optimal social welfare outcomes when products and services are developed and sold by private entities, such as corporations, that focus primarily on profit-maximization.¹⁴⁵

In this Part, we focus on three characteristics that distinguish healthcare markets in ways that make traditional profit-focused models of healthcare production problematic. We explain how these characteristics allow for a divergence of private incentives and public health needs when traditional corporations are left to produce and price healthcare products and services.

A. Healthcare Market Failures

Producers in a market-based system make production and pricing decisions in response to (1) consumer demand and willingness to pay; (2) their own costs of production; and (3) competition from other producers. In a simple neoclassical world, the outcome is an efficient one.¹⁴⁶ Private companies compete with each other in the price and quality of their goods and services in efforts to maximize profits. Profit reflects both supply costs and consumer demand, and competition pushes prices down until supra-normal profits are eliminated and goods are provided at prices that equate the cost of production and value of consumption for the marginal unit produced. Although the neoclassi-

¹⁴⁵ See, e.g., Karshedt, *supra* note 138 (finding that numerous factors lead to the practice of product hopping by pharmaceutical companies).

¹⁴⁶ See Richard A. Epstein, *The Neoclassical Economics of Consumer Contracts*, 92 MINN. L. REV. 803, 804 (2008) (referring to “the neoclassical conclusion that competitive markets . . . will generate a mix of goods and services that is superior to those that can be generated with various forms of government regulation”).

cal assumptions required for perfectly competitive markets are rarely, if ever, satisfied, operating via the market continues to be viewed as an efficient means of meeting consumer needs under most circumstances in developed market economies such as the United States.¹⁴⁷ Arguments for government intervention into the operation of the market are limited primarily to redistributive concerns or situations of clear market failure, such as the underproduction of public goods, natural monopolies, or the presence of externalities.¹⁴⁸

Few commentators would disagree that healthcare markets are not perfectly competitive, and many would agree that the government has some role to play in the healthcare market. Yet, there remains much disagreement over the magnitude, nature, and sources of the failure(s) of healthcare markets as well as over what the appropriate policy responses should be.¹⁴⁹ We focus here on the market conditions that make relying on profit-focused companies to produce healthcare products and services to meet public health needs problematic.

Corporations in healthcare markets, like corporations in other markets, make their decisions based primarily on maximizing shareholder value, which involves maximizing revenue streams from their portfolio of products and services over time. The time frame over which to optimize shareholder value is determined in part by investors for private companies and the stock market for public companies. In the case of public companies, managing a company's stock price becomes an additional important driver of corporate decision-making, with executive compensation structures often exacerbating existing incentives to focus on stock price.¹⁵⁰ The profits that corporations earn will

¹⁴⁷ See, e.g., JAMES D. COX & THOMAS LEE HAZEN, TREATISE ON THE LAW OF CORPORATIONS § 1:1 (3d ed. 2016) (“Much of the industrial and commercial development of the nineteenth and twentieth centuries was made possible by the corporate mechanism.”); David McBride, *General Corporation Laws: History and Economics*, L. & CONTEMP. PROBS., Winter 2011, at 5 (“[N]o one could reasonably question the success of the corporate form in promoting growth and economic innovation.”).

¹⁴⁸ See generally James M. Poterba, *Government Intervention in the Markets for Education and Healthcare: How and Why?*, in INDIVIDUAL AND SOCIAL RESPONSIBILITY: CHILD CARE, EDUCATION, MEDICAL CARE, AND LONG-TERM CARE IN AMERICA 277 (Victor R. Fuchs ed., 1996) (diagnosing the characteristics and differences in the government's involvement in education and healthcare).

¹⁴⁹ See generally Martin Gaynor & Robert J. Town, *Competition in Health Care Markets*, in 2 HANDBOOK OF HEALTH ECONOMICS 499 (Mark V. Pauly et al. eds., 2012) (analyzing the healthcare market structure and empirical evidence of healthcare outcomes); Uwe E. Reinhardt, *Is Health Care Special?*, N.Y. TIMES: ECONOMIX (Aug. 6, 2010), https://economix.blogs.nytimes.com/2010/08/06/is-health-care-special/?_r=0 [<https://perma.cc/Q777-HHH3>] (discussing whether neo-classical theories of economics apply equally to the healthcare industry).

¹⁵⁰ Many of the ways in which corporate executives and directors in the United States are compensated, including the use of stock options and bonuses, are tied to corporate performance indicators such as stock price, which intensifies the corporate focus shareholder value. See, e.g., Dan Cable & Freek Vermeulen, *Stop Paying Executives for Performance*, HARV. BUS. REV. (Feb. 23, 2016),

reflect their costs, the volume of products or services that they can sell, and the prices they can charge for their products and services, both during periods of market exclusivity and beyond. In an efficient market, consumers have sufficient information about the comparative benefits that a product or service will afford them. They can value those benefits and have the ability to choose from a range of competing alternatives that they can also value and compare. Furthermore, they know what the price is, and they elect to purchase the good or service when the value it provides to them exceeds the cost. Competition among producers acts to reduce prices that diverge too much from underlying costs of production. In healthcare markets, however, most of these conditions are absent, allowing for markets where profits have been maximized at the expense of, rather than in pursuit of, public health value.

We argue that this divergence of private and public value is due to three distinctive characteristics of healthcare markets that together lead to market failure when traditional corporations are left to select and produce healthcare products and services.¹⁵¹ These distinct characteristics are: (1) the failure of price to serve as a good indicator of public health value; (2) the public sharing of costs but not benefits; and (3) regulations and market structure that limit competition. Even though there may be other markets that have one or more of these characteristics, their combination and magnitude in healthcare markets creates and perpetuates a divergence of private sector incentives and public health needs. In the discussion below, we suggest that these three characteristics of healthcare markets limit the responsiveness of companies to the health needs of individuals as well as public health and allow profit-driven decisions to distort product choice and pricing.

1. Failure of Price to Reflect Public Health Value

Although public health value lacks a single accepted definition and encompasses variables that are hard to quantify, most measures of public health value include two basic components: some measure of comparative therapeutic

<https://hbr.org/2016/02/stop-paying-executives-for-performance> [<https://perma.cc/WV5A-BQVM>] (documenting the adverse outcomes from incentivized executive and director compensation models); David F. Larcker & Brian Tayan, *CEO Pay at Valeant: Does Extreme Compensation Create Extreme Risk?*, STAN. CLOSER LOOK SERIES (Apr. 2016), <https://www.gsb.stanford.edu/sites/gsb/files/publication-pdf/cgri-closer-look-56-ceo-pay-valeant-extreme-pay-risk.pdf> [<https://perma.cc/VSR2-JPGN>] (discussing negative outcomes from performance-based compensation of executives based on increased stock prices).

¹⁵¹ Tax-exempt nonprofit organizations often are assumed to be the natural alternative to traditional for-profit organizations, particularly in markets that are underserved by private enterprises. In Part III, *infra*, we identify the limitations of tax-exempt nonprofit organizations—primarily, the lack of available investment capital—to explain why such organizations are not the solution to the problems created by for-profit organizations in healthcare markets.

benefit and some measure of cost effectiveness in meeting public health needs, which together indicate the quality of health outcomes per dollar.¹⁵² Although the debate over how best to measure public health value continues, there is little disagreement (at least among those not benefiting from the high prices) that whatever the measure of public health value, such value is not what is driving healthcare pricing. Healthcare pricing has received increased scrutiny from both the government and the public, especially in the wake of massive price increases for essential drugs, escalating prices for a range of healthcare services, and rising premiums for health insurance.¹⁵³ Here we identify four interrelated factors contributing to the gulf between price and public health value.

a. Lack of Pricing Transparency

The first factor is the lack of transparency in healthcare pricing, including a lack of clear and accessible information both about what the price of a product or service actually is and about what the quality and therapeutic value of that product or service is as compared to alternatives.¹⁵⁴ The complexity and fragmentation of healthcare pricing and provision often leaves consumers with little or no information about the true price of the healthcare products and services they receive or the cost of alternatives. In many cases, consumers receive little or no upfront information about what they will end up paying later. In addition, public and private payors alike lack effective mechanisms for assessing the cost-effectiveness and therapeutic results of healthcare treatments

¹⁵² See Peter J. Neumann et al., *Measuring the Value of Public Health Systems: The Disconnect Between Health Economists and Public Health Practitioners*, 98 AM. J. PUB. HEALTH 2173, 2176–77 (2008) (defining and quantifying the public health benefit from government-led public health systems).

¹⁵³ See, e.g., Hagop Kantarjian & Vivian Ho, *The Harm of High Drug Prices*, U.S. NEWS (Dec. 12, 2016), <https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-high-drug-prices-to-americans-a-continuing-saga> [<https://perma.cc/7G68-76U9>] (reporting on astronomical price increases to vital cancer drugs); Sydney Lupkin, *5 Reasons Prescription Drug Prices Are So High in the U.S.*, TIME (Aug. 23, 2016), <http://time.com/money/4462919/prescription-drug-prices-too-high/> [<https://perma.cc/ZR5Y-MGUA>] (documenting five key findings from a Journal of the American Medical Association study analyzing the factors for rising drug prices in the United States).

¹⁵⁴ See Leah Binder, *Why Health-Care Price Transparency Isn't Enough for Consumers*, WALL ST. J. (Mar. 26, 2015), <http://blogs.wsj.com/experts/2015/03/26/why-health-care-price-transparency-isnt-enough-for-consumers/> [<https://perma.cc/3NWZ-HRPG>] (discussing why Americans want greater insight into healthcare costs and why transparency does not mean greater outcomes); see also Robert Pearl, *America's Broken Health Care System: The Role of Drug, Device Manufacturers*, FORBES (Apr. 24, 2014), <https://www.forbes.com/sites/robertpearl/2014/04/24/americas-broken-health-care-system-the-role-of-drug-device-manufacturers/> [<https://perma.cc/F9VU-WG82>] (describing how patients tend to opt for expensive new therapies despite the absence of proven clinical benefits over traditional alternatives, for example in the case of prostate surgery).

as well as mechanisms for tying such cost-benefit assessments to price.¹⁵⁵ Increasing efforts are being made by some healthcare payors to insert some measure of healthcare value into pricing, including recent moves to transition from fee-for-service to value-based reimbursement and to use reference pricing to cap payments for standardized products and services.¹⁵⁶ Yet, the pricing of healthcare products and services remains highly non-transparent. Healthcare consumers must make decisions about their healthcare without a clear idea (sometimes without any idea) of the cost of their proposed treatment or the availability and cost of alternative treatments.¹⁵⁷ In some cases, consumers are also uncertain of the expected health value of the product or service.¹⁵⁸ Producers and intermediaries can take advantage of price and product information opacity to keep their prices high even in situations where the health value to consumers is low.

b. Disconnect Between Purchasing Power and Consumer Value

A second and closely related factor lies in the disconnect among (1) the person or entity making many of the healthcare purchasing decisions; (2) the

¹⁵⁵ See Ifrad Islam, *Rising Cost of Drugs: Where Do We Go from Here?*, HEALTH AFF. (Aug. 31, 2015), <https://www.healthaffairs.org/doi/10.1377/hblog20150831.050265/full/> [<https://perma.cc/M974-ZQDS>] (recommending three measures for improving drug pricing: participative pricing, joint accountability for outcomes, and increased regulation of generics); see also Press Release, World Health Org., New WHO Report Shows That Transparency and Cooperation Help to Reduce High Prices for New Medicines (Mar. 26, 2015), <http://www.euro.who.int/en/media-centre/sections/press-releases/2015/03/new-who-report-shows-that-transparency-and-cooperation-help-to-reduce-high-prices-for-new-medicines> [<https://perma.cc/8MZF-WWZF>] (emphasizing need for and importance of mechanisms for ensuring that prices for new drugs reflect therapeutic results).

¹⁵⁶ See Ann Boynton & James C. Robinson, *Appropriate Use of Reference Pricing Can Increase Value*, HEALTH AFF. (July 7, 2015), <http://healthaffairs.org/blog/2015/07/07/appropriate-use-of-reference-pricing-can-increase-value/> [<https://perma.cc/3JJW-GD8G>] (reporting on reference pricing and consumer access to healthcare); Bruce Merlin Fried & Jeremy David Sherer, *Value-Based Reimbursement: The Rock Thrown into the Health Care Pond*, HEALTH AFF. (July 8, 2016), <http://healthaffairs.org/blog/2016/07/08/value-based-reimbursement-the-rock-thrown-into-the-health-care-pond/> [<https://perma.cc/PM39-WUBE>] (analyzing the benefits to healthcare costs based on value instead of the traditional fee for service structure which leads to excessive and unnecessary spending).

¹⁵⁷ See, e.g., Martha Hostetter & Sarah Klein, *Health Care Price Transparency: Can It Promote High Value Care?*, COMM. FUND, <https://www.commonwealthfund.org/publications/newsletter-article/health-care-price-transparency-can-it-promote-high-value-care> [<https://perma.cc/27TC-XGYJ>] (“It’s no secret that the U.S. health care market is unlike any other market: patients rarely know what they’ll pay for services until they’ve received them; health care providers bill different payers different prices for the same services; and privately insured patients pay more to subsidize the shortfalls left by uninsured patients.”).

¹⁵⁸ See, e.g., D. ANDREW AUSTIN & JANE G. GRAVELLE, CRS REPORT FOR CONGRESS: DOES PRICE TRANSPARENCY IMPROVE MARKET EFFICIENCY? IMPLICATIONS OF EMPIRICAL EVIDENCE IN OTHER MARKETS FOR THE HEALTH SECTOR (2008) (reporting on the complexity of pricing in healthcare, including limitations on patient information).

person or entity paying for those decisions; and (3) the end user.¹⁵⁹ Whereas prices bear a clear relationship to consumer value and purchasing power in competitive markets, “the forces of competition do not work well in [healthcare markets] where the consumer who pays does not choose and the physician who chooses does not pay.”¹⁶⁰ Further, in many cases, given the role of private insurance and government provided benefits, the consumer is also unlikely to be the one paying directly for healthcare, which distances consumer value and purchasing power even more.¹⁶¹ There are a number of intermediaries involved in the process of providing healthcare products and services, and these intermediaries often determine what products and services are available, when they should be provided, at what price, and to whom. These intermediaries make these determinations through a highly opaque process that leaves the consumer with little or no information about relative costs and value apart from advice received from physicians who are neither consumers nor payors. The intermediaries are compensated in ways that are not directly tied to the health benefits of their decisions, but rather are dependent on price arbitrage and profit-sharing relationships among industry stakeholders, further widening the gap between consumer health value and purchasing decisions.

Take for example the prescription and provision of pharmaceutical products. Physicians, who are responsible for selecting and prescribing drugs to their patients, are not compensated for time spent learning about costs or helping patients manage costs, nor are they rewarded for finding cheaper ways of

¹⁵⁹ See, e.g., Stuart Guterman, *Making Markets Work in Health Care: What Does That Mean?*, HEALTH AFF. (June 3, 2014), <http://healthaffairs.org/blog/2014/06/03/making-markets-work-in-health-care-what-does-that-mean/> [<https://perma.cc/A8W2-KLMS>] (noting, for example, that only 11.7 % of national health expenditures were paid directly by consumers in 2012); see also *Abbott Labs. v. Andrx Pharms., Inc.*, No. 05 C 1490, 2005 WL 1323435, at *15 (N.D. Ill. June 3, 2005), *vacated*, 452 F.3d 1331 (Fed. Cir. 2006) (discussing how benefits organizations create drug formularies to provide which drugs are covered under the plan, and further discussing how some organizations, including Medicaid, will not cover any cost if the drug is not a “preferred drug” found on the “formulary”); Gordon D. Schiff et al., *A Prescription for Improving Drug Formulary Decision Making*, PLOS MED., May 2012, at 1, <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001220&type=printable> [<https://perma.cc/G8A4-XHUQ>] (describing how some clinicians consider drug formularies as a limit to clinical autonomy and as a clinical hurdle for both patients and physicians).

¹⁶⁰ Engelberg, *supra* note 10.

¹⁶¹ See, e.g., Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643 (2008) (explaining how healthcare markets work differently than other markets because of the role of insurers and other intermediaries); see also *How Price Transparency Can Control the Cost of Healthcare*, ROBERT WOOD JOHNSON FOUND. (Mar. 1, 2016), <http://www.rwjf.org/en/library/research/2016/03/how-price-transparency-controls-health-care-cost.html> [<https://perma.cc/7Q46-YR4C>] (finding that healthcare consumers would alter their consumption of healthcare services with greater price transparency); AUSTIN & GRAVELLE, *supra* note 158 (discussing special characteristics of healthcare markets that may reduce importance of prices as signals, including presence of third-party payment systems).

achieving the same health benefit.¹⁶² Further, although direct kickbacks are illegal, physicians often have business relationships with pharmaceutical companies that influence the information they have about alternative products, their views about the comparative benefits of such products, and their decisions to prescribe them.¹⁶³

Wholesalers, pharmacies, and pharmacy benefit managers also play an important role in the distribution chains for drugs and other medical products.¹⁶⁴ Even though pharmacy benefit managers actually do use comparative effectiveness data in their decision-making, they do so largely to extract rebates from drug manufacturers rather than to rationalize prices for end users.¹⁶⁵ Indeed, pharmacy benefit managers have recently come under attack for the opacity of their pricing decisions, the rebates they command and retain, and the divergence that is created between prices received by drug manufacturers and prices charged to end users or insurers.¹⁶⁶

Although consumers are the end users of the drugs, many do not pay directly for the drugs they use. The main purchasers of healthcare products and services are private insurance plans, HMOs, and federal and state governments—whether through Medicare, Medicaid, Department of Veterans Affairs, Department of Defense, or state and federal programs for government employees.¹⁶⁷ But, federal and state governments have limited information about public health value and are also restricted in their ability to bargain for prices and make decisions to forego treatments based on price.¹⁶⁸

¹⁶² See, e.g., *Doctors and Rx Prices: Ending the Silence*, CONSUMER REP. (June 21, 2016), <http://www.consumerreports.org/drugs/doctors-and-rx-prices-ending-the-silence/> [<https://perma.cc/V8G2-KLV9>] (reporting on the disconnect between physicians prescribing medication and a patient's awareness of cost).

¹⁶³ See Charles Ornstein et al., *Now There's Proof: Docs Who Get Company Cash Tend to Prescribe More Brand-Name Meds*, PROPUBLICA (Mar. 17, 2016), <https://www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs> [<https://perma.cc/8QNW-YNZL>] (reporting on a study linking increased prescribing of certain medications by physicians who have received a form of benefit from the drug company).

¹⁶⁴ See, e.g., THE KAISER FAMILY FOUND., FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 1–2 (2005) (documenting the lifecycle of pharmaceutical drugs and the important players involved).

¹⁶⁵ Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J., (Oct. 3, 2016), <https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336> [<https://perma.cc/A282-CB8F>].

¹⁶⁶ See, e.g., *id.* (tracing the effect of pharmacy benefit managers on increased drug prices).

¹⁶⁷ See generally CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES 2016 HIGHLIGHTS, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf> [<https://perma.cc/PRC9-7LNS>].

¹⁶⁸ See Islam, *supra* note 155 (noting the government's inability to regulate the pricing of pharmaceutical drugs); see also Ed Silverman, *Should Medicare Negotiate Part D Drug Prices?*, WALL ST. J. (Feb. 3, 2015), <https://blogs.wsj.com/pharmalot/2015/02/03/should-medicare-negotiate-part-d>

Even when end-users are directly involved in paying for drugs, they typically lack adequate information about the health benefits they are getting and the choices that they have when making their purchasing decisions.¹⁶⁹ Indeed, end-users are often not even sure of what price they will ultimately pay for their healthcare product or service.¹⁷⁰ Overall, the fragmentation of the process for purchasing healthcare and the range of intermediaries who exercise control over the process leads to pricing that is not commensurate with or responsive to patient or public health value.

c. Inelastic (and Sometimes Irrational) Demand

Even when end users do have some role in their purchasing decisions, many healthcare purchasing decisions are made in situations of duress where the end users perceive a lack of choice in their decision. Often, healthcare products and services are perceived by end users as the difference between life and death or between quality of life and suffering. In other cases, decisions are made under emergency conditions.¹⁷¹ Purchasing decisions made under a state of physical and emotional duress or in a state of emergency may not be considered as either informed or rational. A lack of transparency about alternative choices and true costs in healthcare markets exacerbates this problem. Even where the decisions are made by third parties who are not subject to such duress, demand for expensive life-saving drugs remains fairly inelastic.¹⁷² The

drug-prices-take-our-reader-poll/ [https://perma.cc/JC24-ZAM4] (polling readers on whether they believe the government should take part in regulating drug pricing).

¹⁶⁹ See generally ETHICS AND THE PHARMACEUTICAL INDUSTRY (Michael A. Santoro & Thomas M. Gorrie eds., 2005) (exploring policy proposals for addressing the ethical dilemmas of drug industry behavior).

¹⁷⁰ According to Marc-André Gagnon, the end-user dilemma can be described by the following analogy:

Pharmaceutical markets can be compared to a dinner for three: the first person (the physician) orders the meal (from a heavily regulated menu), the second person (the patient) eats it, and the third one (the third-party payer) pays for it. While the third person might want to have a say about which meal is being ordered, the waiter is pretty aggressive in promoting the newest (patent-protected) meals—which also happen to be the most expensive.

Gagnon, *supra* note 9, at 573.

¹⁷¹ See Pearl, *supra* note 154 (“Outside of health care, people can choose whether to pay inflated prices for a patent-protected technology or minimally better products. But patients don’t have that same choice—at least not without facing potentially serious health consequences.”).

¹⁷² Islam, *supra* note 155, at 5; see also Marcelle Arak & Sheila Tschinkel, *Why the ‘Free Market’ for Drugs Doesn’t Work and What We Can Do About It*, THE CONVERSATION (Jan. 18, 2017), <http://theconversation.com/why-the-free-market-for-drugs-doesnt-work-and-what-we-can-do-about-it-70007> [https://perma.cc/H426-3DD7] (“Drug companies . . . can get away with raising prices without losing customers because the demand for certain medications is insensitive to their cost. If a drug will save your life, you’ll probably pay whatever the cost, if you can.”).

essential and often time-sensitive nature of many healthcare products and services creates inelasticities in the market that companies can exploit at the expense of consumers and/or government payors. For Medicare and commercial health plans and for individuals paying out of pocket, there are few, if any, rules dictating the price that a company can charge or the ability of a company to raise prices, even in emergency settings.¹⁷³ Where a product has a substantial impact on health and there are no alternatives and no competition, demand is inelastic, and companies have the ability to raise their prices to what the market will bear, raising prices is exactly what profit-maximizing companies do.

Furthermore, even in situations where there is no threat of imminent harm and no life or death choice at stake, people often have difficulty making rational, informed decisions about healthcare choices. Healthcare choices are often complex, and the information needed to make informed decisions is either unavailable or too difficult for a non-expert to understand. Patients are treated like consumers and asked to make healthcare choices without a clear understanding of what they are choosing between and what the likely health value of their choice will be. Concern about their health, which is often exacerbated by consumer advertising of healthcare products, can encourage consumers to pay high prices for products without having a rational basis for doing so.

d. Underpricing of Certain Healthcare Products and Services

A fourth factor causing divergence of price and public health value is the failure of price to reflect both positive and negative externalities associated with some types of healthcare products and services, such as antibiotics, opioids, and vaccines.¹⁷⁴ There may be important externalities associated with particular healthcare choices that are not captured in the prices, or profitability, of healthcare products and services. The externality could be negative, such as the impact on populations when antibiotics are overused and concerns of antibiotic resistance grow or when opioids are over-used with severe public health consequences. Alternatively, the externalities could be positive, such as the benefits to the population when individuals receive vaccinations. Prices do not reflect these external effects. In some cases, for example, prices may end up being too low, driving healthcare companies to forego efforts to develop prod-

¹⁷³ See generally Rachel Sachs, *Delinking Reimbursements*, 102 MINN. L. REV. 2307 (2018) (analyzing the power of pharmaceutical companies to protect their products and set arbitrary drug prices).

¹⁷⁴ See, e.g., Aaron S. Kesselheim & Kevin Outterson, *Fighting Antibiotic Resistance: Marrying New Financial Incentives to Meeting Public Health Goals*, 29 HEALTH AFF. 1689, 1693 (2010) (criticizing over-prescribing of antibiotics and analyzing the health repercussions of failing to take into account the negative health consequences of over-prescribing).

ucts and services that would yield significant public health value simply because the risk-adjusted profits they anticipate are not high enough.¹⁷⁵ In the case of antibiotics, healthcare companies' incentives to increase sales through lower prices are in direct conflict with public health needs to curtail antibiotic sales and use.¹⁷⁶

In summary, the four factors enumerated here each contribute to a poor correlation between the price charged by healthcare companies for their products and services and the actual public health value that individuals and the public gain from such products and services. As a result, companies focusing on maximizing revenues may not be—indeed, are unlikely to be—maximizing shareholder value and public health outcomes simultaneously.

2. Public Sharing of Costs but Not Benefits

A 2016 study found that tax-funded expenditures accounted for 64.3% of U.S. healthcare expenditures in 2013, with an expected rise to 67.1% by 2024.¹⁷⁷ These expenditures primarily take the form of (1) direct government payments for Medicare, Medicaid, the Veterans Health Administration, the National Institute of Health, public health departments, and other government funded programs; (2) public employees' health insurance; and (3) tax subsidies for healthcare at the local, state, and federal level.¹⁷⁸ The state thus plays a huge role in financing both the production and the consumption of healthcare products and services.

Starting first with public investments in production, government support is justified on the ground that there will be an underproduction in the knowledge needed to produce healthcare goods. Private markets are designed to provide private goods, which are goods characterized by rivalry and exclud-

¹⁷⁵ See *supra* notes 31–66 and accompanying text (discussing the profit maximization focus for drug companies and its impact on healthcare outcomes).

¹⁷⁶ Kevin Outterson et al., *Delinking Investment in Antibiotic Research and Development from Sales Revenues: The Challenges of Transforming a Promising Idea into Reality*, PLOS MED., June 2016, at 2, <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1002043&type=printable> [<https://perma.cc/QFZ2-TVZ4>]; Kevin Outterson, *The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation*, 31 CARDOZO L. REV. 613, 616, 624 (2009) (discussing the dire health consequences from overuse of antibiotics); see also Maryn McKenna, *The Case for Expensive Antibiotics*, WIRED (Sept. 19 2018), <https://www.wired.com/story/antibiotics-pharma-price-jump-is-testing-one-of-medicines-oldest-questions/> [<https://perma.cc/ZEX8-6DET>] (discussing why the low price of antibiotics, as compared to other treatments, might sometimes be a problem).

¹⁷⁷ David U. Himmelstein & Steffie Woolhandler, *The Current and Projected Taxpayer Shares of US Health Costs*, 106 AM. J. PUB. HEALTH 449, 450 (2016).

¹⁷⁸ *Id.* at 449.

ability.¹⁷⁹ They are not designed to provide public goods, which are goods characterized by non-rivalry—i.e., consumption by one does not reduce the availability of the good for consumption by another—and non-excludability—i.e., once they are made available to one, others cannot be effectively excluded from using that good.¹⁸⁰ Relying on private markets to produce public goods results in underproduction and overpricing of public goods or even in no production at all. This type of market failure justifies government intervention to pay for and even sometimes to produce or at least regulate the price and distribution of these goods. The absence of such public support and intervention will result in social welfare loss. Although healthcare is sometimes referred to in popular literature as a public good, most healthcare products and services are not public goods in a strict economic sense. But, the research and development that underlies the discovery and development of many healthcare products and services, particularly medical technologies and therapies, is regarded as a public good and financed heavily by the government through administrative agencies such as the National Institutes of Health and the National Science Foundation.

Public investment in healthcare R&D in the United States reflects an understanding that the R&D that leads to healthcare goods is a quasi-public good that will be under-produced under normal market conditions without government intervention.¹⁸¹ Hence, in the United States, the government attempts to offset such an outcome via direct financial subsidies and regulatory protections for healthcare innovators, such as by instituting patents and tax breaks.¹⁸²

¹⁷⁹ Hassan Y. Aly, *Privatization of Public Goods and Vice-Versa*, MARION STAR (Jan. 29, 2009), <http://econ.ohio-state.edu/Aly/docs/Privatization%20of%20public%20goods%20and%20vice-versa.pdf> [https://perma.cc/EB9P-68WH].

¹⁸⁰ *Id.*; see Paul A. Samuelson, *The Pure Theory of Public Expenditure*, 36 REV. ECON. & STAT. 387, 387 (1954).

¹⁸¹ Save defense, public investment in healthcare R&D in the United States is unmatched by investment in R&D in any other area. Hamilton Moses III et al., *The Anatomy of Medical Research: US and International Comparisons*, 313 JAMA 174, 175, 179, 186 (2015), <https://www.ncbi.nlm.nih.gov/pubmed/25585329> [https://perma.cc/7D5P-TLNL]; see *Historical Trends in Federal R&D*, AM. ASS'N FOR THE ADVANCEMENT OF SCI., <https://www.aaas.org/programs/r-d-budget-and-policy/historical-trends-federal-rd> [https://perma.cc/2N6H-W5NU] (collecting and charting data on R&D spending by various disciplines and agencies).

¹⁸² Notably, various commentators have argued that, although the costs of such government investment are borne by taxpayers, (1) there is not a similar socialization of decision-making about product choice or price or of the benefits resulting from the investment of public funds, and (2) there is no recoupment of public investment or price discount, and no sharing of profits that takes place in return for public subsidies in the production process. See Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFF. 332, 333 (2011) (analyzing the outcomes from public funding for drug research); John T. Aquino, *NIH Won't 'March-in' to Allow Generics of Astellas's Xtandi*, BNA NEWS (June 22, 2016), <https://www.bna.com/nih-wont-marchinto-n57982074540/> [https://perma.cc/2PFH-7X2R].

Downstream applications of this publicly funded R&D, including profit-making from this R&D, are left to the private market. As a result, the allocation of the risks and benefits of publicly financed R&D is becoming increasingly tilted toward benefitting private companies, with the public bearing the risk and paying high costs for the results and the private companies earning high profits.¹⁸³ The tensions between public and private interests have grown over time as federal and state government funders have increasingly prioritized the commercialization of biomedical research without adequate attention to the asymmetric distribution of the resulting benefits of the research, thereby socializing the costs of healthcare production but not the benefits.¹⁸⁴

Public investment in the production of healthcare products and services is not limited to financial support for R&D. In addition to their role as payors for healthcare products and services through programs such as Medicare and Medicaid, as discussed below, federal, state, and local governments offer financial support for all kinds of healthcare costs, both directly through grants and other subsidies and indirectly through vehicles such as tax deductions and granting tax-exempt status. Taxpayer funds have helped to finance the adoption of electronic healthcare records,¹⁸⁵ subsidize many aspects of hospital services beyond the tax-exempt status that non-profit hospitals can claim,¹⁸⁶ allow employers to deduct employee healthcare costs as business expenses,¹⁸⁷ fund training programs for physicians,¹⁸⁸ and be useful in all kinds of other ways to subsidize the costs of producing healthcare products and services.

(highlighting the government's lack of action in allowing for a cancer generic, which would have significantly decreased the cost of the drug).

¹⁸³ See generally Ron A. Bouchard & Trudo Lemmens, *Privatizing Biomedical Research—A “Third Way,”* 26 NATURE BIOTECHNOLOGY 31 (2008) (discussing implications of the privatization of research on public health and the public interest and exploring increased tension between public and private interests).

¹⁸⁴ *Id.*

¹⁸⁵ See David Dranove et al., *Investment Subsidies and the Adoption of Electronic Medical Records in Hospitals*, 44 J. HEALTH ECON. 309, 310 (2015) (discussing effects of the passage of HITECH and the funds provided to hospitals to support EMR adoption).

¹⁸⁶ Kateryna Fonkych & Glenn Melnick, *Disproportionate Share Hospital Subsidies for Treating the Uninsured*, 48 MED. CARE 809, 809 (2010); see Stephen Smith, *How Are Hospitals in the USA Funded, Private or Government?*, QUORA (Sept. 25, 2018), <https://www.quora.com/How-are-hospitals-in-the-USA-funded-private-or-government> [<https://perma.cc/NV7L-YRZU>] (analyzing the monetary paths for non-profit hospitals).

¹⁸⁷ Edward Kleinbard, *The Huge Health-Care Subsidy Everybody Is Ignoring*, WASH. POST: WONKBLOG (Oct. 15, 2013), https://www.washingtonpost.com/news/wonk/wp/2013/10/15/the-huge-health-care-subsidy-everyone-is-ignoring/?noredirect=on&utm_term=.6a02c2259a2e [<https://perma.cc/M26R-3739>].

¹⁸⁸ Jason Millman, *The US Spends \$15 Billion a Year to Train Doctors, but We Don't Know What We Get in Return*, WASH. POST: WONKBLOG (July 29, 2014), https://www.washingtonpost.com/news/wonk/wp/2014/07/29/the-u-s-spends-15b-a-year-to-train-doctors-but-we-dont-know-what-we-get-in-return/?utm_term=.8c8acf5b994e [<https://perma.cc/D772-Y2A2>].

In addition to sharing the costs and risks of production, the state (including local, state, and federal governments) plays an important role in the purchase of healthcare products and services through public health insurance programs such as Medicare and Medicaid. Although it plays important roles as purchaser of healthcare, there are both legal and political limitations on the ability of the government to negotiate prices. Private companies thus benefit from government support both at the production and consumption stages.

3. Regulation and Market Structure That Limit Competition

Healthcare markets have many features that distinguish them from the economic benchmark of a perfectly competitive market.¹⁸⁹ A combination of concentrated market structure and company-friendly regulation have limited competition in many parts of the healthcare marketplace, with subsequent effects on price and quality of healthcare.

Starting first with market structure: the structure of healthcare markets has become increasingly concentrated as a result of consolidation of hospital chains, healthcare provider groups, healthcare payers, and drug developers.¹⁹⁰ An increasingly concentrated group of healthcare providers and private insurers use their market power in the purchasing and provision of healthcare to influence the price, quality, and nature of healthcare products and services, thereby making choices that favor profits over public health value.¹⁹¹ Where competition in the healthcare system does occur, some commentators suggest that it “occurs at the wrong level, over the wrong things, in the wrong geographic markets, and at the wrong time.”¹⁹² The lack of competition and ine-

¹⁸⁹ D. ANDREW AUSTIN & THOMAS L. HUNGERFORD, CONG. RESEARCH SERV., R40834, THE MARKET STRUCTURE OF THE HEALTH INSURANCE INDUSTRY 11 (2010); see R. Douglas Scott II et al., *Applying Economic Principles to Health Care*, 7 EMERGING INFECTIOUS DISEASE J. (SPECIAL ISSUE) 282, 282 (2001) (discussing the unique nature of the healthcare market and its variation from traditional economic behavior).

¹⁹⁰ See AUSTIN & HUNGERFORD, *supra* note 189, at Summary (reporting on the ill-effects of consolidation of the health insurance market); GAYNOR & TOWN, *supra* note 149, at 502 (“US hospital markets are highly concentrated and have become even more concentrated over time.”). See generally BARAK D. RICHMAN, AM. ENTER. INST. CONCENTRATION IN HEALTH CARE MARKETS: CHRONIC PROBLEMS AND BETTER SOLUTIONS (Thomas P. Miller ed., 2012) (discussing the particularly problematic results for healthcare outcomes from monopoly power in the industry).

¹⁹¹ See Diane Archer, *No Competition: The Price of a Highly Concentrated Health Care Market*, HEALTH AFF. (Mar. 6, 2013), <http://healthaffairs.org/blog/2013/03/06/no-competition-the-price-of-a-highly-concentrated-health-care-market/> [<https://perma.cc/C3HG-8YAZ>] (contributing rising costs to monopoly power by healthcare companies instead of technological advancement or other factors); see also AUSTIN & HUNGERFORD, *supra* note 189, at Summary (discussing the factors contributing to high costs in the healthcare market).

¹⁹² Michael E. Porter & Elizabeth Olmstead Teisberg, *Redefining Competition in Health Care*, HARV. BUS. REV., June 2004, at 65, 66.

lastic demand, in turn, allow for a large and continued divergence between cost of production and price. The CEO of Mylan, for example, when called out for the more than 400% price hike in EpiPens,¹⁹³ suggested that it was not her company, but the healthcare system, that was at fault—her job was simply to see what prices the market would accept.¹⁹⁴ Pricing is based not on cost or on health value, but rather on what the market will bear.¹⁹⁵

Regulation also plays an important role in limiting competition. Healthcare markets are characterized by regulations that frequently confer significant market power on incumbents.¹⁹⁶ The reward for making the significant investment necessary to enter healthcare markets is a shelter from competition created through patents and data and market exclusivities. Often such regulatory protections from competition are cumulative and long-lasting. As a result, healthcare companies are able to control prices and/or production over long periods of time without the discipline that market pressures impose.¹⁹⁷ In other words, competition will exert discipline on the production and pricing decisions of corporations in a competitive market, forcing corporations to compete on product choice, pricing, and product quality. Where corporations are sheltered from competition, they can increase prices, reduce output, and shirk on product quality.¹⁹⁸

¹⁹³ Nicole Puglise, “Exorbitantly Expensive” EpiPen Prompts Letter from 20 US Senators, THE GUARDIAN (Aug. 30, 2016), <https://www.theguardian.com/business/2016/aug/30/epipen-mylan-price-increase-senators-letter-warren-sanders> [https://perma.cc/S4SQ-RSMF].

¹⁹⁴ Matt Egan, *EpiPen CEO: Blame the ‘Broken’ System, Not Me*, CNN BUS. (Aug. 25, 2016), <http://money.cnn.com/2016/08/25/investing/epipen-cost-ceo-lowers-price-mylan/> [https://perma.cc/Q6KT-DKJP]; see Liz Voyles, *The EpiPen Boss Tried to Defend Price Hikes to Congress. No One Bought It*, THE GUARDIAN (Sept. 22, 2016), <https://www.theguardian.com/commentisfree/2016/sep/22/epipen-mylan-ceo-defend-price-hikes-congress-heather-bresch> [https://perma.cc/JM7Z-P6PQ] (Mylan CEO argued that her company had the right to earn a profit and that the company was showing corporate responsibility by striking the right balance between price and access).

¹⁹⁵ See *supra* notes 100–102 and accompanying text.

¹⁹⁶ Healthcare in the United States is regulated by a multitude of laws, both state and federal, which create an intricate (and, at times, daunting) set of institutions and rules. At the federal level alone, these laws include major statutes such as: the Public Health Service Act, 42 U.S.C. §§ 201–300mm-61 (2012); the Federal Food Drug and Cosmetics Act, 21 U.S.C. §§ 301–399f (2012); the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001–1461 (2012); the Patient Protection and Affordable Care Act, 42 U.S.C. §§ 18001–18122 (2012), and more. These statutes are administered by several government agencies, including, most prominently, the Food and Drug Administration, through 21 C.F.R. §§ 1.1–1299 (2018), and the National Institutes of Health, through 5 C.F.R. § 5501.112 (2018), 42 C.F.R. §§ 52a.1-9, 52h.2(i), 63a.1-11, 68b.1-12 (2017), and 45 C.F.R. §§ 3.1-61 (2017). In addition to the benefits the patent system confers on inventors, healthcare innovation enjoys a unique set of sui generis incentive regimes aimed at bestowing different economic advantages that often rise to the level of market power. See, e.g., Heled, *supra* note 131, at 330–52 (documenting the various economic protections afforded to drug companies through regulations).

¹⁹⁷ See *supra* notes 134–142 (Part I.D).

¹⁹⁸ Numerous studies show the impact of increased market concentration on prices, with higher concentration leading to higher prices. RICHMAN, *supra* note 190, at 3; Engelberg, *supra* note 10; Tim

Further, incentive structures created by regulation often distort the relative attractiveness of different projects in ways that do not reflect public health need. Regulations designed to encourage the development of therapies for orphan diseases through market exclusivities and tax incentives, for example, have led many large drug companies to refocus their efforts away from diseases with large public health burdens and towards niche markets that promise lower financial risk and high potential returns.¹⁹⁹

The three characteristic of healthcare markets that have been identified above: (1) the failure of price to reflect public health value, (2) the public sharing of costs but not benefits, and (3) regulations and market structure that limit competition, combine to create a persistent and even growing divergence between private incentives and public health needs. Even in competitive market settings, maximizing profits using prices that do not correlate well with public health value will result in inefficient production. But, this divergence of private incentives and public health need is compounded by the other two characteristics of the healthcare market. By treating publicly subsidized healthcare goods and services as private goods and leaving them to the market to produce, where private corporations sheltered from competition and benefiting from limited demand elasticity and a lack of price transparency make production and pricing choices to maximize profits instead of public health value, we get sub-optimal healthcare outcomes at a very high cost. Traditional corporations operating in healthcare markets with these characteristics have too much power over price and product choice since they operate in markets with distorted and often relatively inelastic (desperate) demand. Furthermore, they neglect the public goods aspects of both inputs in the R&D process and the products and services they produce, and they exploit regulations that limit entry and competition.

The importance of this from a policy perspective is that corporations operating in healthcare markets fail to take public health interests into account when making product and service pricing and production choices on purpose. Healthcare companies are limited in their ability to take the public interest under account because, as discussed earlier, they are focused on maximizing their value for their shareholders.²⁰⁰ Where maximizing shareholder value involves actions that diverge from measures designed to maximize public health benefit,

Hyde, *When Hospitals Compete, Do Patients Win?*, AM. ECON. ASS'N (May 6, 2016), <https://www.aeaweb.org/research/when-hospitals-compete-do-patients-win> [<https://perma.cc/R2F9-TQCQ>]; Robert Pear, *F.T.C. Wary of Mergers by Hospitals*, N.Y. TIMES (Sept. 18, 2014), http://www.nytimes.com/2014/09/18/business/ftc-wary-of-mergers-by-hospitals-.html?_r=0 [<https://perma.cc/M2MG-ZMAE>].

¹⁹⁹ See Herder, *supra* note 54, at 2 (highlighting the impact of the Orphan Drug Act and the subsequent profitability for pharmaceutical companies entering this market).

²⁰⁰ See *supra* notes 25–144 and accompanying text.

corporations are expected to and indeed take the actions they are permitted or even encouraged to take under the law.²⁰¹ It is this focus on profits in a market where profits do not reflect consumer value, and indeed sometime come at the expense of consumer health, that leads to poor health outcomes.

B. Why Targeting Company Structure Makes Sense

The considerations discussed above suggest that relying on profit-maximizing corporations operating within current market structures to provide healthcare products and services will lead to poor public health outcomes. As discussed in Part I, the recognition that the healthcare market is broken and in need of reform is not new and has been widely discussed. Yet most, if not all, policy responses have focused on interventions designed to change the market rather than the market actors themselves. We argue that changing market actors directly provides a sound mechanism for improving the operation of healthcare markets. We suggest that changing the corporate form can be used to change the incentives of corporate actors from the inside, forcing them to internalize and respond to public health needs while realizing profits. Part III identifies the benefits of targeting the corporate form as a core part of current healthcare market reforms and begins to explore how such an approach might be implemented. Given the novelty of hybrid entities and the legal frameworks that govern them, our discussion in this Article is confined largely to how such hybrid entities could perform in the presence of robust regulatory structures to enforce their core principles.²⁰²

III. A NEW APPROACH: HYBRIDS FOR HEALTHCARE MARKETS

Until recently, there has been a largely binary approach towards company structure in the United States that forces a separation between the pursuit of profits and the pursuit of social objectives. This approach toward company structure is manifested in the choice between a “for-profit” business form, focused largely on maximizing shareholder value, and a “non-profit” organizational form, focused on the pursuit of one or more charitable purposes. The traditional “for-profit” or business corporation can be organized for any legal business purpose, has private owners, can raise private capital, and can distribute profits to its investors. Its profits are taxed and it is not entitled to receive tax-deductible funds or grants. In contrast, the “non-profit” organization is

²⁰¹ See *supra* notes 25–144 and accompanying text.

²⁰² A detailed assessment of how benefit corporations have performed to date and an evaluation of emerging legal structures for enforcing the core attributes of hybrid entities, along with a more detailed analysis of the consequences of mandating this kind of corporate form, are left for subsequent treatment.

generally required to have a charitable, educational, scientific, or other non-commercial purpose, does not have shareholders, and cannot raise private capital or distribute profits. It is subject to oversight by governmental authorities only (or almost-exclusively) and to certain restrictions on its operations, but in return, it can raise tax-deductible funds and its activities are tax-exempt. This binary approach toward corporate structure exacerbates the conflict between the desire to pursue the public interest and the desire to generate profits, which has led to inefficiencies where there are opportunities to “do well by doing good.”²⁰³

New hybrid legal forms offer the possibility of accomplishing both social good and private wealth creation within the same entity. We argue that encouraging (or requiring) healthcare companies to operate under new hybrid legal forms that mandate consideration of stakeholder (not just shareholder) interests will narrow the divergence between private incentives and public health needs in ways that benefit public health, provided that there is robust regulatory enforcement of the hybrid rules. After a brief discussion of hybrid corporate forms in the United States, we show how the core features of hybrid forms offer advantages over alternative, current organizational forms in the production of healthcare products and services.

A. Alternative Corporate Forms: Choices and Implications

1. Evolution of the Corporate Form and Shareholder Primacy

Great corporations exist only because they are created and safeguarded by our institutions; and it is therefore our right and our duty to see that they work in harmony with those institutions.

—Theodore Roosevelt, First Annual Message to Congress, 1901²⁰⁴

In a free-enterprise, private property system, a corporate executive is an employee of the owners of the business. He has direct responsibility to his employers. That responsibility is to conduct the business in accordance with their desires, which generally will be to make as much money as possible while conforming to the basic rules of the society, both those embodied in law and those embodied in ethical custom.

—Milton Friedman, 1970²⁰⁵

²⁰³ Katherine R. Lofft et al., *Are Hybrids Really More Efficient? A ‘Drive-By’ Analysis of Alternative Company Structures*, BUS. L. TODAY, Sept. 2012, at 1, 3.

²⁰⁴ Theodore Roosevelt, First Annual Message to Congress (Dec. 3, 1901), *reprinted in A COMPILATION OF THE MESSAGES AND PAPERS OF THE PRESIDENTS*, SUPP. VOL. (James D. Richardson, ed. 2004).

The corporate form in the United States dates back to the 1790s, when the United States “began to lead the world in the development of the corporation as the most dynamic form of modern business enterprise.”²⁰⁶ The creation of a business entity with limited liability and a perpetual lifespan provided a good vehicle for securing investors and pooling resources, which resulted in robust economic growth. Although many early corporations were small and their operations and governance tailored to the needs of a range of stakeholders, by the 1930s some corporations had become much larger and a formalized separation of ownership and control began to take place.

Modern corporations are controlled by their directors and managers, who are legally required to act as fiduciaries in accordance with the interests of their shareholders and other stakeholders. One of the biggest debates in corporate law is whether and to what extent (if at all) the interests of non-shareholder stakeholders should be considered for purposes of corporate decisions.²⁰⁷ Yet, even as this debate continues to occupy corporate theorists, it is largely resolved in favor of shareholders under the corporate laws of virtually all fifty states.²⁰⁸ In practice, if not in theory, for-profit corporations are designed to benefit shareholders, not to pursue the interests of other stakeholders. This approach is clearly reflected in the corporate laws of Delaware, the leading state for corporate jurisprudence.²⁰⁹

The notion that the duty of managers and directors is primarily to maximize shareholder value is famously captured in Milton Friedman’s depiction of the social responsibility of a corporation to increase its profits. According to Friedman, managers have a fiduciary duty to act with the same care and dili-

²⁰⁵ Milton Friedman, *The Social Responsibility of Business Is to Increase Its Profits*, N.Y. TIMES MAG., Sept. 13, 1970, at 33.

²⁰⁶ See generally Ralph Gomory & Richard Sylla, *The American Corporation*, 142 DAEDALUS 102 (2013) (reviewing the evolution of the corporation, including during the current shift away from stakeholder view of corporate interests and purposes to one dominated by profit and shareholder wealth-maximization).

²⁰⁷ See *id.* (providing an overview of the evolution of the corporation as seen in historical, economic and political terms).

²⁰⁸ See COX & HAZEN, *supra* note 147, § 4:1 (tracing the evolution of corporate law in the U.S. and the role of directors); WILLIAM MEADE FLETCHER, 1A FLETCHER CYCLOPEDIA OF THE LAW OF CORPORATIONS § 91 (rev. ed. 2010) (analyzing the purposes behind the corporation and the duties of directors).

²⁰⁹ See, e.g., Leo E. Strine, Jr., *Our Continuing Struggle with the Idea That For-Profit Corporations Seek Profit*, 47 WAKE FOREST L. REV. 135, 147–48, 155 (2012) (“[C]orporate law requires directors, as a matter of their duty of loyalty, to pursue a good faith strategy to maximize profits for the stockholders.”). But see, e.g., LYNN STOUT, *THE SHAREHOLDER VALUE MYTH: HOW PUTTING SHAREHOLDERS FIRST HARMS INVESTORS, CORPORATIONS, AND THE PUBLIC* 3–4 (2012) (chronicling the history of the shareholder-value theory throughout U.S. history).

gence in corporate matters as they would in their own affairs,²¹⁰ which is generally understood as “[to] conduct business activities with a view to enhancing corporate profit and shareholder gain.”²¹¹ Although managers and directors are protected in their reasonable exercise of “business judgment,” their decisions must ultimately be justifiable as efforts consistent with the protection of shareholder value.²¹² The interests of non-shareholder constituencies on the other hand, such as those of employees, creditors, and suppliers, are protected largely through contracts rather than fiduciary duties, and the interests of the general public receive no formal protection.

These views have been both captured and delineated in the seminal case of *Dodge v. Ford Motor Company*:

A business corporation is organized and carried on primarily for the profit of the stockholders. The powers of the directors are to be employed for that end. The discretion of directors is to be exercised in the choice of means to attain that end, and does not extend to a change in the end itself, to the reduction of profits, or to the non-distribution of profits among stockholders in order to devote them to other purposes.²¹³

The primacy of shareholder value embodied in this decision has since been widely accepted by courts,²¹⁴ and shareholder wealth maximization has come to dominate corporate governance as the fundamental norm that guides all cor-

²¹⁰ See Friedman, *supra* note 205, at 33 (“[An executive] has a direct responsibility to his employers. That responsibility is to conduct the business in accordance with their desires, which generally will be to make as much money as possible while conforming to the basic rules of the society, both those embodied in law and those embodied in ethical custom.”); see also Ronald M. Green, *Shareholders as Stakeholders: Changing Metaphors of Corporate Governance*, 50 WASH. & LEE L. REV. 1409, 1410 (1993) (“Senior managers must act loyally to the corporation, avoid taking personal advantage of information or opportunities that come their way; and act with the same care and diligence in corporate matters as they would in their own affairs.”).

²¹¹ Green, *supra* note 210, at 1410.

²¹² See DOUGLAS K. MOLL & ROBERT A. RAGAZZO, 1 CLOSELY HELD CORPORATIONS § 6.02 (Lexis 2017) (defining the “business judgment rule” as a deferential standard that insulates managers from liability from poor decisions if the decision is made in good faith, absent from conflicts of interest). *But see* R. EDWARD FREEMAN & DANIEL R. GILBERT, JR., CORPORATE STRATEGY AND THE SEARCH FOR ETHICS 6–7 (1988) (arguing that organizations should use “values principles” and “interdependence principles” when making decisions, and further stating that “[c]orporate strategy[ies] must reflect an understanding of the ethical nature of strategic choice”); E. Merrick Dodd Jr., *For Whom Are Corporate Managers Trustees?*, 45 HARV. L. REV. 1145, 1156–57 (1932) (expressing an early view that corporate managers have a plurality of obligations).

²¹³ *Dodge v. Ford Motor Co.*, 170 N.W. 668, 684 (Mich. 1919).

²¹⁴ William H. Clark, Jr. & Elizabeth K. Babson, *How Benefit Corporations Are Redefining the Purpose of Business Corporations*, 38 WM. MITCHELL L. REV. 817, 826 (2012).

porate decision-makers.²¹⁵ Although for-profit corporations can and sometimes do engage in altruistic behavior, the law is clear that their overriding legal purpose must be to benefit shareholders, not third-party stakeholders.²¹⁶ Accordingly, the directors, officers, and managers of for-profit corporations have a fiduciary duty to make decisions that are in the best financial interests of shareholders notwithstanding competing considerations, and corporate officers who do not meet that duty are subject to liability in both their corporate and personal capacities.²¹⁷

In routine or day-to-day contexts, the “business judgment rule” protects directors who make decisions based on non-shareholder interests so long as they are rationally related to the long-term promotion of shareholder value.²¹⁸ A corporate action that clearly and admittedly harms shareholder value or seeks to achieve non-shareholder benefits is likely to be found by courts to constitute a breach of a director’s fiduciary duties. In contrast, directors who choose shareholder primacy over competing non-shareholder considerations, or even ignore these considerations, compelling as they might be, do not face any such liability. There is no cause of action against directors for making too much money for shareholders. In fact, many would agree that over the past few decades, there has been a continued shift in corporate law away from a broad view of stakeholder interests and towards an almost exclusive focus on shareholder value.²¹⁹ This trend has been further exacerbated by the increasing prevalence of executive compensation packages that provide hefty rewards for managers and directors who produce growth in shareholder value.²²⁰

²¹⁵ See, e.g., Stephen M. Bainbridge, *In Defense of the Shareholder Wealth Maximization Norm: A Reply to Professor Green*, 50 WASH. & LEE L. REV. 1423, 1423–25 (1993) (arguing that mainstream corporate law remains committed to principles encapsulated in the *Dodge* decision).

²¹⁶ See *supra* notes 204–215 and accompanying text.

²¹⁷ CG Hintmann, Comment, *You Gotta Have Faith: Good Faith in the Context of Directorial Fiduciary Duties and the Future Impact on Corporate Culture*, 49 ST. LOUIS U. L.J. 571, 579 (2005) (stating that “directors will be held personally liable if they cannot . . . prove that they exercised the requisite care”). This focus on shareholder value is at its peak in the context of acquisitions, when the business judgment rule is limited, and at least under Delaware law, the sole fiduciary duty of the board is to maximize shareholder value. See *Revlon, Inc. v. MacAndrews & Forbes Holdings, Inc.*, 506 A.2d 173, 182 (Del. 1986) (finding that the company’s directors should have been guided by maximizing the financial payout in a hostile takeover).

²¹⁸ J. Haskell Murray, *Social Enterprise and Investment Professionals: Sacrificing Financial Interests?*, 40 SEATTLE U. L. REV. 765, 783 (2017) (“[B]enefit corporations are needed for the times when for-profit firms want to admit to pursuing social ends at the short and long-term expense of shareholders.”).

²¹⁹ Gomory & Sylla, *supra* note 206, at 108.

²²⁰ Nicholas Donatiello et al., *CEO Pay, Performance, and Value Sharing*, STAN. CLOSER LOOK SERIES (Mar. 3, 2016), <https://www.gsb.stanford.edu/sites/gsb/files/publication-pdf/cgri-closer-look-53-ceo-pay-performance-value-sharing.pdf> [<https://perma.cc/HY89-M2WW>] (discussing how executive pay should be linked to shareholder value created by the executive, and further discussing the difficulty in measuring value creation).

Perhaps in response to this corporate focus on shareholder value at the expense of broader public interests, a number of states, beginning with Pennsylvania in 1983, started adopting statutes that permit directors to take the interests of a variety of constituencies other than shareholders into account in their decision-making.²²¹ In practice, however, these constituency provisions have been seldom used, and where they are used, they often require that the interests of any non-shareholder constituency bear a relationship to the best interests of the corporation, viewed in terms of shareholder value.²²² As explained by Chancellor Strine, Chief Justice of the Delaware Supreme Court:

Precisely because it is ultimately the equity market that is the primary accountability system for public firms, efforts to tinker around with the margins of corporate law through initiatives like constituency statutes, the so-called Corporate Social Responsibility movement, and antitakeover provisions have been of very little utility in insulating corporate boards from stockholder and stock market pressures.²²³

As a result, even with constituency provisions in place, when a corporate decision hangs in the balance, a decision that is made to benefit the financial interests of shareholders carries the least risk of fiduciary liability and most often the largest financial compensation for the decision-maker.

2. Emergence of Benefit and Social Purpose Corporations

It is against this background, with the increasingly stark choice between a for-profit focus on shareholder value and a not-for-profit focus on charitable goals, that states have begun enacting statutes authorizing so-called “hybrid” for-profit business entities. Within the past decade, thirty-seven states and the District of Columbia have adopted laws authorizing distinct types of legal entities—generally, special forms of corporations and limited liability companies—that cater to business owners who desire to pursue profit-making as well as a social or environmental mission.²²⁴ This trend can be seen in a number of

²²¹ Green, *supra* note 210, at 1411; Charles Hansen, *Other Constituency Statutes: A Search for Perspective*, 46 BUS. LAW. 1355, 1357 (1991); Anthony Bisconti, Note, *The Double Bottom Line: Can Constituency Statutes Protect Socially Responsible Corporations Stuck in Revlon Land*, 42 LOY. L.A. L. REV. 765, 780–81 (2009).

²²² See, e.g., Strine, *supra* note 209, at 153 (“[C]onstituency statutes . . . have been of very little utility in insulating corporate boards from stockholder and stock market pressures.”); Bisconti, *supra* note 221, at 783 (explaining that some constituency statutes require a shareholder to bring suit in order to challenge a failure to consider non-shareholders).

²²³ Strine, *supra* note 209, at 153.

²²⁴ A table listing the enacting states with citations to relevant law is attached as an appendix to this Article. See *infra* Appendix A.

other jurisdictions around the world where similar laws authorizing hybrid business entities have been adopted.²²⁵

The two main hybrid corporate forms instituted in the United States to date are the benefit corporation and the “social purpose corporation.”²²⁶ These new types of corporations attempt to balance the competing and sometimes conflicting interests that arise when a business seeks to be both for-profit and mission-driven within a single entity. Just like regular corporations, these hybrid forms have private owners, can raise private capital, and can distribute profits to their investors. They are treated like regular for-profit businesses for federal, state, and local tax purposes, receiving no special income tax benefits or incentives.²²⁷ Yet, these entities are similar to nonprofit corporations in their required pursuit of a social good. The achievement of social objectives—such as improving public health outcomes—is made a part of the objectives of the business along with generating revenue and profits.

Both benefit corporations and social purpose corporations are variants of states’ regular business corporation statutes. Of the thirty-eight jurisdictions in the United States that have enacted some type of hybrid corporate form, thirty-four have authorized the establishment of benefit corporations with Maryland being the first state to pass benefit corporation legislation in 2010.²²⁸ Since then, thirty-three more states (including Delaware) and the District of Columbia have followed with their own variants.²²⁹

Just like a corporation, benefit corporations are managed by a board of directors, and their day-to-day affairs are carried out by officers and employees. Stockholders invest capital into the benefit corporation in exchange for shares, and the stockholders determine the members of the board of directors and re-

²²⁵ See generally Cassady V. Brewer, *The Ongoing Evolution in Social Enterprise Legal Forms*, in *THE SOCIAL ENTERPRISE ZOO: A GUIDE FOR PERPLEXED SCHOLARS, ENTREPRENEURS, PHILANTHROPISTS, LEADERS, INVESTORS, AND POLICYMAKERS* 33, 46–49 (Dennis R. Young, Elizabeth A.M. Searing, & Cassady V. Brewer eds., 2016) (mapping the progression of legal measures taken to support social enterprise models).

²²⁶ Alicia E. Plerhoples, *Social Enterprise as Commitment: A Roadmap*, 48 WASH. U. J.L. & POL’Y 89, 89–90 (2015) (identifying several hybrid corporate forms, including the “low-profit limited liability company, benefit limited liability company, benefit corporation, public benefit corporation, [and] social purpose corporation”).

²²⁷ There is a notable exception to the general rule that hybrid corporations are taxed as regular, for-profit businesses. Philadelphia recently amended its regulations to create a local “Sustainable Business Tax Credit” to incentivize businesses to incorporate as benefit corporations. Richard Freeh, *Sustainable Business Tax Credit*, PHILA.GOV (Feb. 1, 2017), <https://beta.phila.gov/posts/office-of-sustainability/2017-02-01-sustainable-business-tax-credit/> [<https://perma.cc/A2F6-CRXY>]. The program requires either certification by B Lab as a B Corporation or evidence that the business conducts itself as a benefit corporation. *Id.* The \$4,000 tax credit is currently available to fifty businesses, and that number is expected to increase to seventy-five businesses in 2019. *Id.*

²²⁸ See *infra* Appendix A.

²²⁹ *Id.*

tain voting privileges over certain major decisions.²³⁰ But, unlike regular business corporations, which primarily pursue profits for the benefit of shareholders, a benefit corporation must (1) pursue a “general public benefit” (and may adopt a “specific public benefit” as well); (2) consider non-financial interests of its shareholders and other stakeholders when making decisions; and (3) issue reports on how well it is achieving its overall social and environmental objectives.²³¹ In addition, unlike corporations that have adopted constituency statute language in their articles of incorporation, benefit corporations are required, rather than merely permitted, to pursue a general public benefit.

Indeed, the legal mandate and requirement to produce a “general public benefit” is the hallmark of the benefit corporation. In most states that have enacted benefit corporation legislation, the definition of a “general public benefit” is a “material positive impact on society and the environment.”²³² The motivating idea behind this language is to create for-profit corporations that will generate revenue and earn profits, but that will do so in a manner benefitting society and the environment as well as shareholders. In so doing, the general public benefit requirement turns benefit corporations into so-called “triple bottom line companies,” focusing their efforts on profits, people, and planet. In that regard, benefit corporations are different both from social purpose corporations (discussed below) that pursue either a social or environmental purpose primarily, and regular corporations subject to constituency statutes that may consider other purposes but are still primarily governed by the profit-making imperative.²³³

²³⁰ MARILYN E. PHELAN, 1 NONPROFIT ORGANIZATIONS: LAW AND TAXATION § 1:1 (West 2010).

²³¹ MODEL BENEFIT CORPORATION LEGISLATION § 201(a) (BENEFIT CORP. 2017), http://benefitcorp.net/sites/default/files/Model%20benefit%20corp%20legislation%20_4_17_17.pdf [<https://perma.cc/VPX9-EX8V>]. Most state benefit corporation statutes are based upon various iterations of the Model Benefit Corporation Legislation published by B-Lab, the promoter of the “B Corp” designation and a third-party certifying agency, as contemplated by the new law. *See About B Lab*, B-LAB, <https://www.bcorporation.net/what-are-b-corps/about-b-lab> [<https://perma.cc/RYY4-Q63P>] (describing B Lab and its goals). *See generally* C. BREWER ET AL., SOCIAL ENTERPRISE BY NON-PROFITS AND HYBRID ORGANIZATIONS, BNA Portfolio #489 at A-55 (2014) (summarizing the emergence of hybrid organizations to maximize social and charitable purposes).

²³² *How Do I Create General Public Benefit?*, BENEFIT CORP. <http://benefitcorp.net/businesses/how-do-i-create-general-public-benefit> [<https://perma.cc/X8AY-XJ5A>].

²³³ *Id.*; *see also* WILLIAM H. CLARK, JR. ET AL., BENEFIT CORP. THE NEED AND RATIONALE FOR THE BENEFIT CORPORATION: WHY IT IS THE LEGAL FORM THAT BEST ADDRESSES THE NEEDS OF SOCIAL ENTREPRENEURS, INVESTORS, AND, ULTIMATELY, THE PUBLIC App. C, at 6–7 (2013), http://benefitcorp.net/sites/default/files/Benefit_Corporation_White_Paper.pdf [<https://perma.cc/CC5X-B6YL>].

Social purpose corporations are an alternative hybrid form that has been adopted, to date, by four states²³⁴ in response to the concern that directors and officers of benefit corporations are required to consider the interests of too many stakeholders in addition to shareholders. Rather than pursue a general public benefit, a social purpose corporation need only pursue and attempt to accomplish the specific social or environmental purpose or purposes articulated in its articles of incorporation.²³⁵ Moreover, with the exception of California, the directors of a social purpose corporation are not required to consider the corporation's social or environmental purpose(s) unless explicitly required to do so by the corporation's articles of incorporation. In this regard, outside of California, the social purpose corporation is similar to a regular corporation that has adopted constituency language in its articles of incorporation.

3. Unique Desirable Features of Hybrids

Both the benefit corporation and the social purpose corporation have special corporate governance features that distinguish them from traditional corporations in ways that make them better vehicles for responding to healthcare needs. We identify four such features: (1) required consideration of non-pecuniary purposes in decision-making, including general and specific public benefits and a broad set of stakeholder interests; (2) protection of directors from liability for considering non-pecuniary purposes; (3) reporting requirements assessed against third-party reporting standards; and (4) enforcement mechanisms. Understanding these special corporate governance features is important for appreciating the potential that benefit corporations and social purpose corporations have for improving healthcare outcomes.

a. Consideration of Non-Pecuniary Purposes and Stakeholder Interests

Benefit corporation directors are not only permitted but are required to consider the impact of any proposed corporate action on a broad range of stakeholders as well as general and specific public interests. These stakeholders and public interests include: (1) the interests of the corporation's shareholders; (2) the interests of its employees and workforce; (3) the interests of its subsidiaries and suppliers; (4) the interests of its customers to the extent they are beneficiaries of the general or specific public benefit purposes of the benefit corporation; (5) the impact on its surrounding community and society at large; (6) the impact on the local and global environment; (7) the long-term

²³⁴ See *infra* Appendix A. As can be seen in the table, California, Florida, Minnesota, and Texas have adopted both benefit corporation and social purpose corporation statutes. Washington is the only state that has adopted a social purpose corporation statute exclusively. *Id.*

²³⁵ E.g., CAL. CORP. CODE § 2602(b)(2) (West 2017).

and short-term interests of the benefit corporation, including whether the benefit corporation should remain “independent”; and (8) the ability of the benefit corporation to accomplish its general and specific benefit purposes.²³⁶ In addition, a director of a benefit corporation may consider any other pertinent factors or the interests of any other group that the director determines to be appropriate.²³⁷ In performing their fiduciary duties, directors of benefit corporations are not required to give priority to the interests of any particular person or group unless the benefit corporation has stated its intention of doing so in its articles of incorporation.²³⁸ Officers of benefit corporations are likewise required to weigh a variety of such considerations in addition to and beyond the bottom line.²³⁹ Further, in addition to the generic declaration in their incorporation documents, benefit corporations can (in most states) or even must (e.g., in Delaware) expressly include one or more specific public benefit goals. Some states even require benefit corporations, particularly those that are publicly traded, to have a “benefit director” on their board whose responsibility it is to ensure that the benefit corporation is meeting its stated public purpose.²⁴⁰

For social purpose corporations, the non-pecuniary purpose (e.g., improving healthcare outcomes in the United States) must likewise be stated in the corporation’s incorporation documents. The incorporation documents must also explicitly state that the corporation’s directors are required to pursue the non-pecuniary purpose.²⁴¹ In addition to the normal duties of care and loyalty to shareholders, a director of a social purpose corporation may consider factors the director deems relevant to discharging his or her duties, including: (1) the short-term and long-term prospects of the social purpose corporation; (2) the best interests of the social purpose corporation and its shareholders; and (3) the purposes of the social purpose corporation as set forth in its articles of incorporation.²⁴²

b. Limiting Liability of Directors for Implementing Benefit Purpose

Directors and officers of benefit corporations enjoy certain protections from fiduciary liability that are not available to directors of regular corporations. Most importantly, benefit corporation directors and officers may not be

²³⁶ MODEL BENEFIT CORPORATION LEGISLATION, *supra* note 231, §§ 101(a)(1), 102.

²³⁷ *Id.* § 301(a)(2).

²³⁸ *Id.* § 301(a)(3).

²³⁹ *Id.*

²⁴⁰ BREWER ET AL., *supra* note 231, at A-58-60.

²⁴¹ If the documents of incorporation fail to do so, then—with the exception of California—pursuing the public benefit goal becomes optional. Compare WASH. REV. CODE § 23B.25.050 (West 2017) (stating that directors “may consider”), with CAL. CORP. CODE § 2700(c) (West 2017) (stating that directors “shall consider”).

²⁴² CAL. CORP. CODE § 2700(c).

held monetarily liable by shareholders or by the corporation for pursuing or failing to pursue the corporation's general and specific public benefit. This limitation on liability, which is significantly different from that imposed on directors and officers of a traditional for-profit corporation,²⁴³ protects directors and officers of benefit corporations from fiduciary liability even when they act with an avowed purpose that would require the sacrificing of the financial interests of shareholders. Social purpose corporations adopt similar limitations on the liability of directors.²⁴⁴

c. Enforcement and Remedies

Shareholders of benefit corporations retain the same rights they would have in traditional corporate models.²⁴⁵ They have the right to elect directors and to vote on important corporate decisions such as amendments to the charter or mergers or acquisitions. They have the same rights to bring derivative suits for a director's breach of fiduciary duty and suits to compel review of the company's books and records. But, in addition to these standard corporate rights, benefit corporation shareholders and stakeholders can also have a private right of action to enforce the public benefit mission of a benefit corporation.

More specifically, in several states the benefit corporation itself, its shareholders, directors, any individuals named in the articles of incorporation,²⁴⁶ and, in the case of a benefit corporation that is a subsidiary, any owner of five percent or more of the stock of the parent company, may avail themselves of a special type of derivative proceeding.²⁴⁷ This proceeding allows qualifying plaintiffs to bring a "benefit enforcement proceeding" for the corporation's alleged failure to pursue a general or specific public benefit and the violation

²⁴³ Many traditional corporate statutes allow a corporation's articles of incorporation to include optional exculpation from monetary liability (subject to exceptions for bad faith, intentional misconduct, and conflicting interest transactions), but the benefit corporation statute makes such exculpation automatic. Compare DEL. CODE ANN. tit. 8, § 102(b)(7) (West 2017) (allowing a certificate of incorporation to optionally include a provision limiting a director's liability for breach of fiduciary duty), with MODEL BENEFIT CORPORATION LEGISLATION, *supra* note 231, § 302(e) ("Regardless of whether the articles of incorporation or bylaws of a benefit corporation include a provision eliminating or limiting the personal liability of directors . . . a benefit director shall not be personally liable for an act or omission in the capacity of a benefit director . . .").

²⁴⁴ See MODEL BENEFIT CORPORATION LEGISLATION, *supra* note 231, § 301(c) (providing for exoneration from personal liability for directors).

²⁴⁵ See *General Questions*, BENEFIT CORP., <http://benefitcorp.net/faq> [<https://perma.cc/RA2D-THEB>].

²⁴⁶ *E.g.*, CAL. CORP. CODE ANN. § 14623(b) (West 2017); CONN. GEN. STAT. ANN. § 33-1362(c) (West 2014); FLA. STAT. ANN. § 607.611(2)(b) (West 2014); 15 PA. STAT. AND CONS. STAT. ANN. § 3325(b)(2) (West 2017).

²⁴⁷ See, *e.g.*, BREWER, *supra* note 231, at A-57.

of any special duty or standard of conduct imposed by statute or the corporation's articles.²⁴⁸ The ability of non-shareholder stakeholders named in a benefit corporation's articles to pursue a benefit enforcement proceeding is unprecedented and completely foreign to traditional for-profit corporation statutes. This right of standing, when granted to non-shareholder stakeholders in a benefit corporation's articles, serves as a powerful deterrent against a corporation favoring profits over a general public benefit.

Benefit corporations are such a new phenomenon that there are no decided cases or other guidance regarding the remedies available pursuant to a benefit enforcement proceeding. Presumably, because monetary damages are ordinarily not allowed, remedies will involve some form of injunctive relief or specific performance.²⁴⁹ A court might require the directors of a benefit corporation to comply with the terms of the statute or the corporation's governing documents (e.g., failure to issue an annual report). Alternatively, after directors cause the corporation to take an action to which the shareholders object (e.g., raising prices, declining to utilize solar energy, etc.), a court might require the directors to reconsider their decision before allowing the corporation to proceed with the implementation of such a decision. Even though this private right of action is available only to directors and shareholders in the absence of a designation in the benefit corporation's articles, the presence of a broader range of stakeholders leaves open interesting questions about the ability of a benefit corporation to grant the right to bring such actions to third-party beneficiaries, such as patients and patient groups.²⁵⁰

For social purpose corporations, the available remedy is less clear. California, for instance, allows traditional shareholder derivative actions in the name of the social purpose corporation against a director or directors, but because monetary damages are not available (except for bad faith, intentional

²⁴⁸ MODEL BENEFIT CORPORATION LEGISLATION, *supra* note 231, § 305.

²⁴⁹ See, e.g., Carl J. Dahlman, *The Problem of Externality*, 22 J.L. & ECON. 141, 141–42 (1979) (highlighting the issue of transaction costs). Several other articles provide an excellent discussion of whether and how damages might be assessed in the hybrid corporation context for failure to pursue or achieve a non-pecuniary purpose. See John Tyler et al., *Producing Better Mileage: Advancing the Design and Usefulness of Hybrid Vehicles for Social Business Ventures*, 33 QUINNIAC L. REV. 235, 256 (2015) (“[C]auses of action and remedies to enforce the contracted duties depend on what is available under breach of contract, which requires that the plaintiff prove damages that are normally described in terms of financial loss.”); Kyle Westaway & Dirk Sampselle, *The Benefit Corporation: An Economic Analysis with Recommendations to Courts, Boards, and Legislatures*, 62 EMORY L.J. 999, 1064–71 (2013) (concluding that the benefit corporation statutes of New York and Maryland theoretically allow monetary damages against directors for failure to consider the corporation's social or environmental purpose, but also concluding that it is unclear how, under current law, the harm so caused by such failure could be economically determined, quantified, and remedied).

²⁵⁰ See CAL. CORP. CODE ANN. § 14620(h) (West 2017) (“[T]he liability of a director for monetary damages may be eliminated or limited in a benefit corporation's articles to the extent provided in paragraph (10) of subdivision (a) of Section 204.”).

misconduct, or conflicting interest transactions), presumably only injunctive relief is available. Such injunctive relief is likely to be similar to that allowed in benefit enforcement proceedings in the benefit corporation context.

d. Annual Reports

Most relevant state statutes require benefit corporations to produce annual written reports concerning their performance, which may or may not be public, depending upon the state.²⁵¹ Such annual reports are meant to provide a mechanism for analyzing a benefit corporation's progress in achieving its public benefit(s). In some states, the reports must assess the corporation's performance against independent, third-party standards designed to measure "general public benefit," while in other states, reports must assess a corporation's performance against standards adopted by its board of directors.²⁵² Where the reports must be based upon independent, third-party standards, B Lab is the leading publisher of such standards. The B Lab standards require reporting on five broad categories: environment, workers, community, customers, and governance.²⁵³ Similarly, while social purpose corporations are also typically required to report on their progress towards achieving their specific social purpose, the reporting requirements are generally less comprehensive than those for benefit corporations.²⁵⁴ For a healthcare benefit corporation, the reporting requirement could extend to include health-specific reporting requirements, analogous to the 501(r) requirements for tax exempt hospitals to conduct and post their community health assessments. These healthcare reporting requirements could also be used for comparative performance analysis of healthcare companies.

e. Further Limitations on Ability to Deviate from Benefit Form or Purpose

Benefit corporations provide directors with the ability to take into account factors other than price even when deciding whether and to whom to sell the

²⁵¹ See, e.g., KAN. STAT. ANN. § 17-72a06(b) (West 2017); VA. CODE ANN. § 13.1-791 (West 2011); W. VA. CODE ANN. § 31F-5-501 (West 2014).

²⁵² Compare KAN. STAT. ANN. § 17-72a06(d), (f) (relying on a third-party certification), with NEV. REV. STAT. ANN. § 78B.180 (West 2014) (requiring an annual benefit report stating whether the corporation failed to meet any specific benefit "identified in the articles of incorporation").

²⁵³ *Impact Areas: Governance, Workers, Community, Environment and Customers*, B-LAB, <https://b-lab.uservoice.com/knowledgebase/articles/864318-impact-areas-governance-workers-community-envi> [<https://perma.cc/P7V6-BCHN>].

²⁵⁴ See Brad Edmondson, *Social Purpose vs. Benefit Corporations: Small Distinction, Big Difference*, TRIPLEPUNDIT (Mar. 1, 2016), <http://www.triplepundit.com/2016/03/social-purpose-vs-benefit-corporations-small-distinction-big-difference/> [<https://perma.cc/KC7Y-QWWR>] ("Although [a social purpose corporation] requires their directors to consider these social purposes when making management decisions and to issue an annual social report, it does not require them to consider their environmental impacts, hire an auditor or release the report to the public.").

company.²⁵⁵ Moreover, relinquishing benefit corporation status prior to or in connection with a sale or other major transaction usually requires a higher than normal shareholder vote, as do material changes to the corporation's charter, including changes to its purpose and form.²⁵⁶

B. An Argument for Mandating Hybrid Business Forms in Healthcare Markets

Incorporating general and specific benefits into corporate decision-making offers a promising way of reconciling conflicts between private profit driven interests and public need. As discussed in Part II, healthcare markets have special features that result in a divergence of private incentives from public health value. Yet, the same special features that make healthcare markets unique (and uniquely troubled), also make them an ideal site for hybrid entities such as benefit corporations and special purpose corporations. As discussed above, benefit corporations have special governance features that allow for a balanced consideration of shareholder value and the healthcare benefit corporation's stated public objectives. These governance features include: (1) annual reporting and assessment against objective standards of progress toward achieving the benefit corporation's non-pecuniary purpose; (2) the ability of directors and shareholders to sue the corporation for failure to pursue its non-pecuniary purpose; and (3) higher shareholder voting thresholds for altering the non-pecuniary purpose or converting the corporation (via reincorporation, merger, sale of assets, etc.) from benefit status to a regular corporation. Most importantly, adopting a hybrid form involves, or at least should involve, explicitly recognizing that the identified social mission is a part of the corporate mission and therefore, informs all decisions. This can be distinguished from most forms of corporate social responsibility, which are essentially tangential to corporate decisions.²⁵⁷ These beneficial features would allow for a positive change in corporate decision-making by changing incentives to address public

²⁵⁵ See Mark A. Underberg, *Benefit Corporations vs. "Regular" Corporations: A Harmful Dichotomy*, HARV. L. SCH. F. ON CORP. GOVERNANCE & FIN. REGULATION (May 13, 2012), <https://corp.gov.law.harvard.edu/2012/05/13/benefit-corporations-vs-regular-corporations-a-harmful-dichotomy/> [<https://perma.cc/X6NL-3HCK>] (recommending that state benefit corporation statutes allow directors to consider factors other than price when analyzing takeover offers).

²⁵⁶ See, e.g., MODEL BENEFIT CORPORATION LEGISLATION, *supra* note 231, § 105(b) (stating that any sale shall not be effective unless the transaction is approved by two-thirds vote, and further stating that an amendment to remove the status of the corporation must be approved by two-thirds vote). Shareholders who dissent from major changes in the benefit corporation's purpose can bring appraisal rights claims. See CAL. CORP. CODE ANN. § 14603(a) (West 2012); MASS. GEN. LAWS ch. 156E, § 5 (2012); S.C. CODE ANN § 33-38-600 (West 2012).

²⁵⁷ See BAKAN, *supra* note 19, at 34–35, 37 (detailing how the corporate model dissuades directors from being socially responsible).

needs from the inside. We therefore argue that healthcare companies should be required or, at the very least, strongly incentivized to incorporate or re-incorporate as benefit corporations and social purpose corporations (for simplicity, benefit corporations).

This approach has many potential advantages. The main advantage of requiring, or incentivizing, healthcare companies to incorporate as benefit corporations is in giving them the ability, and the mandate, to internalize public health concerns and incorporate such concerns into the company's decision-making. As explained earlier, for a benefit corporation, shareholder value need not be the ultimate test of success. Replacing traditional corporations with benefit corporations would modify the metrics on which corporate decisions are based to include broader public health measures. Although profitability (and therefore, financial sustainability) would still be a concern, the addition of other required considerations would cause companies to consider a broader range of choices and weigh a broader range of consequences. Concern about stock price would be tempered with concerns about meeting the social objectives of the corporation. Similarly, manager performance—and hence compensation—could be measured by accomplishment of a social mission as well as profitability. Directors and managers would fulfill their fiduciary duties guided by both mission and profitability rather than profitability alone, while being sheltered from the threat of personal liability for doing so.

To see how this ability, and mandate, might have a positive public health impact, suppose, for example, that a company that produces a drug used to mitigate the symptoms that certain patients with Alzheimer's disease experience is facing two kinds of decisions—one about whether to increase the price of its existing drug in light of limited competition, and a second decision about whether to invest in a low risk improvement of this drug rather than to make a bigger investment in a much riskier new drug candidate that has the potential to cure the disease. A for-profit corporation will likely increase the price to maximize profits, taking into account only the likely impact on demand and constraints on price imposed by payors, if any. This same company will consider the expected risk-adjusted profits from investing in each drug project and, given the high risk, will likely choose the safer project. A benefit corporation that has included the pursuit of public health as one of its objectives, alongside profit, will pay attention to the negative health impact of a price increase and be less likely to raise prices. This same benefit corporation will include the significant public health benefit of the second project and the nominal public health benefit of the first project in its cost-benefit calculations and will be more likely to select the second project.

Second, as benefit corporations, healthcare companies would be required to report on their decisions—in many cases publicly—thus making such decisions available for scrutiny by patient advocacy groups, other healthcare stake-

holders, and shareholders alike. This reporting requirement would increase transparency on important corporate decisions such as what R&D projects to pursue, what prices to charge for products and services, what research data to make publicly available, and what approach to take in the face of competition. Much of the policy discussion over drug pricing has focused on price transparency, and this reporting requirement will facilitate the desired increase in transparency and thus allow for easier monitoring of corporate decisions.

Third, like traditional corporations, shareholders of a healthcare benefit corporation would remain the primary watchdogs of corporate behavior. Yet, as benefit corporations, healthcare companies are likely to attract at least some investors interested in social impact. Hence, unlike in traditional corporations, corporate watchdogs would now likely include shareholders who seek social objectives alongside private wealth creation. The effectiveness of this approach will depend on the nature and strength of the mechanisms that shareholders have available for measuring social impact and enforcing the public interest. Current mechanisms are likely too weak to overcome the natural tendency towards profit maximization, but future mechanisms—instituted alongside corporate governance reforms such as the one proposed in this Article—could allow for a more active stakeholder role in policing the public interest.

Fourth, changing the corporate form of healthcare companies to benefit corporations would introduce new and potentially more effective ways of regulating firm behavior. Current benefit corporations statutes mandate a variety of means of checking firm behavior, including the requirement to appoint benefit directors to the board and the institution of mechanisms for allowing shareholders to address corporate deviations from stated public benefits.²⁵⁸ Even though experience with such enforcement mechanisms is limited due to the newness of hybrid corporate forms, they would provide potentially effective tools to check corporate behavior “from the inside.” Addressing problems from the inside could also reduce the problem of regulatory capture that pervades many aspects of the healthcare industry.

The resulting aggregate effect of the potential advantages described above is likely to be a narrowing of the gap between private incentives of healthcare corporations and public health need. Finally, to ensure that the changes are enduring, healthcare companies that are benefit corporations will have the ability to include restrictions on amending corporate purpose, on unilaterally converting to traditional corporate form, and on acquisition of hybrid corporations by traditional corporations.

There are strong reasons for targeting the corporate form as a means of affecting change in healthcare. Primary among them is the ability to harness the

²⁵⁸ See *supra* notes 236–256 and accompanying text.

private information and private decision making of companies to achieve public goals. Companies are both the best source of and in the best position to evaluate information about their cost structures, assets, and opportunities, and the trade-offs involved in alternative decisions. Further, even under the strictest public reporting requirements, companies still make many decisions that are not visible to the market and would be difficult or impossible to regulate externally (e.g., whether to terminate an R&D program for a promising drug with low market value or how to price their products and services).

We also suggest that at least in some cases, benefit corporations offer advantages over non-profit corporations. Despite stated good intentions, non-profit corporations often suffer from a lack of market discipline—an undeniably strong driver for innovation and economic efficiencies—and effective monitoring of their performance.²⁵⁹ In addition, non-profit organizations are not immune to the role of profit, although it is not considered profit. They care about the magnitude of their revenues and their ability to increase spending, they have flexibility in determining whether their actions are in furtherance of their mission, and their executives are compensated in ways that are increasingly similar to the compensation of for-profit executives.²⁶⁰ Benefit corporations, on the other hand, lack neither market discipline nor monitoring of performance. Equity (via shares) creates accountability to shareholders, and if accomplishment of a social mission was to become an integral part of healthcare corporations, accountability for pursuing such missions would follow. In addition, the availability of financing and risk capital may well be the same as with tradi-

²⁵⁹ Although regulated by the IRS and state AGs, nonprofit corporations often lack direct and effective oversight. See Terry L. Corbett, *Healthcare Corporate Structure and the ACA: A Need for Mission Primacy Through a New Organizational Paradigm?*, 12 IND. HEALTH L. REV. 103, 126–30 (2015) (summarizing studies of the performance of non-profit hospitals and finding mixed results, including findings that suggest little difference between for-profits and non-profits in their concern for public benefit and expressing various concerns about the performance of non-profit hospitals).

²⁶⁰ See, e.g., Karen E. Joynt et al., *Compensation of Chief Executive Officers at Non-Profit Hospitals*, 174 JAMA INTERNAL MED. 61, 61 (2014), <https://www.ncbi.nlm.nih.gov/pubmed/24126743> [<https://perma.cc/5C3L-MPFY>] (analyzing hospital CEOs' compensation models and whether they are tied to quality healthcare outcomes); Elizabeth K. Keating & Peter Frumkin, *What Drives Non-profit Executive Compensation?*, NONPROFIT Q. (Oct. 6, 2017), <https://nonprofitquarterly.org/2017/10/06/what-drives-nonprofit-executive-compensation/> [<https://perma.cc/GT3G-LKTR>] (showing some similarities in factors that influence executive compensation); see also Salvador Curiel, *Are For-Profit Salaries Higher than Nonprofit Salaries?*, CTR FOR NON-PROFIT MGMT. NEWSLETTER, <https://cnmsocial.org/featured/are-for-profit-salaries-always-higher-than-nonprofit-salaries/> [<https://perma.cc/M3P4-MDWE>] (reporting some non-profit hospital salaries to be higher than for-profit); Andrea Fuller, *Charity Officials Are Increasingly Receiving Million-Dollar Paydays*, WALL ST J., (Mar. 6, 2017), <https://www.wsj.com/articles/charity-officials-are-increasingly-receiving-million-dollar-pay-days-1488754532> [<http://perma.cc/W2R7-DBBX>] (documenting the rise in number of people receiving seven-figure compensation packages at the non-profit level).

tional for-profit corporations—not limited to debt-financing as in the nonprofit sector.

There are, of course, some significant risks and limitations with our proposed approach, but we believe these can be surmounted or at least managed with appropriate regulatory support. The main concerns with relying on benefit corporations (in their current statutory forms) as a mechanism for improving healthcare outcomes include: (1) adequate enforcement of the duty of the benefit corporation to pursue and protect non-shareholder interests; (2) measuring and balancing non-shareholder interests against shareholder interests in maximizing company value; and (3) concerns about the ability of benefit corporations to attract the investment needed to pursue ambitious healthcare projects.

Starting with the question of enforcement: having a duty to pursue non-shareholder interests will result in change in healthcare outcomes only if, and to the extent that, company decision-makers are (1) motivated to pursue such interests and (2) face negative consequences when failing to do so. A mechanism for addressing this challenge is the “benefit enforcement proceeding” instituted under many state statutes, which gives shareholders and dissenting directors the ability to seek remedies for breaches of the benefit corporation’s public benefit duties.²⁶¹

The challenge of finding good measures of public benefit is especially pertinent in the context of healthcare. Indeed, measuring the value of healthcare has plagued many types of healthcare reforms, including more recent efforts to shift to value-based models of healthcare provision.²⁶² Such efforts have nonetheless led to improved methods of quantifying healthcare value that can also be deployed for measuring the performance of healthcare benefit corporations. Even where measures of value are most challenging, there remain clear decisions that have no positive effect on the public interest, such as gratuitous price increases or decisions to hide information about adverse effects of a healthcare product, that can be addressed.

The remaining challenge of attracting adequate investment to pursue healthcare innovation and finance healthcare production may be the most concerning. One of the weaknesses of the non-profit model is the inability to harness private sector investment, and although in theory benefit corporations do

²⁶¹ Ian Kanig, Note, *Sustainable Capitalism Through the Benefit Corporation: Enforcing the Procedural Duty of Consideration to Protect Non-Shareholder Interests*, 64 HASTINGS L.J. 863, 871–72 (2012).

²⁶² See, e.g., *Six Serious Problems with “Value-Based” Purchasing and How to Solve Them*, MICH. HEALTH POLICY F., <http://michiganhpf.msu.edu/index.php/2-uncategorised/28-six-serious-problems-with-value-based-purchasing> [<https://perma.cc/RW45-ZE2V>] (discussing the difficulty Medicare faces in assigning retrospective accountability to medical providers using value-based purchasing decisions).

not suffer from this limitation since they are free to raise funds by selling equity, they might in practice be less attractive for private investors than traditional for-profit corporations. There are reasons to believe that this challenge can be overcome, however. First, the healthcare sector offers many opportunities for profit, and if most or all of healthcare companies were required or sufficiently incentivized to be (or become) benefit corporations, investors who wanted to access the profits in this sector would have no choice but to invest in benefit corporations. Second, there has been a rise in socially conscious investing, with a particular focus on health. And third, benefit corporations might offer useful vehicles for the pooling of public and private funds, with public funding justified on the grounds of supporting public goods and addressing externalities. With the expectation of favorable treatment by the public, and possibly also philanthropic funders, private investors may well be willing to invest despite the additional restrictions imposed on benefit corporations.

*C. Proposed Approach: Making HealthCare Companies
(Re)Incorporate as Benefit Corporations*

The change in the business form of healthcare corporations that we propose is, admittedly, not easy to accomplish. Yet, for the reasons discussed in this Article, we believe this change is not only warranted but necessary to address the disconnect between corporate decision making and public health needs. Determining how to begin such a shift in approach in healthcare markets is challenging. Since the first benefit corporations law was passed in Maryland in 2010, a number of businesses have become benefit corporations.²⁶³ Although relatively few are in the healthcare market, early examples are promising.²⁶⁴ In order to reap the benefits of the proposed approach for healthcare markets, however, healthcare companies must either be required or strongly incentivized to adopt a hybrid form. Anything short of a comprehensive shift in healthcare corporate form is likely to place healthcare benefit corporations at a significant competitive disadvantage in relation to the profit-driven corporations that currently occupy healthcare markets.

²⁶³ Well-known examples of benefit corporations include Kickstarter, Patagonia, and Laureate Education. *General Questions*, *supra* note 245.

²⁶⁴ One such notable example is HomeCare Associates (“HCA”) of Philadelphia, which demonstrates how the approach proposed here might work to improve performance in the healthcare industry without direct government intervention. HCA has focused on tackling the competing objectives of quality homecare at low costs while also improving training and providing higher compensation for homecare workers. *Why Home Care Workers Struggle with Low Wages*, PBS NEWSHOUR (Mar. 16, 2015), <http://www.pbs.org/newshour/bb/home-health-care-workers-struggle-low-wages/> [<https://perma.cc/55BA-4RV4>].

One possible course of action would be for states to require companies operating in certain sectors pertaining to healthcare to incorporate or restructure themselves as hybrid organizations. We suggest that this requirement should apply broadly to all providers of healthcare products and services, including not just pharmaceutical and medical device companies but also healthcare maintenance organizations, pharmacy benefit management companies, healthcare services such as nursing homes, home health, and health staffing companies. This approach, while having the potential to be effective, however, is bound to raise numerous legal and practical challenges, most notably the need for a critical mass of states to act in unison to avoid forum shopping by healthcare corporations.

Alternatively, and perhaps preferably, states and the federal government could provide incentives for certain critical sectors of healthcare businesses to incorporate or restructure themselves as hybrid entities. First, property and other taxes, licensing requirements, and regulatory provisions normally imposed upon healthcare corporations could be decreased or eliminated for hybrid organizations. Second, federal and state laws could be used to provide legal, regulatory, tax, and other incentives for the incorporation of certain healthcare businesses as benefit corporations. FDA laws could, for example, grant “fast-track” approval or even additional exclusivity periods for biomedical products developed by benefit corporations; tax laws could impose lower tax rates on them; federal and state laws could provide preferential treatment in dealing with benefit corporations under state Medicare and Medicaid programs, and so forth.²⁶⁵

Perhaps the most important condition for success of this proposal will be the ability to hold healthcare benefit corporations accountable for acting in ways consistent with their public purpose. We believe that this will require stronger oversight mechanisms than those existing under current state laws. If the directors and shareholders are disingenuous about advancing the non-pecuniary purpose of the healthcare benefit corporation, for example, there is very little or no recourse at all available to the public or consumers.²⁶⁶ To address this concern, we propose that the Federal Trade Commission, with its roots in the protection of the consumer and the public, or some other similar government or state agency,

²⁶⁵ See Eiser & Field, *supra* note 23, at 651–52 (proposing that Congress should give benefit corporations preferred treatment when seeking partners for NIH Cooperative Research and Development Agreements).

²⁶⁶ Third parties have no right of action against a corporation, benefit or not. See Haig Panossian, *Workers vs. Shareholders Under United States Corporate Law: Reforming Corporate Fiduciary Law to Protect Worker Interests*, 10 U. PA. J.L. & SOC. CHANGE 81, 106 (2007) (stating that even when state statutes allow corporations to consider the interests of non-shareholder constituencies, the statutes “do not give the non-shareholder constituencies a private right of action with which to seek recourse when their interests are not considered”).

be granted the right to sue benefit corporations for failure to pursue their non-pecuniary purpose. This right may be mandated by law or explicitly included in healthcare benefit corporations' articles of incorporation. In case of the latter, healthcare benefit corporations could be incentivized to include such voluntary submission to regulation by making it a pre-requisite for entitlement to one or more governmental benefits such as those enumerated above.

CONCLUSION

In this Article we have argued that the disconnect between healthcare market outcomes and public health needs can be traced to a divergence between the private incentives that for-profit healthcare companies face in healthcare markets and the public health benefit of their actions. Our proposal is to change these incentives "from the inside" by making healthcare companies (re)incorporate in hybrid corporate forms. We suggest that given the current state of the law, benefit corporations offer an attractive form for healthcare corporations since they require the pursuit of both profit and non-pecuniary objectives. If a healthcare company incorporates (or reincorporates) as a benefit corporation with advancing public health as the non-pecuniary purpose, its directors would be required to cause the corporation to advance public health, even at the expense of some decline in revenue for the corporation. This is not to say that profits will no longer inform healthcare (benefit) corporations' decisions, but rather that profit considerations will represent part of a balance of interests among shareholder and non-shareholder stakeholders in corporate decision-making. In short: profitability will no longer be the sole measure of a healthcare corporation's success, opening up opportunities for incorporating public health directly into corporate decision making. Although hybrids are still a relatively new phenomenon in corporate law, we conclude that they have the potential to mitigate at least some of the problems with the current incentive structure faced by healthcare corporations, and thus to improve the ability of our healthcare system to meet public health needs.

APPENDIX

Social Enterprise Entity Comparison Chart Jan. 14, 2018

States with Types of “Social Enterprise” Entities	Benefit Corporation Legislation	Social Purpose Corporation Legislation	Low-Profit Limited Liability Company (“L3C”) Legislation
Arizona	ARIZ. REV. STAT. ANN. § 10-2401-2442 (2015).		
Arkansas	ARK. CODE ANN. § 4-36-101 to -401 (2013).		
California	CAL. CORP. CODE §§14600–14631 (2013).		
Colorado	COLO. REV. STAT. ANN. §§ 7-101-501 to -511 & 7-113-102 (West 2014).	CAL. CORP. CODE §§ 2500–3503 (2013). S.B. 1301 CAL. LAWS (effective Jan. 1, 2015) changed the name from “flexible purpose corporation” to “social purpose corporation.”	
Connecticut	2014 Conn. Acts 217 §§ 140–154 (Reg. Sess.).		
D.C.	D.C. CODE §§ 29-1301.01 to -1304.01 (2013).		
Delaware	DEL. CODE ANN. tit. 8, §§ 361–368 (2013).		
Florida	FLA. STAT. §§ 607.601 - .613 (2014).	FLA. STAT. ANN. §§ 607.501–.513 (2014).	
Hawaii	HAW. REV. STAT. §§ 420D-1 to -13 (2013).		
Idaho	IDAHO CODE §§ 30-2001 to -2013 (2015).		
Illinois	805 ILL. COMP. STAT. 40/1-5.01 (2013).		805 ILL. COMP. STAT. 180/1-26 (2013).
Indiana	IND. CODE §§ 23-1.3-1 to -10 (2015).		

States with Types of “Social Enterprise” Entities	Benefit Corporation Legislation	Social Purpose Corporation Legislation	Low-Profit Limited Liability Company (“L3C”) Legislation
Kansas	KAN. STAT. ANN. §§ 17-72a01 to -72a09.		
Kentucky	2017 Ky. Acts 28, Ky. H.B. 35 (2017).		
Louisiana	LA. REV. STAT. ANN. §§12:1801–1832 (2013).		LA. REV. STAT. ANN. § 12:1302.C (2013).
Maine			ME. REV. STAT. tit. 31, § 1611 (2013).
Maryland	MD. CODE ANN., CORPS. & ASS’NS §§ 5-6C-01 to -08 (2013).		
Massachusetts	MASS. GEN. LAWS ch. 156E, §§ 1–16 (2013).		
Michigan			MICH. COMP. LAWS § 450.4204 (2013).
Minnesota	2014 MINN. LAWS ch. 172, 1–11 (2015).		
Montana	MONT. CODE ANN. §§ 35-1-101 to -112 (2015).		
Nebraska	NEB. REV. STAT. §§ 21-401 to -414 (2014).		
Nevada	NEV. REV. STAT. §§ 78B.010–.090 (2014).		
New Hampshire	N.H. REV. STAT. ANN. § 293-C (2015).		
New Jersey	N.J. STAT. ANN. §§ 14A:18-1 to -11 (West 2013).		
New York	N.Y. BUS. CORP. LAW §§ 1701–1709 (McKinney 2013).		
Oregon	OR. REV. STAT. §§ 60.750 to .770 (2014).		
Pennsylvania	15 PA. CONS. STAT. §§ 3301–3305 (2013).		

States with Types of “Social Enterprise” Entities	Benefit Corporation Legislation	Social Purpose Corporation Legislation	Low-Profit Limited Liability Company (“L3C”) Legislation
Rhode Island	7 R.I. GEN. LAWS §§ 5.3-1 to -13 (West 2013).		R.I. GEN. LAWS § 7-16-76 (2013).
South Carolina	S.C. CODE ANN. §§ 33-38-110 to -600 (2013).		
Tennessee	TENN. CODE ANN. §§ 48-28-101 to 402 (2016).		
Texas	TEX. BUS. ORGS. CODE §§ 3.007(d); 21.951–959 (2017).	TEX. BUS. ORGS. CODE §§ 1.002(82-A); 3.007; 21.101; 21.401 (2013).	
Utah	UTAH CODE ANN. §§ 16-10B-101 to -106 (West 2014).		UTAH CODE ANN. § 48-2C-412 (2013)].
Vermont	VT. STAT. ANN. tit. 11, §§ 21.01 to .14 (2013).		VT. STAT. ANN. tit. 11, § 3001(27) (2013).
Virginia	VA. CODE ANN. §§ 13.1-782 to -800 (2013).		
Washington		WASH. REV. CODE §§ 23B.25.005 to 23B.25.150 (2013).	
West Virginia	W. VA. CODE §§ 31F-1-101 to -501 (2014).		
Wyoming			WYO. STAT. ANN. § 17-29-102(a)(ix) (2013).
Intended Purpose of Each Types of Legislation:	Generally, any lawful “general public benefit,” meaning “a material positive impact on society and the environment, taken as a whole, assessed against a third-party standard, from the business and opera-	Any lawful purpose, but tailored to advance environmental, employment, or more specified purposes. Any purpose that promotes positive effects or minimizes negative	Any lawful purpose, but specifically designed to attract program-related investments (“PRIs) and must be an instrumentality of wholly charitable pursuits even if the L3C itself is not a charity.

	tions of the benefit corporation.” Since 2013, however, many states have followed Delaware and Colorado’s lead by allowing “general” or “specific” benefit.	effects on employees, suppliers, customers, creditors, community or environment.	
Federal Income Tax Treatment of Entity	C corporation taxation: 15–35% corporate-level tax and generally 20% ⁱ + shareholder-level tax unless elect Subchapter S status in which case flow-through taxation applies.	C corporation taxation: 15–35% corporate-level tax and generally 20% ⁱⁱ + shareholder-level tax unless elect Subchapter S status in which case flow-through taxation applies.	NOT tax-exempt. Flow-through tax treatment (assuming no election of corporate tax treatment” under IRC § 7701).
Federal Income Tax Treatment of Distributions to Individual Owners	Subject to Subchapter S election, dividends taxed at 20%+. ⁱⁱⁱ	Subject to Subchapter S election, dividends taxed at 20%+. ^{iv}	Generally, distributable share of income or loss taxable to members based upon character of income.
Federal Income Tax Benefits (if any)	None.	None.	None.

ⁱ May be subject to new 3.8% Medicare surtax on net investment income.

ⁱⁱ *Id.*

ⁱⁱⁱ *Id.*

^{iv} *Id.*