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## A Corporate Duty to Rescue: Biopharmaceutical Companies and Access to Medications

Rebecca E. Wolitz

Stanford Center for Law and the Biosciences, [rwolitz@law.stanford.edu](mailto:rwolitz@law.stanford.edu)

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## A CORPORATE DUTY TO RESCUE: BIOPHARMACEUTICAL COMPANIES AND ACCESS TO MEDICATIONS

REBECCA E. WOLITZ\*

*Controversies regarding the pricing of biopharmaceutical products are pervasive. Patients must choose between treatment and rent, prescriptions go unfilled, and health systems are forced to restrict access to life-saving medications—all because of cost. Though there is often consensus that these issues are problematic, there is disagreement as to what are appropriate solutions and who has responsibility to bring about those solutions. Most efforts to address biopharmaceutical pricing concerns focus on governmental regulation. This Article has a different focus. It provides a legal and normative analysis of a form of corporate self-regulation that could help address access and pricing concerns—a moral “corporate duty to rescue” (CDTR). Scholars in health law, business ethics, and bioethics have proposed that a CDTR applies to biopharmaceutical companies regarding access to their products. Rescue efforts are conceived as including product donations, price reductions, or tinkering with intellectual property management. This Article advances three primary arguments. First, analyzing pertinent law and principles, it argues that corporate managers and directors have the legal discretion to discharge a CDTR. Second, while there is legal discretion to discharge a CDTR, this Article argues that it is unclear what this moral duty demands of biopharmaceutical companies. Its application to the drug pricing and access context is not straightforward, morally speaking. Third, this Article argues that focus on a CDTR in the biopharmaceutical context, in some instances, may be misplaced. A duty to rescue allocates responsibility for rescue on the basis of who can help now and not on the basis of who has historically done what. Yet, wronging others generates significant reasons for the mitigation of that wrong to be the wrongdoer’s special moral responsibility. If there is culpable conduct, focus on a CDTR will fail to hold companies accountable, thereby obfuscating morally problematic corporate conduct. As access and pricing problems are at root normative, this Article contributes to larger debates both about what drug manufacturers owe patients regarding product access as well as what sorts of self-regulatory changes they justifiably could be urged to implement.*

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\* Fellow, Center for Law and the Biosciences, Stanford Law School; J.D., Yale Law School; M.Phil., Philosophy, Yale Graduate School; B.A., Rutgers University. For their time and comments—in some instances on multiple drafts—my sincere thanks to Steve Darwall, Abbe Gluck, Hank Greely, Joan MacLeod Heminway, Cathy Hwang, Shelly Kagan, Amy Kapczynski, Ted Lechterman, Wendy Lipworth, Daniel Markovits, Michelle Mello, Amy Motomura, Shmulik Nili, Lisa Larrimore Ouellette, Govind Persad, W. Nicholson Price II, Alix Rogers, Rachel Sachs, Jake Sherkow, Larry Temkin, Spencer Williams, Andrew Winden, and Patti Zettler. This Article also benefited from in-person conversations with Robert Daines, G. Marcus Cole, George Triantis as well as feedback at the Business and Human Rights Young Researchers Summit at the University of St. Gallen and the Regulation and Innovation in the Biosciences Workshop at Michigan Law School.

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## INTRODUCTION

Controversies regarding the pricing of prescription medications are pervasive. Cross-cutting jurisdictional boundaries and disease types, the purportedly high cost and unaffordability of medications dominate the news cycle.<sup>1</sup> Pricing controversies have been of particular recent prominence in the United States. Patients are forced to choose between treatment and rent,<sup>2</sup> prescriptions go unfilled,<sup>3</sup> and health systems restrict access to life-saving medications<sup>4</sup>—all because of cost. Individuals like Martin Shkreli and companies like Gilead Sciences, Inc., have become notable names. The former became infamous for dramatically raising the price of a decades-old lifesaving medication,<sup>5</sup> the latter for launching a series of innovative hepatitis C

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1. See, e.g., U.S. SENATE SPECIAL COMM. ON AGING, SUDDEN PRICE SPIKES IN OFF-PATENT PRESCRIPTION DRUGS: THE MONOPOLY BUSINESS MODEL THAT HARMS PATIENTS, TAXPAYERS, AND THE U.S. HEALTH CARE SYSTEM 7 (2016) [hereinafter SENATE COMMITTEE ON AGING REPORT] (describing price-gouging practices utilized for off-patent therapies); STAFF OF S. COMM. ON FIN., 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTHCARE SYSTEM (Comm. Print 2015) [hereinafter SENATE FINANCE REPORT] (discussing pricing of treatments for the hepatitis C virus (HCV) and impact on ability to treat those affected); ELLEN 'T HOEN, OXFAM INT'L, ACCESS TO CANCER TREATMENT: A STUDY OF MEDICINE PRICING ISSUES WITH RECOMMENDATIONS FOR IMPROVING ACCESS TO CANCER MEDICATION (2015), <http://policy-practice.oxfam.org.uk/publications/access-to-cancer-treatment-a-study-of-medicine-pricing-issues-with-recommendati-344070> [<https://perma.cc/MP6C-KVW3>] (noting access and pricing issues worldwide with cancer therapies); Lisa L. Gill, *How to Pay Less for Your Meds*, CONSUMER REP. (Apr. 5, 2018), <https://www.consumerreports.org/drug-prices/how-to-pay-less-for-your-meds> [<https://perma.cc/CS9S-SMPD>]; Ed Silverman, *Italy Proposes the WHO Set International Standards for Drug-Pricing Transparency*, STAT (Feb. 14, 2019), <https://www.statnews.com/pharmalot/2019/02/14/italy-who-drug-prices-transparency> [<https://perma.cc/JV8K-R7ZG>].

2. Ann Killion, *Season of Sharing: A Cancer Patient Finds Joy*, S.F. CHRON. (Dec. 9, 2017, 1:55 PM), <http://www.sfchronicle.com/bayarea/article/Season-of-Sharing-A-cancer-patient-finds-joy-12418126.php> [<https://perma.cc/V6FK-DQFY>].

3. NAT'L ACADS. OF SCIS., ENG'G & MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 99 (Norman R. Augustine, Guru Madhavan & Sharyl J. Nass eds., 2018) (ebook) [hereinafter MAKING MEDICINES AFFORDABLE REPORT], <https://www.nap.edu/catalog/24946/making-medicines-affordable-a-national-imperative> [<https://perma.cc/CH8D-DZXX>]; see also SARA R. COLLINS, PETRA W. RASMUSSEN, MICHELLE M. DOTY & SOPHIE BEUTEL, THE COMMONWEALTH FUND, THE RISE IN HEALTH CARE COVERAGE AND AFFORDABILITY SINCE HEALTH REFORM TOOK EFFECT 4 (2015), [http://www.commonwealthfund.org/~media/files/publications/issue-brief/2015/jan/1800\\_collins\\_biennial\\_survey\\_brief.pdf](http://www.commonwealthfund.org/~media/files/publications/issue-brief/2015/jan/1800_collins_biennial_survey_brief.pdf) [<https://perma.cc/QV6C-4N9M>] (noting, however, the number of unfilled prescriptions due to cost is down from twenty-seven percent in 2012 due to the increased number of Americans with insurance coverage).

4. See, e.g., Ed Silverman, *State Medicaid Programs Continue to Restrict Access to Hepatitis C Drugs*, STAT (Nov. 14, 2016), <https://www.statnews.com/pharmalot/2016/11/14/medicaid-hepatitis-gilead> [<https://perma.cc/4D9W-K79T>].

5. SENATE COMMITTEE ON AGING REPORT, *supra* note 1, at 32–41 (describing Turing Pharmaceutical's pricing of Daraprim which Martin Shkreli oversaw).

therapies at prohibitively expensive prices.<sup>6</sup> New examples of drug pricing controversies appear seemingly every day.<sup>7</sup>

Prescription drug costs have been called “the hardest” problem in health policy.<sup>8</sup> While there is often consensus that these issues are problematic, there is significant disagreement as to *what* are appropriate solutions and *who* has responsibility to bring about those solutions. With some exceptions,<sup>9</sup> nearly all current efforts to address the purportedly high costs and unaffordability of prescription medications focus on governmental regulation. At the federal level, for instance, President Trump released a “Blueprint to Lower Drug Prices” which includes the Food and Drug Administration (FDA) taking steps to close legal loopholes and address anticompetitive industry practices.<sup>10</sup> At the state level, efforts include price regulation,<sup>11</sup> regulation of the biopharmaceutical industry’s disclosure of pricing

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6. See generally SENATE FINANCE REPORT, *supra* note 1 (investigating Gilead’s pricing of its, at the time, new HCV medications).

7. See, e.g., Adam Feuerstein, *A New Parkinson’s Drug Is a Long-Acting Version of a Cheap Generic. Should It Cost \$30,000 a Year?*, STAT (Aug. 25, 2017), <https://www.statnews.com/2017/08/25/adamas-parkinsons-pricing> [<https://perma.cc/YR88-ZZ9R>] (describing controversy surrounding Gocovri, a “new” Parkinson’s drug that may not be all that new); Damian Garde, *Pioneering Cancer Drug, Just Approved, to Cost \$475,000—and Analysts Say It’s a Bargain*, STAT (Aug. 30, 2017), <https://www.statnews.com/2017/08/30/novartis-car-t-cancer-approved> [<https://perma.cc/3ATJ-4NX3>] (describing anticipated cost of Novartis’ new CAR-T therapy); Eric Sagonowsky, *Pfizer’s Prevnar 13 Set for Another Price Hike in 2018 as U.S. Price-Per-Dose Climbs Near \$180* (Nov. 28, 2017, 3:30 PM), FIERCEPHARMA, <https://www.fiercepharma.com/vaccines/pfizer-s-prevnar-13-set-for-another-price-hike-2018-as-u-s-price-per-dose-climbs-to-180> [<https://perma.cc/U2NQ-M9UA>] (noting additional price increases planned for Pfizer’s popular pneumococcal vaccine).

8. Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?*, 102 MINN. L. REV. 2273 (2018).

9. For instance, some companies have undertaken voluntary initiatives to limit annual price increases. See, e.g., Press Release, Allergan, Allergan PLC Board of Directors Issues Statement on Company’s Social Contract with Patients (Dec. 22, 2016), <https://www.allergan.com/news/news/thomson-reuters/allergan-plc-board-of-directors-issues-statement-o> [<https://perma.cc/R397-VT5B>]; *Our Social Contract with Patients*, ALLERGAN CEO BLOG (Sept. 6, 2016), <https://www.allergan.com/news/ceo-blog/september-2016/our-social-contract-with-patients> [<https://perma.cc/3HWN-TUKF>].

10. U.S. DEP’T OF HEALTH & HUMAN SERVS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS (2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> [<https://perma.cc/K593-VUES>]; see also Scott Gottlieb, *Reducing the Hurdles for Complex Generic Drug Development*, FDA (Oct. 2, 2017), <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612010.htm> [<https://perma.cc/VR2A-T5X2>].

11. *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018) (holding that Maryland’s generic price-gouging law violates the dormant commerce clause), *cert. denied*, 139 S. Ct. 1168 (2019); *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (invalidating the District of Columbia’s attempt to regulate the prices of patented medicines).

information, efforts to rein in costs through restrictions on payment,<sup>12</sup> and legislation to facilitate drug importation.<sup>13</sup>

Governmental regulation is an important tool for addressing the problem of costly prescription medications, but this Article has a different focus. Scholars in health law, business ethics, and bioethics have drawn on the widely discussed duty to rescue in the philosophical and legal literatures and proposed that biopharmaceutical companies are subject to a moral duty to rescue regarding access to their products.<sup>14</sup> For ease of exposition, this Article refers to the application of a moral duty to rescue to for-profit companies as a “corporate duty to rescue.”<sup>15</sup>

Proposals for a corporate duty to rescue (CDTR) stand in contrast to and complement governmental regulatory efforts. A CDTR, as applied in the biopharmaceutical context, states that biopharmaceutical companies have a *moral* obligation to increase access to medications. Rescue efforts are conceived as including in-kind donations to needy patients, reducing product prices, or tinkering with the management of a company’s intellectual property—for instance, by refraining from patent enforcement or engaging in licensing agreements. A CDTR offers a form of self-regulation. It is not a legal requirement. Rather, it presents a moral foundation for corporate management to comport itself in a manner that could help address biopharmaceutical access and pricing concerns.

The biopharmaceutical industry has a bad reputation.<sup>16</sup> It is frequently and consistently perceived as behaving unethically, and this perception specifically applies to issues of product access and pricing.<sup>17</sup> Yet, robust public perception aside, the morals of the matter are not obvious. What *are* the ethical obligations of biopharmaceutical companies regarding product access and pricing? Further, if there are obligations, are they compatible with existing legal frameworks?

As access and pricing problems are at root normative, getting increased clarity on these questions is a national imperative. And, while ethical analysis is important for

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12. Alan M. Kirschenbaum & David C. Gibbons, 2017: *A Banner Year for State Laws on Drug Pricing, Price Reporting, and Discounting*, FDA L. BLOG (Nov. 2, 2017), <http://www.fdalawblog.net/2017/11/2017-a-banner-year-for-state-laws-on-drug-pricing-price-reporting-and-discounting> [<https://perma.cc/L58F-UENJ>].

13. Ctr. for State Rx Drug Pricing, *Vermont First in the Nation to Approve Rx Drug Importation from Canada*, NASHP, <https://nashp.org/vermont-legislature-first-in-the-nation-to-approve-rx-drug-importation-from-canada> [<https://perma.cc/8LLB-5FK2>].

14. See *infra* note 20 (collecting citations). The term “biopharmaceutical” is used throughout this Article as a shorthand referring to both pharmaceuticals and biologics. Likewise, use of the term “companies” is intended in its generic sense and not as referring specifically to limited liability companies. The legal analysis provided in Section II.B specifically concerns corporations.

15. Others have used similar terminology. Cf. Julian Friedland, *Sustainability, Public Health, and the Corporate Duty to Assist*, 34 BUS. & PROF. ETHICS J. 215 (2015) (describing a corporate duty to assist); Kevin T. Jackson, *Global Distributive Justice and the Corporate Duty to Aid*, 12 J. BUS. ETHICS 547 (1993) (discussing a corporate duty to assist); Stepan Wood, *The Case for Leverage-Based Corporate Human Rights Responsibility*, 22 BUS. ETHICS Q. 63 (2012) (discussing corporations and the moral duty to rescue or aid).

16. Mark Kessel, *Restoring the Pharmaceutical Industry’s Reputation*, 32 NATURE BIOTECHNOLOGY 983 (2014).

17. *Id.*

crafting informed laws, given the often slow pace of regulatory change, it is also crucial for assessing potential mechanisms of reform operating outside of government action. This Article contributes to these larger conversations by analyzing and critiquing a set of proposals that occupy a corner of the ethical landscape. By critically examining a corporate duty to rescue, specifically in the biopharmaceutical context, this Article contributes to the debates both about what drug manufacturers might owe patients as well as what sorts of self-regulatory changes they justifiably could be urged to implement.

This Article makes three primary arguments. *First*, from a legal perspective, it analyzes applicable law and principles and argues that though a moral CDTR is unlikely to be enforceable as a tort, managers and directors do have the legal discretion to discharge this duty on behalf of a corporation. Such discretion is not only compatible with shareholder primacy theories of corporate governance, but discharging a CDTR will likely be protected by the business judgment rule. Further, some rescue efforts may even be costless or beneficial to biopharmaceutical corporations.

*Second*, while discharging a CDTR is legally permissible, this Article argues that a critical examination of this moral duty reveals that what it demands of biopharmaceutical companies is undertheorized. As presented by its proponents, a CDTR has an initial, intuitive attractiveness. Systematic evaluation, however, demonstrates that moving from the paradigm duty to rescue case involving a drowning child to the corporate context introduces numerous moral complexities and sources of disanalogy. Critical examination reveals that application of a duty to rescue to the biopharmaceutical drug pricing and access context is not straightforward, morally speaking.

*Third*, this Article argues that the CDTR is potentially vulnerable to a broader criticism. A duty to rescue either presumes no causal relationship or is agnostic about the relationship between the parties involved in a situation of rescue. By design, a moral duty to rescue allocates responsibility for rescue on the basis of who can help now and not on the basis of who has historically done what. Yet, wronging others generates significant reasons for the mitigation of that wrong to be the wrongdoer's special moral responsibility. Drug pricing and access controversies have different features. Contextual features in the biopharmaceutical case are often relevant. Thus, there may be cases where patients are impeded from accessing or unable to access medications because biopharmaceutical companies have behaved in ways that make those companies responsible for that lack of access. *If* there is culpable corporate conduct, focus on a CDTR seems misplaced. Not only would it add insult to injury by casting companies in the light of rescuers as opposed to wrongdoers, it would fail to hold companies accountable, thereby obfuscating morally problematic corporate conduct.

This Article advances this argument in four Parts. Part I introduces proposals in the literature for a CDTR and traces their derivation from the paradigm duty to rescue case. Part II turns to the practical significance of CDTR proposals, analyzing applicable law and principles, and evaluating both their legal enforceability and legal permissibility. Part III, by providing concrete examples of the "rescue-like" activities that biopharmaceutical companies engage in, offers support for the argument that discharging a CDTR is legally permissible. It also demonstrates the necessity for further normative assessment as it is uncertain whether any of these activities actually

would count as discharging a company's moral obligation. Part IV critically and systematically analyzes a CDTR. It examines the features of the paradigm rescue case and argues that contrary to first appearances, application of the duty to the biopharmaceutical context is far from straightforward and is subject to criticism.

## I. A CORPORATE DUTY TO RESCUE

### *A. Introducing a Corporate Duty to Rescue*

A moral duty to rescue is not only familiar but enjoys immense intuitive support. Despite some variability, most commentators—whether philosophical or legal—often mean by a duty to rescue an “easy” duty to rescue. Peter Singer, for example, famously illustrates this duty through the example of a drowning child: “[I]f I am walking past a shallow pond and see a child drowning in it, I ought to wade in and pull the child out. This will mean getting my clothes muddy, but this is insignificant, while the death of the child would presumably be a very bad thing.”<sup>18</sup>

Though some believe that a duty to rescue may permissibly impose significant costs,<sup>19</sup> the crux of an *easy* duty to rescue is that given minimal cost to the rescuer and significant benefit to the rescuee, there is an obligation to rescue. Few would deny the intuitive force of an easy duty to rescue. As a moral matter, it seems plainly wrong to continue about one's business if muddy clothing, for instance, is the *only* difference between saving a drowning child's life or permitting him to perish.

Scholars in health law, business ethics, and bioethics have been inspired by the easy duty to rescue. They contemplate its application to for-profit entities in the

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18. Peter Singer, *Famine, Affluence, and Morality*, 1 PHIL. & PUB. AFF. 229, 231 (1972).

19. See, e.g., *id.* Singer actually advocates for more than an easy duty to rescue. He puts forward two principles. The more robust principle involves not “sacrificing anything of comparable moral importance.” *Id.* The more limited principle involves not “sacrificing anything morally significant.” *Id.*; see also PETER UNGER, *LIVING HIGH AND LETTING DIE: OUR ILLUSION OF INNOCENCE* (1996).

context of access to and affordability of biopharmaceutical products.<sup>20</sup> The bystander walking by the pond is replaced by a biopharmaceutical company with rights to or control over the mechanism of rescue. An ill patient (or patients) stands in for the drowning child. Rescue is contemplated as involving donating medications, reducing prices, or various tinkering with the management of a company's intellectual property—for instance, by licensing the medication to generic firms or becoming less litigious over patent protections.<sup>21</sup> The main idea is that *if* there are minimal cost interventions that a biopharmaceutical company could deploy that would have significant benefits for patients in need, these companies are subject to a moral duty to rescue.

This Article refers to the application of a moral duty to rescue to for-profit companies as a “corporate duty to rescue” or “CDTR.”<sup>22</sup> Proponents of these proposals suggest that a CDTR not only exists, but in the biopharmaceutical context could help to improve access to medications. Moreover, a CDTR maintains the current intellectual and regulatory property system while responding to great human need.<sup>23</sup> This might be viewed as a feature and not necessarily a bug. Without sufficient intellectual property protection, the thought is that corporate profits will suffer and in turn innovation will be materially curtailed.<sup>24</sup> It is a solution that seeks

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20. Thomas W. Dunfee, *Do Firms with Unique Competencies for Rescuing Victims of Human Catastrophes Have Special Obligations? Corporate Responsibility and the AIDS Catastrophe in Sub-Saharan Africa*, 16 BUS. ETHICS Q. 185 (2006); Anita Ho, *Global Health Disparity and Pharmaceutical Companies' Obligation to Assist*, in PHILOSOPHICAL ISSUES IN PHARMACEUTICS 29, 31 (Dien Ho ed., 2017) [hereinafter Ho, *Global Health Disparity*]; Anita Ho, *Pharmaceutical Corporations and the Duty to Aid in HIV/AIDS Epidemic*, 24 BUS. & PROF. ETHICS J. 51 (2005) [hereinafter Ho, *Pharmaceutical Corporations*]; Nien-hê Hsieh, *Corporate Moral Agency, Positive Duties, and Purpose*, in THE MORAL RESPONSIBILITY OF FIRMS 188, 190–92 (Eric W. Orts & N. Craig Smith eds., 2017) (ebook) (discussing Dunfee's proposal); Nien-hê Hsieh, *Property Rights in Crisis: Managers and Rescue*, in ETHICS AND THE PHARMACEUTICAL INDUSTRY 379 (Michael A. Santoro & Thomas M. Gorrie eds., 2005) [hereinafter Hsieh, *Property Rights in Crisis*] (ebook); Florencia Luna, *Responsibility—In Public Health*, in GLOBAL ETHICS FOR LEADERSHIP: VALUES AND VIRTUES FOR LIFE 111, 125–27 (Christoph Stückelberger, Walter Fust & Obiora Ike eds., 2016); Kevin Outterson & Donald W. Light, *Global Pharmaceutical Markets*, in A COMPANION TO BIOETHICS 417 (Helga Kuhse & Peter Singer eds., 2009) (putting forward a related argument that drug companies may have an ethical duty to permit rescue), [https://papers.ssrn.com/sol3/papers2.cfm?abstract\\_id=1565536](https://papers.ssrn.com/sol3/papers2.cfm?abstract_id=1565536) [<https://perma.cc/W74Z-4ZPX>]; see also Paul G. Harris & Patricia Siplon, *International Obligation and Human Health: Evolving Policy Responses to HIV/AIDS*, 15 ETHICS & INT'L AFF. 29, 44–45 (2001) (drawing on Singer's work to make a related claim that developed countries have a duty to rescue).

21. One might wonder why rescue efforts are framed as focusing solely on access to existing medications and not further encompassing certain research agendas themselves. Conceivably, a duty to rescue could cover research efforts, but a significant challenge would be overcoming the minimal cost clause. See, e.g., Ho, *Global Health Disparity*, *supra* note 20, at 42 (discussing Ebola and noting the open question of “who may have the moral obligation to develop such treatment, since the principle of rescue does not require potential actors to make substantial sacrifice”).

22. Cf. sources cited *supra* note 15.

23. Hsieh, *Property Rights in Crisis*, *supra* note 20, at 381–82.

24. *Id.* at 380–81. Of course, the desirability of some system of intellectual and regulatory

to avoid messy, if not uncomfortable, inquiries into the underlying fairness of the background distribution of wealth and resources.

A duty to rescue is a general obligation, applicable to all moral agents.<sup>25</sup> Yet, some proposals for a CDTR are framed as one of special obligation.<sup>26</sup> Whereas the former would position biopharmaceutical companies as just one of all moral agents potentially under an obligation of rescue, the latter singles out biopharmaceutical companies as uniquely responsible for rescue.<sup>27</sup> The idea that biopharmaceutical companies have obligations of rescue, and potentially special obligations at that, is not unique to the drug pricing and access context. CDTR arguments are implicated beyond the biopharmaceutical space more generally within the corporate social responsibility and business and human rights literatures.<sup>28</sup>

Before taking a closer look at CDTR proposals, it is worthwhile to be clear about two preliminary assumptions. The analysis in this Article assumes both that biopharmaceutical companies can be moral agents, and, further, that biopharmaceutical companies, at least sometimes, can have positive moral obligations. These assumptions are important because the transition from the paradigm rescue case to the corporate one involves a move from natural to juridical persons. This move inherently brings with it philosophical complexities that cannot be attended to here.<sup>29</sup> Nevertheless, these assumptions for the sake of moving the analysis forward ought not to be unduly controversial.

A moral CDTR has intuitive appeal. Yet, as will be argued in Part IV, application of a duty to rescue to the biopharmaceutical context is far from straightforward, morally speaking. It is unclear what this moral duty requires of biopharmaceutical

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property does not prove the desirability of the version currently in place.

25. Tina Rulli & Joseph Millum, *Rescuing the Duty to Rescue*, 42 J. MED. ETHICS 260, 260 (2016).

26. Dunfee, *supra* note 20.

27. Georg Marckmann, *Access to Essential Drugs: The Ethical Challenge of Allocating Obligations*, in BIOETHICS IN A SMALL WORLD 111, 112 (Felix Thiele & R. E. Ashcroft eds., 2005); Christian Barry & Kate Raworth, *Access to Medicines and the Rhetoric of Responsibility*, 16 ETHICS & INT'L AFF. 57, 58 (2002); David Miller, *Distributing Responsibilities*, 9 J. POL. PHILOS. 453, 453 (2001) (discussing special obligations).

28. See, e.g., Friedland, *supra* note 15, at 226–27 (focusing on obesity and climate change contexts and arguing that corporations have a moral duty to assist when they have superior or unique capabilities to assist and assistance comes with “relatively little effort”); Jackson, *supra* note 15, at 550 (discussing a corporate duty to assist, though distinguishing as broader than a duty to rescue); Wood, *supra* note 15, at 82–83 (arguing in the human rights context that corporations are subject to a duty to rescue and using this framework as a basis of moral obligations where a special relationship exists between a corporation and the perpetrator, victim rights-holders, or interests at stake); *Business Ethics*, STAN. ENCYCLOPEDIA PHIL. ARCHIVE (Nov. 17, 2016), <https://plato.stanford.edu/archives/fall2017/entries/ethics-business> [<https://perma.cc/D4GA-H83C>] (not using the label “rescue,” but observing that arguments for corporate social responsibility rely on the premise that “any agent with the resources and knowledge necessary to ameliorate these problems has a moral responsibility to do so, assuming the costs they incur on themselves are not great”).

29. Debates regarding the moral agency and obligations of firms are philosophically rich areas of interdisciplinary scholarship. For a recent anthology, including a variety of perspectives, see THE MORAL RESPONSIBILITY OF FIRMS, *supra* note 20.

companies, and the merits of this ethical approach, in some instances, may be contestable. Before getting to the critique of a CDTR provided in Part IV, the below introduces discussions of a CDTR in the literature.

*B. Corporate Duty to Rescue Proposals and Access to Medications*

Applying a moral CDTR to issues of drug pricing and access to medications has attracted the attention of scholars in several disciplines. Among others, business ethicists Nien-hê Hsieh and Thomas Dunfee have each put forward CDTR proposals. Health law scholar Kevin Outterson and bioethicist and health policy expert Donald Light have also explored the application of a CDTR to drug pricing issues.

Nien-hê Hsieh's proposal draws upon the work of moral philosopher Thomas Scanlon. Following Scanlon, this proposal identifies three components of a rescue principle: The "plight is dire."<sup>30</sup> The would-be rescuer is both "in a position to alleviate the plight and has the means by which to do so at his or her disposal."<sup>31</sup> Finally, the duty is limited to cases in which the sacrifice is not "above some threshold."<sup>32</sup>

Hsieh then applies this framework to the HIV/AIDS crisis in developing countries. He concludes that pharmaceutical companies are subject to a CDTR. "First, if the plight of those suffering from HIV/AIDS does not count as dire, then it is unclear what does. Second, pharmaceutical companies are well positioned to help alleviate the plight in ways that other parties are not."<sup>33</sup> According to Hsieh, pharmaceutical companies as patent holders can provide relief by forgoing the enforcement of their patents, reducing prices, or by donating essential medications.<sup>34</sup> Finally, despite how large the problem of HIV/AIDS is in developing countries, he argues that the burden on companies may be small. HIV medications already exist, and, furthermore, pharmaceutical companies do not expect market price sales to poor people in developing countries.<sup>35</sup> If parallel importation problems can be avoided, the amount of foregone profits—the real sacrifice under this scheme—arguably would be minimal.<sup>36</sup> Therefore, Hsieh states that "pharmaceutical companies incur relatively little sacrifice by providing these medicines for free, or at manufacturing cost, to developing countries and by relaxing the enforcement of patent protection."<sup>37</sup> Since there is great need, pharmaceutical companies are in a position to help, and that help comes at minimal cost, pharmaceutical companies are under a CDTR.

Thomas Dunfee's CDTR proposal also responds to the HIV/AIDS crisis. While the proposal discussed above appears motivated in part by the desire to provide aid without undermining patent protection, this proposal focuses on the fact that some

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30. Hsieh, *Property Rights in Crisis*, *supra* note 20, at 382.

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.* at 382–83.

35. *Id.* at 383.

36. *Id.* Roughly, parallel importation occurs when products intended for sale in one jurisdiction are imported to another jurisdiction to take advantage of pricing differences.

37. *Id.*

firms possess a “unique human catastrophe rescue competency.”<sup>38</sup> The combination of a unique competency and a corresponding catastrophe gives rise to a CDTR. Dunfee’s duty is “grounded in the simple claim that possession of a *unique* capacity to respond to a *devastating catastrophe* creates a mandatory obligation of rescue.”<sup>39</sup> The duty is a limited one, arising only in extreme situations of “devastating, overwhelming . . . human need.”<sup>40</sup>

According to Dunfee, a company possesses a unique catastrophe rescue competency when it satisfies three conditions.<sup>41</sup> First, its core competency must allow it to “mitigate or alleviate” either the cause or effect of the catastrophe.<sup>42</sup> Second, the company needs to be able to provide mitigation or alleviation.<sup>43</sup> Third, the firm must be unique in its abilities to address the catastrophe.<sup>44</sup> It must have a “comparative advantage.”<sup>45</sup> The company is not off the moral hook unless there is another entity better suited to the job.

Under this proposal, some pharmaceutical companies purportedly have unique catastrophe rescue competencies for addressing the HIV/AIDS crisis:

The catastrophe overlaps with their core competencies, particularly for those firms that produce or distribute the drugs commonly used in current treatment regimes. They hold patents on essential drugs. They have special knowledge concerning treatment regimes. They know about promising research leads for future treatment strategies. They either own manufacturing facilities or have special contractual relationships with suppliers. They have experience with transporting large quantities of drugs. They also have experience with educating medical staff in the use of the drugs. The uniqueness of their position is strengthened by the fact that they hold legal rights that may restrict others from providing relief without a license.<sup>46</sup>

In sum, according to Dunfee, some biopharmaceutical companies are uniquely positioned given their institutional knowledge, infrastructure, and intellectual property rights. This uniqueness is claimed to hold relative to other potential actors. “[B]ecause of their patent protection, productive resources and specialized knowledge, the case can be made that the global pharmaceuticals have comparative advantages over other possible providers, including other private sector providers, NGOs and government agencies.”<sup>47</sup>

Dunfee’s proposal for a CDTR does not explicitly condition rescue obligations upon their being undertaken at minimal cost. Rather, he ties the magnitude of the

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38. Dunfee, *supra* note 20, at 186.

39. *Id.* at 187 (emphasis in original).

40. *Id.* More specifically, Dunfee requires that the harm involve severe physical injury or death, affect hundreds of thousands of people, and be immediate. *Id.* at 188.

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.* at 188–89.

47. *Id.* at 189.

obligation to various ways of accounting for corporate resources spent on voluntary social initiatives.<sup>48</sup> For instance, if money spent on the previous year's social initiatives is the largest of specified alternatives, this is the minimal amount that must be spent on rescue efforts.<sup>49</sup> Presumably, however, the resources a biopharmaceutical company voluntarily spends on social initiatives comes at minimal cost to the company. Thus, in practice, Dunfee's proposal may line up with the duty to rescue's minimal cost clause. In theory, however, without more explicit indication, the two can come apart.

A third proposal is put forward by Outterson and Light. Whereas Hsieh and Dunfee's proposals focus specifically on the accessibility of HIV/AIDS medications, Outterson and Light's discussion focuses more generally on global access to important medications given high drug prices.<sup>50</sup> They begin their analysis with the "important normative assumption . . . that if we can promote access without harming innovation, then we should do so. . . . [W]e have an ethical duty to rescue people who need essential medicines, especially when the rescue can be accomplished with minimal risk and cost."<sup>51</sup>

Outterson and Light's analysis emphasizes concern for costs to innovation. They argue that biopharmaceutical companies could allow different kinds of activities that would facilitate access to medications in less well-off countries without incurring significant—or potentially even any—costs to innovation incentives.<sup>52</sup> This is so because the economic realities simply exclude some markets from sales to begin with, and the authors further claim that concerns over product arbitrage are overstated.<sup>53</sup>

Outterson and Light's discussion takes many turns. Embedded within it is an argument resembling a "straightforward" CDTR. They argue, for instance, that "patent-based drug companies may be subject to an ethical duty to permit an easy rescue."<sup>54</sup> Discussing the potential for voluntary licensing agreements between brand and generic companies,<sup>55</sup> a straightforward CDTR, for them, therefore might involve an obligation for branded biopharmaceutical companies to engage in transactions when those arrangements come at minimal cost to innovation.<sup>56</sup> Ultimately, however, the authors are clear that their CDTR proposal is different. It is framed as being predicated on noninterference in harm. "Patent-based drug companies," according to the authors, are not innocent bystanders.<sup>57</sup>

Outterson and Light's analysis is informed by both moral and legal discussions of a duty to rescue. Observing that generally there is no *legal* duty to rescue, the authors note that an exception to this legal rule is interference in rescue: "[I]f the bystander was in some way responsible for the situation, or was impeding rescue by others,

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48. *Id.* at 190.

49. *Id.*

50. Outterson & Light, *supra* note 20, at 417.

51. *Id.* at 419.

52. *Id.* at 426.

53. *Id.*

54. *Id.* at 427.

55. *Id.* at 426; *see also* Ho, *Global Health Disparity*, *supra* note 20, at 32.

56. Outterson & Light, *supra* note 20, at 425–26.

57. *Id.* at 424.

then a court might categorize the incident as misfeasance rather than nonfeasance, even absent any fault on the part of the bystander.”<sup>58</sup> In other words, even though there is no legal liability for failing to rescue, there can be legal liability if one *caused* the need to be rescued *or interfered* with the rescue efforts of third parties.

In the authors’ view, biopharmaceutical companies with patent protected products “actively work to prevent rescue by others.”<sup>59</sup> Such companies do this by preventing generic entry during the patent period for products that would be directed to less well-off countries.<sup>60</sup> The exercising of these rights “transforms the companies from innocent bystanders into entities claiming the legal right to prevent rescue.”<sup>61</sup> The authors argue that this is morally problematic: biopharmaceutical companies should not be able to prevent other parties from engaging in rescue activities when those activities can occur at little or no cost to those companies. Thus, they “argue that global intellectual property law should be modified to *permit rescue by others*, especially when the patent-based drug companies are not significantly disadvantaged thereby.”<sup>62</sup> They go on to conclude:

As contributors to the creation of, and active participants in, global pharmaceutical markets, the patent-based drug companies may be subject to an ethical duty to permit an easy rescue, which in this case includes allowing opportunities to expand equitable access while preserving optimal innovation. At the very least, they should not actively hinder the rescue efforts of others and should permit generic licensing for those unable to pay wealthy country market prices.<sup>63</sup>

A reading of Outterson and Light’s discussion might conform to a CDTR proposal. To the extent, however, their proposal focuses on misfeasance and causal contribution to harm, their proposal *is not* strictly speaking a moral CDTR, invocation of “duty to rescue” language notwithstanding. Causal contribution arguments provide a different theoretical grounding for corporate obligations.

Outterson and Light’s discussion of interference with rescue is important.<sup>64</sup> It provides a basis of critique of a moral CDTR. As will be argued in Part IV, some biopharmaceutical corporate activity is suggestive of culpability for harm caused by higher-than-they-probably-would-or-should-be-prices. For instance, as others have detailed, and the FDA has commented, biopharmaceutical companies utilize

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58. *Id.* at 420.

59. *Id.* at 424.

60. *Id.*

61. *Id.*

62. *Id.* at 422. Note that whereas this Article frames a corporate duty to rescue as a potential form of self-regulation, Outterson and Light contemplate its use for external regulation.

63. *Id.* at 427.

64. There is also much to discuss, triggered by Outterson and Light, regarding existing legal tools that “permit rescue.” Such mechanisms might include the “march-in rights” provisions of the Bayh-Dole Act under 35 U.S.C. § 203 and government patent use under 28 U.S.C. § 1498. Furthermore, as their argument targets on-patent therapies, it overlooks that some generic companies also act in ways that appear to interfere with rescue.

numerous tactics to suppress generic competition.<sup>65</sup> Yet, an interference argument relies on distinct considerations of causal contribution, an issue bracketed until Part IV.<sup>66</sup>

## II. DISCHARGING A CORPORATE DUTY TO RESCUE: LEGAL ENFORCEABILITY AND LEGAL ABILITY

With the moral duty to rescue introduced and proposals for a moral CDTR in the biopharmaceutical space presented, practical considerations arise. The duty must be considered from a legal perspective.<sup>67</sup> After all, interest in a moral CDTR for addressing drug pricing and access controversies loses steam if this mechanism is legally untenable.

Two legal issues must be addressed. First, is a CDTR legally *enforceable* as a tort? Second, do managers and directors of biopharmaceutical companies—specifically biopharmaceutical corporations—have the legal *ability* to discharge a corporation’s CDTR? The second of these issues is more important. Even though a CDTR likely is not legally enforceable under existing tort law, it is also not proscribed. Lack of legal enforceability is, to be sure, a challenge. Yet, if managers and directors are not able within the bounds of current law to discharge a CDTR, proposals for such a duty are, practically speaking, a dead end.

Significant debate exists about the purpose of for-profit corporations and their legal ability to take nonshareholder interests into consideration. However, corporations do have the legal ability to discharge a CDTR. Moreover, biopharmaceutical corporations routinely engage in “rescue-like” activities.

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65. See, e.g., Gregory H. Jones, Michael A. Carrier, Richard T. Silver & Hagop Kantarjian, *Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD 1398, 1399 (2016); Michael A. Carrier, *High Prices & No Excuses: 6 Anticompetitive Games* (Nov. 6, 2017), <https://ssrn.com/abstract=3066514> [<https://perma.cc/XZ8U-WQUV>] (presentation slides for 2017 Federal Trade Commission workshop on “Understanding Competition in Prescription Drug Markets”); Gottlieb, *supra* note 10; *Reference Listed Drug (RLD) Access Inquiries*, FDA, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm> [<https://perma.cc/P4L8-QNH6>] (last updated Aug. 13, 2018) (naming companies that have allegedly prevented generic applicants from acquiring needed samples).

66. For the purposes of this Article, I adopt the commonsense morality assumption that there is a tenable moral difference between doing, or causing harm, and “merely” allowing harm. I do not adopt the more stringent position that moral agents only have moral duties with respect to harms they have caused. See generally Larry S. Temkin, *Thinking About the Needy, Justice, and International Organizations*, 8 J. ETHICS 349 (2004).

67. This Article observes an analytical distinction between a moral duty to rescue and cases involving (morally) wrongful causal contribution to harm. The law, however, appears to sometimes blur this line by borrowing language and features from each. Tort law, for instance, contemplates cases in which an individual might innocently causally contribute to a hazard, yet have a legal duty to aid in order to prevent further harm. See, e.g., RESTATEMENT (SECOND) OF TORTS § 322 (AM. LAW INST. 1965).

*A. A Corporate Duty to Rescue Tort Is Likely Not Legally Enforceable*

As a tort, a CDTR faces severe legal impediment. A duty to rescue under existing law, at least in the United States, is generally legally unenforceable.<sup>68</sup> Thus, a legally enforceable corporate duty to rescue appears to be a nonstarter.

The common law draws a sharp distinction between *misfeasance* and *nonfeasance*; misfeasance roughly involves an individual wrongly making another worse off.<sup>69</sup> Nonfeasance, by contrast, can be understood as a failure to prevent a harm for which one plays no part.<sup>70</sup> The common law does not recognize legal liability for nonfeasance.<sup>71</sup> Since paradigm moral duty to rescue cases involve instances of nonfeasance, there is no legal liability for failing to rescue. “Generations of law students have learned of the no-duty rule by reading hypothetical cases of babies who drowned in bathtubs and actual cases of people who drowned in ditches and lakes while bystanders did nothing.”<sup>72</sup>

Several states—Vermont, Minnesota, and Rhode Island—do recognize a statutory duty to rescue.<sup>73</sup> Vermont’s statute, for instance, covers situations of “expos[ure] to grave physical harm”<sup>74</sup> and subject to some exclusions, a person must, “give reasonable assistance to the exposed person unless that assistance or care is being

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68. RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 37 (AM. LAW INST. 2012) (“An actor whose conduct has not created a risk of physical or emotional harm to another has no duty of care to the other unless a court determines that one of the affirmative duties provided in §§ 38–44 is applicable.”); *see also* Outterson & Light, *supra* note 20, at 420. But, things are different in continental Europe. *See, e.g.*, 1 JOEL FEINBERG, *THE MORAL LIMITS OF THE CRIMINAL LAW: HARM TO OTHERS* 127 (1984).

69. Francis H. Bohlen, *The Moral Duty to Aid Others as a Basis of Tort Liability*, 56 U. PA. L. REV. 217, 219 (1908) (“There is no distinction more deeply rooted in the common law and more fundamental than that between misfeasance and non-feasance, between active misconduct working positive injury to others and passive inaction, a failure to take positive steps to benefit others, or to protect them from harm not created by any wrongful act of the defendant.”); *see also* RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 37 cmt. a (AM. LAW INST. 2012) (quoting Bohlen).

70. Bohlen, *supra* note 69.

71. *Id.* at 221.

72. David A. Hyman, *Rescue Without Law: An Empirical Perspective on the Duty to Rescue*, 84 TEX. L. REV. 653, 655 (2006).

73. I do not include Wisconsin’s statute which applies to crime victims. WIS. STAT. ANN. § 940.34 (West 2005). Further, a duty to rescue should not be confused with Good Samaritan Statutes. Good Samaritan statutory provisions offer an individual protection from liability, should she decide to become a rescuer. For previous surveys of duty to rescue and Good Samaritan statutes, *see* DECHERT FOR Savelife Found., *GOOD SAMARITAN LAWS: A COMPARATIVE STUDY OF LAWS THAT PROTECT FIRST RESPONDERS WHO ASSIST ACCIDENT VICTIMS* (May 2014), <http://www.trust.org/contentAsset/raw-data/7be34cce-ea0d-4c90-8b39-53427acf4c43/file> [<https://perma.cc/YP85-SCHN>]; Eugene Volokh, *Duty to Rescue/Report Statutes*, VOLOKH CONSPIRACY (Nov. 3, 2009, 12:24 AM), <http://volokh.com/2009/11/03/duty-to-rescuereport-statutes> [<https://perma.cc/626C-CZLW>]. Duty to rescue statutes may further be distinguished from duty to report statutes which focus on crimes. *See, e.g.*, CAL. PENAL CODE § 152.3 (West 2014).

74. VT. STAT. ANN. tit. 12, § 519(a) (2017).

provided by others.”<sup>75</sup> Both Minnesota and Rhode Island’s statutes apply to situations in which the person is “at the scene of an emergency.”<sup>76</sup> These statutes have never been applied to the biopharmaceutical context here contemplated.<sup>77</sup>

To the extent corporate entities are properly brought within the scope of these statutes<sup>78</sup>—and even if a plaintiff could clear all the hurdles—as a practical matter, they seem to be of limited utility. In Vermont, for instance, the only and maximum penalty is for *willful* violation and for \$100.<sup>79</sup> The statute does not mention an injunction. If that amount could be aggregated over a large patient population, it would not be nothing. Yet, given the amount of money at stake with high cost medications in the tens or even hundreds of thousands of dollars per treatment, a favorable verdict would probably be little more than symbolic.

Given the above, utilizing a CDTR as a form of external regulation under current tort law appears unpromising.<sup>80</sup> Litigating under a CDTR tort theory for addressing problems of biopharmaceutical pricing and access can be left aside.

### *B. Corporate Governance and Legal Ability to Discharge a Corporate Duty to Rescue*

While a CDTR is unlikely to be enforceable under current tort law, discharging such a duty is legally permissible as an internal corporate strategy. An easy CDTR involves a corporation making a minimal cost sacrifice in order to benefit others. Corporate rescue in the biopharmaceutical context involves assisting patients with access to medications. An obvious way to think about “cost” in the corporate setting is in terms of forgone profits. For instance, instead of accruing \$1,000,000 in profits *without* discharging a CDTR, suppose a company instead accrues \$950,000 in profits *with* discharging a CDTR. Discharging a CDTR in this example, comes at a cost of \$50,000. Whether 5% of a corporation’s profits counts as minimal is debatable (particularly if this spending were to become iterative), but it seems uncontroversial that the diversion of the \$50,000 would be, barring additional facts, a cost.

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75. *Id.*

76. MINN. STAT. ANN. § 604A.01 (West 2010); 11 R.I. GEN. LAWS § 11-56-1 (2002).

77. Searches, last conducted on April 17, 2019, in Westlaw of cases citing VT. STAT. ANN. tit. 12, § 519 returned 25 results, citing MINN. STAT. ANN. § 604A.01 returned 10 results, citing 11 R.I. GEN. LAWS § 11-56-1 returned 3 results. None of these cases involved a biopharmaceutical company, and none had facts resembling those that would be at issue in a case regarding the unaffordability of medications.

78. *See, e.g.*, MINN. STAT. ANN. § 604A.01 subd. 2(c) (West 2010) (including “[f]or the purposes of this section” that “‘person’” can mean “any partnership, corporation, association, or other entity”) Clarification is needed whether “section” means section as opposed to subdivision. The distinction being whether this definition of person is only meant to apply to the Good Samaritan portion of the statute.

79. VT. STAT. ANN. tit. 12, § 519(c) (2017); FEINBERG, *supra* note 68, at 127 (describing penalty as a slap on the wrist).

80. *But see* 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 (2016) (exploring the role of courts, class actions, and claims for emotional distress to impose liability on pharmaceutical companies for drug pricing).

Can corporate managers and directors sacrifice a corporation's profits to discharge a CDTR within the bounds of the law?<sup>81</sup> Though somewhat contested, this Article argues yes. Managers and directors are not required to maximize profits in all contexts. This Section argues for two main points. First, managers and directors have the legal discretion to discharge a corporation's moral CDTR. Second, corporate decisions to discharge a CDTR likely will be accorded deference and protected under the business judgment rule. Further, though an easy CDTR, as a philosophical matter, can involve a minimal cost to the rescuer, it may be that some or even many instances of corporate rescue are costless or beneficial to a corporation. Engaging in costless or beneficial rescue is clearly within the legal powers of corporate management.

### 1. The Ability to Trade-off Profits in Order to Discharge a Corporate Duty to Rescue

Corporate management's legal ability to discharge a CDTR intersects with larger conversations about the role of for-profit corporations in society. A CDTR is a specialized issue within this broader context.

The more general issue of corporate social responsibility has been debated since at least the early twentieth century with a famous exchange appearing in the *Harvard Law Review*. Reacting to problems generated by the separation of ownership (shareholders) and control (officers and directors) and the prospect of manager self-enrichment, Professor Berle argued that corporations must be run exclusively for the benefit of shareholders.<sup>82</sup> In response, Professor Dodd, though sensitive to Berle's concerns, responded that a corporation is run not just for shareholder profit. A corporation, in Dodd's assessment, is "an economic institution which has a social service as well as a profit-making function."<sup>83</sup> He therefore considered it "undesirable . . . to give increased emphasis . . . to the view that business corporations exist for the sole purpose of making profits for their stockholders."<sup>84</sup>

While recent scholarship offers several competing theories of corporate governance,<sup>85</sup> "[t]oday, most corporate law scholars embrace some variant of shareholder primacy."<sup>86</sup> Under a shareholder primacy view, the end of corporate decision-making and the purpose of corporations themselves is the increase—and

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81. Einer Elhauge, *Sacrificing Corporate Profits in the Public Interest*, 80 N.Y.U. L. REV. 733 (2005) (framing the general issue of corporate social responsibility in terms of profit sacrifice).

82. A. A. Berle, Jr., *Corporate Powers as Powers in Trust*, 44 HARV. L. REV. 1049 (1931); see also Stephen M. Bainbridge, *Interpreting Nonshareholder Constituency Statutes*, 19 PEPP. L. REV. 971, 971–72 (1992).

83. E. Merrick Dodd, Jr., *For Whom Are Corporate Managers Trustees?*, 45 HARV. L. REV. 1145, 1148 (1932).

84. *Id.* at 1147–48.

85. See Stephen M. Bainbridge, *Director Primacy: The Means and Ends of Corporate Governance*, 97 NW. U. L. REV. 547 (2003).

86. *Id.* at 563; see also LYNN STOUT, *THE SHAREHOLDER VALUE MYTH: HOW PUTTING SHAREHOLDERS FIRST HARMS INVESTORS, CORPORATIONS, AND THE PUBLIC* 21–23 (2012); Elhauge, *supra* note 81, at 736 (describing the "canonical view").

some believe maximization—of shareholder wealth.<sup>87</sup> According to the American Law Institute’s *Principles of Corporate Governance* (“*Principles*”),<sup>88</sup> for instance, a for-profit corporation “should have as its objective the conduct of business activities with a view to enhancing corporate profit and shareholder gain.”<sup>89</sup> Some argue this is the *only* obligation of for-profit corporations, subject to obeying the law.<sup>90</sup>

Despite the dominance of shareholder primacy views in the academy and public rhetoric,<sup>91</sup> an examination of law and principles reveals—as others have pointed out<sup>92</sup>—space for corporate management to incorporate considerations that may not maximize shareholder wealth. This can be true for operational business decisions as well as corporate charitable contributions. While promoting shareholder gain may be the primary obligation of for-profit corporations, arguably its pursuit may be permissibly limited.<sup>93</sup>

This position is reflected in the *Principles*, above noted. The *Principles*, while not law, are “considered a significant, if not controlling, source of doctrinal authority.”<sup>94</sup>

87. See, e.g., 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.”); Jonathan R. Macey, *A Close Read of an Excellent Commentary on Dodge v. Ford*, 3 VA. L. & BUS. REV. 177, 178 (2008); Joan MacLeod Heminway, *Shareholder Wealth Maximization as a Function of Statutes, Decisional Law, and Organic Documents*, 74 WASH. & LEE L. REV. 939, 939 (2017); Mark J. Roe, *The Shareholder Wealth Maximization Norm and Industrial Organization*, 149 U. PA. L. REV. 2063, 2065 (2001) (“Shareholder wealth maximization is usually accepted as the appropriate goal in American business circles.”).

88. PRINCIPLES OF CORP. GOVERNANCE: ANALYSIS & RECOMMENDATIONS (AM. LAW INST. 1994) [hereinafter PRINCIPLES].

89. *Id.* § 2.01.

90. See, e.g., Leo E. Strine, Jr., *The Dangers of Denial: The Need for a Clear-Eyed Understanding of the Power and Accountability Structure Established by the Delaware General Corporation Law*, 50 WAKE FOREST L. REV. 761, 763 (2015); see also Milton Friedman, *A Friedman Doctrine—The Social Responsibility of Business Is to Increase Its Profits*, N.Y. TIMES, Sept. 13, 1970, at 33. Yet, Friedman also says more broadly: “That responsibility is to conduct the business in accordance with . . . mak[ing] 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.” *Id.* at 33; see also STOUT, *supra* note 86, at 21 (noting the pervasiveness of this view).

91. STOUT, *supra* note 86, at 2–3.

92. See, e.g., Elhauge, *supra* note 81.

93. PRINCIPLES, *supra* note 88, at § 2.01 cmt. e (“The provisions of Subsection (b) reflect a recognition that the corporation is a social as well as an economic institution, and accordingly that its pursuit of the economic objective must be constrained by social imperatives and may be qualified by social needs.”).

94. Macey, *supra* note 87, at 178. § 2.01 is a “central Restatement rule[] of the *Principles*.” Melvin Aron Eisenberg, *An Overview of the Principles of Corporate Governance*, 48 BUS. LAW. 1271, 1275 (1993). But note PRINCIPLES, *supra* note 88, § 2.01 cmt. a (“Present law on the matters within the scope of § 2.01 cannot be stated with precision, because the case law is evolving and not entirely harmonious, while the statutes cover only some of the relevant issues and leave open significant questions even as to the issues they do cover. However, there is direct or indirect authoritative support for all of the principles embodied in § 2.01.”).

After stating in section 2.01(a) that corporations should aim to enhance “corporate profit and shareholder gain,” section 2.01(b) lists three exceptions:

*Even if corporate profit and shareholder gain are not thereby enhanced, the corporation, in the conduct of its business:* (1) Is obliged, to the same extent as a natural person, to act within the boundaries set by law; (2) May take into account ethical considerations that are reasonably regarded as appropriate to the responsible conduct of business; and (3) May devote a reasonable amount of resources to public welfare, humanitarian, educational, and philanthropic purposes.<sup>95</sup>

Though section 2.01(b)(1) is stated as a requirement, (b)(2) and (b)(3) provide options. Corporations are neither required nor prohibited from taking ethical or philanthropic considerations into account, even if management does not determine that corporate profit is enhanced. The *Principles* therefore indicate that corporations have the discretion to attend to moral obligations “whether or not they enhance [economic] returns (that is, even if the conduct either yields no economic return or entails a net economic loss).”<sup>96</sup> The commentary further notes, “Corporate officials are not less morally obliged than any other citizens to take ethical considerations into account, and it would be unwise social policy to preclude them from doing so.”<sup>97</sup>

A duty to rescue is considered to be a general moral obligation applicable to all moral agents. The commentary of the *Principles* supports the position that for-profit corporations not only are subject to a CDTR as moral agents, but that corporate governance law allows managers and directors to discharge a CDTR. Shareholder primacy does not necessarily preclude discharging a CDTR.

Though federal securities laws play a role, corporate governance law is generally a matter of state statutory and case law.<sup>98</sup> The internal law of a corporation’s charter and bylaws can also provide guidance.<sup>99</sup> Two cases, *Dodge v. Ford Motor Co.*<sup>100</sup> and *eBay Domestic Holdings, Inc. v. Newmark*,<sup>101</sup> are often cited in debates about shareholder primacy and the objectives of for-profit corporations. As argued below, however, neither case appears to foreclose a corporation from discharging a CDTR.

*Dodge v. Ford* is a Michigan Supreme Court case.<sup>102</sup> While Delaware is the most influential source of state corporate law in the United States,<sup>103</sup> this case is nevertheless perhaps the one most cited by legal academics for the “core lesson that corporate officers and directors have a duty to manage the corporation for the purpose

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95. PRINCIPLES, *supra* note 88, § 2.01(b) (emphasis added).

96. *Id.* § 2.01 cmt. f.

97. *Id.* § 2.01 cmt. h.

98. STOUT, *supra* note 86, at 27–29; *see also* Heminway, *supra* note 87, at 941.

99. STOUT, *supra* note 86, at 27–28; Heminway, *supra* note 87, at 941 & n.4.

100. 170 N.W. 668, 684 (Mich. 1919).

101. 16 A.3d 1, 34 (Del. Ch. 2010). I leave aside other Delaware cases frequently cited regarding shareholder primacy given that they arise in the context of takeovers or company sales, though the court in *eBay* applies heightened scrutiny to some of the Board’s actions.

102. *Dodge*, 170 N.W. 668.

103. Delaware is widely viewed as the most important jurisdiction for corporate law. *See* Lynn A. Stout, *Why We Should Stop Teaching Dodge v. Ford*, 3 VA. L. & BUS. REV. 163, 166–67 (2008).

of maximizing profits for the benefit of shareholders.”<sup>104</sup> At issue was the Ford Motor Company’s decision not to issue additional special dividends to shareholders. Instead, the money would be used “to employ still more men; to spread the benefits of this industrial system to the greatest possible number, to help them build up their lives and their homes.”<sup>105</sup> Interpreting this as running a for-profit corporation for the primary purpose of promoting the greater good and only of incidental benefit to shareholders, the court found this impermissible.<sup>106</sup> The court ordered Ford to issue a dividend, though left its business plans intact.<sup>107</sup>

Though *Dodge v. Ford* puts forward a shareholder primacy view of corporate governance,<sup>108</sup> it does not take the stronger position of shareholder wealth maximization as the only end of corporate decision-making.<sup>109</sup> Its position is not inconsistent with corporate directors discharging a CDTR. Despite “some strong pro-shareholder profits language . . . the opinion never stated that directors’ exclusive duty is to maximize shareholder profits. Rather, it states that profits should be the primary but not exclusive goal of managers.”<sup>110</sup> The court leaves unquestioned that for-profit corporations can “engage in humanitarian works.”<sup>111</sup> It draws a distinction between incidental expenditures “and a general purpose and plan to benefit mankind at the expense of others.”<sup>112</sup> Thus, “an incidental humanitarian expenditure of corporate funds” is permissible given it is not the company’s main business.<sup>113</sup> An easy CDTR with its feature of minimal cost, presumably fits within this rubric. A compelling reading of *Dodge v. Ford* is not one that obligates directors to exclusively profit maximize for the benefit of shareholders, but one that “limits the degree of profit-sacrificing discretion.”<sup>114</sup>

A more recent case cited for articulating a shareholder primacy view is the Delaware Chancery Court’s *eBay Domestic Holdings, Inc. v. Newmark*.<sup>115</sup> In brief, eBay was a minority shareholder of the popular classified ads website craigslist.<sup>116</sup> The court described craigslist and eBay as being “a study in contrasts, with different business strategies, different cultures, and different perspectives on what it means to run a successful business.”<sup>117</sup> Whereas craigslist “largely operate[d] its business as a

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104. Macey, *supra* note 87, at 178.

105. *Dodge*, 170 N.W. at 671.

106. *Id.* at 684; *see also id.* at 683–84.

107. *Id.* at 685.

108. “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.” *Id.* at 684.

109. *See generally* Stout, *supra* note 103 (expressing skepticism of the case’s authority and prevailing interpretation).

110. Elhauge, *supra* note 81, at 772–73; *see also* STOUT, *supra* note 86; Heminway, *supra* note 87, at 951.

111. *Dodge*, 170 N.W. at 684.

112. *Id.*

113. *Id.*

114. Elhauge, *supra* note 81, at 773.

115. 16 A.3d 1, 34 (Del. Ch. 2010).

116. *Id.* at 7.

117. *Id.*

community service” without a focus on monetization,<sup>118</sup> eBay “operate[d] its business with an eye to maximizing revenues, profits, and market share.”<sup>119</sup>

After eBay launched a competitor website, craigslist’s two other board members sought mechanisms to diminish eBay’s control as well as access to confidential information.<sup>120</sup> In analyzing the propriety of one of the board’s actions, the court expounded on the purpose of for-profit corporations:

The corporate form in which craigslist operates, however, is not an appropriate vehicle for purely philanthropic ends, at least not when there are other stockholders interested in realizing a return on their investment. . . . [T]he craigslist directors are bound by the fiduciary duties and standards that accompany that form. Those standards include acting to promote the value of the corporation for the benefit of its stockholders.<sup>121</sup>

Though the language in this opinion supports a shareholder primacy view,<sup>122</sup> like *Dodge v. Ford*, it leaves space for other ends. Promoting “the value of the corporation for the benefit of its stockholders” is broad language that does not necessarily call for profit maximization. A plausible interpretation of this case is that a for-profit corporation must ensure that other considerations are not *too* dominant. Clearly craigslist did not, in the court’s opinion, strike the right balance. This is so despite craigslist not being “purely philanthropic” as it did engage in limited fee charging.<sup>123</sup>

Circling back to sections 2.01(b)(2) and (3) of the *Principles*, *Dodge* and *eBay* might be read as situations in which ethical or other-regarding concerns were unreasonably pursued. The issue is *not* that such concerns were pursued in the first instance. It is plausible to think that a CDTR could be reasonably pursued, given that the “easy” form of the duty discussed here is only triggered if rescue occurs at minimal cost. Moreover, as discussed below, it is a real possibility that biopharmaceutical corporations may be able to engage in “rescue” efforts that are either costless or beneficial to those corporations.<sup>124</sup>

Before turning to the business judgment rule and the parameters of director discretion, two sources of state statutory law are of pertinence. These are constituency statutes and statutes governing corporate charitable contributions. Though this statutory authority is of relevance, it has argumentative limitations. Delaware—the jurisdiction where many significant biopharmaceutical corporations are incorporated—lacks a constituency statute. And, while Delaware *does* permit corporate charitable contributions, morally speaking, framing a CDTR as charity is inaccurate. Nevertheless, constituency statutes could be useful where applicable to

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118. *Id.* at 8.

119. *Id.* at 9.

120. *Id.* at 22.

121. *Id.* at 34.

122. Heminway, *supra* note 87, at 960; Strine, *supra* note 90, at 776–77. The Rights Plan at issue in *eBay* was subjected to the enhanced level of scrutiny described under *Unocal* and was not evaluated under the business judgment rule. *eBay*, 16 A.3d at 28–35.

123. *eBay*, 16 A.3d at 8.

124. *See infra* Section II.B.2.

firms incorporated in non-Delaware jurisdictions, and corporate charitable contribution statutes could provide legal cover for discharging a CDTR.

Constituency statutes vest directors with the authority to consider and “serve the interests not only of shareholders but of other constituencies as well, such as employees, customers, creditors, and the local community.”<sup>125</sup> Though their interests may align, discharging a CDTR involves consideration of groups beyond a corporation’s shareholders. In particular, it involves consideration of the corporation’s customers or potential customers who are priced out. A majority of states, though again significantly not Delaware, have adopted constituency statutes.<sup>126</sup>

Though numerous biopharmaceutical companies are incorporated in Delaware, several of the largest companies are not.<sup>127</sup> For instance, Johnson & Johnson<sup>128</sup> and Merck & Co.<sup>129</sup> are incorporated in New Jersey. New Jersey’s constituency statute permits consideration of an action’s impact on nonshareholders including customers as well as the community.<sup>130</sup> Likewise, Indiana, where Eli Lilly and Company is incorporated,<sup>131</sup> has an even broader statute. When “considering the best interests of a corporation,” the statute allows a director to consider the “customers of the corporation” and “any other factors the director considers pertinent.”<sup>132</sup> Under Indiana law, directors further may weigh the interests of various groups “as the directors deem appropriate.”<sup>133</sup>

Relying on constituency statutes has at least two limitations.<sup>134</sup> First, under the internal affairs doctrine, the law of the state of incorporation applies to actions

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125. STOUT, *supra* note 86, at 28; *see also* Bainbridge, *supra* note 82, at 973–74.

126. STOUT, *supra* note 86, at 28; Christopher Geczy, Jessica S. Jeffers, David K. Musto & Anne M. Tucker, *Institutional Investing When Shareholders Are Not Supreme*, 5 HARV. BUS. L. REV. 73 app. A (2015) (observing that thirty-three states have constituency statutes, but that seventeen states, including Delaware and California, do not). These statutes, however, vary when they apply.

127. Johnson & Johnson, Merck & Co., and Eli Lilly and Company are among the twenty-five largest biopharmaceutical companies by both market cap and revenue as reported in Bloomberg. Data from Bloomberg Terminal (accessed Feb. 5, 2018) (on file with author).

128. Johnson & Johnson, Annual Report (Form 10-K) (Feb. 20, 2019) (indicating New Jersey as place of incorporation), <https://www.sec.gov/Archives/edgar/data/200406/000020040619000009/form10-k20181230.htm> [<https://perma.cc/PC7E-QWLH>].

129. Merck & Co., Inc., Annual Report (Form 10-K) (Feb. 27, 2019) (indicating New Jersey as place of incorporation), <https://www.sec.gov/Archives/edgar/data/310158/000031015819000014/mrkl231201810k.htm> [<https://perma.cc/HH8S-L6P5>].

130. N.J. STAT. ANN. § 14A:6-1(2) (West 2003).

131. Eli Lilly and Company, Annual Report (Form 10-K) (Feb. 19, 2019) (indicating Indiana as place of incorporation), <https://www.sec.gov/Archives/edgar/data/59478/000005947819000082/lly-20181231x10xk.htm> [<https://perma.cc/SE49-RK5W>].

132. IND. CODE ANN. § 23-1-35-1(d) (West 2011).

133. *Id.* § 23-1-35-1(g).

134. An additional limitation is that some constituency statutes are limited to certain contexts such as takeovers. *See, e.g.*, OR. REV. STAT. § 60.357(5) (2017).

against officers and directors.<sup>135</sup> Relying on the existence of a constituency statute to argue that directors have the legal ability to sacrifice profits in the service of discharging a CDTR may be therefore jurisdictionally dependent. Several of the recent high-profile drug pricing and access controversies involve companies that are *not* incorporated in states with constituency statutes. Gilead Sciences, Inc., the manufacturer of important hepatitis C medications, for instance, is incorporated in Delaware (and has executive offices in California).<sup>136</sup> Neither Delaware nor California has a constituency statute.<sup>137</sup> Likewise, Biogen Inc., the maker of Spinraza, controversially expensive at \$750,000 per year,<sup>138</sup> is incorporated in Delaware.<sup>139</sup> Furthermore, many biopharmaceutical companies are incorporated in foreign jurisdictions. Turing Pharmaceuticals AG, which caused the public uproar over its pricing of Daraprim, was incorporated in Switzerland.<sup>140</sup> Incorporation in a foreign jurisdiction is not necessarily detrimental to the argument of legal permissibility. It may be that the law of foreign jurisdictions is favorable,<sup>141</sup> though an inquiry into foreign law will need to be reserved for another day.

The second limitation pertains to constituency statutes themselves. Constituency statutes are critiqued on at least two primary grounds. First, there is a lack of clarity about key provisions.<sup>142</sup> Important questions include the weight nonshareholder interests may be given and the categories of nonshareholder interests that may be considered.<sup>143</sup> The second critique is that constituency statutes are an ineffective tool for advancing nonshareholder interests. Chief Justice Strine of the Supreme Court of Delaware does not mince words: “declaring that directors may consider other interests without giving those interests voting or enforcement rights, or any real leverage to influence decision-making, is more an exercise in feeling good than in

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135. *McDermott Inc. v. Lewis*, 531 A.2d 206, 215 (Del. 1987) (“The internal affairs doctrine requires that the law of the state of incorporation should determine issues relating to internal corporate affairs.”).

136. Gilead Sciences, Inc., Quarterly Report (Form 10-Q) (Nov. 7, 2017) (indicating Delaware as place of incorporation and California as address of principal executive offices), <https://www.sec.gov/Archives/edgar/data/882095/000088209517000027/q317form10-q.htm> [<https://perma.cc/WWH5-6H3Q>].

137. Geczy et al., *supra* note 126, at app. A.

138. Julie Appleby, *Drug Puts a \$750,000 ‘Price Tag on Life,’* NPR (Aug. 1, 2017, 1:05 PM), <https://www.npr.org/sections/health-shots/2017/08/01/540100976/drug-puts-a-750-000-price-tag-on-life> [<https://perma.cc/CP5M-6XKM>].

139. Biogen Inc., Current Report (Form 8-K) (Nov. 21, 2017) (noting Delaware as place of incorporation), <https://www.sec.gov/Archives/edgar/data/875045/000119312517348663/d281870d8k.htm> [<https://perma.cc/ZG9H-TLJZ>].

140. Turing Pharmaceuticals AG, Notice of Exempt Offering of Securities (Form D/A) (Aug. 19, 2015) (noting Switzerland as place of incorporation), [https://www.sec.gov/Archives/edgar/data/1650139/000165013915000002/xslFormDX01/primary\\_doc.xml](https://www.sec.gov/Archives/edgar/data/1650139/000165013915000002/xslFormDX01/primary_doc.xml) [<https://perma.cc/LK3P-6HU7>].

141. Novo Nordisk Inc., a Danish company, for instance, commits to a triple bottom line in its bylaws. *Triple Bottom Line*, NOVO NORDISK, <http://www.novonordisk-us.com/whoware/about-novo-nordisk/triple-bottom-line.html> [<https://perma.cc/MX2K-TAUR>].

142. Bainbridge, *supra* note 82, at 988.

143. *Id.*

doing good.”<sup>144</sup> While these critiques are important, the existence of constituency statutes, warts and all, generally supports the argument that where such statutes are applicable and sufficiently broad, biopharmaceutical corporations may engage in corporate rescue.

While constituency statutes are a relatively recent development,<sup>145</sup> corporate charitable contribution statutes are an older and important source of state statutory law. Almost all states, including Delaware, have these provisions,<sup>146</sup> though there is diversity in how they relate to shareholder or corporate benefit.<sup>147</sup> As two examples, Delaware includes the power to make donations among a corporation’s enumerated powers.<sup>148</sup> It is silent as to the relationship with profit sacrifice. California, by contrast, explicitly states that corporations have such powers even if there is no corporate benefit. Under California law, a corporation has the power to “[m]ake donations, regardless of specific corporate benefit, for the public welfare or for community fund, hospital, charitable, educational, scientific, civic, or similar purposes.”<sup>149</sup> Several cases have upheld the ability to make charitable contributions.<sup>150</sup>

As previewed above, from a philosophical perspective, discussing a CDTR under the umbrella of corporate philanthropy muddies the analytical water. Doing so, however, is motivated by the legal inquiry.

A duty to rescue is generally regarded as a positive, perfect moral duty.<sup>151</sup> It is nonoptional and applies in every instance of rescue where the underlying criteria are met. One acts wrongly if one is subject to a duty to rescue but fails to so act. Acts of philanthropy, by contrast, while good or even great, are generally not viewed as morally required. They are supererogatory.<sup>152</sup>

Furthermore, *even if* corporations are subject to a positive moral duty of charity, or beneficence, the duty is imperfect. A duty of charity, or beneficence is a duty “owed to someone or other, but to no one in particular. You are immoral, according to this view, if you never help anyone, but who you help and when is up to you.”<sup>153</sup> Obligations of rescue seem different. One might legitimately respond to a request for money to save the whales with, “I donated last week.” When someone is drowning, however, saying “I *just* saved someone last week—sorry, find someone else” appears morally inadequate.<sup>154</sup>

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144. Strine, *supra* note 90, at 768.

145. Bainbridge, *supra* note 82, at 973.

146. PRINCIPLES, *supra* note 88, § 2.01 reporter’s n. 4.

147. See Elhauge, *supra* note 81, at 767–68.

148. DEL. CODE ANN. tit. 8, § 122(9) (2011).

149. CAL. CORP. CODE § 207(e) (West 2014).

150. See, e.g., Theodora Holding Corp. v. Henderson, 257 A.2d 398, 404 (Del. Ch. 1969); A. P. Smith Mfg. Co. v. Barlow, 98 A.2d 581, 586 (N.J. 1953).

151. Patricia Smith, *The Duty to Rescue and the Slippery Slope Problem*, 16 SOC. THEORY & PRAC. 19, 21 (1990).

152. SHELLY KAGAN, *NORMATIVE ETHICS* 155 (1998) (“Sacrificing your personal pleasure in this way is above and beyond the call of duty; it is *supererogatory* (a term traditionally used to mark acts that, although meritorious, are not obligatory).”).

153. Smith, *supra* note 151, at 21.

154. See *id.* at 23 (using example of a heart attack victim on doorstep).

Discussion of the legal ability of corporations to engage in charitable activities is not meant to blur this philosophical distinction. Rather, the discussion is pertinent because the legal mechanism for permitting corporate charity may provide additional legal authority for discharging a moral CDTR.

## 2. Business Judgment Rule Protection for Discharging a Corporate Duty to Rescue

In addition to the foregoing, there is further the practical reality of judicial review of corporate decision-making. Discharging a CDTR falls under an operational, as opposed to a structural (e.g., takeover, sale of company, etc.), business decision.<sup>155</sup> Operational business decisions “generally receive much less probing review” by courts.<sup>156</sup> As a practical matter, as this Section argues, discharging a CDTR (depending upon the specifics) likely would be protected under the business judgment rule. Furthermore, the breadth of discretion provided by the business judgment rule scuttles, from a legal perspective, the need for a searching analysis of what counts as a “minimal cost.”

The business judgment rule is a standard of judicial review employed when a plaintiff questions a board’s decision as a breach of fiduciary duty.<sup>157</sup> The business judgment rule “is a presumption that in making a business decision the directors of a corporation acted on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the company.”<sup>158</sup> It is not an evaluative standard for determining the lawful ends of for-profit corporations.<sup>159</sup>

The business judgment rule is extremely deferential.<sup>160</sup> Rationality, and not reasonableness, is the metric. “A board of directors enjoys a presumption of sound business judgment, and its decisions will not be disturbed if they can be attributed to *any rational business purpose*. A court under such circumstances will not substitute its own notions of what is or is not sound business judgment.”<sup>161</sup> The business judgment rule is difficult for a challenger to overcome. The plaintiff has the burden of showing that a majority of directors approving a challenged action were not disinterested, not fully informed in their approval, or did not act in good faith.<sup>162</sup>

As others note, *Dodge v. Ford* and *eBay v. Newmark* are anomalous for the directors’ motivational transparency.<sup>163</sup> Take the case involving Mr. Ford. It would have been fairly easy for him to have won.<sup>164</sup> Rather than expressing a motivation to

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155. Bainbridge, *supra* note 82, at 974.

156. *Id.*

157. R. FRANKLIN BALOTTI & JESSE A. FINKELSTEIN, BALOTTI AND FINKELSTEIN’S DELAWARE LAW OF CORPORATIONS AND BUSINESS ORGANIZATIONS § 4.19 (2019), 2006 WL 2450349.

158. *Aronson v. Lewis*, 473 A.2d 805, 812 (Del. 1984), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000); *see also* *eBay Domestic Holdings, Inc. v. Newmark*, 16 A.3d 1, 36 (Del. Ch. 2010).

159. Strine, *supra* note 90, at 777.

160. *eBay*, 16 A.3d at 36. *See generally* BALOTTI & FINKELSTEIN, *supra* note 157.

161. *Sinclair Oil Corp. v. Levi*, 280 A.2d 717, 720 (Del. 1971) (emphasis added).

162. *eBay*, 16 A.3d at 36–37.

163. *Macey*, *supra* note 87, at 182–83; Strine, *supra* note 90, at 774–75.

164. *Macey*, *supra* note 87, at 182.

promote the greater good, he could have made a business case for the various changes he sought to implement.<sup>165</sup> The court would not have questioned those decisions.<sup>166</sup> “In other words, what mattered in this case was not what Mr. Ford did, but what he said he was doing.”<sup>167</sup> This raises interesting questions about good lawyering and professional ethics.<sup>168</sup> For our purposes, it demonstrates a fairly low bar for biopharmaceutical corporations wishing to discharge a CDTR. It is plausible to think that every proposed mechanism of rescue bears a rational relationship to a business purpose.

Engaging in corporate rescue, at a minimum, has the *potential* to foster good will (e.g., reputational enhancement, brand value, customer loyalty, etc.), if not in some instances, forestall regulation or provide additional profits or tax deductions. Discharging an easy CDTR involves (at most) minimal financial cost. Yet, there is the further possibility of costless or even profitable “rescue.”<sup>169</sup>

In some cases, discharging a CDTR might come at no cost to a corporation or even be of benefit. As the *Principles* observe: “An orientation toward lawful, ethical, and public-spirited activity will normally [foster long-run profit]. The modern corporation by its nature creates interdependencies with a variety of groups . . . . The long-term profitability of the corporation generally depends on meeting the fair expectations of such groups.”<sup>170</sup>

Costless or beneficial rescue in the biopharmaceutical context could occur in several ways. For example, if a corporation can successfully price discriminate, avoid arbitrage, and on average sell its products at a price above the marginal cost of production, engaging in “rescue” might increase a corporation’s profits. Likewise, if a corporation negotiates a licensing agreement for a commercially irrelevant jurisdiction, this might also be costless. The salaries of in-house counsel negotiators are already accounted for, and a royalty could neutralize any costs of the negotiation and technology transfer.

Other potential costless rescue possibilities include current costs that are outweighed by long-term or later anticipated benefits. Discharging a CDTR might be costless or even profit enhancing over the long term through things like good will or forestalling external regulation that cuts into profits more severely.<sup>171</sup> AbbVie’s commitment, for instance, “to limit[] price increases to below 10% no more than once a year” may have been motivated by the desire to forestall external regulation.<sup>172</sup> Alnylam Pharmaceuticals also recently promised to limit price hikes.<sup>173</sup> Calling price

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165. *Id.*

166. *Id.* at 182–83.

167. *Id.* at 183.

168. *See generally id.*

169. *Cf. Elhauge, supra* note 81, at 744–45.

170. *PRINCIPLES, supra* note 88, § 2.01 cmt. f.

171. The *PRINCIPLES* contemplate this possibility. *Id.* at cmt. e.

172. Bob Herman, *AbbVie Believes Political Risks of Drug Pricing Are “Waning,”* AXIOS (Sept. 22, 2017), <https://www.axios.com/abbvie-believes-political-risks-of-drug-pricing-are-waning-2488356410.html> [https://perma.cc/5KPZ-B69Y].

173. Ed Silverman, *Alnylam Chief Turns to An Old Remedy to Rein in Drug Prices*, STAT (Nov. 30, 2017), <https://www.statnews.com/pharmalot/2017/11/30/alnylam-chief-turns-old-remedy-rein-drug-prices> [https://perma.cc/PNR5-2CWV].

increases “an indefensible act,” Alnylam’s CEO said price increases for their new rare disease drug will be in step with the Consumer Price Index.<sup>174</sup> Their drug, however, has a six-figure price tag.<sup>175</sup>

It seems uncontroversial that when biopharmaceutical corporations can help patients at a profit or at no cost to themselves, they ought to.<sup>176</sup> As Einer Elhauge has written more generally of companies engaging in profit maximizing socially responsible behavior, “such profitable activities raise no real issue of legal or normative interest. Of course, corporate managers can and should do good when it maximizes profits: What could be the argument to the contrary?”<sup>177</sup>

Whether discharging a CDTR in the biopharmaceutical access to medicines context is costless or profit enhancing is unclear. Deciphering as much would require an empirical analysis.<sup>178</sup> It is conceivable, however, that engaging in rescue is aligned with enhancing a company’s bottom line. Some, for instance, have noted a business case for differential pricing as a means for providing greater exposure to emerging markets.<sup>179</sup> Other corporate activities to be discussed below such as in-kind donations and patient assistance programs that (controversially) look like rescue have been heavily critiqued as profit-enhancing tools. Regardless, there should be little to debate—legally or morally—about costless and profitable “rescue.” If biopharmaceutical corporations have opportunities to do good at no cost or even benefit to themselves, they ought to do so.

It is also conceivable that some instances of discharging a CDTR will involve profit sacrifice. Skepticism that socially responsible conduct aligns with profit maximization may be warranted since “[a]gitating for corporations to engage in responsible conduct that increases their profits is a lot like saying there are twenty-dollar bills lying on the sidewalk that they have missed.”<sup>180</sup> Companies generally have adequate profit-maximizing incentives not to leave free cash lying on the sidewalk. Such arguments, therefore, may be more about “creat[ing] a patina of conceivable profitability that makes it easier for managers to engage in conduct that really sacrifices expected corporate profits.”<sup>181</sup>

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174. *Id.*

175. Matthew Herper, *Alnylam Prices First Gene Silencing Drug at \$450,000 per Patient, but Offers Money-Back Guarantee*, FORBES (Aug. 10, 2018, 3:21 PM), <https://www.forbes.com/sites/matthewherper/2018/08/10/alnylam-prices-breakthrough-drug-at-450000-per-patient-but-offers-money-back-guarantee/#7da08f1c5941> [<https://perma.cc/5AH9-4U39>] (noting annual list price of \$450,000 but also existence of money-back guarantee for insurers).

176. The two cases are slightly different. Both market and moral reasons can be at play in “profitable rescue,” however, the former would likely be emphasized over the latter. In cases of merely “costless rescue,” the reverse appears true. There may be no market reason and so emphasis would be placed on a moral reason for engaging in rescue.

177. Elhauge, *supra* note 81, at 744.

178. It is further unclear whether an analysis could be undertaken on the basis of publicly available information.

179. See ACCESS TO MED. FOUND., ACCESS TO MEDICINE INDEX 2016, at 15, 33 (2016), <https://accessmedicineindex.org/media/atmi/Access-to-Medicine-Index-2016.pdf> [<https://perma.cc/MX5E-FMTA>] [hereinafter ACCESS TO MEDICINE INDEX 2016].

180. Elhauge, *supra* note 81, at 744–45.

181. *Id.* at 745.

In light of the immense amount of discretion courts give to operational decisions, it is unsurprising that there are no hard and fast rules to pin down what counts as rescue at minimal cost.<sup>182</sup> Yet, at least one court reflecting on the permissible amount of corporate philanthropy employed a reasonableness standard tied to the federal tax code.<sup>183</sup> This is so despite the fact that evaluation of charitable contributions fall under the business judgment rule.<sup>184</sup> The court ruled that so long as philanthropic spending falls within the tax-deductible amount, such spending is reasonable and therefore permissible.<sup>185</sup> Generally, corporations may deduct charitable contributions valued at up to “10 percent of the taxpayer’s taxable income.”<sup>186</sup> Special rules allowing enhanced deductions also apply to contributions of inventory “used by the donee solely for the care of the ill, the needy, or infants”—clearly a pertinent provision for biopharmaceutical corporations.<sup>187</sup>

The *Principles*’ discussion may shed some light here. The *Principles* acknowledge that a business case exists in many instances for corporate philanthropy and resources devoted to public welfare. Yet, there might also be situations where such activities are “justified *solely* by social considerations.”<sup>188</sup> When justified *solely* by social considerations, such activities “should be subject to a limit of reasonableness.”<sup>189</sup> This is because “the relevant considerations do not necessarily bear on the manner in which business should be conducted, and (partly for those reasons) there is no limit inherent in the considerations themselves on the extent to which corporate resources may be devoted to such purposes.”<sup>190</sup> The *Principles* go on to suggest circumstances that might feed into a reasonableness determination. Proposed important factors to consider “are the customary level at which resources are devoted to such purposes among comparable corporations in proportion to earnings and assets, and the strength of the nexus between the use of corporate resources and the corporation’s business.”<sup>191</sup>

In the absence of a rational business purpose, one could attempt to cobble together a standard for determining a legally permissible “minimal cost” expenditure for discharging a CDTR. For legal purposes, the minimal cost requirement morphs into

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182. Cf. *id.* at 842–43. See generally PRINCIPLES, *supra* note 88, at § 2.01 illus. 5 & 6 (discussing variations of an insurance company relaxing loan standards and sacrificing profits to finance inner city projects).

183. *Theodora Holding Corp. v. Henderson*, 257 A.2d 398, 405 (Del. Ch. 1969).

184. See, e.g., *eBay Domestic Holdings, Inc. v. Newmark*, 16 A.3d 1, 33 (Del. Ch. 2010) (“When director decisions are reviewed under the business judgment rule, this Court will not question rational judgments about how promoting non-stockholder interests—be it through making a charitable contribution, paying employees higher salaries and benefits, or more general norms like promoting a particular corporate culture—ultimately promote stockholder value.”).

185. *Theodora Holding*, 257 A.2d at 405.

186. 26 U.S.C. § 170(b)(2)(A) (2012).

187. 26 U.S.C. § 170(e)(3)(A)(i) (2012); see also Roger Colinvaux, *Charitable Contributions of Property: A Broken System Reimagined*, 50 HARV. J. ON LEGIS. 263, 315 (2013).

188. PRINCIPLES, *supra* note 88, § 2.01 cmt. i (emphasis added).

189. *Id.*

190. *Id.*

191. *Id.*

a suggested one of reasonableness. Reasonableness might be determined in accordance with how much a corporation may deduct from its taxes, how much comparable corporations are spending, and the relationship between the expenditure and the corporation's business. *Prima facie*, from a moral perspective, however, none of these proposals are compelling.<sup>192</sup> Further, and interestingly, replacing a minimal cost requirement with a reasonableness standard could serve to broaden the legally permissible burden imposed by a CDTR. While an easy CDTR as a moral matter only requires rescue at *minimal* cost, the law might actually tolerate rescue at *reasonable* cost.

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In sum, the business judgment rule provides broad director discretion. This discretion covers decisions that may not maximize profits, and certainly covers decisions where rescue would be costless or beneficial. The business judgment rule thus likely protects biopharmaceutical corporations discharging a CDTR.

### III. DO PHARMACEUTICAL COMPANIES ALREADY ENGAGE IN RESCUE?

Biopharmaceutical corporations have the legal ability to discharge a CDTR. Further, they actually engage in the activities proponents of a CDTR have proposed. These activities include the forbearance of patent rights and issuance of non-assertion declarations, voluntary licenses, donations of medical products, price reductions and differential pricing, as well as patient assistance programs.<sup>193</sup> The below briefly describes each of these mechanisms and provides examples for illustration.

Beyond providing additional “real-world” evidence in support of the arguments made in Section II.B, this discussion brings two related issues to the fore. First, though certain activities are identified as a means for discharging obligations of corporate rescue, one might wonder whether, in any particular instance, this is an accurate characterization. Biopharmaceutical companies may not act out of a sense of moral obligation to rescue, so much as good business sense or even optional charity. Second, and more importantly, consideration of these candidate mechanisms necessitates further moral analysis. Though proposals for a CDTR claim that rescue involves certain activities, and an examination of law and principles demonstrates that biopharmaceutical corporations may sacrifice profits in order to rescue, neither provides an analysis of what discharging a moral CDTR requires. This issue, addressed in Part IV, is far more complicated than might seem at first glance. As will be argued in Part IV, a duty to rescue does not apply to the biopharmaceutical context in a straightforward way.

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192. See Elhage, *supra* note 81, at 842–43. As noted below, this critique also applies to Dunfee's attempt to operationalize a CDTR.

193. Companies also engage in other access to medicine strategies such as efforts to “improve service delivery” as well as efforts to “improve population health indirectly.” Peter C. Rockers, Veronika J. Wirtz, Chukwuemeka A. Umeh, Preethi M. Swamy & Richard O. Laing, *Industry-Led Access-to-Medicines Initiatives in Low- and Middle-Income Countries: Strategies and Evidence*, 36 HEALTH AFF. 706, 707 (2017).

*A. Forbearance of Patent Rights and Non-assertion Declarations*

Patents and regulatory exclusivities create legal barriers for others entering a market. Patent holders, for instance, may exclude others from making, using, selling or otherwise practicing a patented invention for a set period of time.<sup>194</sup> In the United States, patents typically have a term of twenty years,<sup>195</sup> though pharmaceutical patent terms may be extended due to regulatory review.<sup>196</sup> Biopharmaceutical companies can also receive various regulatory exclusivities—for instance, they can be given the ability to exclude others from using their data or marketing a similar product.<sup>197</sup> Rights of exclusion (patent and regulatory) are justified on the basis of innovation incentives.<sup>198</sup> Without the prospect of sufficient reward, it is argued that innovation will lag, new products will not come to market, and patients will suffer.<sup>199</sup> The merits of the current patent and regulatory exclusivity regime may be debated. It is largely uncontroversial, however, that these rights impede access to presently existing therapies. Indeed, an exclusive right does so by design.

One set of strategies, therefore, for increasing access to existing therapies subject to legal exclusivities is to forgo either the legal rights themselves or their enforcement. Several CDTR proposals call upon biopharmaceutical companies to relax their rights.<sup>200</sup> Many companies do. Of the twenty companies profiled in the Access to Medicine Index (AMI), for example, fifteen companies now have publicly

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194. 35 U.S.C. § 154(a)(1) (2012).

195. *Id.* § 154(a)(2).

196. *Id.* § 156 (2012).

197. *Id.*; 42 U.S.C. § 262(k) (2012); *see, e.g.*, Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 83 (2016); Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419 (2012); Anna B. Laakmann, *A Property Theory of Medical Innovation*, 56 JURIMETRICS J. 117 (2016).

198. *See, e.g.*, MERCK & CO., INC., PUBLIC POLICY STATEMENT: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN THE DEVELOPING WORLD (2016), <https://www.merck.com/about/views-and-positions/FINAL%20Public%20Policy%20Statement%20-%20Access%20to%20Medicines%20April%202016.pdf> [<https://perma.cc/RWX3-44VV>]; PFIZER INC., GLOBAL INTELLECTUAL PROPERTY RIGHTS (2015), <https://www.pfizer.com/files/about/Position-Global-Intellectual-Property-Rights.pdf> [<https://perma.cc/48EU-3HYM>]; Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007); Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 193, 194 (2005) (noting the view that “the research and development (R&D) enterprise must be nurtured by high prices to yield the next generation of breakthrough therapies”).

199. *See, e.g.*, *Intellectual Property*, PhRMA, <http://www.phrma.org/advocacy/intellectual-property> [<https://perma.cc/8TJM-RXW5>].

200. Ho, *Global Health Disparity*, *supra* note 20, at 33; Ho, *Pharmaceutical Corporations*, *supra* note 20, at 74; Hsieh, *Property Rights in Crisis*, *supra* note 20, at 382–83; *see also* Ho, *Global Health Disparity*, *supra* note 20, at 29 (noting some believe pharmaceutical companies have a moral obligation to assist which includes “waiver of patent rights”).

available patent filing and enforcement policies—up from thirteen companies in 2016.<sup>201</sup> The policies vary both in terms of covered jurisdictions and products.<sup>202</sup>

Some companies choose to forgo patent protection entirely—in certain markets. Of those thirteen companies with publicly available policies discussed in the 2016 AMI, the majority have nonfiling policies that apply either to least developed countries, low income countries, or both.<sup>203</sup> Merck & Co., for instance, has “a long standing general policy of not filing for patents for our products in low income countries.”<sup>204</sup> Likewise, neither Roche,<sup>205</sup> Novartis,<sup>206</sup> nor GlaxoSmithKline “file for patent protection in Least Developed and Low Income Countries.”<sup>207</sup> Roche further does not file patents “for any antiretroviral HIV medicines in sub-Saharan African countries.”<sup>208</sup> Two of the profiled companies have policies that apply to middle-income countries.<sup>209</sup>

Typically involving a patent, non-assertion declarations are pledges not to enforce the legal rights one possesses.<sup>210</sup> Such declarations are often tailored to apply to specified products, in specified circumstances, and for specified jurisdictions.<sup>211</sup> Non-assertion declarations allow space for others to enter the market. They allow “third parties to make, use, sell or import the patented article within the scope of the declaration, including in resource-limited settings, without fear of an infringement suit.”<sup>212</sup>

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201. ACCESS TO MED. FOUND., ACCESS TO MEDICINE INDEX 2018, at 96 (2018), [https://accessmedicinefoundation.org/media/uploads/downloads/5c1a82b34aa87\\_Access-to-Medicine-Index-2018.pdf](https://accessmedicinefoundation.org/media/uploads/downloads/5c1a82b34aa87_Access-to-Medicine-Index-2018.pdf) [<https://perma.cc/6XJ5-X2Q3>] [hereinafter ACCESS TO MEDICINE INDEX 2018]. Thirteen companies with such policies were noted in the 2016 ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 39.

202. ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 39.

203. *Id.*

204. MERCK & CO., INC., *supra* note 198, at 3; *see also* Asher Mullard, *What New GSK Patent Policy Means for the Developing World*, NATURE (Apr. 5, 2016), <http://www.nature.com/news/what-new-gsk-patent-policy-means-for-the-developing-world-1.19695> [<https://perma.cc/86ZW-R9NG>].

205. ROCHE, IMPROVING ACCESS: OVERCOMING BARRIERS 9 (2013), [https://www.roche.com/dam/jcr:a9c0006a-fed9-4864-a8c9-d8ffec6ca508/en/access\\_to\\_healthcare.pdf](https://www.roche.com/dam/jcr:a9c0006a-fed9-4864-a8c9-d8ffec6ca508/en/access_to_healthcare.pdf) [<https://perma.cc/B4HT-5GY6>].

206. *Expanding Access to Healthcare*, NOVARTIS, <https://www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare> [<https://perma.cc/UU3D-4LCF>].

207. *GSK Expands Graduated Approach to Patents and Intellectual Property to Widen Access to Medicines in the World's Poorest Countries*, GSK (Mar. 31, 2016), <https://www.gsk.com/en-gb/media/press-releases/gsk-expands-graduated-approach-to-patents-and-intellectual-property-to-widen-access-to-medicines-in-the-world-s-poorest-countries> [<https://perma.cc/59LJ-RZQQ>].

208. ROCHE, *supra* note 205, at 9.

209. ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 39.

210. IFPMA, POLICY POSITION: VOLUNTARY LICENSES AND NON-ASSERT DECLARATIONS 2 (2015), <https://www.ifpma.org/wp-content/uploads/2016/03/IFPMA-Position-on-VL-and-Non-Assert-Declarations-18FEB2015.pdf> [<https://perma.cc/5Q4U-H5LL>].

211. *Id.*

212. *Id.*

As with decisions to forgo patent rights, non-assertion declarations tend to apply to jurisdictions of less commercial significance. Indeed, many of the covered countries can choose not to enforce patents as the World Trade Organization granted an extension to Least Developed Countries (LDCs) “from needing to recognise patent rights on pharmaceuticals until 2033.”<sup>213</sup> Several biopharmaceutical companies have non-assertion declarations and agreements.<sup>214</sup> For example, Janssen has a policy, expanded in 2015, not to enforce its patents on the antiretroviral drug darunavir “for pediatric products used in low- and middle- income countries.”<sup>215</sup>

### B. Voluntary Licenses

Another candidate corporate rescue mechanism is voluntary licensing.<sup>216</sup> “A voluntary license is an authorization given by the patent holder to a third party (e.g., a generic pharmaceutical manufacturer), allowing that party to make, use, sell or import the patented article, e.g., a medicine.”<sup>217</sup> Licensing terms vary and can be designed in various ways,<sup>218</sup> including quality requirements as well as jurisdictional restrictions.<sup>219</sup> Voluntary licenses can be exclusive or non-exclusive.<sup>220</sup> The AMI recommends that “[t]o have a significant impact on access, licences should be non-exclusive, transparent and include access-friendly terms.”<sup>221</sup>

Whereas biopharmaceutical companies are generally opposed to compulsory licensing, they are more receptive to voluntary licensing as a means for increasing access to their products. A recent study of initiatives across twenty-one companies found that twenty-two percent of access to medicines initiatives involved licensing agreements.<sup>222</sup> Two recent examples of licensing arrangements are licenses facilitated by the Medicines Patent Pool, which focuses on HIV, hepatitis C, and

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213. ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 39.

214. *Id.*; see also IFPMA, *supra* note 210, at 3 (providing selected examples of ARV initiatives using voluntary licenses or non-assert declarations); Quentin A. Palfrey, *Expanding Access to Medicines and Promoting Innovation: A Practical Approach*, 24 GEO. J. ON POVERTY L. & POL’Y 161, 191–92 (2017).

215. Press Release, Johnson & Johnson, Johnson & Johnson Expands IP Policy to Create Broad Access in 128 Countries for Development of New and Optimized HIV Medicine Formulations for Children Living with HIV (May 11, 2015), <https://www.jnj.com/media-center/press-releases/johnson-johnson-expands-ip-policy-to-create-broad-access-in-128-countries-for-development-of-new-and-optimized-hiv-medicine-formulations-for-children-living-with-hiv> [<https://perma.cc/5RWT-LSL7>]; see also ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 86.

216. Outterson & Light, *supra* note 20, at 426–27; see also Ho, *Global Health Disparity*, *supra* note 20, at 35.

217. IFPMA, *supra* note 210, at 2.

218. Palfrey, *supra* note 214, at 185–91.

219. IFPMA, *supra* note 210, at 2.

220. Palfrey, *supra* note 214, at 190.

221. ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 38.

222. Rockers et al., *supra* note 193, at 708. The study focused on low- and middle-income countries, excluding high-income countries.

tuberculosis,<sup>223</sup> and Gilead's licensing of its hepatitis C medications.<sup>224</sup> Gilead's licensing policies have been controversial. Among other criticisms, advocacy groups have criticized the exclusion of several middle-income countries where large segments of the population are poor and suffer from hepatitis C.<sup>225</sup> In response to external pressure, Gilead expanded its licensing agreement in August 2017 to include Ukraine, Belarus, Thailand, and Malaysia.<sup>226</sup>

### C. Donations of Medical Products

In addition to alterations to intellectual property management strategies, several of the CDTR proposals contemplate the provision of in-kind donations.<sup>227</sup> Donations of medicines is a common, though fraught,<sup>228</sup> practice among biopharmaceutical companies.<sup>229</sup>

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223. *The Medicines Patent Pool*, UNITAID, <https://unitaid.eu/project/medicines-patent-pool/#en> [<https://perma.cc/FK6M-UJRZ>]. The Medicines Patent Pool (MPP) works with a number of pharmaceutical companies including ViiV Healthcare, Bristol-Myers Squibb, Gilead, AbbVie, and MSD. *Licence Overview*, MEDICINES PATENT POOL, <https://medicinespatentpool.org/what-we-do/global-licence-overview> [<https://perma.cc/QA9V-4DBV>].

224. GILEAD, CHRONIC HEPATITIS C TREATMENT EXPANSION: GENERIC MANUFACTURING FOR DEVELOPING COUNTRIES (2015), <https://www.gilead.com/~media/files/pdfs/other/hcv%20generic%20agreement%20fast%20facts%2072815.pdf> [<https://perma.cc/77CP-WDQZ>].

225. Letter from Rohit Malpani, Dir. of Policy & Analysis, Médecins Sans Frontières, to Gregg Alton, Exec. Vice President, Gilead Scis. Inc. (Sept. 5, 2016), <https://www.msfnaccess.org/content/letter-gilead-sciences-attempts-remove-generic-sofosbuvir-ukraine> [<https://perma.cc/8WH2-DM9S>] (expressing concern and opposition to Gilead's attempts to remove generic sofosbuvir from Ukraine); see also ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 40.

226. Ed Silverman, *Under Pressure, Gilead Expands Sovaldi Licensing Deal to Four Middle-Income Countries*, STAT (Aug. 24, 2017), <https://www.statnews.com/pharmalot/2017/08/24/gilead-sovaldi-malaysia-ukraine> [<https://perma.cc/ZB9Z-TLAZ>].

227. Dunfee, *supra* note 20, at 191–92 (noting in-kind and cash contributions); Hsieh, *Property Rights in Crisis*, *supra* note 20, at 382–83; see also Ho, *Global Health Disparity*, *supra* note 20, at 29 (noting some believe pharmaceutical companies have a moral obligation to assist which includes “drug donation”).

228. WORLD HEALTH ORG., RESPONDING TO INDUSTRY INITIATIVES TO INCREASE ACCESS TO MEDICINES AND OTHER HEALTH TECHNOLOGIES IN COUNTRIES (2017), <https://apps.who.int/iris/bitstream/handle/10665/259359/WHO-EMP-2017.04-eng.pdf;jsessionid=B743EBB95D18D643086AA24D0D7E7D5F?sequence=1> [<https://perma.cc/W7ZQ-HMDT>]; Pakoyo Fadhuru Kamba, Munanura Edson Ireeta, Sulah Balikuna & Bruhan Kaggwa, *Threats Posed by Stockpiles of Expired Pharmaceuticals in Low- and Middle-Income Countries: A Ugandan Perspective*, 95 BULL. WORLD HEALTH ORG. 594 (2017), <https://www.who.int/bulletin/volumes/95/8/16-186650.pdf> [<https://perma.cc/X8K2-VJQL>]; Cristina P. Pinheiro, *Drug Donations: What Lies Beneath*, 86 BULL. WORLD HEALTH ORG. 580 (2008), <https://www.who.int/bulletin/volumes/86/8/07-048546.pdf?ua=1> [<https://perma.cc/7YXD-Y3XY>]. Note that in-kind donations rather than sales at cost also allow companies to avoid disclosing their cost structures.

229. Some companies do not pursue donations of medical products except in certain circumstances. See, e.g., MERCK & CO., INC., PUBLIC POLICY STATEMENT: CHARITABLE

Donations are one of the primary strategies of corporate access to medicines initiatives.<sup>230</sup> One study found that forty-eight percent of examined initiatives utilized a “medicine donation strategy.”<sup>231</sup> Corporate donations fall across the disease spectrum—from neglected tropical diseases and communicable diseases to noncommunicable diseases—but appear most heavily to emphasize the former categories.<sup>232</sup>

Merck’s donation of Mectizan, which treats onchocerciasis (river blindness) and lymphatic filariasis where it coexists with river blindness, is a well-known and successful example of a corporate drug donation program.<sup>233</sup> Begun in 1987, Merck made a commitment to treat “all who needed [Mectizan], for as long as needed.”<sup>234</sup> Donations continue to this day, and as of 2013, river blindness has been eliminated in Colombia, Ecuador, Guatemala, and Mexico.<sup>235</sup>

Companies also have donation programs targeted at emergency situations.<sup>236</sup> Pfizer, for instance, “donates a variety of products to assist with humanitarian emergencies, including essential health and over-the-counter (OTC) medicines.”<sup>237</sup> The company cites donations in response to Hurricane Matthew and the cholera outbreak in Haiti as well as “providing in-kind donations of up to 170,000 doses of long-acting contraceptive product” to help curtail the effects of the Zika outbreak in Puerto Rico.<sup>238</sup> Pfizer also operates a Naloxone Access Program in the United States, which will donate up to one million doses over four years.<sup>239</sup>

Though in-kind donations “can be temporary solutions to defined problems,”<sup>240</sup> they are a controversial access to medicine strategy. As the World Health Organization notes, “medicine donations are neither a long-term solution to underfunded health systems nor a solution to the lack of access to medicines in poor countries – especially for diseases that require lifelong treatment or large numbers of treatments.”<sup>241</sup> Some such as Gavi, the Vaccine Alliance, “[a]s a general principle . .

PRODUCT DONATIONS (2010), <https://www.merck.com/about/views-and-positions/charitable-product-donations.pdf> [<https://perma.cc/THE6-LTVA>].

230. Rockers et al., *supra* note 193, at 710.

231. *Id.* at 708.

232. ACCESS TO MEDICINE INDEX 2018, *supra* note 201, at 125; ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 42–43.

233. *Id.* at 42.

234. *Mectizan Donation Program*, MSD, <https://www.msdrresponsibility.com/access-to-health/key-initiatives/mectizan-donation-program> [<https://perma.cc/U7N5-RDTB>].

235. *Id.*

236. ACCESS TO MEDICINE INDEX 2018, *supra* note 201, at 125 (distinguishing between ad hoc donation programs in response to “humanitarian crises” and “structured donation programmes”).

237. *Providing Relief and Emergency Humanitarian Assistance*, PFIZER, <https://www.pfizer.com/purpose/medicine-access/humanitarian-aid> [<https://perma.cc/E988-LA7V>].

238. *Id.*

239. PFIZER, PFIZER NALOXONE ACCESS PROGRAM 2, [https://www.pfizer.com/files/health/Naloxone\\_Fact\\_Sheet.pdf](https://www.pfizer.com/files/health/Naloxone_Fact_Sheet.pdf) [<https://perma.cc/7EMR-E3QP>].

240. WORLD HEALTH ORG., GUIDELINES FOR MEDICINE DONATION 7 (2011), [http://apps.who.int/iris/bitstream/10665/44647/1/9789241501989\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44647/1/9789241501989_eng.pdf) [<https://perma.cc/GD6T-XMA9>]; see also ACCESS TO MEDICINE INDEX 2018, *supra* note 201, at 125.

241. WORLD HEALTH ORG., *supra* note 240.

. will not accept in-kind donations of vaccines except under . . . exceptional circumstances.”<sup>242</sup> And, in October 2016, Médecins Sans Frontières (MSF) rejected Pfizer’s offer to donate a million doses for children of Prevnar 13, an important pneumonia vaccine.<sup>243</sup> MSF provided many reasons for why it turned down Pfizer’s offer. Stating that “[f]ree is not always better,”<sup>244</sup> MSF noted that donations come with restrictions on use, can “undermine long-term efforts to increase access to affordable vaccines and medicines,” are used to justify keeping prices high for others, and operate at a donor’s whim, which can result in supply interruptions and shortages.<sup>245</sup> Others echo these criticisms of in-kind donations as well as raise additional ones—for instance, the practice of companies sending medicines that are not of need, of unknown or poor quality, or that have expired which causes complicated and expensive disposal problems—all while donors get to receive favorable tax treatment for their charitable contributions.<sup>246</sup> In the Prevnar 13 case, MSF’s preferred resolution was a price reduction for humanitarian organizations. Pfizer complied with this request in November 2016.<sup>247</sup>

#### D. Price Reductions and Price Discrimination

Advocates for improved access to medicines often call for price reductions or differential pricing.<sup>248</sup> Several of the CDTR proposals likewise suggest price reductions,<sup>249</sup> and at least one author calls for increased utilization of differential pricing.<sup>250</sup> Price reductions and differential pricing are also popular mechanisms

242. *Vaccine Donation Policy*, GAVI: VACCINE ALLIANCE (2010), <http://www.gavi.org/about/programme-policies/vaccine-donation> [<https://perma.cc/N6C9-XJUG>].

243. Eric Sagonowsky, *Here’s Why MSF Turned Away Pfizer’s Offer to Donate a Million Prevnar 13 Doses*, FIERCEPHARMA (Oct. 12, 2016, 8:58 AM), <https://www.fiercepharma.com/vaccines/msf-turns-away-pfizer-s-1m-dose-donation-offer-prevnar-13> [<https://perma.cc/8V8C-EN2Q>].

244. Jason Cone, *There Is No Such Thing as “Free” Vaccines: Why We Rejected Pfizer’s Donation Offer of Pneumonia Vaccines.*, MEDIUM (Oct. 9, 2016), [https://medium.com/@MSF\\_access/there-is-no-such-thing-as-free-vaccines-why-we-rejected-pfizers-donation-offer-of-pneumonia-6a79c9d9f32f](https://medium.com/@MSF_access/there-is-no-such-thing-as-free-vaccines-why-we-rejected-pfizers-donation-offer-of-pneumonia-6a79c9d9f32f) [<https://perma.cc/8QRV-XYVE>].

245. *Id.*; see also Colinvaux, *supra* note 187, at 316–17.

246. WORLD HEALTH ORG., *supra* note 240, at 5–7 (noting various problems with medicine donations), at 19 (noting problems with donations that occurred in three examples—after the 2001 earthquake in India, the 2004 Tsunami in Sri Lanka, and issues in Tanzania); Kamba et al., *supra* note 228; Pinheiro, *supra* note 228; see also Linda Sugin, *Encouraging Corporate Charity*, 26 VA. TAX REV. 125, 159–60 (2006).

247. Cone, *supra* note 244.

248. See, e.g., *id.*; Palfrey, *supra* note 214; see also Suerie Moon, Elodie Jambert, Michelle Childs & Tido von Schoen-Angerer, *A Win-Win Solution?: A Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries*, 7 GLOBALIZATION & HEALTH 39, 1 (2011) (noting “widespread support” for tiered pricing, but registering several drawbacks and criticisms).

249. Dunfee, *supra* note 20, at 189 (noting that part of what gives pharmaceutical companies a special obligation is their ability “to employ repricing and other strategies to combat the catastrophe.”); Hsieh, *Property Rights in Crisis*, *supra* note 20, at 382–83.

250. Ho, *Global Health Disparity*, *supra* note 20, at 33; Ho, *Pharmaceutical Corporations*,

among corporate access to medicines initiatives.<sup>251</sup> In one study, forty-four percent of initiatives involved price reductions.<sup>252</sup>

Differential pricing (a.k.a. price discrimination or tiered-pricing) is a well-known and often used practice<sup>253</sup> whereby different consumers or markets are charged different prices for essentially the same product.<sup>254</sup> Price discrimination is rampant through regulation in the U.S. market where government programs such as Medicaid, the Federal Department of Veterans Affairs, and qualifying 340B participants receive mandatory discounts.<sup>255</sup> More generally, given the lack of transparency regarding pricing arrangements between insurers, manufacturers, and intermediaries such as pharmacy benefit managers, U.S. patients can end up paying dramatically different prices for the same medication.<sup>256</sup>

Price discrimination, of the voluntary variety, offers the prospect of a win-win situation. Knowing that consumers differ regarding their ability or “willingness” to pay for a product, businesses can maximize profits by charging different consumers different amounts. This can also have the beneficial effect of enlarging the number of people accessing a product.<sup>257</sup>

Price discrimination can take different forms,<sup>258</sup> and it can be implemented between and within countries.<sup>259</sup> For companies to be able to successfully engage in price discrimination, typically three conditions must be satisfied: (1) the company must have market power, (2) the company must be able to prevent or limit arbitrage, and (3) the company must be able to successfully divide up its consumer markets.<sup>260</sup> In the biopharmaceutical context, preventing arbitrage—the sale of lower priced medicines in higher priced jurisdictions thus cannibalizing higher priced sales—is a major concern with implementing differential pricing.<sup>261</sup> Given the recent U.S. Supreme Court ruling in *Impression Products, Inc. v. Lexmark International, Inc.*—which held that overseas sales of a patented product exhausts the patent holder’s rights and thus there can be no infringement suit—this may be even more of a concern.<sup>262</sup>

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*supra* note 20, at 74.

251. *See, e.g.*, MERCK & CO., INC., *supra* note 198.

252. Rockers et al., *supra* note 193, at 708.

253. William W. Fisher III, *When Should We Permit Differential Pricing of Information?*, 55 UCLA L. REV. 1, 2–3 (2007).

254. *Id.*

255. MAKING MEDICINES AFFORDABLE REPORT, *supra* note 3, at 103–07.

256. *Id.* at 75.

257. Moon et al., *supra* note 248, at 2.

258. Fisher, *supra* note 253, at 4; *see also* Moon et al., *supra* note 248, at 2.

259. *See, e.g.*, ACCESS TO MEDICINE INDEX 2018, *supra* note 201, at 81; ACCESS TO MEDICINE INDEX 2016, *supra* note 179, at 34; Palfrey, *supra* note 214, at 170–72.

260. Fisher, *supra* note 253, at 3–4.

261. Outterson, *supra* note 198, at 195–96. But arguing that “the threat of pharmaceutical arbitrage is overstated and rarely observed empirically.” *Id.* at 198.

262. 137 S. Ct. 1523 (2017). *But see* Daniel Hemel & Lisa Larrimore Ouellette, *How ‘Price Discrimination’ Helps Less-Affluent Countries*, WALL ST. J. (Mar. 20, 2017, 7:03 PM), <https://www.wsj.com/articles/how-price-discrimination-helps-less-affluent-countries-1490051000> [<https://perma.cc/897X-MFZ8>] (observing the potential importance of the *Impression Products* decision for foreign consumers and patients); Daniel Hemel & Lisa

Many examples exist of biopharmaceutical companies employing price reductions or differential pricing. To note just a few, Novartis offers a collection of therapies addressing noncommunicable diseases “to governments, NGOs and other institutional customers in lower-income countries at a price of USD 1 per treatment per month.”<sup>263</sup> Pfizer, as already mentioned, eventually lowered the cost of Prevnar 13 for use by civil service organizations working in emergency settings,<sup>264</sup> and Gilead has cited “a tiered pricing model” as “[o]ne key initiative that helps expand access to our HIV and HCV medicines.”<sup>265</sup> Gilead “set[s] prices according to a country’s specific situation” and credits tiered pricing with enabling them to make “significant progress in increasing access to our medicines in low- and lower-middle-income countries suffering the greatest unmet need.”<sup>266</sup>

### E. Patient Assistance Programs

Patient assistance programs come in many varieties, differing “in what they do, who they help, and how they obtain funding.”<sup>267</sup> Some are directly funded by biopharmaceutical companies and others are funded through charitable foundations that receive payments from a manufacturer.<sup>268</sup> The purported aim of patient assistance programs is to help patients who cannot afford their medication. Eligibility and inclusion requirements vary, with programs offering assistance to those who are insured, underinsured, as well as those who are not insured at all.<sup>269</sup> CDTR proposals do not explicitly call upon biopharmaceutical companies to have or contribute to patient assistance programs. Yet, *prima facie*, patient assistance programs are a poster-child mechanism of corporate rescue. They are programs designed to provide expensive therapies at reduced or no out-of-pocket costs to patients.

Patient assistance programs, however, face significant criticism. Far from “rescuing” needy patients, such programs, particularly copay assistance permutations, have been accused of merely perpetuating an environment that permits high-cost medications to thrive.<sup>270</sup> By reducing patient price sensitivity,

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Larrimore Ouellette, *Licensing in the Shadow of Impression Products*, WRITTEN DESCRIPTION (May 31, 2017), <https://writtendescription.blogspot.com/2017/05/licensing-in-shadow-of-impression.html> [<https://perma.cc/7ZL3-2DTH>] (questioning whether patent holders can get around the *Impression Products* holding by utilizing licensing arrangements).

263. *How Novartis Access Works*, NOVARTIS, <https://www.novartis.com/about-us/corporate-responsibility/expanding-access-healthcare/novartis-social-business/Novartis-access/how-access-works> [<https://perma.cc/WW5X-Q4J3>].

264. *Providing Relief*, *supra* note 237.

265. *Tiered Pricing*, GILEAD, <https://web.archive.org/web/20171207033255/http://www.gilead.com/responsibility/corporate-contributions/2014%20corporate%20contributions%20report/how%20we%20contribute/providing%20access/tiered%20pricing> [<https://perma.cc/MS9Z-8Q3C>].

266. *Id.*

267. S. Yousuf Zafar & Jeffrey M. Peppercorn, *Patient Financial Assistance Programs: A Path to Affordability or a Barrier to Accessible Cancer Care?*, 35 J. CLINICAL ONCOLOGY 2113, 2113 (2017).

268. *Id.* at 2114.

269. *Id.*

270. *Id.*

“manufacturers have a free pass to charge more, have insurers cover the majority of costs, and provide assistance for whatever portion of costs insurers decline to cover.”<sup>271</sup> Mylan, for instance, used this strategy with EpiPen. When insurers balked at covering, in full, the new increased price, Mylan responded not by reversing its price hikes but by offering patients copay coupons.<sup>272</sup>

From a system perspective, copay assistance programs are especially concerning when there are several competitor therapies, including a generic option. Research indicates that in such situations, patient assistance programs are not costly to companies, but rather profit enhancing. As the National Academies of Sciences, Engineering, and Medicine report observes, “One recent analysis estimated that copay coupons increase branded drug sales by 60 percent or more, almost entirely by reducing the sales of generic competitors, and that branded drug manufacturers receive a return of between four-to-one and six-to-one on every dollar spent on copay coupons.”<sup>273</sup> To the extent particular patient assistance programs sustain high prices and raise costs for others, characterizing them as mechanisms of rescue may be misplaced.<sup>274</sup>

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Biopharmaceutical companies engage in “rescue” activities. They employ a wide range of strategies that, at least in theory, can be utilized to increase access to needed therapies. While the different practices detailed above have been *proposed* as candidate mechanisms of rescue, it remains unclear whether they would discharge that moral duty. Despite an intuitive sense of what a CDTR demands, as will be argued next, much about the duty is presently opaque.

#### IV. A CORPORATE DUTY TO RESCUE: NORMATIVE CHALLENGES

An easy duty to rescue has great intuitive appeal, and its existence enjoys broad consensus. It is unsurprising that scholars have sought its application to the corporate context, and specifically to biopharmaceutical companies and access to medications. As argued in Parts II and III, biopharmaceutical firms have the legal discretion to discharge a moral CDTR, and they *do in fact engage* in the very “rescue” activities identified by proponents of this duty.

Yet, important unacknowledged differences exist between the paradigm and CDTR cases.<sup>275</sup> Many thorny moral issues complicate application of this duty to the

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271. *Id.*

272. *Id.*

273. MAKING MEDICINES AFFORDABLE REPORT, *supra* note 3, at 95.

274. Patient assistance programs might most faithfully be characterized as “rescue” for the subset of programs that apply to therapies that lack an alternative.

275. Compare Larry Temkin’s recent Uehiro Lectures for an analogous and illuminating discussion noting sources of disanalogy between Peter Singer’s pond case and obligations to support international aid organizations. Larry Temkin, Professor, Rutgers Univ., Lecture 2: Obligations to the Needy: Singer’s Pond Example Versus Supporting International Aid Organizations—Some Disanalogies and Their Normative Significance, Uehiro Lecture Series at the Univ. of Oxford (Nov. 8, 2017), <https://www.practicaethics.ox.ac.uk/uehiro-lectures>

drug pricing and access context. Applying the duty to rescue to this context is far from straightforward, morally speaking.

In what follows, Section IV.A analyzes the core features of the paradigm duty to rescue case and observes sources of differentiation when moving to the corporate context. Section IV.B then widens the lens arguing that there are broader moral concerns about the CDTR approach itself.

*A. Sources of Disanalogy: What Exactly Does a Corporate Duty to Rescue Require?*

The paradigm case of a duty to rescue may be characterized by five features:<sup>276</sup> (1) rescuee, (2) capable rescuer, (3) emergency situation, (4) rescuee receipt of significant benefit, and (5) rescuer bears minimal cost. Some of the issues raised by a given feature will be inevitably crosscutting. The below examines each of these features, points out their increased complexity in the corporate case, and raises questions about what they might involve for a CDTR regarding access to biopharmaceutical products.

1. Rescuer

For a duty to rescue to be triggered, there must be someone in need of rescuing (for short, a “rescuee”). In the paradigm rescue case it is clear who the rescuee is and ought to be. It is the child drowning in the pond. But who are and ought to be the rescuees in the corporate drug pricing and access case? CDTR proposals suggest that patients suffering from a treatable, serious illness who cannot afford treatment are analogous to Singer’s drowning child. Yet, there are two complications.

First, though it is intuitive to analogize the drowning child in the paradigm case to a needy patient in the corporate case, this is not the only option. When insurance systems are involved, this raises the question of whether the pertinent rescuee “unit” is the patient in need of a therapy as opposed to all participants in a health plan. Participation in insurance ties the fates of everyone in the pool together. High drug costs, even if only applicable to some covered by a plan, can cause higher premiums, copays, or deductibles for those who do not need the medication.

Further, in the paradigm case the hapless rescuee is a natural person. Moving to the corporate context raises the possibility that the rescuee “unit” could be an institutional entity—for instance, a struggling state Medicaid program. It may be that the obvious rescuee unit is the morally relevant one, but these alternative possibilities need to be considered.

The second issue, and source of disanalogy (though a more familiar one), is the likely move from the one to the many. It is not *one* patient in need of medication, but *many* patients in need. This can be significant. Compounding the complexity is the

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-2017#tab-420616 [<https://perma.cc/55JJ-TRPF>].

276. For an adjacent discussion of features of a duty to rescue, see UNGER, *supra* note 19, at 53–54 (arguing potential duty to rescue features fail to distinguish obligations to rescue from more general obligations).

fact that problems of high drug prices exist across diseases, not just within a single disease.

What happens when need outstrips resources? Expenditures are subject to a minimal cost constraint. In such scenarios, biopharmaceutical companies would need to apply an allocation principle to determine which patients are rescuees. Problems involving the allocation of scarce resources, though perhaps not ultimately insurmountable, are notoriously difficult. These complications are absent from the paradigm rescue case. The corporate context, by contrast, likely will involve normative judgments about who the rescuees ought to be.

## 2. Capable Rescuer

Identifying who ought to be the rescuer—that is, who bears responsibility for rescue—in the corporate rescue context, likewise, is exceedingly more complicated than in the paradigm case. There are at least two categories of complications to consider.

First, who counts as a *capable* rescuer in the corporate biopharmaceutical context? Rescue is not possible if there is no capable rescuer. Suppose the bystander in Singer's pond example could not swim or was bound by a straightjacket. Given ought implies can, even though a bystander with these features would be a potential rescuer, she is not a *capable* rescuer and therefore is not subject to a duty to rescue.

CDTR proposals argue that biopharmaceutical companies are capable rescuers because of their legal rights, competencies, and resources. Biopharmaceutical companies, as patent holders or licensees of a needed medication, are conceived as gatekeepers to rescue. They have the ability to improve access through, for instance, forgoing legal protections for their products, licensing their products to others, discounting their prices, or providing the necessary medications themselves.

Yet, it would be a rare case in which a biopharmaceutical company was the *only* capable rescuer. As others point out, while biopharmaceutical companies can be gatekeepers to implementing rescue efforts, this does not mean that they are the only gatekeepers.<sup>277</sup> Other candidate capable rescuers are numerous—for instance, governments, other drug companies with substitute medications, pharmacy benefit managers, insurers, foundations, NGOs, philanthropists, or even companies operating in other sectors—all could be capable rescuers.<sup>278</sup> In the context of costly medications, being a capable rescuer may just reduce to a matter of fungible

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277. Pepe Lee Chang, *Pharmaceutical Companies and Their Obligations to Developing Countries: Psychopaths or Scapegoats?*, in INNOVATION AND THE PHARMACEUTICAL INDUSTRY 46 (H. Tristram Engelhardt, Jr. & Jeremy R. Garrett eds., 2008) (ebook) (arguing that the claim that pharmaceutical companies have special moral obligations to assist needy patients is wrong); see also Ho, *Global Health Disparity*, *supra* note 20, at 36 (observing that if obstacles to access exist beyond pharmaceutical companies “holding only pharmaceutical companies responsible without calling upon other industries to assist under the duty of rescue is going too far and unfair to the drug companies”); Ian Maitland, *Priceless Goods: How Should Life-Saving Drugs Be Priced?*, 12 BUS. ETHICS Q. 451, 460 (2002) (arguing that pharmaceutical companies have no special obligation to reduce the prices of their medications).

278. See Chang, *supra* note 277.

resources—that is, money. Numerous entities have money that *could* be spent on purchasing or subsidizing expensive medications.

Second, given the possibility of *multiple* capable rescuers, unlike in the paradigm case, the corporate case raises significant questions regarding the allocation of responsibility to rescue.<sup>279</sup> For those proposals that place the responsibility for rescue uniquely, or nearly uniquely, at the feet of biopharmaceutical companies, justification is presently undertheorized. Particularly in the context of costly medications, why think there is specifically a *corporate*, and *biopharmaceutical corporate*, duty to rescue? Biopharmaceutical companies appear to have legitimate grounds to ask, “Why me?”

Allocation issues raise two lines of inquiry: (1) Is there a capable rescuer who is best situated or who ought to have primary responsibility for rescue? (2) If rescue responsibilities are to be shared amongst multiple rescuers, what is a fair allocation of responsibilities?

Regarding the first issue, many believe that governments bear primary responsibility for addressing issues concerning the health of their citizens.<sup>280</sup> Indeed, “[m]ost companies will argue that it is not their role to step in when those first in the line of responsibility fail to perform their duty.”<sup>281</sup> Biopharmaceutical companies act in compliance with and take advantage of what the law allows. They are contingent creatures of their habitat.<sup>282</sup> Laws could be different; they could be less favorable to industry. Governments could also make better use of existing legal mechanisms, such as compulsory licensing or march-in rights, to facilitate increased access to expensive medications.<sup>283</sup>

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279. Richard T. De George, *Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis*, 15 BUS. ETHICS Q. 549, 555 (2005); Ho, *Pharmaceutical Corporations*, *supra* note 20, at 61; *see also* James Griffin, *Human Rights: Whose Duties?*, in HUMAN RIGHTS AND THE MORAL RESPONSIBILITIES OF CORPORATE AND PUBLIC SECTOR ORGANISATIONS 31, 42–43 (Tom Campbell & Seumas Miller eds., 2004).

280. *E.g.*, Klaus M. Leisinger, *Corporate Responsibilities for Access to Medicines*, 85 J. BUS. ETHICS 3, 11 (2009) (“The Nation State, supported by the international community, bears the primary responsibility for ensuring that the right to health is respected, protected, and fulfilled.”).

281. *Id.* at 10–11.

282. *See* Rafi Mohammed, *It’s Time to Rein in Exorbitant Pharmaceutical Prices*, HARV. BUS. REV. (Sept. 22, 2015), <https://hbr.org/2015/09/its-time-to-rein-in-exorbitant-pharmaceutical-prices> [<https://perma.cc/X4AY-SEWZ>].

283. Mohammed El Said & Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy* 9 (Glob. Comm’n on HIV and the Law, Working Paper, 2011), <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56547292e4b0e74bc872ee41/1448374930129/ACCESS-TO-MEDICINES-THE-ROLE-OF-INTELLECTUAL-PROPERTY-LAW-AND-POLICY-1+%281%29.pdf> [<https://perma.cc/UPJ8-DXYR>]; *see also* Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275 (2016) (discussing the U.S. government’s ability under 28 U.S.C. § 1498 to use patents without prior permission in exchange for reasonable compensation); Alfred B. Engelberg & Aaron S. Kesselheim, *Use the Bayh-Dole Act to Lower Drug Prices for Government Healthcare Programs*, 22 NATURE MED. 576 (2016) (discussing § 202 of the Bayh-Dole Act, which allows a royalty-free license to the United States if the patent is based

Government, at least in theory, not only is more probably the entity with responsibility for addressing pressing public needs,<sup>284</sup> but is the one best situated by institutional design. When drinking water is poisoned, the first call should be to the pertinent government agency. By institutional design, at least in well-functioning countries, they are the ones who ought to help. One does not call up Perrier and ask for donations. Between a for-profit company and the government, presumably the latter is the one whose purpose includes protecting the public and fulfilling basic needs. There may also be political (e.g., legitimacy) and efficiency (e.g., informational asymmetry, coordination, resource) reasons for thinking that a government might be better placed to be a rescuer than individual companies.

To the second issue, the corporate context generally raises significant issues of fairness in the distribution of responsibility for rescue that are not present in the paradigm case. Without additional argument, it seems unfair to single out biopharmaceutical companies to sacrifice their profits or products to rescue others.<sup>285</sup> Why not say that other groups noted above have an obligation of rescue to pitch in and pony up? Why effectively impose a moral tax on a particular industry merely qua that industry being that industry?<sup>286</sup> Researching, developing, and manufacturing medications is crucially important work not to be disincentivized. Moreover, concerns regarding fairness may be further exacerbated if the need for rescue is iterative. The presence of other capable rescuers may not absolve biopharmaceutical companies of rescue obligations, but a successful account of a biopharmaceutical CDTR will have to contend with these difficult questions of shared responsibility.

### 3. Emergency Situation

Traditional examples of a duty to rescue involve circumstances where life, limb, or health are at significant, imminent, and sometimes, though not necessarily, unexpected risk. The paradigm example, Singer's pond case of a drowning child, involves imminent risk of death. Its remedy requires immediate action since loss of life happens rapidly. Death by drowning can occur within several minutes.

How should "an emergency" be construed in the context of access to expensive medications? Some medical situations involving expensive interventions are akin to

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on federally funded research).

284. See, e.g., Dan W. Brock, *Some Questions About the Moral Responsibilities of Drug Companies in Developing Countries*, 1 DEVELOPING WORLD BIOETHICS 33, 35 (2001) ("Meeting other basic needs such as for food and shelter is commonly taken to be, even among those who regard them as human rights, a governmental responsibility, not a special responsibility of the food or real estate industries.").

285. See, e.g., LIAM B. MURPHY, MORAL DEMANDS IN NONIDEAL THEORY 7 (2000) (arguing that under conditions of partial party compliance, moral demands placed on an individual agent "should not exceed what they would be under full compliance with . . . [a moral] principle").

286. See, e.g., Carly Helfand, *Insulin Costs Are Way Up, but Drugmakers Say PBMs Are Collecting the Loot*, FIERCEPHARMA (Oct. 11, 2016, 8:37 AM), <http://www.fiercepharma.com/pharma/price-increases-formulary-competition-boost-pbm-earnings-drugmakers-say> [https://perma.cc/LN8V-PK58] (manufacturers pointing at pharmacy benefit managers (PBMs) regarding insulin price hikes).

an emergency situation of drowning. For instance, patients who need Kaléo's antidote Evzio to reverse an opioid overdose or patients who need Mylan's EpiPen in response to an allergic reaction experience a medical emergency. As with drowning these can be situations of imminent death.<sup>287</sup> Does a CDTR therefore only apply to a narrower set of health conditions that involve imminent and severe risks?<sup>288</sup>

Both Hsieh and Dunfee apply their principles to the HIV/AIDS epidemic.<sup>289</sup> Outterson and Light's discussion does not single out a particular disease.<sup>290</sup> HIV, though a very serious illness, even when it deteriorates to AIDS, is typically not like drowning. It progresses through stages, and the time horizon for someone suffering from HIV/AIDS is generally multiple years.<sup>291</sup> That death occurs on a longer timeline than drowning does not detract from its tragedy or grimness. Given available medications, untreated HIV/AIDS cuts lives tragically short. Yet, serious, life threatening, chronic conditions like HIV/AIDS, hepatitis C, diabetes, or cancer operate on a different timeline than the threat to life presupposed by the paradigm case. There is no simple on/off switch where an emergency appears, is urgently addressed, and is completely resolved for good or ill. Are these situations any less of an "emergency"? What if the conditions are pervasive within a population?

Emergency situations perhaps need not be construed quite so narrowly. Thomas Scanlon's articulation of a "Rescue Principle," for instance, contemplates situations of "dire straits."<sup>292</sup> Dire straits exist when the lives of "those in need of aid . . . are immediately threatened, for example, or they are starving, or in great pain, or living in conditions of bare subsistence."<sup>293</sup> Even with a more capacious understanding of emergency, however, justified criteria will need to be provided for determining what kinds of afflictions and situations count as emergencies in the biopharmaceutical context versus those that do not.

#### 4. Rescuer Receipt of Significant Benefit

That a rescuer stands to receive a significant benefit is baked into the idea of "rescue." Being rescued confers a significant life, limb, or more generally health-preserving benefit. But what exactly counts as "rescue"? In the paradigm case, preserving the life of the drowning person is what is meant by rescue. So long as the drowning child is extricated and brought to safety, various bystander efforts count as rescue.

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287. A further departure from the paradigm case is that if an EpiPen is not on hand, it does not matter how inexpensive it is. This raises issues of emergency preparedness.

288. Some state that chronic conditions do not fall within the umbrella of emergencies. Smith, *supra* note 151, at 29 ("An emergency can be contrasted with a chronic condition.").

289. *See supra* Section I.B.

290. *See supra* Section I.B.

291. According to one source, the average life expectancy of a patient with untreated clinically latent HIV is a decade. *The Stages of HIV Infection*, AIDSINFO, <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/46/the-stages-of-hiv-infection> [<https://perma.cc/CD7S-NSMU>] (last updated July 27, 2018).

292. T. M. SCANLON, *WHAT WE OWE TO EACH OTHER* 224 (1998).

293. *Id.*

But, suppose that the bystander threw the drowning child a flotation device with the ability to pull the child closer to shore, but not all the way. Is this partial rescue still rescue? The child seems better off. She is closer to shore, but she is not saved. The corporate rescue case raises several puzzles involving “partial” and “part of a” rescue that are absent in the paradigm case. The essential issue is whether something less than the complete saving of an ill patient is sufficient for rescue.

First, rescue in the biopharmaceutical context introduces the possibility of two kinds of partial rescues in which a situation is improved, but not resolved. One kind of partial rescue involves temporal limitations. In the HIV case, for instance, complete saving presumably would mean something like treatment required to live a normal lifespan. But, particularly given the minimal cost condition, is someone suffering from HIV rescued if he receives medication for a portion of his life, but not all? Is this sufficient for discharging obligations of rescue?

Another potential kind of partial rescue might involve providing something less than the optimal standard of care. What if a company has the rights to a therapy that is a fourth best treatment? Or, if a company while it cannot address someone’s tumor could address that person’s pain? What does rescue require in these instances?

Second, unlike in the pond case where the bystander has the ability to rescue *on her own*, rescue in the biopharmaceutical case will likely require multiple actors to work together—each playing its own part. Proposals for a CDTR construe rescue activities as including forgoing the enforcement of patent rights, executing licensing agreements, reducing prices, or donating medications. Yet, it is not obvious that *any* of these proposed rescue efforts *on their own* would in fact rescue.

Mere abstention from the enforcement of a patent, for instance, does not automatically entail that patients can access a medicine.<sup>294</sup> If the CDTR only requires that companies with pertinent patents turn a blind eye to enforcement, this means that others are free to practice the patent. A multiplicity of actors, however, plays a part in the process of getting regulatory approval, manufacturing, delivering, providing, and paying for medications. Likewise, though a company might donate expensive treatments, actual use of those treatments might require a distribution system or physician supervision and supplemental care provided in a hospital setting.

In cases where complete, or effective, rescue depends upon collective action, what does a duty to rescue require of biopharmaceutical companies? If other necessary actors do not do their part, are companies nevertheless subject to obligations of rescue even if the result is no one will be rescued?

Without a clearer idea of what the obligations of rescue in the health emergency context involves, it is hard to say whether biopharmaceutical companies attempting to effectuate that duty will lead to patients getting the medications that they need or otherwise being significantly benefited. These issues distinguish the corporate case from the paradigm rescue case.

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294. CARL H. COLEMAN, SETON HALL LAW, CTR. FOR HEALTH & PHARM. LAW & POLICY, ETHICAL CONSIDERATIONS IN SELLING PHARMACEUTICALS IN EMERGING ECONOMIES 11 (2017), <https://issuu.com/seton-hall-law-school/docs/whitepaper-ethical-considerations-s/1> [<https://perma.cc/3QPR-MAXS>].

## 5. Rescuer Bears Minimal Cost

An *easy* duty to rescue *only* exists if the rescue is minimally burdensome for the rescuer.<sup>295</sup> This is what makes the rescue “easy.” Beyond some threshold the costs of a rescue eliminate the duty. In Singer’s pond example, the cost to the rescuer is muddy clothes. Muddy clothing, under regular circumstances, is clearly a minimal cost. In the access to medications context, do the proposed rescue activities constitute minimal cost rescue?

Given the foregoing discussion, it is presently not possible to definitively answer this question. Before a plausible evaluation can be made regarding *whether* a rescue involves minimal cost to the rescuer, the scope of the required rescue must be articulated. If it is unclear what rescue requires, it cannot be clear how much it costs.

That said, *prima facie*, some of the mechanisms of rescue employed by biopharmaceutical companies may be of minimal cost. As discussed, some rescue efforts may be costless or profit enhancing—such efforts would surely count as “minimal.” Forgoing the enforcement of patent rights in commercially irrelevant jurisdictions, for example, is a seemingly costless policy. Licensing agreements that include a sufficient royalty, price discrimination, and patient assistance programs could all be profit enhancing. The wrinkle here is whether any of these activities rise to the level of discharging a CDTR. This is precisely the open question.

Beneficial-to-the-company rescue provides a plausible, though not very perspicacious, floor for rescue at “minimal cost.” It is the ceiling that is unclear. When rescue *does* come at a cost, where ought that minimal cost threshold be?<sup>296</sup> If medication to alleviate a chronic disease, for instance, falls within the CDTR and provision of medication for the entirety of each and every rescuee’s life is the only thing that counts as rescue, this begins to sound like more than a minimal cost. This is particularly so if a company has many drugs in its portfolio that treat different chronic diseases all subject to the duty. A standard needs to be worked out to provide what “minimal” ought to mean.

Dunfee’s proposal attempts to provide a minimal cost standard. He argues that the cost of a company’s rescue obligations ought to be capped by keying them to certain financial benchmarks involving spending on social initiatives.<sup>297</sup> This is a pragmatic suggestion; persuading corporate management that they must act in accordance with a duty to rescue could be facilitated by saying an initiative will not cost more than present social initiatives, etc. As with the legal standards regarding corporate charitable contributions, however, from a moral point of view, this approach is wanting. Not only is this standard vulnerable to manipulation, but without more, utilizing benchmarks of historical giving is morally arbitrary. “We’ll give this much

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295. See, e.g., Smith, *supra* note 151, at 26 (“[A]s accepted this duty is *very minimal*. It requires virtually no risk, no cost, and minimal inconvenience to the agent.”). But again, some deny that obligations are limited to low-cost rescue. See, e.g., UNGER, *supra* note 19.

296. Though not a minimal cost view, some have proposed a cost-ceiling threshold for duties to assist in the case of individuals as giving until “further aid would significantly worsen our lives.” Temkin, *supra* note 66, at 359. Allowances might be made for pursuing one’s “deepest projects and commitments.” *Id.* at 358 n.8 (citing to Bernard Williams).

297. Dunfee, *supra* note 20, at 190.

because this is how much we gave in the past” is not particularly persuasive, morally speaking.

The need to determine a minimal cost standard is not a problem unique to the corporate rescue case, but this context does present distinctive features absent in the paradigm case. The above notes the issue of what sorts and levels of profit-sacrificing activities count as minimally burdensome. This is distinctive, but analogous, to trying to decipher what kinds of self-sacrificing burdens are minimal for the bystander.

There are, however, further complications. In the paradigm case, there are no externalities. There are no third parties who might suffer or experience a setback upon the child being rescued.<sup>298</sup> This is not necessarily true of the corporate case. Depending upon the details, for instance, though the company experiences only a minimal cost, a reduction in profits might be experienced as costly to shareholders. In the corporate case, there are obligations to others that must be considered. The corporate context could involve not just burdens to the rescuer but burdens to third parties, as well as costs in terms of moral trade-offs in the balancing of a rescuer’s competing obligations. These issues are taken up in the following Section.

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This analysis demonstrates that applying an easy duty to rescue to the biopharmaceutical drug pricing and access to medicines context is far from straightforward, morally speaking. None of the five core features of the paradigm pond case apply in an obvious way to the corporate case. Despite intuitive appeal, it remains presently uncertain what discharging a CDTR actually requires of biopharmaceutical companies.

Does this mean that individual biopharmaceutical companies are not subject to a corporate duty to rescue? Not necessarily. Problems of product access are factually diverse and complex, and more work remains for those interested in advocating for a CDTR. The framework of rescue, however, does not appear to fit as easily as one might assume with problems of product access in the biopharmaceutical corporate context.

#### *B. Broader Normative Issues with Application of a Corporate Duty to Rescue to Biopharmaceutical Companies*

A CDTR is not, and ought not to be offered as, a cure-all solution to problems associated with drug pricing and access to biopharmaceutical products. A duty to rescue is triggered at the back end in response to a critical situation, as opposed to heading off the creation of that situation in the first instance. Moreover, the form of the duty that enjoys broad consensus is a limited one. A CDTR, therefore, is perhaps best regarded as providing the possibility of moral justification for a range of internal corporate efforts that could be employed alongside governmental regulation.

Whether and to what extent a CDTR has its place needs clarification. Clarification is needed regarding what the duty actually requires as well as when its application is appropriate. As the analysis above makes obvious, moving from the paradigm duty

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298. Temkin, *supra* note 275.

to rescue example, exemplified by Singer's pond case, to the corporate biopharmaceutical case is not a smooth transition. The corporate case inserts numerous additional complexities into the moral analysis for each feature of a CDTR.

Two broader sets of normative issues regarding a CDTR must now be analyzed. First, does discharging a CDTR require biopharmaceutical companies to act in morally undesirable ways? Discharging a CDTR raises the possibility of harming or violating obligations to shareholders as well as negatively impacting innovation incentives.<sup>299</sup> This Section will argue that, though common, these sorts of arguments likely have little traction against a CDTR.

A second set of issues is more serious. Focus on a CDTR excludes pertinent contextual features of why rescue is needed in the first instance. Yet, the relationships between biopharmaceutical companies and patients who need their products is far more complex than that which exists in the paradigm pond case. This Section argues that an examination of those relationships raises the possibility that, in some instances, a moral framing of innocent bystander as opposed to culpable causal contributor is inappropriate and fails to hold companies accountable for potentially harmful conduct.

### 1. Obligations to Shareholders and Innovation Incentives

The paradigm rescue case does not involve violating the rights of others or negative externalities. In contrast to Singer's pond case, corporate rescue raises the possibility that a company "may have to impose costs on *others*, violate the rights of others, or act *immorally*, in order to effectively aid the needy, and that may make it impermissible . . . to do so."<sup>300</sup> Two potential criticisms of a CDTR are in this vein.

The first is that biopharmaceutical companies may not permissibly discharge a CDTR because doing so transgresses obligations to others, mainly shareholders. The second is that biopharmaceutical companies may not permissibly discharge a CDTR because doing so will negatively impact innovation incentives and thus have bad consequences for the public writ large. These criticisms while distinct—one is about duties to others and the other is about consequences—are both potential sources of constraints upon discharging a CDTR. Though industry defenders rely on these sorts

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299. See, e.g., MAKING MEDICINES AFFORDABLE REPORT, *supra* note 3, at 16 (noting obligations to shareholders); Alex M. Azar II, Sec'y, Health & Human Servs., Remarks on Drug Pricing Blueprint (May 14, 2018), <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html> [<https://perma.cc/K53P-KV39>] (describing the innovation incentives argument as "tired").

300. Larry S. Temkin, Professor, Rutgers Univ., Lecture 1: Obligations to the Needy: Effective Altruism, Pluralism, and Singer's Pond Example, Uehiro Lecture Series at the Univ. of Oxford 31 (Nov. 6, 2017) (unpublished manuscript) (on file with author) (forthcoming 2020–2021 in the Uehiro Series in Practical Ethics published by Oxford University Press); see also Shelly Kagan, *The Structure of Normative Ethics*, 6 PHIL. PERSP. 223, 224 (1992) (raising hypothetical rescue case where rescuer must steal a boat to rescue the drowning person and thus violates another's property rights).

of responses, particularly the latter, regarding critiques of biopharmaceutical pricing practices,<sup>301</sup> they may be dispensed with rather quickly in the context at issue here.

Regarding obligations to shareholders, corporate management's obligations are a legal construct. The law dictates the metes and bounds of shareholder rights and correspondingly the duties that are owed to them. The legal analysis provided above demonstrates the discretion to discharge a CDTR. So long as discharging a CDTR falls within this discretion, officials and directors do not transgress their obligations to shareholders; they do not violate the rights of a biopharmaceutical corporation's shareholders.

One might attempt to abstract from the legal reality of shareholder rights and frame things in terms of a trade-off between saving lives and a violation of some sort of property right. Discharging a CDTR—when it does in fact come at a cost—entails a redistribution from one group to another. For instance, perhaps instead of getting \$*x* in dividends *without* rescue (*and assuming* a right to that dividend in the first instance), shareholders will get \$*x-y* in dividends *with* rescue, where *y* is the cost of rescue.

Against a background of heart-wrenching hardship over the unaffordability of important medications, the popular accusation of “profits over people”<sup>302</sup> is an enticing one. Involuntary redistribution of resources, however, from one group to another raises serious and complicated moral questions, particularly in a capitalist society. It is not obvious that positive moral obligations to save lives always ought to outweigh negative obligations to respect property interests.<sup>303</sup> Fortunately, however, for the purposes of a CDTR, this issue may be largely sidestepped. As a limited duty, the easy CDTR is subject to a minimal cost requirement. The minimal cost requirement is what, after all, makes the duty so compelling. If there is *any* case where the obligation to save lives ought to outweigh an obligation to respect property interests, it will be in situations where harms to property interests are minimal.

That said, a more difficult framing might involve a potential trade-off between the lives and health of shareholders and the lives and health of needy (nonshareholder) patients. As noted above, it is possible that while rescue could come at minimal cost to a company, the corresponding reduction in profits might be acutely experienced by a shareholder. One could imagine, for instance, a retiree for whom every penny matters. Though this is a concern to be reckoned with, it is not specific to management's obligations to shareholders. If discharging a CDTR is legally permissible, imposition of costs on the life and health of a shareholder would not violate management's duty to that person *qua* the shareholder relationship. Rather, if a moral transgression exists, it would derive from general moral obligations about not imposing costs on someone *qua* that person being a person.

Yet, far from thinking of shareholders as possible victims of corporate rescue, empirical evidence suggests that at least some shareholders are actively concerned about the drug pricing practices of biopharmaceutical companies. This is evidenced

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301. See *supra* note 299.

302. See, e.g., Ho, *Global Health Disparity*, *supra* note 20, at 34.

303. Things are even more complicated when a medication confers a health benefit, though not a life-saving one.

by a number of shareholder resolutions that have been submitted for inclusion on proxies over the past several years.<sup>304</sup>

In the 2017 proxy season, for instance, companies including AbbVie, Amgen, Biogen, Bristol-Myers Squibb, Eli Lilly, Gilead Sciences, Johnson & Johnson, Merck, Pfizer, Regeneron Pharmaceuticals, and Vertex Pharmaceuticals<sup>305</sup> all received shareholder resolutions requesting that their boards issue a report regarding product price increases, their rationale, and associated risks.<sup>306</sup> Importantly, the resolutions' supporting statement cited affordability and access issues: "Current price increases severely limit access to life-saving medicines, particularly for economically challenged patients: this has serious repercussions for public health and the economy."<sup>307</sup>

Shareholder resolutions in this space, however, historically have not enjoyed much success. A majority of the companies requested and received a no-action letter from the U.S. Securities and Exchange Commission (SEC) stating that the agency "will not recommend enforcement action to the Commission if [the company] omits the proposal from its proxy materials."<sup>308</sup> Thus, these companies were able to omit putting these resolutions to a shareholder vote without fear of legal repercussions.

Shareholder resolutions in 2018 pertaining to drug pricing concerns have enjoyed greater, but limited, success. The SEC greenlit shareholder proposals submitted to AbbVie, Amgen, Biogen, Bristol-Myers Squibb, and Eli Lilly.<sup>309</sup> These proposals sought information regarding the connection between risks related to pricing strategies and executive compensation.<sup>310</sup> They are not, however, framed in terms of the public good. Rather, they are motivated by the interests of long-term investors.<sup>311</sup> The supporting statement, for instance, in the AbbVie proposal makes this clear.<sup>312</sup>

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304. Ed Silverman, *Interfaith Investor Coalition Pushes Shareholder Resolutions on Drug Prices*, STAT (Oct. 24, 2016), <https://www.statnews.com/pharmalot/2016/10/24/interfaith-coalition-drug-prices> [<https://perma.cc/7ME6-A3ZM>] [hereinafter Silverman, *Interfaith Investor Coalition*]; Ed Silverman, *SEC Greenlights Shareholder Proposals for Several Big Drug Makers over Pricing*, STAT (Mar. 26, 2018), <https://www.statnews.com/pharmalot/2018/03/26/sec-shareholders-drug-prices> [<https://perma.cc/LTX6-W4K8>] [hereinafter Silverman, *SEC Greenlights Shareholder Proposals*].

305. Silverman, *Interfaith Investor Coalition*, *supra* note 304.

306. *Id.*

307. Eli Lilly & Co., SEC No-Action Letter, 2016 WL 7426886, at \*10 (Feb. 10, 2017).

308. *Id.* at \*1; AS YOU SOW, PROXY PREVIEW 49 (2017) (providing an overview of these resolutions and noting companies seeking no-action letters).

309. Silverman, *SEC Greenlights Shareholder Proposals*, *supra* note 304.

310. *Id.* This strategy is again being utilized in 2019 proposals. AS YOU SOW, PROXY PREVIEW 49, 72–73 (2019).

311. Ed Silverman, *In Rebuke to Pharma, One-Fifth of Bristol-Myers Shareholders Favor Proposal Tying Pricing Risks to Executive Pay*, STAT (May 1, 2018), <https://www.statnews.com/pharmalot/2018/05/01/bristol-myers-shareholders-drug-prices> [<https://perma.cc/Z6HB-DHK2>] ("It's really important to make clear that this is not some granola-eating group that is trying to make a trade-off between shareholder returns and the public good. . . . This is a very analytic initiative that is based on what is best for shareholders in the long term.")

312. AbbVie Inc., Proxy Statement (Form DEF 14A), at 71–72 (Mar. 19, 2018), [https://www.sec.gov/Archives/edgar/data/1551152/000104746918001843/a2234787zdef14a.htm#Item\\_9](https://www.sec.gov/Archives/edgar/data/1551152/000104746918001843/a2234787zdef14a.htm#Item_9) [<https://perma.cc/TG32-4F7S>].

It cites concerns about “backlash against high drug prices” compelling price rollbacks, reputational harm, investigations, and new regulations.<sup>313</sup>

As long-term investors . . . [i]n our view, excessive dependence on drug price increases is a risky and unsustainable strategy, especially when price hikes drive large senior executive payouts. . . . The disclosure we request would allow shareholders to better assess the extent to which compensation arrangements encourage senior executives to responsibly manage risks relating to drug pricing and contribute to long-term value creation.<sup>314</sup>

In each instance, the proposals failed to secure the necessary votes,<sup>315</sup> but proponents were encouraged by the percentages of votes the proposals did receive.<sup>316</sup>

Another potential objection to biopharmaceutical companies discharging a CDTR is that it may negatively impact innovation incentives. This line of argument is oft repeated by industry representatives in response to nearly any sort of critique regarding their pricing practices.<sup>317</sup> Appropriately and sufficiently incentivizing R&D into new therapies is obviously a serious consideration. Few, if any, would argue that it is not.

There are, however, two points to be made. First, this line of response to *any* critique of a company’s drug pricing practices is overstated. As the recent National Academies of Sciences, Engineering, and Medicine report notes, reduced revenue does not “lead inevitably” to reduced R&D.<sup>318</sup> Rather, biopharmaceutical companies have “many choices” they “could make in response to such reductions.”<sup>319</sup> These actions “include moving funds allocated for product marketing and promotion to research and development, reducing stock buy-back programs, limiting administrative expenses such as executive compensation, and reducing lobbying

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313. *Id.* at 71.

314. *Id.* at 71–72.

315. AbbVie Inc., Current Report (Form 8-K), at Item 5.07(9) (May 8, 2018), [https://www.sec.gov/Archives/edgar/data/1551152/000110465918031358/a18-13062\\_18k.htm](https://www.sec.gov/Archives/edgar/data/1551152/000110465918031358/a18-13062_18k.htm) [<https://perma.cc/383S-DC9A>]; Amgen Inc., Current Report (Form 8-K), at Item 4 (May 22, 2018), <https://www.sec.gov/Archives/edgar/data/318154/000119312518170986/d570410d8k.htm> [<https://perma.cc/2L25-73G9>]; Biogen Inc., Current Report (Form 8-K), at Item 5.07(5) (June 14, 2018), <https://www.sec.gov/Archives/edgar/data/875045/000087504518000012/annualmeeting8-k2018.htm> [<https://perma.cc/DYC8-R6UY>]; Bristol-Myers Squibb Co., Current Report (Form 8-K), at Item 5.07(4) (May 3, 2018), [https://www.sec.gov/Archives/edgar/data/14272/000114036118021522/s002260x1\\_8k.htm](https://www.sec.gov/Archives/edgar/data/14272/000114036118021522/s002260x1_8k.htm) [<https://perma.cc/9N7H-MS88>]; Eli Lilly & Co., Current Report (Form 8-K), at Item 5.07(j) (May 7, 2018), <https://www.sec.gov/Archives/edgar/data/59478/000005947818000145/a2018amvoterresults8-k.htm> [<https://perma.cc/MMN9-ZKWY>].

316. *See, e.g.*, Ed Silverman, *In a Message to Pharma, OneFifth of AbbVie Shareholders Support Proposal Tying Pricing Risks to Exec Pay*, STAT (May 4, 2018), <https://www.statnews.com/pharmalot/2018/05/04/abbvie-shareholders-drug-prices> [<https://perma.cc/P367-VGCC>].

317. De George, *supra* note 279, at 551–52 (referring to this argument as a “mantra”).

318. MAKING MEDICINES AFFORDABLE REPORT, *supra* note 3, at 133.

319. *Id.*

expenditures.”<sup>320</sup> Department of Health and Human Services Secretary Alex Azar puts the point more bluntly: “I’ve been a drug company executive—I know the tired talking points: the idea that if one penny disappears from pharma profit margins, American innovation will grind to a halt. I’m not interested in hearing those talking points anymore, and neither is the President.”<sup>321</sup>

Second, whatever merits recourse to an innovation incentives argument might have, its force is greatly attenuated in the context of a CDTR. A CDTR in the form discussed here is a minimal duty. As such, its impact on innovation incentives ought to be negligible. A potential, minimally negative impact on innovation incentives is not a compelling argument against discharging a CDTR.

## 2. Contextual Agnosticism and Causal Contribution to Harm

A more serious concern has to do with the relationship between the corporate rescuer and those in need of rescue. As foreshadowed by Outterson and Light’s commentary, biopharmaceutical companies may not be innocent actors. Yet, a duty to rescue is a forward-looking moral duty. Context in rescue cases is taken to be irrelevant; the focus is on which actor is able—or sometimes best able—to help.<sup>322</sup>

The duty to rescue either presumes no historical causal relationship or is agnostic about the relationship between the parties and the situation of rescue.<sup>323</sup> This is evidenced by rescuers often being referred to as “bystanders.” When the *bystander* happens upon the drowning child, she *happens* upon the child. She did not push the child into the pond, remove a reachable life preserver, negligently repair a safety railing, etc. She has not causally contributed, in a manner of moral or legal significance, to the need to be rescued. The assumption in Singer’s pond case is “that the child’s drowning is a terrible *accident*.”<sup>324</sup>

320. *Id.* Likewise, a recent report by Senator Cory Booker sought to discern what pharmaceutical companies will do with savings from the Tax Cuts and Jobs Act. Such reports must be considered with caution, but this “early snapshot” of Q4 2017 was deemed “discouraging.” Though based on extremely limited data, it found that rather than use new tax savings to lower drug prices, tens of billions of dollars in new stock buyback programs were announced, and only some companies discussed expansions of research and development. OFFICE OF SENATOR CORY BOOKER, WITH NEW TAX SAVINGS, DRUG COMPANIES START BY REWARDING SHAREHOLDERS, NOT PATIENTS STRUGGLING WITH SKYROCKETING PRICES (Apr. 9, 2018), <https://www.scribd.com/document/375935848/Pharma-Tax-Report-April-2018> [<https://perma.cc/7NWJ-QVPT>].

321. Azar, *supra* note 299.

322. A corporate duty to rescue might be considered a species of the capacity principle for allocating special responsibilities. The principle of capacity holds that those who ought to be responsible for addressing a harm are simply those who are able to remedy that harm: the “capacity to bring remedy entails the responsibility to do so.” Barry & Raworth, *supra* note 27, at 65. A narrower version of the principle distributes responsibility based on who is *best* able to remedy harm. Miller, *supra* note 27, at 460–61.

323. The former is the stronger and the latter the weaker version the irrelevancy of the rescuer’s prior conduct can take.

324. Larry S. Temkin, Professor, Rutgers Univ., Lecture 2: Obligations to the Needy: Singer’s Pond Example Versus Supporting International Aid Organizations, Uehiro Lecture Series at the Univ. of Oxford 18 (Nov. 8, 2017) (unpublished manuscript) (on file with author)

Contextual features in the biopharmaceutical case, however, are often not irrelevant. When a patient cannot afford her medicine, this may not be the result of a random event or terrible accident. Contextual features may be salient, indicating whether the corporate duty of easy rescue is the most appropriate moral framework for analytical focus.<sup>325</sup>

Suppose a modification to Singer's pond case where the "bystander" pushes the child into the pond.<sup>326</sup> This fact fundamentally changes the situation. The bystander is no longer an admirable individual rescuing an accident victim. Rather, she is an object of opprobrium. Under these circumstances would focus still be on the bystander's easy duty to rescue? Emphasis shifts from the bystander's obligations to the drowning child *qua bystander* to her obligations *qua person who pushed the child into the pond*.

Intuitions generated by this modified case may be explained by a causal contribution principle. Causal contribution arguments provide a different theoretical grounding for moral and legal corporate duties. Rather than focus on who has the *ability* to fix a harm, causal contribution arguments allocate responsibility on the basis of who *brought about* that harm.<sup>327</sup> Many have strong intuitions that when we wrong others, we have significant reasons to consider the mitigation of that wrong our special moral responsibility.<sup>328</sup> "All other things being equal, the person who harms another has a special obligation to correct the harm, by undoing it or otherwise compensating the victim."<sup>329</sup> Further, reasons grounded in one's causal contributions to harm appear weightier than other kinds of reasons—for instance, having the capacity to rescue.<sup>330</sup>

That reasons grounded in an entity's causal contributions appear weightier than others, of course, is *not* to say that they are decisive.<sup>331</sup> One can imagine situations in which other considerations ought to carry the day. For instance, though a company irrefutably wrongfully causes harm, perhaps it is bankrupt or otherwise unable to remedy the problem. What then? There might also be situations in which an entity's causal contributions are extremely diluted, but its capacity to assist is great. Thus, a

(forthcoming 2020–2021 in the Uehiro Series in Practical Ethics published by Oxford University Press); Jeremy R. Garrett, *Collectivizing Rescue Obligations in Bioethics*, 15 AM. J. BIOETHICS 3, 3 (2015) ("[T]he rescue paradigm . . . conceptualizes rescue cases . . . as unanticipated, unavoidable, random events for which context is irrelevant.").

325. Cf. Garrett, *supra* note 324.

326. Cf. Shelly Kagan, *Causation and Responsibility*, 25 AM. PHIL. Q. 293, 295 (1988).

327. *Id.* at 293.

328. *Id.* at 295 (noting common intuition though not subscribing to it); Christian Barry, *Understanding and Evaluating the Contribution Principle*, in REAL WORLD JUSTICE 103, 106 (Andreas Follesdal & Thomas Pogge eds., 2005); Miller, *supra* note 27, at 471; accord Marckmann, *supra* note 27, at 117 ("This causal relationship is certainly one of the most compelling ethical reasons: If someone has contributed to inflicting harm to someone else he or she bears an especially strong remedial obligation.").

329. Kagan, *supra* note 326, at 293.

330. See Barry & Raworth, *supra* note 27, at 64 (quoting Samuel Scheffler); Harris & Siplon, *supra* note 20, at 45–46 (noting that developed countries' complicity in the HIV crisis entails a greater responsibility to act than under a rescue principle); see also Kagan, *supra* note 326, at 297.

331. See Kagan, *supra* note 326, at 297.

moderate, flexible form of the causal contribution principle is most appealing—one that grants “priority to addressing those deprivations to which we have contributed over those to which we have not contributed *so long as the other normative factors are roughly equal.*”<sup>332</sup>

Thus, in the modified pond case, if the bystander is implicated in the reasons why the child needs to be rescued, she incurs an obligation to help *because* she contributed to the child’s precarious predicament, not just because she *could* help the child to safety. If a would-be rescuer wrongfully contributed to the need of the rescuee to be rescued, other things equal, a duty to rescue likely merits decreased emphasis. If causal responsibility is present, special obligations deriving from that fact make focus on a duty to rescue misplaced.

While contextual features are important in the biopharmaceutical case, the modified pond case is not a perfect analogy. Biopharmaceutical companies generally are not responsible for patients’ illnesses.<sup>333</sup> Rather the relationship is akin to creating barriers that make it *more* difficult for patients to get out of the pond and to safety. In line with Outterson and Light’s suggestion, biopharmaceutical companies may sometimes inhibit patients from rescuing themselves or receiving help from third parties.

Attention to wrongful causal contributions to harm refocuses the controversy. The debate shifts to the conditions under which special obligations for causal responsibility are triggered. This likely will involve consideration of how to draw the line between corporate activities which do versus merely allow harm.

Conclusively establishing wrongful causal contribution to harm via pricing and associated activities requires a significant moral and empirical discussion that space does not permit. A number of practices pervasive in the biopharmaceutical industry, however, at least raise this possibility. The following notes two broad sets of examples: (1) anticompetitive practices, and (2) various efforts to influence, craft, and participate in articulating the legal rules that govern the industry.

First, and most prominently, there is a growing literature documenting numerous anticompetitive efforts. Under the assumption that competition generally, though not always, significantly drives down the price of medical interventions, efforts to suppress competition may make prices of important medications higher than they otherwise would be. Many—including pay-for-delay settlements, product hopping, abuse of citizen petitions, and the withholding of samples—are practices that branded companies engage in to suppress successful generic market entry.<sup>334</sup> Generic companies, however, also take steps to prevent competition.<sup>335</sup>

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332. Barry, *supra* note 328, at 108 (emphasis added).

333. An exception may include the complicity of certain drug manufacturers in the present opioid epidemic. See, e.g., Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies’ Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2304 (2017) (noting fraud and deceptive business practices by opioid makers regarding “their products’ addictiveness and effectiveness, all calculated to mislead the state, prescribers, and the public.”).

334. See, e.g., Michael A. Carrier, *Five Actions to Stop Citizen Petition Abuse*, 118 COLUM. L. REV. ONLINE 81 (2018); Carrier, *supra* note 65; Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499 (2016); Jones et al., *supra* note 65.

335. SENATE COMMITTEE ON AGING REPORT, *supra* note 1.

Improving competition is a “key” strategy in President Trump’s drug pricing blueprint.<sup>336</sup> As one example of these efforts, the FDA has sought to address gaming of the system involving sample withholding.<sup>337</sup> For generics to efficiently enter the market, they need access to branded samples to facilitate their applications for FDA approval.<sup>338</sup> Yet, “[t]he inability of generic companies to purchase the samples they need slows down, or entirely impedes, the generic drug development process – leading to delays in bringing affordable generic alternatives to patients in need.”<sup>339</sup> To help address these issues, the FDA has posted a list of the drugs and inquiries it has received alleging a company’s inability to procure a sample.<sup>340</sup> An analysis found that the drugs listed as purportedly stalling generic competition underwent double-digit price hikes “since 2012 and cost Medicare and Medicaid nearly \$12 billion in 2016.”<sup>341</sup> The implication is that these companies may have caused prices to be more than they would have been if generic companies had access to the samples.<sup>342</sup>

Second, biopharmaceutical companies might causally contribute to harming patients through their participation in defining the scope and parameters of their legal rights. Three potential examples include political spending, the drafting of legislation, and committee participation.

Biopharmaceutical companies and their trade associations spend a tremendous amount of money in an effort to obtain legislative influence. According to the Center for Responsive Politics, during the 2017–2018 election cycle, nearly all U.S. Senators received donations (albeit of widely varying amounts) from the pharmaceutical industry.<sup>343</sup> Furthermore, in 2018 pharmaceutical manufacturers spent \$172,278,923 on lobbying.<sup>344</sup> The broader category of pharmaceuticals and

336. U.S. DEP’T OF HEALTH AND HUMAN SERVS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 9 (2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> [<https://perma.cc/5X8A-79TZ>]; see also Ameet Sarpatwari, Jerry Avorn & Aaron S. Kesselheim, *An Incomplete Prescription: President Trump’s Plan to Address High Drug Prices*, 319 JAMA 2373 (2018) (discussing the Blueprint’s proposals).

337. *Reference Listed Drug (RLD) Access Inquiries*, *supra* note 65.

338. *Id.*

339. *Id.*

340. *Id.*

341. This figure excludes rebates. Sydney Lupkin, *Drugmakers Blamed for Blocking Generics Have Jacked Up Prices and Cost U.S. Billions*, KHN (May 23, 2018), [https://khn.org/news/drugmakers-blamed-for-blocking-generics-have-milked-prices-and-cost-u-s-billions/?utm\\_campaign=KFF-2018-The-Latest&utm\\_source=hs\\_email&utm\\_medium=email&utm\\_content=63167126&\\_hsenc=p2ANqtz-94Ldiv\\_yabTms97y9cQm30erY-GoBVIRravctBYddziulw4Igl\\_-Hxq44jSulcaqWtV63FfgCKFgdZJGtuk3sdUr1I0w&\\_hsmi=63167126](https://khn.org/news/drugmakers-blamed-for-blocking-generics-have-milked-prices-and-cost-u-s-billions/?utm_campaign=KFF-2018-The-Latest&utm_source=hs_email&utm_medium=email&utm_content=63167126&_hsenc=p2ANqtz-94Ldiv_yabTms97y9cQm30erY-GoBVIRravctBYddziulw4Igl_-Hxq44jSulcaqWtV63FfgCKFgdZJGtuk3sdUr1I0w&_hsmi=63167126) [<https://perma.cc/H9WH-55E3>].

342. *Id.* (“By delaying development of generics, drugmakers can maintain their monopolies and keep prices high.”).

343. *Pharmaceutical Manufacturing: Money to Congress*, OPENSECRETS.ORG, <https://www.opensecrets.org/industries/summary.php?ind=H4300&cycle=2018&recipdetail=S&sortorder=S&mem=Y> [<https://perma.cc/8JMJ-ZQSN>] (sorted by “All Senators” and then by “State” for 2018).

344. *Pharmaceutical Manufacturing: Lobbying, 2018*, OPENSECRETS.ORG, <https://www.opensecrets.org/industries/lobbying.php?cycle=2018&ind=H4300> [<https://perma.cc/9PVR>].

health products (which includes medical products and dietary supplements) spent \$281,472,969 on lobbying.<sup>345</sup> The day after President Trump identified campaign contributions as a possible source of “outrageous” drug prices in March of 2017, “drugmakers donated more money to political campaigns than they had on any other day in 2017 so far.”<sup>346</sup> Though money is spent to obtain influence, influence is not a guarantee. These contributions do not in themselves establish contribution to harm. “[A] dollar . . . gets you in the door, and it gets your argument heard. Any lobbyist worth their salt believes that if they can get their foot in the door, they can make a persuasive argument for their issue.”<sup>347</sup>

Biopharmaceutical companies also assist with the drafting of legislation that governs their industry. This phenomenon is not unique to the biopharmaceutical industry. Many are under the mistaken assumption that elected officials are the ones drafting legislation.<sup>348</sup> In reality, the process varies with “staffers, lobbyists, and professional drafters writ[ing] laws rather than elected representatives.”<sup>349</sup>

One example in the biopharmaceutical space is the persistent inability of Medicare Part D to negotiate drug prices.<sup>350</sup> Medicare covers people who are sixty-five and older, some younger people who are disabled, and people with end-stage renal disease.<sup>351</sup> At an additional cost, Medicare Part D provides an option for prescription drug coverage.<sup>352</sup> Historically, Medicare did not include prescription drug coverage,<sup>353</sup> which was added in 2003 through the Medicare Prescription Drug, Improvement, and Modernization Act.<sup>354</sup> This Act contained a number of contentious

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345. *Pharmaceuticals / Health Products: Lobbying, 2018*, OPENSECRETS.ORG, <https://www.opensecrets.org/industries/lobbying.php?ind=H04> [<https://perma.cc/7FBQ-9BKT>].

346. Sydney Lupkin & Elizabeth Lucas, *Trump Blamed Pharma's Political Donations for 'Outrageous' Drug Prices. The Next Day, Those Donations Spiked*, STAT (Sept. 27, 2017), <https://www.statnews.com/2017/09/27/pharma-political-donations> [<https://perma.cc/827Z-4LEV>].

347. Niv M. Sultan, *Senate Vote on Prescription Drug Price Legislation Calls Loyalties into Question*, OPENSECRETS.ORG (Jan. 18, 2017), <https://www.opensecrets.org/news/2017/01/a-senate-vote-on-prescription-drug-price> [<https://perma.cc/P8S5-DP7C>].

348. Abbe R. Gluck & Lisa Schultz Bressman, *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation, and the Canons: Part I*, 65 STAN. L. REV. 901, 906 (2013).

349. Victoria F. Nourse & Jane S. Schacter, *The Politics of Legislative Drafting: A Congressional Case Study*, 77 N.Y.U. L. REV. 575, 575 (2002).

350. While President Trump formerly suggested this reform, it was notably lacking from his drug pricing blueprint. See, e.g., Rachel Sachs, *Trump's Drug Pricing Speech Breaks Little New Ground, Largely Spares Industry*, HEALTH AFF. (May 14, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180514.295639/full> [<https://perma.cc/74DC-EWB7>].

351. *Glossary - M*, MEDICARE.GOV, <https://www.medicare.gov/glossary/m> [<https://perma.cc/57C5-8T7E>] (explaining the term “Medicare”).

352. *Id.* (explaining the term “Medicare prescription drug coverage (Part D)”).

353. See Thomas R. Oliver, Philip R. Lee & Helene L. Lipton, *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283, 285 (2004).

354. *Id.* at 283.

provisions, including a prohibition on the government from directly negotiating drug prices with manufacturers.<sup>355</sup>

Prohibiting the government from negotiating drug prices is controversial because it prevents the government from “leverage[ing] its purchasing power to pay less for drugs.”<sup>356</sup> The thought is government would have greater leverage than fractionalized and competing prescription drug plans.<sup>357</sup> There are also issues for “dual eligibles” who are covered by both Medicare and Medicaid. Individuals in this category get their prescriptions through Medicare.<sup>358</sup> This increases costs because Medicaid implements certain cost controls on drug pricing that Medicare does not.<sup>359</sup> Why have these rules that would seem to increase costs for taxpayers and patients? “[D]rug manufacturers had a major role in writing and getting through Congress” the provisions which prevent government negotiation of drug prices.<sup>360</sup> Representative Walter Jones, for instance, a Republican from North Carolina stated: “The pharmaceutical lobbyists wrote the bill . . . .”<sup>361</sup>

Third, in the international context the biopharmaceutical industry and individual companies may influence law and policy by direct participation in committees. The importance of consulting with applicable stakeholders has been formally recognized and codified in the context of international trade. The institutional design of the U.S. Trade Representative (USTR) includes the participation of the private sector.<sup>362</sup>

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355. See, e.g., *id.* at 317–18, 322.

356. Theodore T. Lee, Abbe R. Gluck & Gregory D. Curfman, *The Politics of Medicare and Drug-Price Negotiation (Updated)*, HEALTH AFF. (Sept. 19, 2016), <http://healthaffairs.org/blog/2016/09/19/the-politics-of-medicare-and-drug-price-negotiation> [<https://perma.cc/B5JZ-62YL>].

357. Juliette Cubanski & Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations*, KFF (Apr. 26, 2018), <https://www.kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations> [<https://perma.cc/48G4-B9SJ>] (observing that proponents believe the Secretary of HHS would have greater leverage than private plans particularly for high-priced drugs lacking competition). *But see* Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2326 (2018) (noting Medicare’s ability to negotiate is undercut by mandated coverage requirements).

358. See, e.g., Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D of Medicare? And If So, How?*, 27 HEALTH AFF. 33, 35 (2008).

359. *Id.* at 35–37.

360. Lee, Gluck & Curfman, *supra* note 356; see also DEAN BAKER, TAKING ECONOMICS SERIOUSLY 27 (2010).

361. Michelle Singer, *Under the Influence*, CBS NEWS: 60 MINUTES (Mar. 29, 2007), <http://www.cbsnews.com/news/under-the-influence> [<https://perma.cc/5EMC-N9V8>]. Note that biopharmaceutical companies do not restrict their participation in drafting legislation to the federal level. A study regarding a pharmaceutical company’s role in HPV immunization policy at the state level also found participation in drafting. Michelle M. Mello, Sara Abiola & James Colgrove, *Pharmaceutical Companies’ Role in State Vaccination Policymaking: The Case of Human Papillomavirus Vaccination*, 102 AM. J. PUB. HEALTH 893, 894 (2012).

362. The USTR is the executive agency “responsible for developing and coordinating U.S. international trade, commodity, and direct investment policy, and overseeing negotiations with other countries.” *Mission of the USTR*, OFF. U.S. TRADE REPRESENTATIVE, <https://ustr.gov/about-us/about-ustr> [<https://perma.cc/MMS9-Z9VH>]. Among many other agreements, the USTR was the U.S. agency negotiating TRIPS and, more recently, the Trans-

Under the Trade Act of 1974, “[t]he President shall seek information and advice from representative elements of the private sector.”<sup>363</sup> Members of committees created under the Act, “[t]o the maximum extent practicable . . . shall be informed and consulted before and during any” negotiations.<sup>364</sup> Representatives from large biopharmaceutical companies, the Biotechnology Innovation Organization, the Pharmaceutical Research and Manufacturers of America, and the Association for Accessible Medicines sit on pertinent committees.<sup>365</sup>

These examples are suggestive, though not conclusive. It is possible that biopharmaceutical companies have special moral obligations, in some instances, on the basis of causal responsibility for harm. Whatever further examination reveals, however, the corporate context generally is not analogous to the paradigm rescue case.

Wrongful causal contribution to harm is an important potentially serious critique of a CDTR. In cases where there is causal responsibility, other things equal, focus on a CDTR appears to miss the mark in two important and related ways. First, a CDTR in such cases does not fully capture why one might think that biopharmaceutical companies ought to be picked out for an obligation to address pricing and access issues. Even if biopharmaceutical companies have an obligation to engage in rescue, companies shirking their rescue obligations does not appear to be the main moral concern for those worried about access to medications and drug pricing.

Second, and more perniciously, where there is wrongful causal contribution to harm, application of the CDTR tacitly mischaracterizes the relationship between the parties. It constructs a vignette in which a company is lauded as a rescuer, not construed as a wrongdoer. Likewise, patients are cast as merely suffering from unmet needs as opposed to being in need because of, and with legitimate claims against, another.<sup>366</sup>

The distinction between a corporate obligation to rescue and an obligation to redress harm is not merely academic. These moral issues are on display in numerous examples. In response to pressure from shareholders, for instance, the CEO of drug wholesaler Cardinal Health stepped down in light of controversies regarding causal connections between the company and the opioid epidemic.<sup>367</sup> Shareholders

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Pacific Partnership. Both agreements have been controversial for their intellectual-property related provisions and impact on health.

363. 19 U.S.C. § 2155(a)(1) (2012).

364. *Id.* § 2155(k).

365. For the complete list of committee members, see *Industry Trade Advisory Committee on Intellectual Property Rights ITAC15*, INT’L TRADE ADMIN., <https://www.trade.gov/itac/committees/itac15.asp> [<https://perma.cc/MHC8-JZYL>]; *Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Science Products and Services ITAC3*, INT’L TRADE ADMIN., <https://www.trade.gov/itac/committees/itac03.asp> [<https://perma.cc/BVB4-E88A>].

366. A similar concern has been raised in the context of housing grants by Facebook in Silicon Valley. Carl Rhodes & Peter Bloom, *The Trouble with Charitable Billionaires*, GUARDIAN (May 24, 2018, 1:00 PM), <https://www.theguardian.com/news/2018/may/24/the-trouble-with-charitable-billionaires-philanthrocapitalism> [<https://perma.cc/C6YZ-XCZZ>] (“Zuckerberg’s apparent generosity, it would seem, is a small contribution to a large problem that was created by the success of the industry he is involved in.”).

367. Eric Eyre, *Drug Wholesaler CEO to Step Down Amid WV Pain-Pill Probe*, CHARLESTON GAZETTE-MAIL (Nov. 6, 2017), <https://www.wvgazette.com/news/health>

observed that the outgoing CEO's "tone was notably off-pitch" on an earnings call in which the CEO "said the 'search for blame' in the opioid problem is the 'enemy of the search for solutions.'"<sup>368</sup> They noted that "[s]uch remarks undermine corporate accountability."<sup>369</sup> Similarly, when MSF rejected vaccine donations from Pfizer, it did so in part because it claimed that such donations are used to justify keeping prices high.<sup>370</sup> Pfizer had to that point refused to make any concessions on price.<sup>371</sup> MSF's rejection of the attempted donation reflects both concerns about the role of the donations themselves in sustaining the very pricing practices in question as well as Pfizer's alleged role in contributing to the harms requiring relief. As a final example, California State Senator Ed Hernandez recently sent a pointed letter to Eli Lilly's CEO regarding its new "Diabetes Solution Center."<sup>372</sup> This Center launched on August 1, 2018 to help those who cannot afford their insulin "find answers that best fit the personal circumstances of patients."<sup>373</sup> Noting a 700% price increase over the past two decades for insulin, however, Senator Hernandez wrote, "[i]f pharmaceutical companies like yours priced their drugs reasonably, there would be no need for a helpline. . . . Californians shouldn't have to plead their case to telephone operators."<sup>374</sup>

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Drug pricing controversies have diverse features. As argued above, only some raise the specter of wrongful harm, and even in those cases the issues are not as straightforward as in the modified pond case. Yet, in applicable cases, focus on a CDTR may fail to hold companies accountable for morally problematic actions. It gives companies a moral pass. Morally and pragmatically, this is undesirable. Care must be taken not to add insult to injury, and accountability is important so as not to further incentivize troubling behavior.

#### CONCLUSION

This Article has examined and critiqued a proposal in the literature that a CDTR applies to biopharmaceutical companies in the context of access to medications. Whereas most efforts to address biopharmaceutical pricing and access concerns

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/drug-wholesaler-ceo-to-step-down-amid-wv-pain-pill/article\_10fd09ae-5666-5905-90db-382815eb4dd0.html?utm\_source=STAT+Newsletters&utm\_campaign=d0a8f9cd1a-MR&utm\_medium=email&utm\_term=0\_8cab1d7961-d0a8f9cd1a-150064633 [https://perma.cc/VQ7X-WHSB].

368. *Id.*

369. *Id.*

370. Cone, *supra* note 244.

371. *Id.*

372. Letter from Senator Ed Hernandez, Cal. State Senate, to David A. Hicks, Chairman & Chief Exec. Officer, Eli Lilly (July 30, 2018) (on file with the *Indiana Law Journal*).

373. Press Release, Eli Lilly & Co., New Lilly Diabetes Helpline to Assist People Seeking Solutions to Insulin Affordability (July 12, 2018), <https://investor.lilly.com/node/39211/pdf> [https://perma.cc/QU6T-9J9J].

374. Letter from Senator Ed Hernandez, *supra* note 372.

focus on governmental regulation, a CDTR is particularly interesting as it offers a moral foundation for corporate self-regulation.

Problems of access and pricing regarding prescription medications are at root normative. By analyzing and critiquing a CDTR, this Article contributes to the larger ongoing debates about what the ethical obligations of biopharmaceutical companies are regarding access to their products, and further, how these obligations intersect with existing law. To that end, this Article has advanced three primary arguments.

*First*, analyzing pertinent law and principles, this Article argued that managers and directors possess the legal discretion to discharge a corporation's CDTR. *Second*, though managers and directors have this legal discretion, this Article examined features of the paradigm duty to rescue case and argued that it is unclear what this moral duty demands in the corporate biopharmaceutical context. Its application to problems of drug pricing and access is not straightforward, morally speaking. *Third*, this Article argued that there is a more general concern about application of the CDTR framework to the biopharmaceutical context. In some instances, emphasis on a duty to rescue may be misplaced. A duty to rescue allocates responsibility for rescue on the basis of who can help *now* and not on the basis of who has *historically* done what. Yet, wronging others generates significant reasons for the mitigation of that wrong to be the wrongdoer's special moral responsibility. *If* there is culpable corporate conduct, focus on a corporate duty to rescue might fail to hold companies accountable, thereby obfuscating morally problematic corporate conduct. Justified advocacy for a CDTR must therefore keep these potential challenges in mind.