



# The problem with relying on profit-driven models to produce pandemic drugs

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## ABSTRACT

In this article, we explain why profit-driven models for developing treatments for epidemic pathogens produce sub-optimal and sometimes negative public health outcomes. Using the example of the drug remdesivir, we demonstrate how the divergence of private incentives from public health needs has led to such outcomes during the COVID-19 pandemic. We conclude that policy responses to this and future pandemics ought to be conceived and designed in ways that narrow the divergence of private interests from public health needs, including through greater public-sector involvement in pharmaceutical R&D.

**KEYWORDS:** COVID-19, coronavirus, SARS-CoV-2, pandemic, pharmaceuticals, vaccines

The longstanding problems of relying on a market response to a pandemic are becoming readily apparent in the USA, which has quickly become the epicenter of the coronavirus disease 2019 (COVID-19) outbreak. The problems are particularly pronounced in pharmaceutical markets, where we are pinning our hopes for both cures and vaccines.<sup>1</sup> In previous work we have shown how characteristics of healthcare markets

1 See eg Ed Yong, *How the Pandemic Will End*, ATLANTIC, (Mar. 25, 2020), <https://www.theatlantic.com/health/archive/2020/03/how-will-coronavirus-end/608719/> (accessed Jul. 6, 2020).

in the USA create a divergence between the private incentives of for-profit companies and public health needs, leading to suboptimal health outcomes in what is a uniquely market-driven healthcare system.<sup>2</sup> In this essay, written as the COVID-19 pandemic unfolds, we illustrate how this divergence of private incentives from public health needs widens in contexts of pandemic preparedness and pandemic response. The essay begins by explaining why the design of pharmaceutical markets in the USA yields suboptimal and sometimes even negative health outcomes. The essay then follows the trajectory of the drug remdesivir as a case study that illustrates the consequences of relying on profit-driven pharmaceutical research and development (R&D) models for pandemic preparedness and response.<sup>3</sup> We conclude that, contrary to what many commentators suggest, government policy responses to pandemic threats that rely primarily on increasing private market incentives within our existing pharmaceutical markets are unlikely to yield pandemic treatments that meet public healthcare needs.<sup>4</sup> Policy interventions should instead be designed in ways that narrow the divergence of private interests from public health needs, especially in pandemic contexts. Achieving this will likely require greater public-sector involvement in pharmaceutical R&D.<sup>5</sup>

#### DIVERGENCE OF PROFIT-BASED INCENTIVES FROM PUBLIC HEALTH NEEDS IN US PHARMACEUTICAL MARKETS

The USA is an outlier among developed economies in its reliance on the market to provide healthcare products and services, albeit with substantial public financial support. If healthcare markets functioned in the same way as the perfectly competitive markets of neoclassical economics, this might be a good idea. In theory, in a market-based system, producers make production and pricing decisions in response to (1) consumer demand and willingness to pay, (2) their own costs of production, and (3) competition from other producers. In such a simple neoclassical world, the outcome is an efficient one. Private companies compete on price and quality of their goods and services in efforts to maximize profits. Profit reflects both supply costs and consumer demand. Competition pushes prices down until supra-normal profits are eliminated and goods are provided at prices that equate the cost of production and the marginal value of consumption. In an efficient market, consumers have sufficient information

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2 See Yaniv Heled, Liza Vertinsky & Cass Brewer, *Why Healthcare Companies Should Be (come)Benefit Corporations*, 60 B. C. L. REV. 73 (2019); Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729 (2019).

3 While we acknowledge that the response by the US federal government has also been inadequate, this does not make a strategy of relying on the market to drive response to a healthcare crisis a prudent one. Indeed, perhaps the federal government response has been inadequate in part because of the heavy reliance that the current administration has placed on the private sector, particularly large corporate actors, to meet public health needs.

4 See eg Editorial Board, *Drug Innovation to the Rescue*, WALL ST. J., May 1, 2020, <https://www.wsj.com/articles/drug-innovation-to-the-rescue-11588373344> (accessed Jul. 6, 2020). Public healthcare needs in this context relates to availability, accessibility, and timeliness of treatments.

5 While in other work we have explored the opportunities, and limits, of alternative hybrid strategies such as public-private partnerships, exploring hybrid ways of engaging in drug R&D in preparation for, and in response to, pandemics is beyond the scope of this paper. See, however, Esha Chhabra, *How This Pandemic Could Help Fix Capitalism*, FORBES, Apr. 30, 2020, <https://www.forbes.com/sites/eshachhabra/2020/04/30/how-this-pandemic-could-help-fix-capitalism/#389e65d2d56b> (discussing changes to corporate norms in the wake of the COVID-19 pandemic) (accessed Jul. 6, 2020).

about the comparative benefits that a product or service will afford them; they can value those benefits; they have the ability to rationally choose from a range of competing alternatives; they know what the price is, and they elect to purchase the good or service when the value it provides to them exceeds the cost. Competition among producers acts to reduce prices that diverge too much from underlying costs of production. The result, in this ideal neoclassical world, is that consumers get the products they want at a price that is reasonably tied to costs of production and reflective of consumer value.

But healthcare markets diverge in important ways from this competitive market ideal.<sup>6</sup> In earlier work we have argued that healthcare markets have distinctive characteristics that produce suboptimal public health outcomes when products and services are developed and sold by entities such as corporations that focus primarily on profit-maximization.<sup>7</sup> Using pharmaceutical markets as the most salient example,<sup>8</sup> we illustrated how the structure of US healthcare markets has resulted in a persistent divergence of private market incentives from public health needs at every stage of the pharmaceutical product life cycle. This divergence too often leads to companies maximizing profits at the expense of, rather than in pursuit of, public health value. We have argued that this divergence of incentives arises from the combination of three important features of US healthcare markets.

First, in healthcare markets prices often fail to serve as a good indicator of either cost or public health value. The entity or person who pays for the product is often different from the patient-consumer and from the entity or person who prescribes the product, the product is rarely viewed as anything other than essential, payors (including patients themselves) often lack information about the health value of the product for the patient, and the fragmentation of the market makes it difficult to ascertain cost and price information.<sup>9</sup> The normal forces of supply and demand, with price as the mediator, do not work well in this opaque and fragmented system, even with the (contested) assumption that we can reasonably view patients as consumers,<sup>10</sup> leaving producers with too much control over product choice and price.

Second, US healthcare markets are characterized by the socialization of costs but privatization of benefits, leaving producers with access to subsidies and guaranteed purchases while allowing them control over what to produce and what to charge for it. This reflects both a paradigm and a powerful political narrative of biomedical innovation that has driven US policymaking in this area since the end of World War II.<sup>11</sup> The basic scientific research and discovery that feeds R&D is treated as a public good

6 See eg Kenneth Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 82 AM. ECON. REV. 141 (2004); Paul Krugman, *Why Markets Cannot Cure Healthcare*, N.Y. TIMES, Jul. 25, 2009 (summarizing Arrow's seminal argument about why health care cannot be sold like other goods).

7 See Heled & Vertinsky *supra* note 2 at 76 n. 8 (defining healthcare companies).

8 We use the term 'pharmaceutical markets' in this essay to refer broadly to markets for pharmaceutical and biopharmaceutical products, including drugs, vaccines, and drug-device combinations.

9 For further discussion of how price fails to reflect public health value see *Why Healthcare Companies Should Be(come)Benefit Corporations* *supra* note 2, at 36–43.

10 See eg Paul Krugman, *Patients are not Consumers*, N.Y. TIMES, Apr. 21, 2011, <https://www.nytimes.com/2011/04/22/opinion/22krugman.html> (accessed Jul. 6, 2020).

11 See eg Ron A. Bouchard & Trudo Lemmens, *Privatizing Biomedical Research—A 'Third Way'*, 26 NATURE BIOTECH. 31 (2008); Amy Kapczynski and Gregg Gonsalves, *Alone Against the Virus*, BOSTON REV., Mar. 19, 2020 (exploring the negative consequences of having a health system with a 'laser-like focus on maximizing profit' in the context of a pandemic).

and subsidized as such by the government. The private sector is tasked with taking the discoveries made by publicly funded efforts through the later stages of R&D and turning them into products and services by navigating a lengthy and costly regulatory approval process. For this risk and investment, pharmaceutical companies have been granted exclusive rights to heavily publicly funded research and the right to commercialize the resulting products on their own terms.<sup>12</sup> The government is also a substantial purchaser of these products, primarily through publicly funded insurance programs like Medicaid and Medicare, but with limited ability to bargain over price.<sup>13</sup> Any attempts to implement price controls or cost recoupment measures are challenged on the grounds that they will stifle innovation.<sup>14</sup>

Finally, healthcare markets in the USA are characterized by extensive regulations and a market structure that limits competition. This is especially true for pharmaceutical markets due to (a) the increased use of exclusivities as incentives for innovation and data secrecy; (b) a high regulatory burden; and (c) concentration in pharmaceutical product markets. The ability to obtain, maintain, and expand exclusivity is a key driver of company decisions at every stage of the product life cycle, beginning with selection of potential drug candidates to pursue and extending through the development of the drug and its marketing and sale. Extensive regulatory capture, in which healthcare companies influence policymakers and regulators in ways that serve their own special interests, enhances the role of regulatory exclusivities as mechanisms for limiting competition and enhancing profit opportunities, further widening the divergence of private incentives from the public interest.<sup>15</sup>

While other markets may share some of these characteristics, it is the combination of all three, in full force, that makes healthcare markets, and pharmaceutical markets in particular, uniquely problematic as a way of meeting public health needs.<sup>16</sup> In pharmaceutical markets, these features allow companies to select R&D projects based on the potential for profits rather than public health impact. Pharmaceutical companies benefit from publicly funded science and a variety of development subsidies with few strings attached. They control decisions along the product development and distribution

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12 There are several provisions embedded in current laws governing transfers of publicly funded technology that subject these transfers to a regime designed to encourage the commercialization of drugs and other products at affordable prices. See eg 35 U.S.C. § 209 (establishing both procedural and substantive requirements for the licensure of publicly funded inventions); 28 U.S.C. § 1498. These legal frameworks, however, remain underutilized. See Ana Santos Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the United States Army Zika Vaccine*, 127 *YALE L.J.F.* 651 (2018) (explaining how several of these limitations are often disregarded in practice by both the public and the private sectors, with specific reference to pharmaceutical products for which there is little to no private-sector appetite prior to an outbreak of an infectious disease).

13 See eg Sarah Kliff, *The True Story of America's Sky-High Prescription Drug Prices*, *VOX*, May 10, 2018.

14 See eg Wayne Winegarden, *Price Controls Are Not the Answer to Expensive Drugs*, *FORBES*, Oct. 18, 2019 (arguing that price controls over pharmaceutical products may 'transform(. . .) the system of capitalism and free enterprise into socialism'); Michael Wornow, *Just What the Doctor Ordered: The Case for Drug Price Controls*, *HARV. POL. REV. ONLINE*, Dec. 2, 2018 (surveying arguments against and in favor of pharmaceutical price controls).

15 See eg John Abraham, *The Pharmaceutical Industry as a Political Player*, 360 *LANCET* 1498 (2002).

16 For an in-depth discussion of these three factors in the context of healthcare markets, See Benefit Corp. paper.

pathway and set prices with the primary goal of maximizing profits.<sup>17</sup> With the use of a variety of exclusivities<sup>18</sup> that limit competition and with limits imposed on government purchasers bargaining power, pharmaceutical companies are able to take advantage of public and private procurement of their products with little if any need to compete on either price or health benefit for extended periods of time.<sup>19</sup>

### WHY THE DIVERGENCE OF PRIVATE INCENTIVES AND PUBLIC HEALTH WIDENS IN PANDEMIC PREPAREDNESS AND RESPONSE

This divergence of private incentives from public health needs widens in contexts of pandemic preparedness and response.

**First**, forces of supply and demand mediated by price do not work well to respond either to the possibility of future pandemics or, on an emergency basis, to allocate resources and guide economic activity once the public health emergency has struck.<sup>20</sup>

Even in well working markets, price does a poor job of reflecting the value of being prepared for unknown future contingencies. The price mechanism does not and cannot capture the difficult-to-quantify and heavily discounted public health value of being better prepared in the uncertain event that a (corona) virus or other pathogen of a particular type will spread rapidly within economically profitable markets at some future time. Pandemic preparedness requires ‘inefficiencies’ from an economic point of view: carrying excess capacity, stockpiling equipment, and ensuring geographically spread production and distribution infrastructure that exceed market demand or for which there will never be any realized demand.<sup>21</sup> It involves investing in the R&D of vaccines and treatments for pathogens that are likely to never emerge, and for diseases that are most likely to remain contained,<sup>22</sup> and/or for pathogens that might mutate over time such that approved products might not work for future infections and outbreaks. Compounding these bleak economic prospects is the fact that outbreaks of infectious diseases often start with, and remain limited to, neglected regions and populations,

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17 While the case study in this essay focuses on the behavior of a single pharmaceutical company, the phenomena we identify and describe are transversal to the pharmaceutical industry—or, more precisely, reflects the ingrained adoption of profit-driven pharmaceutical R&D and commercialization models which are largely at odds with the pursuit of the public health goals.

18 See eg Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299 (2015).

19 See eg Shawn Tully, *The Best Way to Lower Drug Prices: End the Medicaid Program that Blocks Discounts*, FORTUNE, Feb. 5, 2019, <https://fortune.com/2019/02/05/the-best-way-to-lower-drug-prices-end-the-medicaid-program-that-blocks-discounts/> (describing limitations imposed on Medicaid and Medicare Part D’s ability to negotiate pharmaceutical prices) (accessed Jul. 6, 2020).

20 See Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200 (2018). For an expanded analysis of this argument in connection with the role of intellectual property as a system of incentives for innovation, See Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. (2012).

21 See eg David P. Fidler & Lawrence O. Gostin, *WHO’s Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health*, 306 JAMA 200 (2011).

22 It takes a very particular combination of pathogen characteristics to turn into a successful pandemic, including non-lethality while contagious, effective spreading mechanisms, non-detectability during incubation, and ability to avoid effective immune response. See eg JOHNS HOPKINS SCHOOL OF PUBLIC HEALTH, *THE CHARACTERISTICS OF PANDEMIC PATHOGENS* (2018), [http://www.centerforhealthsecurity.org/our-work/pubs\\_archive/pubs-pdfs/2018/180510-pandemic-pathogens-report.pdf](http://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2018/180510-pandemic-pathogens-report.pdf) (accessed Jul. 6, 2020).

where markets for pharmaceutical products offer limited economic potential.<sup>23</sup> The 2014–2016 transnational Ebola outbreak, which affected primarily countries in West Africa, is a case in point. Coincidentally (or perhaps not), many of the promising leads on treatments for COVID-19 are based on advances made—but then stalled—in response to Ebola.<sup>24</sup> Moreover, under current paradigms, pricing of any existing vaccines and drug products before the start of an outbreak is bound to grossly undervalue the preventative and therapeutic effects of such products.<sup>25</sup>

Once an infectious disease that threatens severe health outcomes starts spreading, it is sure to result in inelastic, and sometimes irrational, maximal market demand for treatments, regardless of individuals' risk status and even regardless of product effectiveness.<sup>26</sup> Panic increases the demand for any potential therapy dramatically, but leaves the ability to pay rather than health need or health benefit as the determinant of who gets the product in times of shortage. Infectious diseases like COVID-19 tend to spread more readily and have greater health effects on poorer communities, where purchasing power, and thus market demand, is low.<sup>27</sup> But when a pandemic emerges, markets allocate resources based on who can pay the most, which reflects neither individuals' need nor the best allocation for achieving public health goals. The tension between ability to pay and medical need is further compounded by the additional tension between individual demand and the public interest: while individuals rationally seek to maximize benefits for themselves and their loved ones, on a population level, herd response is the only method of effectively tackling pandemics, with herd immunity being the ultimate goal. Leaving the allocation of treatments to be decided by who can pay for them will inevitably lead to suboptimal results, to everyone's detriment. This problem takes on an even greater dimension when we consider the needs of poorer countries outside of the USA, and the importance of considering not just treatment effectiveness but also accessibility to large groups of people.

In addition to problems of inelastic demand confronting income constraints and capacity constraints, the rising price for any type of therapy combined with scarcity of effective treatments leads to problems of profiteering and attracts products of uncertain

23 See eg Ben Oppenheim & Gavin Yamey, *Pandemics and the Poor*, BROOKINGS, Jun. 19, 2017, <https://www.brookings.edu/blog/future-development/2017/06/19/pandemics-and-the-poor/> (accessed Jul. 6, 2020); Hitoshi Oshitani et al., *Major Issues and Challenges of Influenza Pandemic Preparedness in Developing Countries*, 14 EMERGING INFECTIOUS DISEASES 875 (2008) (exploring lack of influenza preparedness in the Global South).

24 CTRS. DISEASE CONTROL & PREVENTION, 2014–2016 EBOLA OUTBREAK IN WEST AFRICA (2019), <https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html> (accessed Jul. 6, 2020).

25 See Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170 (2020).

26 An embodiment of this phenomenon during the COVID-19 pandemic has been the emphasis placed on purported treatment candidates with scarce to no scientific support for their efficacy or safety. See eg US Food & Drug Admin., FDA CAUTIONS AGAINST USE OF HYDROXYCHLOROQUINE OR CHLOROQUINE FOR COVID-19 OUTSIDE OF THE HOSPITAL SETTING OR A CLINICAL TRIAL DUE TO RISK OF HEART RHYTHM PROBLEMS (Apr. 30, 2020), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or> (accessed Jul. 6, 2020).

27 See eg Grace A. Noppert, *COVID-19 is Hitting Black and Poor Communities the Hardest, Underscoring Fault Lines in Access and Care for Those on Margins*, THE CONVERSATION, Apr. 9, 2020, <https://theconversation.com/covid-19-is-hitting-black-and-poor-communities-the-hardest-underscoring-fault-lines-in-access-and-care-for-those-on-margins-135615> (accessed Jul. 6, 2020).

quality. During the period of the outbreak, as information gaps increase and, with them, irrational and even desperate individual responses, pharmaceutical companies gain the ability to charge high prices for virtually *any* purported treatment, regardless of its safety and efficacy profile, and with minimal risk of tort liability further down the road.<sup>28</sup> While emergency conditions also include downward pressures on prices, which arise, among other things, from emergency government responses such as compulsory licensing, in the US these pressures are curbed by the dominant political belief in the power of the market and the importance of rewarding private innovation.<sup>29</sup> With the ability to raise prices in a time of crisis, and with limited threat of competition due to limited capacity, market incentives might even encourage *non-preparedness*, *untimely* response, and *profiteering*.<sup>30</sup>

Moreover, although the two are related, it is not product price, but stock price, that drives pharmaceutical company decisions. Profit-driven entities are primarily driven by stock price, executive compensation, and short-term profits, which—in the case of pandemics—creates and exacerbates biases against efforts to prepare for and respond to long-term problems.<sup>31</sup> Long-term planning, investment in potential therapies with uncertain future applications, carrying excess capacity for pandemic preparation, and heeding to need-driven allocation of goods required for pandemic response are unlikely to translate into expectations of short-term stock price increases. Instead, pharmaceutical markets have been increasingly oriented around the ability to reduce risk, enhance proprietary boundaries, and increase expected short-term revenues from product sales. Such inherent short-termism makes profit-driven entities particularly poor at responding to the threat of pandemics. The response once a pandemic threat becomes an actuality is also problematic. Once emergency strikes, interest in potential therapies drives any company that can even remotely claim to have a drug or drug candidate to tout its potential and invest in its development. The immediate impact of the promise of a pandemic drug on the stock price of pharmaceutical companies is incentive enough to promote poorly substantiated and even just rumored benefits of purported treatments.<sup>32</sup> For those companies with legitimate potential therapies in development,

28 A case in point is the hype surrounding hydroxychloroquine and its resulting casualties, shortages, and effect on the stock price of manufacturers. See eg Michael Erman and Deena Beasley, *Doctors embrace drug touted by Trump for COVID-19, without hard evidence it works*, REUTERS, Apr. 6, 2020, <https://www.reuters.com/article/us-health-coronavirus-usa-hydroxychloroq/special-report-doctors-embrace-drug-touted-by-trump-for-covid-19-without-hard-evidence-it-works-idUSKBN21O2VO> (accessed Jul. 6, 2020).

29 See *infra* note 92 and accompanying text.

30 See eg Mariana Mazzucato & Azzi Momenghalibaf, *Drug Companies Will Make a Killing from Coronavirus*, N.Y. TIMES (Mar. 18, 2020), <https://www.nytimes.com/2020/03/18/opinion/coronavirus-vaccine-cost.html> (accessed Jul. 6, 2020).

31 See eg WORLD HEALTH ORG., AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS, (2016), [https://www.who.int/blueprint/what/improving-coordination/workstream\\_5\\_document\\_on\\_financing.pdf?ua=1](https://www.who.int/blueprint/what/improving-coordination/workstream_5_document_on_financing.pdf?ua=1) (noting a chronic lack of investment in R&D on multiple infectious disease pathogens before an outbreak occurs) (accessed Jul. 6, 2020).

32 See eg Jaimy Lee, *Mylan to Restart Production of Hydroxychloroquine*, MARKETWATCH (Mar. 19, 2020), <https://www.marketwatch.com/story/mylan-to-restart-production-of-hydroxychloroquine-2020-03-19> (describing how shares of pharmaceutical company Mylan increased in value as a response to the company's announcement that it would resume manufacturing hydroxychloroquine-sulfate tablets) (accessed Jul. 6, 2020). For discussion of the hype and fallacy of chloroquine and hydroxychloroquine as a potential treatment for SARS-CoV-2, see *supra* note 26.

impact on stock price is an important factor in managing clinical testing and controlling the release of results, even when public health would be clearly better served by the rapid disclosure and sharing of all information, including reports of negative results or information that might support development of competing therapies.<sup>33</sup>

This failure of price to act as a mechanism for directing supply and demand based on public health value of pandemic preparedness and response plays out well beyond the development of therapeutic products. The ongoing COVID-19 pandemic has shed light on similar embodiments of this problem in other areas that are critical to a quick and effective response to a pandemic, including the scarcity of hospital beds,<sup>34</sup> diagnostic tests,<sup>35</sup> and ventilators<sup>36</sup> in the USA. Collectively, these examples illustrate the dangers of relying on price as a signal of healthcare value, a topic we explore in greater detail in the case study on remdesivir below.

**Second**, the US policy choice to emphasize relying on private incentives to drive pandemic preparedness and response, and the resulting socialization of the costs (including the costs of not being prepared) but not the benefits, leaves pharmaceutical companies essentially in exclusive control of the product target choice, R&D process, and intellectual property where public input and shared control are most needed. The outspoken reliance on the private sector to provide pandemic solutions reinforces government efforts to evade accountability for ensuring pandemic preparedness by shifting responsibility to the private sector, which is beholden to stockholders, not the public. In this way the government is able to avoid making the large investments in public capacity and R&D that government preparedness would require. Limited government funding is devoted to academic and government research on potential drug candidates for future outbreaks, but almost always with the idea of handing off early stage ideas to private companies. Government funding is also provided to private companies for R&D into drugs that might be useful for some potential future pandemic, but the funding is inadequate and the return on investment for pharmaceutical companies is too low to attract much of their time or interest.<sup>37</sup>

Once a pandemic or large-scale public health crisis occurs, or, more specifically, reaches the USA, the emergency triggers investment of large sums of government

33 See eg Thomas Franck, *The Stock Market is Rising on Hope for a Pharma Solution to Coronavirus—Here's How Close We Are*, CNBC (Apr. 18, 2020), <https://www.cnbc.com/2020/04/18/the-stock-market-is-rising-on-hope-for-a-pharma-solution-to-coronavirus-heres-how-close-we-are.html> (accessed Jul. 6, 2020).

34 See eg Thomas C. Tsai et al, *American Hospital Capacity and Projected Need for COVID-19 Patient Care*, HEALTH AFF. BLOG (Mar. 17, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200317.457910/full/> (accessed Jul. 6, 2020).

35 See eg Ricardo Alonso-Zaldivar, *A Federal Report Found Coronavirus Test Shortages at United States Hospitals. Trump Attacked the Author*, TIME MAGAZINE, Apr. 6, 2020, <https://time.com/5816134/covid-us-hospitals-patients/> (accessed Jul. 6, 2020).

36 See Joshua Resnik, *The Ventilator Shortage is Here. The Medication Shortage is Next*, WASH. POST, Apr. 9, 2020, <https://www.washingtonpost.com/opinions/2020/04/09/ventilator-shortage-is-here-medications-shortage-is-next/> (accessed Jul. 6, 2020); H. C. Huang et al., *Stockpiling Ventilators for Influenza Pandemics*, 23 EMERGING INFECTIOUS DISEASES 914 (2017) (describing insufficient and intermittent investment in ventilators for the Strategic National Stockpile).

37 See eg Ekaterina Galkina Cleary, *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 PROCEEDINGS NAT'L ACADEM. SCI., 2329 (2018), <https://www.pnas.org/content/115/10/2329> (accessed Jul. 6, 2020).



money in initial R&D and purchasing of treatments.<sup>38</sup> Yet, in the USA such initial investment is almost never accompanied by any measures to secure a reasonable pricing scheme or even just consideration of the public investments in R&D.<sup>39</sup> Moreover, the investment of public funds often takes the form of supporting existing market forces through increased private incentives to speed discovery and development and subsidize capacity building. This practice is underpinned by a narrative promoting the need for unfettered private sector innovation, which is portrayed as incompatible with government efforts to control the price and/or allocation of the R&D outputs.<sup>40</sup> Even in the rare instances in which measures to secure reasonable pricing have been attached to government investments in early R&D, they have not been implemented.<sup>41</sup>

In the midst of the COVID-19 outbreak, the government response to the need for a cure continues to depend heavily on unfettered private sector innovation, as most recently reflected in the emergence of ‘Operation Warp Speed’, a public private partnership formed to identify and speed the development of promising drug and vaccine candidates for COVID-19 through large-scale government support for private sector programs.<sup>42</sup> The heavy reliance that US policymakers have placed on private sector innovation to produce therapies and vaccines stands in stark contrast to international efforts focused on public–private collaborations backed by academic scientists from around the world and the World Health Organization.<sup>43</sup>

**Third**, the nature and extent of regulation in US pharmaceutical markets has favored business models that exploit the availability and use of exclusivities throughout the lifecycle of product selection, development, and sale. The most profitable pharmaceutical business models focus either on large blockbuster drugs that can be sold at prices high relative to cost and/or niche market products (such as orphan drugs) where competition is restricted and prices can be kept high.

38 See eg Rutschman, *IP Preparedness*, *supra* note 20 (describing this phenomenon during the 2014–16 Ebola outbreak).

39 See Rutschman, *Vaccine Licensure in the Public Interest*, *supra* note 12 (describing this phenomenon a previous outbreak of an infectious disease in the USA).

40 See *infra* note 92 and accompanying text.

41 See Carolyn L. Treasure et al., *Do March-In Rights Ensure Access to Medical Products Arising from Federally Funded Research? A Qualitative Study*, 93 *MILIBANK Q.* 761 (2015).

42 See eg Rob Copeland, *The Secret Group of Billionaires and Scientists Pushing a Manhattan Project for Covid-19*, *WALL ST. J.*, Apr. 27, 2020, <https://www.wsj.com/articles/the-secret-group-of-scientists-and-billionaires-pushing-trump-on-a-covid-19-plan-11587998993> (accessed Jul. 6, 2020); See also Jennifer Jacobs & Drew Armstrong, *Trump’s ‘Operation Warp Speed’ Aims to Rush Coronavirus Vaccine*, *BLOOMBERG NEWS*, Apr. 29, 2020 (project bringing together private pharmaceutical companies, the US government and the military to accelerate development of a vaccine, with taxpayers shouldering much of the cost and risk and with limited liability for pharmaceutical companies). See also HHS Press Release, *Trump Administration Announces Framework and Leadership for Operation Warp Speed*, May 15, 2020 (chief advisor of the initiative is a venture capitalist and former chairman of a large pharmaceutical company).

43 See eg Matt Apuzzo and David Kirkpatrick, *Covid-19 Changed How the World Does Science, Together*, *N.Y. TIMES*, Apr. 14, 2020, <https://www.nytimes.com/2020/04/01/world/europe/coronavirus-science-research-cooperation.html> (contrasts the international, collaborative efforts by scientists around the world with the Trump administration’s focus on US focused pharmaceutical R&D) (accessed Jul. 6, 2020); Marcus Scholz and N. Craig Smith, *In the Face of a Pandemic, Can Pharma Shift Gears?*, *MIT SLOAN MANG’T REV.*, Apr. 16, 2020, <https://sloanreview.mit.edu/article/in-the-face-of-a-pandemic-can-pharma-shift-gears/> (contrasting the US pharmaceutical model with collaborative initiatives at the international level such as the global trial organized by the WHO) (accessed Jul. 6, 2020).

The market potential of these exclusivities is limited in the context of developing potential therapies for pandemic preparedness. Exclusivities have little value for drug that do not (yet) have a proven existing use, but they do operate to limit the incentives and ability of others to experiment with and utilize undeveloped and underdeveloped drug candidates. The value of exclusivities in pandemic drugs and drug-candidates is further compromised when the primary market(s) for such drugs are in countries where purchasing power is low, and their value can be limited, especially in pandemic contexts, by temporary government emergency measures such as compulsory licensing. While pharmaceutical companies may not themselves be interested in developing potential therapies for pandemics in the absence of information that an outbreak is likely, they may still prefer to exercise market control over drug-candidates R&D and the capacity to produce such drugs where the area of R&D overlaps with their existing commercial interests.

The commercial value of exclusivities increases for therapies with potential pandemic application once the pandemic occurs, but so too does the social cost of these exclusivities. Effective response to a pandemic requires a commitment to open and rapid sharing of information, including proprietary information, among potential competitors, and across national and geopolitical lines.<sup>44</sup> Yet, the regulatory environment that has allowed for limited pharmaceutical competition outside the context of a pandemic continues to reward responses to healthcare emergencies with both intellectual property and market exclusivities administered by the Food and Drug Administration (FDA), while allowing stringent data secrecy policies to remain in place.<sup>45</sup> Once a pandemic strikes, the lure of exclusivities leads to an ‘arms race’ for potential therapeutics and to development strategies that are designed wherever feasible to safeguard proprietary advantages. If and when the sharing or transfer of data and intellectual property does occur, it takes place on a delayed timeline, often only after substantial public and political pressure and concessions.<sup>46</sup> Furthermore, when data and intellectual property sharing arrangements are implemented, they typically follow the model of strategic licensing, which is designed to limit the capacity of competitors to compete in particularly lucrative markets.<sup>47</sup> Even where there is a willingness to engage in collaborative R&D, the industry lacks well-developed mechanisms and practices for collaborative product development because these mechanisms are so different

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44 See generally VIRAL SOVEREIGNTY AND TECHNOLOGY TRANSFER: THE CHANGING GLOBAL SYSTEM FOR SHARING PATHOGENS FOR PUBLIC HEALTH RESEARCH, SAM F. HALABI, ED. (2020).

45 See Heled, *Regulatory Competitive Shelters*, *supra* note 18; 21 C.F.R. § 20.61(c) (‘Data and information submitted or divulged to the FDA which fall within the definition of a trade secret or confidential commercial or financial information are not available for public disclosure.’). See also Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007).

46 See Rutschman, *IP Preparedness*, *supra* note 20, at 1247.

47 See eg Ed Silverman, *Gilead Deal to Sell Sovaldi in Poor Countries Meets Criticism*, PHARMALOT, Sept. 15, 2014, <https://blogs.wsj.com/pharmalot/2014/09/15/gilead-deal-to-sell-sovaldi-in-poor-countries-meets-criticism/> (accessed Jul. 6, 2020); Brook Baker, *Gilead Remdesivir Licenses: Half Measures are not Nearly Good Enough*, INFOJUSTICE, May 12, 2020, <http://infojustice.org/archives/42348>. But see GILEAD, VOLUNTARY LICENSING AGREEMENTS FOR REMDESIVIR, <https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir> (listing developing countries covered by negotiated by voluntary licensing agreements negotiated by Gilead and generic manufacturers) (accessed Jul. 6, 2020).

from normal drug discovery and development pathways.<sup>48</sup> Efforts at collaboration through public—private partnerships, such as the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership formed by the National Institutes of Health, other government agencies, and a group of large pharmaceutical companies to accelerate the development of vaccines and therapeutics in response to COVID-19, fail to depart significantly from existing proprietary R&D models.<sup>49</sup> Instead of an extension of normal practices, open and collaborative late stage development and distribution requires an entirely different way of operating. Eventually, all of these market dynamics pit pharmaceutical companies against public health pressures, leading to adversity and mistrust where collaboration is urgently needed.<sup>50</sup> This is even more true at the global level, where the national interests of the USA in controlling and receiving priority in access to effective treatments is in tension with much needed global coordination of efforts, data sharing, and widespread production.<sup>51</sup>

### ILLUSTRATING THE DIVERGENCE: A CASE STUDY OF REMDESIVIR

At the time of writing of this essay, the story of pharmaceutical company behavior in the midst of the outbreak continues to evolve, but—at least so far—is evolving along predictable lines, with responses that mirror behaviors observed in previous public health crises. Although it remains too early to examine the complete life cycle of any proven treatment for COVID-19, because none has yet been established, this essay uses what we know already about remdesivir, currently the most promising novel treatment for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), as a case study to illustrate the limitations of relying on for-profit pharmaceutical companies for pandemic preparedness and response.

Remdesivir was identified early in the outbreak as one of the most promising candidates for the treatment of COVID-19 patients.<sup>52</sup> It is one among several drugs—mostly targeting HIV infection and the flu—which scientists have been trying to

48 See eg Marcus Scholz and N. Craig Smith, *In the Face of a Pandemic, Can Pharma Shift Gears?*, MIT SLOAN MANAGEMENT REV., Apr. 16, 2020 at <https://sloanreview.mit.edu/article/in-the-face-of-a-pandemic-can-pharma-shift-gears/> (“The pharmaceutical industry’s competition-based model could be a real liability in the race to develop drugs and vaccines to combat COVID-19”) (accessed Jul. 6, 2020).

49 See United States NAT’L INSTITUTES HEALTH, NIH TO LAUNCH PUBLIC-PRIVATE PARTNERSHIP TO SPEED COVID-19 VACCINE AND TREATMENT OPTIONS (Apr. 17, 2020), <https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options> (accessed Jul. 6, 2020). See also Jens K. Roehrich et al., *Are Public—private Partnerships a Healthy Option? A Systematic Literature Review*, 113 SOCIAL SCI. & MED. (2014), <https://www.sciencedirect.com/science/article/pii/S0277953614002871> (accessed Jul. 6, 2020).

50 See eg Beth Snyder Bulik, *United States Trust in Pharma Ticks Upward, but Consumers Still Distrust the Industry: Survey*, FIERCE PHARMA, Apr. 29, 2019, <https://www.fiercepharma.com/marketing/trust-pharma-increases-u-s-but-still-resides-distrust-territory-annual-survey> (accessed Jul. 6, 2020).

51 One of the more extreme embodiments of this phenomenon during the COVID-19 pandemic was the announcement by Sanofi, a large pharmaceutical company, that it would prioritize the US market in the commercialization of emerging COVID-19 vaccines. See eg France 24, *COVID-19: Sanofi Backpedals on US Vaccine Priority After French Outrage* (May 14, 2020), <https://www.france24.com/en/20200514-france-says-unacceptable-for-sanofi-to-give-coronavirus-vaccine-to-us-first> (further noting that the company quickly abandoned this strategy following widespread public outcry) (accessed Jul. 6, 2020).

52 See eg Tal Axelrod, *Experimental COVID-19 Drug Shows Promise in New Study*, THE HILL (Apr. 10, 2020), <https://thehill.com/policy/healthcare/492322-experimental-covid-19-drug-shows-promise-in-new-study> (accessed Jul. 6, 2020).

repurpose for the treatment of COVID-19.<sup>53</sup> Among the hundreds of clinical trials for a possible treatment for COVID-19 underway,<sup>54</sup> remdesivir quickly emerged as one of the leading candidates.<sup>55</sup> By analyzing the life cycle of the discovery and development of remdesivir, both well before and during the early stages of the pandemic, the case study highlights critical areas in which the private incentives, and consequent actions, of pharmaceutical companies diverge from public health needs.

### Gilead's development of remdesivir

Remdesivir was originally developed by Gilead Sciences, a large California-based biopharmaceutical company with an R&D pipeline that has traditionally included drugs targeting infectious disease.<sup>56</sup> Established in 1987, the company has grown dramatically through a sequence of strategic acquisitions, acquiring 16 other biopharmaceutical companies since 1999. One of the most notable acquisitions was the purchase of Pharmasset, along with its hepatitis C drug, Sovaldi (Sofosbuvir) in 2011, for a price of \$10.4 billion.<sup>57</sup> Gilead turned Sovaldi into a highly priced blockbuster, charging as much as \$84,000 per course of treatment.<sup>58</sup> Gilead's business strategy has secured its place as a Fortune 500 company with a market cap of approximately \$93 billion and annual revenues topping \$22 billion in 2018, mostly resulting from its soaring sales of antiviral drugs.<sup>59</sup> The company sustains its revenue through aggressive product pricing,<sup>60</sup> which is facilitated by patent protection and other exclusivities that limit competition and protect its dominant market position in its core diseases areas.

While Gilead has attracted more public criticism than most pharmaceutical companies for its aggressive exploitation of existing market structures to increase profit oppor-

53 Ned Pagliarulo, *A Closer Look at the Ebola Drug that's Become the Top Hope for a Coronavirus Treatment*, BIOPHARMA DIVE, Mar. 5, 2020, <https://www.biopharmadive.com/news/coronavirus-remdesivir-gilead-antiviral-drug-covid-19/573261/> (accessed Jul. 6, 2020).

54 *Id.*, *ib.*

55 See eg Berkeley Lovelace Junior, *Scientists Race to Find a Cure or Vaccine for the Coronavirus. Here are the Top Drugs in Development*, CNBC (May 13, 2020), <https://www.cnbc.com/2020/05/13/coronavirus-scientists-race-to-find-a-cure-or-vaccine-here-are-the-top-drugs-in-development.html> (surveying the leading vaccine and drug candidates targeting COVID-19) (accessed Jul. 6, 2020); Trefis Team, *Gilead Stock Is Up 25% This Year, Time To Sell?*, FORBES (May 13, 2020), <https://www.forbes.com/sites/greatspeculations/2020/05/13/gilead-stock-is-up-25-this-year-time-to-sell/#67e69b6e7f4e> (accessed Jul. 6, 2020).

56 GILEAD SCIENCES, <https://www.gilead.com> (accessed Jul. 6, 2020); GILEAD SCIENCES, PIPELINE, <https://www.gilead.com/science-and-medicine/pipeline> (accessed Jul. 6, 2020).

57 See eg Margaret Visnji, *How Gilead Sciences Makes Money? Understanding Gilead Business Model*, REVENUES & PROFITS, Feb. 25, 2019, <https://revenuesandprofits.com/how-gilead-sciences-makes-money-understanding-gilead-business-model/> (accessed Jul. 6, 2020).

58 See eg Letter from Gregg Alton, Executive Vice President commercial and Access Operations ALA, Corporate and Medical Affairs, Gilead Sciences, Inc., Re: Betting on Hepatitis C: How financial Speculation in Drug Development Influences Access to Medicine, 354 BMJ i3718 (2016) ('we stand behind the pricing of our therapies because of the benefit they bring to patients and the significant value they represent to payers, providers and our entire healthcare system by reducing the long-term costs associated with managing chronic HCV.').

59 See eg Preston Pyth, *The Intrinsic Value of Gilead*, FORBES MAG., Jan. 1, 2018, <https://www.forbes.com/sites/prestonpyth/2018/01/01/the-intrinsic-value-of-gilead-science/#2faabbce4b6f> (accessed Jul. 6, 2020).

60 See eg John LaMattina, *Gilead's CEO Admits To 'Failures' In Setting Price of \$1,000-A-Pill Breakthrough*, FORBES (Dec. 8, 2016), <https://www.forbes.com/sites/johnlamattina/2016/12/08/gileads-ceo-apologize-tic-about-sovaldis-1000-per-pill-price-tag/#76411c531a97> (accessed Jul. 6, 2020).

tunities on life saving drugs,<sup>61</sup> it has behaved in a way that is consistent with that of other large pharmaceutical companies when faced with similar market opportunities.<sup>62</sup> As further described below, Gilead's actions can be understood as natural responses to existing market—particularly stock market—pressures, and similar patterns of aggressive pricing and anticompetitive product strategies that are prevalent among other large pharmaceutical companies that together dominate US pharmaceutical markets.<sup>63</sup> The way in which Gilead has approached the development and commercialization of remdesivir highlights some of the systemic flaws in the current pharmaceutical R&D ecosystem that make it unable to adapt effectively in response to potential and actual pandemics.

### The development of remdesivir before the COVID-19 pandemic

Remdesivir, originally known as compound GS-5734, emerged from a collaboration between Gilead, the Centers for Disease Control (CDC), and the United States Army Medical Research Institute of Infectious Disease (USAMRIID) to identify potential

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- 61 Over the last decade, Gilead has been the subject of ongoing criticism for its conduct with relation to some of its life-saving drugs, primarily Sovaldi. See eg Ed Silverman, *Lawsuit Alleges Price Gouging by Maker of Hepatitis Drug*, WALL ST. J., Dec. 18, 2014, <https://www.wsj.com/articles/lawsuit-alleges-price-gouging-by-maker-of-hepatitis-drug-1418961024> (accessed Jul. 6, 2020). But perhaps the most representative illustration of how ongoing business practices in non-pandemic scenarios sow the seeds for many of the problems observed during large-scale public health crises is provided by Gilead's role in the development and commercialization of HIV drugs. The drug Truvada for pre-exposure prophylaxis (PrEP) was the first HIV prophylactics to enter the US market. Nevertheless, even though Gilead made Truvada available for purchase in 2012, it chose not to promote it as an HIV prevention drug due to concerns with having its image associated with (a perceived) endorsement of unsafe sexual practices, even though HIV infection in the USA was back then and is still considered an epidemic. In 2016, however, as Truvada became popular among patient communities and was endorsed by the scientific community, Gilead decided to start promoting it for HIV prevention. At the same time, it increased the price of Truvada for PrEP exponentially. When Truvada first entered the market in 2004 (with no preventative indications) its price tag was approximately \$650 per month. The year the FDA approved Truvada for PrEP, Gilead raised the price to \$1159 a month. By 2019, the price had reached \$1750 a month, or \$21,100 a year. The latest available data show that Truvada for PrEP generated \$2.6 billion in 2019 in the USA alone. To this day, Truvada's price tag for PrEP is considered one of the primary causes for non-compliance among patients and individuals in high risk groups. For an expanded case study of Gilead's development and commercialization of Truvada, see generally Ana Santos Rutschman, *Reconfiguring the Relationship Between International Intellectual Property and Public Health*, 53 VAND. J. TRANSN'L L. \_\_\_\_ (forthcoming 2021). See also NBC News, *Switching Course, Gilead Markets HIV Drug for Prevention* (Nov. 30, 2016), <https://www.nbcnews.com/feature/nbc-out/switching-course-gilead-markets-hiv-drug-prevention-n690271> (accessed Jul. 6, 2020); Jason Rhode, *PrEP Drug Priced Out of Most People's Reach*, GEORGIA VOICE (Jul. 13, 2018), <https://thegavoice.com/news/national/prep-drug-priced-out-of-most-peoples-reach/> (accessed Jul. 6, 2020).
- 62 See eg Marcus Scholz and N. Craig Smith, *In the Face of a Pandemic, Can Pharma Shift Gears?*, MIT SLOAN MANAGEMENT REV., Apr. 16, 2020 at <https://sloanreview.mit.edu/article/in-the-face-of-a-pandemic-can-pharma-shift-gears/> ('The pricing behavior of pharma companies is not surprising, given how the industry operates and how individual players compete.')(accessed Jul. 6, 2020); Mike Leonard, *Sanofi, Novo Nordisk, Eli Lilly Must Face Insulin Price Suit*, BLOOMBERG LAW (Feb. 20, 2020), <https://news.bloomberglaw.com/mergers-and-antitrust/sanofi-novo-nordisk-eli-lilly-must-face-insulin-rico-claims> (accessed Jul. 6, 2020).
- 63 See eg Nicholas Florko and Damian Garde, *With Remdesivir, Gilead Finds Itself at Strategic Crossroads, with its Reputation (and Far More) at Stake*, May 5, 2020, [https://www.statnews.com/2020/05/05/remdesivir-gilead-strategic-crossroads-reputation-far-more-at-stake/?utm\\_source=STATNewsletters&utm\\_campaign=927e2ef446-Pharmalot&utm\\_medium=email&utm\\_term=0\\_8cab1d7961-927e2ef446-150798609](https://www.statnews.com/2020/05/05/remdesivir-gilead-strategic-crossroads-reputation-far-more-at-stake/?utm_source=STATNewsletters&utm_campaign=927e2ef446-Pharmalot&utm_medium=email&utm_term=0_8cab1d7961-927e2ef446-150798609) (accessed Jul. 6, 2020).

drug candidates for treating RNA-based viruses with pandemic potential, including members of the coronavirus family.<sup>64</sup> A precursor to remdesivir was identified by a group of Gilead chemists and CDC scientists involved in screening a library of potential antiviral compounds to identify those with the ability to fight off a variety of viruses, one of which was a coronavirus.<sup>65</sup> This precursor to GS-5734 was then refined and further developed by Gilead scientists working with the USAMRIID, which tested it against several pathogens, including the Ebola virus, using animal models in a government laboratory.<sup>66</sup> The results of this study led to a series of government-funded collaborations between Gilead and a group of academic medical centers to test the effectiveness of GS-5743 against two other coronaviruses that cause the dangerous Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS).<sup>67</sup>

Since the SARS outbreak in the early 2000s, it is estimated that the NIH has spent nearly \$700 million on R&D efforts targeting coronaviruses.<sup>68</sup> As part of these efforts, the research that led to the development of remdesivir was funded by a \$37.5 million NIH grant awarded to a public–private partnership between several academic laboratories in the USA and Gilead.<sup>69</sup> USAMRIID and the Defense Threat Reduction Agency, as well as the Medical Countermeasure Systems Joint Project Management Office in the United States Department of Defense, also contributed to research involving remdesivir.<sup>70</sup> Remdesivir’s mechanism of action was specifically studied in coronaviruses in academic laboratories in the USA, again with NIH funding.<sup>71</sup> From this body of largely government-funded research it became clear

64 See eg R. Eastmen et al., *Remdesivir: A Review of its Discovery and Development Leading to Emergency Use Authorization for Treatment of COVID-19*, ACS CENT. SCI. 2020, May 4, 2020 at <https://pubs.acs.org/doi/pdf/10.1021/acscentsci.0c00489> (discussing the discovery and development history of remdesivir) (accessed Jul. 6, 2020).

65 Gilead Sciences, Inc., Development of Remdesivir, [https://www.gilead.com/-/media/gilead-corporate/files/pdfs/covid-19/gilead\\_rdv-development-fact-sheet-2020.pdf](https://www.gilead.com/-/media/gilead-corporate/files/pdfs/covid-19/gilead_rdv-development-fact-sheet-2020.pdf) (accessed Jul. 6, 2020). See also Kathryn Ardizzone, *Role of the Federal Government in the Development of Remdesivir*, KEI BRIEFING, NOTE 2020.1, 1 at [https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020\\_1GS-5734-Remdesivir.pdf](https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020_1GS-5734-Remdesivir.pdf) (accessed Jul. 6, 2020); Andrew Joseph, *As the Coronavirus Spreads, a Drug that Once Raised the World’s Hopes is Given a Second Shot*, STAT, Mar. 16, 2020 at <https://www.statnews.com/2020/03/16/remdesivir-surges-ahead-against-coronavirus/> (accessed Jul. 6, 2020).

66 See Ardizzone *supra* note 65.

67 *Id.*, *ib.*

68 See Public Citizen, *The Real Story of Remdesivir*, <https://www.citizen.org/article/the-real-story-of-remdesivir/> (accessed Jul. 6, 2020); Christopher Rowland, *The Best Hope for Coronavirus Treatment is an Experimental Drug that Fizzled Against Ebola*, N.Y. TIMES, Mar. 11, 2020, [https://www.washingtonpost.com/business/economy/the-best-hope-for-coronavirus-treatment-is-an-experimental-drug-that-fizzled-against-ebola/2020/03/10/8a9e8cd4-5fe8-11ea-b29b-9db42f7803a7\\_story.html](https://www.washingtonpost.com/business/economy/the-best-hope-for-coronavirus-treatment-is-an-experimental-drug-that-fizzled-against-ebola/2020/03/10/8a9e8cd4-5fe8-11ea-b29b-9db42f7803a7_story.html) (accessed Jul. 6, 2020).

69 Savannah Koplon, *Investigational Compound Remdesivir, Developed by UAB And NIH Researchers, Being Used for Treatment of Novel Coronavirus*, UAB NEWS, Feb. 7, 2020, <https://www.uab.edu/news/health/item/11082-investigational-compound-remdesivir-developed-by-uab-and-nih-researchers-being-used-for-treatment-of-novel-coronavirus> (accessed Jul. 6, 2020).

70 See Ardizzone *supra* note 65. The involvement of the public sector in early stages of remdesivir R&D taps into broader debates about the privatization of government-supported research and its specific consequences for consumers/patients in the biopharmaceutical arena. For a general treatment of this problem, see Rebecca E. Wolitz, *The Pay-Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. LEG. MED. 177 (2019).

71 Maria L. Agostini et al. *Coronavirus Susceptibility to the Antiviral Remdesivir (GS-5734) is Mediated by the Viral Polymerase and the Proofreading Exoribonuclease*, 9 MBIO. E00221–18 (2018).

that remdesivir offered promise as a therapeutic agent for coronaviruses that might have the potential to cause pandemics.

Gilead's response to promising preclinical results was to seek patent protection for remdesivir and, once a potential market for the drug emerged, to pursue additional market protections. In 2008, Gilead filed the first provisional applications covering remdesivir and other structurally related compounds.<sup>72</sup> In 2014 Gilead filed the first of another set of patent applications covering remdesivir and other structurally related compounds as well as methods for using these compounds for the treatment of Ebola and other viruses.<sup>73</sup> By 2015, remdesivir was already identified as a potential therapeutic for Ebola and a broad spectrum of other viral infections, including SARS and MERS.<sup>74</sup> At that point, the amenability of remdesivir to large-scale manufacturing was apparent, making it even more attractive as a possible treatment for future coronavirus outbreaks.<sup>75</sup>

Although by 2018 remdesivir's potential against dangerous respiratory diseases was clear, and its mechanism of action against coronaviruses was well understood,<sup>76</sup> Gilead chose to focus its relatively limited R&D efforts for remdesivir only on Ebola and Marburg diseases. When remdesivir failed to show clinical benefit in humans as a treatment for Ebola, further development efforts were quickly abandoned, although Gilead continued to hold on to intellectual property rights covering the drug.<sup>77</sup>

There is no indication that Gilead consulted with any of its public partners and collaborators when deciding whether to cease R&D efforts for remdesivir. There is also no indication that Gilead's decision in August 2019 to abandon development efforts on remdesivir entirely was made with any consideration of the significant public investment that went into its development or with any consideration of the potential public health value of the drug as part of pandemic preparedness. Similarly, as we discuss in further detail below, the public investment in remdesivir has had no visible or

72 See US Provisional Patent Application Nos. 61/047,263, filed Apr. 23, 2008 and 61/139,449, filed Dec. 19, 2008. These two applications and their continuations resulted in a several patents that appear to claim remdesivir. See Claim 15 of US Patent No. 8,008,264; Claim 15 of US Patent No. 8,318,682; and Claim 21 of US Patent No. RE46,762 (which is a reissue of US Patent No. 8,318,682). Notably, these claims may be deficient due to improper dependency from Claim 1 of each of these patents, respectively. The '264 patent—apparently the patent with the longest in the portfolio—will expire on November 6, 2029.

73 See US Provisional Patent Application No. 62/072,331, filed Oct. 29, 2014, which led to the filing of non-provisional US Patent Application No. 14/926,062, filed Oct. 29, 2015, which issued as US Patent No. 9,724,360, on Aug. 8, 2017. The patent portfolio protecting remdesivir also includes the corresponding International Patent Application WO2016/069,825, filed Oct. 29, 2015; US Patent Nos. 9,949,994 and 10,251,898, issued Apr. 24, 2018 and Apr. 9, 2019, respectively, both entitled 'Methods for treating Filoviridae virus infections'; and US Patent Application No. 14/926,063, entitled 'Methods for the preparation of ribosides', for which a notice of allowance was issued on Mar. 18, 2020.

74 Travis K. Warren et al., *Therapeutic Efficacy of the Small Molecule GS-5734 Against Ebola Virus in Rhesus Monkeys*, 531 NATURE 381 (2016); Timothy P. Sheahan et al., *Broad-Spectrum Antiviral GS-5734 Inhibits both Epidemic and Zoonotic Coronaviruses*, 9 SCI. TRANS. MED. eaal3553 (2017).

75 *Id.*, *ib.*

76 See Agostini *supra* note 71.

77 See eg Sabue Mulangu et al., *A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics*, 301 N. ENGL. J. MED. 2293 (2019).

acknowledged role in Gilead's decision of how to price the drug once it was approved as therapy for SARS-CoV-2.<sup>78</sup>

Given Gilead's focus on the price that people might one day pay for remdesivir, and expected profits, adjusted for risk, the decision to pursue a narrow R&D path focused on the potential to address an outbreak of Ebola, which for a short time had threatened to impact the USA and other markets with commercial potential, was a rational one. So too was its decision to stop development when it became clear that remdesivir would not be an effective treatment for Ebola. While the public health benefits of further development of this compound were significant, even once it was determined that the drug would not be useful for the Ebola outbreak, these benefits did not translate into expectations of large product revenues or the potential for stock price appreciation. With SARS and MERS geographically limited and contained outside the USA,<sup>79</sup> there were not sufficient financial incentives (public or private) to pursue remdesivir as a potential generalized treatment of coronavirus infections.<sup>80</sup> While it remained possible that a new SARS- and MERS-like coronavirus might emerge as a global health threat, the expected commercial benefits of investing in further development remained too low to attract further effort by Gilead. In other words, Gilead's decision to only pursue remdesivir for treatment of Ebola and Marburg diseases, and to abandon development when it proved ineffective for Ebola, was a logical response to the market incentives that it faced prior to the outbreak of SARS-CoV-2.

By January 2020, when it became apparent that the global spread of SARS-CoV-2 was inevitable, it was already too late to put remdesivir through the testing that would have been necessary to know in advance whether it would provide an effective treatment for this particular coronavirus. It was also too late to have the capacity ready to manufacture large volumes of remdesivir in the event it did provide an effective treatment. As discussed above, price and profits do not adequately capture the value of pandemic preparedness. When R&D decisions are made based primarily on financial projections, drugs that might have significant value in a pandemic do not get adequately developed in advance, and excess capacity does not get built based on possibilities of future need.

In addition to showing the dangers of relying on expected price and expected profits to direct R&D flows, the early R&D of remdesivir also shows the limitations of the paradigm of innovation central to US healthcare markets, with public sector

78 As of the time of writing this article, in early May 2020, remdesivir is still undergoing clinical evaluation although there are some signs that it may have significant clinical benefits in the treatment of SARS-CoV-2 infections. See FDA, *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment*, FDA News Release (May 1, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment> (accessed Jul. 6, 2020).

79 The last case of SARS was in 2004 and MERS in 2014. See AM. LUNG ASS'N, *Severe Acute Respiratory Syndrome (SARS)*, <https://www.lung.org/lung-health-diseases/lung-disease-lookup/severe-acute-respiratory-syndrome-sars>; CTRS. DISEASE CONTROL & PREVENTION, *MERS in the United States*, <https://www.cdc.gov/coronavirus/mers/us.html> (accessed Jul. 6, 2020).

80 We note that this is a failure of government, *not* profit-driven entities (which are not currently designed to pursue unprofitable goals) inasmuch as it pertains to the lack of adequate financial support for the development of vaccines and drugs like remdesivir for potential health threats *before* the emergence of the diseases they are meant to prevent/treat.



support for R&D and private sector control of the resulting developments.<sup>81</sup> The story of remdesivir's development, and lack of development, reveals a socialization of costs and privatization of benefits in ways that do not lend themselves to adequate pandemic preparedness. The development path of remdesivir was a circuitous one, involving collaborations with academic medical centers and support from government labs pushed along by a combination of federal funding and investment by Gilead, but with a limited scope and a truncated development that failed to reflect its pandemic potential.<sup>82</sup> While development efforts were fueled by federal funding and research support, the R&D path and its eventual termination was controlled by Gilead. The continued control that Gilead exerted over remdesivir through its intellectual property rights even when R&D efforts were abandoned further limited opportunities for others to explore the pandemic potential of the drug.

Finally, Gilead's exclusive intellectual property rights over remdesivir<sup>83</sup> allowed Gilead to control the evolution of the remdesivir R&D efforts. While the market value of these exclusivities might have seemed limited in the pre-pandemic world, Gilead nevertheless retained exclusive control over the potential drug even after abandoning R&D efforts. With these market exclusivities in place, none of Gilead's public partners and collaborators would reasonably consider further R&D efforts to explore the pandemic potential of the drug without Gilead's express permission and involvement.

### Remdesivir and Gilead's response to COVID-19

Subsequent to the emergence of COVID-19 and identification of SARS-CoV-2 as its cause, remdesivir was evaluated by the Centers for Disease Control alongside several other potential antiviral agents and 'rediscovered' as a lead compound against this novel coronavirus.<sup>84</sup> In January 2020, a WHO panel pronounced remdesivir as the most promising therapeutic candidate against the new virus.<sup>85</sup> Remdesivir was subsequently

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81 See The Real Story of Remdesivir *supra* note 68 (estimating public support of remdesivir R&D at over \$70 M); USAMRIID Press Release, Antiviral Compound Provides Full Protection from Ebola Virus in Nonhuman Primates, Oct. 9, 2015, [https://web.archive.org/web/20161224000431/http://www.usamriid.army.mil/press\\_releases/Travis%20ID%20Week%20FINAL.pdf](https://web.archive.org/web/20161224000431/http://www.usamriid.army.mil/press_releases/Travis%20ID%20Week%20FINAL.pdf) (accessed Jul. 6, 2020). See also Development of Remdesivir *supra* note 65.

82 See also Andrew Joseph, *As the Coronavirus Spreads, a Drug that Once Raised the World's Hopes is Given a Second Shot*, STAT, Mar. 16, 2020 at <https://www.statnews.com/2020/03/16/remdesivir-surges-ahead-against-coronavirus/> ('Born as a general antiviral candidate, researchers threw it at an array of viruses and saw where it stuck. It bounced along from Gilead's labs to academic centers, nudged by both federal taxpayer dollars and support from the company. It kept turning up whiffs of potential in cells and animals infected by other coronaviruses like SARS and MERS, but these bugs were not causing sustained global crises.') (accessed Jul. 6, 2020).

83 See *supra* notes 72–73.

84 See eg United States NAT'L INST. HEALTH, *NIH Clinical Trial of Remdesivir To Treat COVID-19 Begins*, Feb. 25, 2020, <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-remdesivir-treat-covid-19-begins> (accessed Jul. 6, 2020).

85 WORLD HEALTH ORG., *WHO R&D Blueprint Novel Coronavirus: Outline of Trial Designs for Experimental Therapeutics* (2020), <https://apps.who.int/iris/bitstream/handle/10665/330694/WHO-HEO-RDBlueprintnCoV-2020.4-eng.pdf?ua=1> (accessed Jul. 6, 2020).

administered to the first patient to have been diagnosed in the USA and was at that time held to be the best hope in the fight against COVID-19.<sup>86</sup>

While the value of pandemic preparedness is not adequately captured by market price, or even expected future price, once a pandemic strikes the market value of any potential therapeutic takes a radical jump upwards, as does the stock price of the company that owns it. In contrast to the value of pandemic preparedness, which does not translate into expectations of future revenue or stock market value, even the faintest promise of being able to provide a treatment in the wake of the outbreak results in a large stock price increase as investors anticipate future profit opportunities. This fuels the efforts of pharmaceutical companies to accelerate R&D of sometimes long abandoned potential drug candidates. Gilead's rediscovery of remdesivir, and the associated hike in Gilead's stock price, has been no exception.<sup>87</sup> The potential future revenue opportunities of remdesivir, translated immediately into higher stock prices, have propelled Gilead into accelerated clinical testing of its once abandoned therapeutic. The potential promise of remdesivir, which has been undergoing extensive testing since February 2020 in six separate clinical trials around the world,<sup>88</sup> has translated into a rise in Gilead's stock price from \$63 in November 2019 to near \$80 in early April 2020, a 26 per cent increase.<sup>89</sup> This stock price hike has occurred even as the US and global stock markets and world economy are plummeting.<sup>90</sup> In response to early questions about what the future price of remdesivir might be, Gilead was non-comittal, recognizing the need to navigate conflicting pressures from its investors to take actions, such as pricing, which continue to fuel stock price growth, and pressures from public and government pressures to keep the prices affordable.

The federal government response to remdesivir has been consistent with its policy approach toward biomedical innovation more generally—relying on a strategy of subsidizing and rewarding private sector innovation as the best way to meet the emergency need for an effective treatment for COVID-19. Despite the significant public funding that went into the development of remdesivir, the federal government has been reluctant to intervene in Gilead's decision-making regarding the development, manufacture, and future pricing of the drug. In the face of public pressure from a variety of public interest groups to make production and pricing decisions that ensure open access and accessibility, the Pharmaceutical Research and Manufacturers of America (PhRMA) organization, the pharmaceutical industry's trade association and lobbying powerhouse—of which Gilead is a member—along with Gilead, have found powerful allies from *within* the public sector in their efforts to shake off attempts to interfere

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86 South China Morning Post, *US Coronavirus Patient Who Was 'World's First' Treated with Experimental Gilead Drug 'Remdesivir' and Recovered*, Feb. 17, 2020, <https://www.scmp.com/news/world/united-states-canada/article/3050949/us-coronavirus-patient-who-was-worlds-first-treated> (accessed Jul. 6, 2020).

87 See Florko & Garde *supra* note 63. After any initial increase, however, the stock price, and the investor expectations that drive it, will be sensitive to new information about the potential effectiveness of the drug as it becomes public.

88 See Katie Thomas, *Coronavirus Patients in Limbo as Gilead Suspends Emergency Drug Access*, N.Y. TIMES, Apr. 9, 2020, <https://www.nytimes.com/2020/03/23/health/coronavirus-drugs-remdesivir.html> (accessed Jul. 6, 2020).

89 Information from Google.com 'NASDAQ: GILD'.

90 See eg Mike Bird, *Stock Markets After the Coronavirus*, WALL ST. J., Mar. 16, 2020, <https://www.wsj.com/articles/stock-markets-after-the-coronavirus-11584352919> (accessed Jul. 6, 2020).

with corporate control over drug development and pricing.<sup>91</sup> When asked whether the administration intended to guarantee that treatments or vaccines for SARS-CoV-2 would be affordable, the Secretary of Health and Human Services, Alex Azar, refused to provide such guarantee, citing concerns that imposing pricing restrictions would dampen investment in developing such treatments in the first place.<sup>92</sup> Similarly, ‘Operation Warp Speed’ references the possibility of some corporate donations of resulting drugs, but does not mention any public control over manufacturing or pricing decisions.

To be sure, this seeming identity of interests and rhetoric between the industry and policymaker and regulators is nothing new and reflects ideological acquiescence to market mechanisms as much as it shows the level of regulatory capture of such policymakers and regulators by the industry. Notably, the reluctance to exercise government control in the COVID-19 crisis is consistent with the federal government approach in prior public health emergencies. During the 2015–16 Zika outbreak, for example, the government ignored requests that Zika vaccines resulting from outbreak-induced R&D be priced affordably.<sup>93</sup> Once again, the socialization of costs but privatization of benefits leaves the private sector—in this case Gilead—in control of the manufacture and pricing of a therapy largely developed through government funding and support, even in the midst of a pandemic, raising concerns about future pricing and access to the drug.

Finally, while in the context of pandemic preparedness the role, and market value, of exclusive controls over a potential pandemic drug may be limited, the value and importance of exclusive rights escalate in the midst of a pandemic. Although Gilead’s use of intellectual property and market exclusivities to control the research and manufacturing of remdesivir likely limited the scope of and participation in early research on the drug, the potential public health costs of these exclusivities become more salient in contexts of pandemic response.

At the start of the outbreak, with no prior incentives to invest in a remdesivir stockpile, manufacturing capacity, or a distribution network, an immediate shortage of the drug was inevitable as SARS-CoV-2 quickly spread throughout the USA and globally. Since Gilead controls both the manufacture and the sale of remdesivir through its intellectual property rights, it controls the ability of other companies to respond to the shortage. After providing remdesivir to several hundred patients on a case-by-case basis for ‘compassionate use’, in March 2020 Gilead announced that it was shutting

91 This is not to say that alliances between the pharmaceutical industry and regulators and policymakers are anything new. Indeed, the pharmaceutical industry is (in) famous for its unmatched expenditures on lobbying and campaign contributions and the significant power it wields over the very same individuals and agencies who would regulate it. See eg Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?*, 102 MINN. L. REV. 2273, 2301 (2018) (discussing the power wielded by the pharmaceutical industry and that it spent \$283 million on lobbying in 2018, which was far more than any other lobbying group and almost twice as much as the insurance industry lobbying group, which came in second).

92 *Secretary Azar Came Before the Energy and Commerce Committee*, YOUTUBE (Feb. 28, 2020), <https://www.youtube.com/watch?v=qcrPsuENZk0> (accessed Jul. 6, 2020).

93 See eg Bernie Sanders, *Bernie Sanders: Trump Should Avoid a Bad Zika Deal*, N.Y. TIMES, Mar. 10, 2017, [https://www.nytimes.com/2017/03/10/opinion/bernie-sanders-trump-should-avoid-a-bad-zika-deal.html?smid=tw-nytopinion&\\_r=0](https://www.nytimes.com/2017/03/10/opinion/bernie-sanders-trump-should-avoid-a-bad-zika-deal.html?smid=tw-nytopinion&_r=0). See also Rutschman, *Vaccine Licensure in the Public Interest*, *supra* note 12 (accessed Jul. 6, 2020).

down its emergency access program for the drug.<sup>94</sup> In a separate statement by Gilead's CEO in early April, the company said it had about 1.5 million doses of remdesivir, enough for only 140,000 treatments.<sup>95</sup> The CEO touted Gilead's efforts to 'rapidly expand production and increase supply' and announced that 'we have set an ambitious goal of producing more than 500,000 treatment courses by October and more than 1 million treatment courses by the end of 2020.'<sup>96</sup> Should the drug receive approval as a treatment for SARS-CoV-2, 1 million treatment courses by the end of 2020 would not even begin to satisfy the public health needs of the USA, let alone the world.

Gilead's efforts to maintain control over access to remdesivir took an even more explicit form in its pursuit, once the outbreak began, of orphan drug exclusivity on the drug. Gilead's original patent applications on remdesivir, other related compounds, and methods of using these compounds were filed as early as April 2008 and at least some of the resulting patents are expected to remain in force through 2035.<sup>97</sup> In early March 2020—taking advantage of the fact that at that point there were still fewer than 200,000 confirmed cases of COVID-19 in the USA—Gilead also filed a request with the FDA to have remdesivir approved as an 'orphan drug' for treatment of SARS-CoV-2.<sup>98</sup> In so doing, the company sought to augment its control over the remdesivir market by supplementing its patents with a litigation-proof orphan drug exclusivity lasting through 2027<sup>99</sup> as well as to secure significant tax benefits that come with an orphan drug designation.<sup>100</sup> On March 23, 2020, the FDA approved Gilead's request to designate remdesivir as an orphan drug.<sup>101</sup> Gilead's original request for orphan drug designation made sense from a financial perspective and is in line with Gilead's (and virtually all other pharmaceutical companies') business model, but lay in direct conflict with the public health need for widespread and affordable access to pharmaceutical products during a pandemic. The public announcement of this approval resulted in a

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94 See Thomas *supra* note 88. Gilead announced it would continue providing remdesivir to pregnant women and children under 18, and that it was 'transitioning from individual compassionate use requests to expanded access programs'. See Gilead, Gilead Sciences Statement on Access to Remdesivir Outside of Clinical Trials, <https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-access-to-remdesivir-outside-of-clinical-trials> (accessed Apr. 13, 2020).

95 Daniel O'Day, *An Update on COVID-19 from our Chairman & CEO*, Apr. 4, 2020, GILEAD, <https://www.gilead.com/stories/articles/an-update-on-covid-19-from-our-chairman-and-ceo>, permanent link available at <https://perma.cc/4RVW-KAAZ> (accessed Jul. 6, 2020).

96 *Id.*, *ib.*

97 See *supra* notes 72–73 and accompanying text.

98 Gilead Sciences Statement on Request to Rescind Remdesivir Orphan Drug Designation, <https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-request-to-rescind-remdesivir-orphan-drug-designation> (accessed Jul. 6, 2020).

99 An exception to Gilead's ability to be the sole manufacturer of remdesivir for the treatment of SARS-CoV-2 would be the company's inability to meet demand for the drug. See 42 U.S.C. §§ 360bb–360 cc. This exception may provide additional, albeit less complementary explanation to Gilead's willingness to relinquish its orphan drug exclusivity in remdesivir.

100 26 U.S.C. § 45C; 42 U.S.C. § 360ee.

101 SMART BRIEF, *FDA Grants Orphan Drug Status to Remdesivir for COVID-19*, (Mar. 25, 2020), <https://www.smartbrief.com/branded/42D8AFC1-5EA8-43A4-9F22-B9F6A962F94B/CFCE51CA-B09B-444D-8B0B-C156DEFB54C2>. Ironically, the FDA grant of Gilead's request for orphan drug status for remdesivir was issued on one day after Gilead announced that it was discontinuing distributing remdesivir for compassionate use. See Gilead Sciences Statement *supra* note 94 and accompanying text.

public outcry, which no doubt influenced Gilead's unprecedented request that the FDA rescind remdesivir's orphan drug designation.<sup>102</sup>

At the time of writing of this essay, although remdesivir has already received emergency authorization to serve as treatment for coronavirus patients,<sup>103</sup> the drug is still undergoing evaluation in clinical trials and has yet to receive final FDA approval for marketing in the USA. PhRMA, on behalf of Gilead and other pharmaceutical companies, has opposed proposals to include provisions addressing pricing issues in a \$8.3 billion coronavirus spending bill<sup>104</sup> and its lobbyists successfully blocked a proposal that would have threatened intellectual property rights for drugs priced unfairly.<sup>105</sup> In addition to eliminating provisions dealing with intellectual property issues, PhRMA further succeeded in introducing language preventing the government from intervening even if there are concerns about the affordability of drugs under development.<sup>106</sup> Public interest advocates argue that since the R&D on remdesivir was supported in significant ways by public actors and funds, and taking reasonable estimates of the costs of manufacturing the drug into account, remdesivir could be priced at relatively low prices, ranging \$1–29 per course of treatment, while still being profitable.<sup>107</sup> They also argue that the U.S. government co-invested in and co-owns patents on the drug, giving it still more reason, and ability, to intervene in pricing and manufacturing decisions for the drug.<sup>108</sup> Yet, Gilead has thus far resisted attempts to commit to pricing the drug affordably for indicated populations.<sup>109</sup> In late June 2020, the company announced that a five-day course (the shortest course) of treatment would

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- 102 See eg Manas Mishra & Michael Erman, *Gilead Asks FDA to Take Back Lucrative Orphan Drug Status on Possible Coronavirus Treatment*, REUTERS, Mar. 25, 2020, <https://www.reuters.com/article/us-health-coronavirus-gilead-sciences/gilead-asks-fda-to-take-back-lucrative-orphan-drug-status-on-possible-coronavirus-treatment-idUSKBN21C3MG> (accessed Jul. 6, 2020); See Mike Masnick, *Why Is The FDA Giving A Potential COVID-19 Treatment 'Orphan' Status?*, TECHDIRT, Mar. 24, 2020, <https://www.techdirt.com/articles/20200323/17334844155/why-is-fda-giving-potential-covid-19-treatment-orphan-status.shtml> (accessed Jul. 6, 2020).
- 103 See Letter from Denise M. Hinton, Chief Scientist, FDA, to Ashley Rhoades, Senior Associate, Regulatory Affairs, Gilead Sciences, Inc. dated May 1, 2020, Perma Link available at: <https://perma.cc/2D57-YL5N> (accessed Jul. 6, 2020).
- 104 See eg Sarah Kaplan-Smith, *How the Drug Industry Got Its Way on the Coronavirus*, POLITICO, March 5, 2020, <https://www.politico.com/news/2020/03/05/coronavirus-drug-industry-prices-122412> (accessed Jul. 6, 2020).
- 105 *Id.*, *ib.*
- 106 *Id.*, *ib.*
- 107 Andrew Hill et al., *Minimum Costs to Manufacture New Treatments for COVID-19*, J. VIRUS ERADICATION, Apr. 9, 2020, [http://viruseradication.com/journal-details/Minimum\\_costs\\_to\\_manufacture\\_new\\_treatments\\_for\\_COVID-19/](http://viruseradication.com/journal-details/Minimum_costs_to_manufacture_new_treatments_for_COVID-19/) (accessed Jul. 6, 2020).
- 108 See eg Christopher Rowland, *Taxpayers paid to develop remdesivir but will have no say when Gilead sets the price*, Washington Post, May 26, 2020; J. Krellenstein and C. Morten, *The U.S. Government's Apparent Co-Ownership of Patents Protecting Remdesivir*, PREP4All & NYU Tech Law & Policy Clinic Report, May 20, 2020 at <https://static1.squarespace.com/static/5e937afb7a75746167b39c/t/5ecd886c5699191ae9bad9ea/1590528109403/The+U.S.+Government%27s+Apparent+Co-Ownership+of+Patents+Protecting+Remdesivir+-+P4A+%26+NYU.pdf> (accessed Jul. 6, 2020).
- 109 See Mariana Mazzucato & Azzi Momenghalibaf, *Drug Companies Will Make a Killing From Coronavirus*, N.Y. TIMES, Mar. 18, 2020, <https://www.nytimes.com/2020/03/18/opinion/coronavirus-vaccine-cost.html> (accessed Jul. 6, 2020); Florko and Garde *supra* note 63 (addressing the pricing discussion, its potential implications for the ongoing debates regarding pharmaceutical pricing, and Gilead's awareness that its decision in that regard might have far-reaching consequences not only for itself but for the entire pharmaceutical industry).

cost \$3120 to Medicaid, Medicare, and private insurers in the USA, and \$2340 to the Department of Veterans Affairs and the Indian Health Service, a division within the Department of Health and Human Services.<sup>110</sup> Gilead also announced that remdesivir would be commercialized at a 25 per cent discounted price in developed market outside the USA, and at an unspecified, 'substantially lower' price throughout the developing world.<sup>111</sup> The US Department of Health and Human Services announced that it has already purchased 500,000 courses of the drug for use in US hospitals, representing all of the doses that Gilead expects to produce in July and almost all of the doses it expects to produce in August and September.<sup>112</sup> In addition to its pricing decisions, Gilead has come under public scrutiny for entering into confidential licensing agreements that would prevent generic versions of the drug from being distributed in countries that account for nearly half of the world's population.<sup>113</sup>

As described above, Gilead's conduct in the early R&D of remdesivir—perfectly logical from a financial standpoint and in line with corporate norms—illustrates how profit-driven responses have delayed remdesivir R&D until it was too late to meet public health needs. Gilead's subsequent actions to control the development, manufacturing and pricing decisions of remdesivir in the wake of the outbreak, illustrate how profit-driven responses to pandemics may lead to siloed R&D, the potential for significant (and tragic) shortages, and/or potentially unaffordable pricing of pandemic drugs.

## CONCLUSION

The divergence of private incentives from public health needs has contributed to profound failures in preparedness and response to the COVID-19 pandemic.<sup>114</sup> The consequences of relying on profit-driven entities for pandemic preparedness and response are playing out in real time, as companies that are inadequately prepared search their existing portfolios for any candidates that may be used in the treatment of COVID-19 with an eye on stock price, government emergency funds, and the lure of lucrative pricing for any resulting treatments. US federal government policy, which has for many decades focused largely on encouraging the private sector to meet public health needs, is—not surprisingly—now focused on providing additional incentives to bring potential treatments, tests, and much needed equipment to the market as rapidly as possible, with few strings attached. Commentators have suggested a variety of different ways of supporting such efforts during the current pandemic including proposals for

110 See Matthew Herper, *Gilead Announces Long-Awaited Price for Covid-19 Drug Remdesivir*, STAT (Jun. 29, 2020), <https://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19/> (accessed Jul. 6, 2020).

111 See Hannah Denham et al., *Gilead Sets Price of Coronavirus Drug Remdesivir at \$3,120 as Trump Administration Secures Supply for 500,000 Patients*, WASH. POST, Jun. 29, 2020, <https://www.washingtonpost.com/business/2020/06/29/gilead-sciences-remdesivir-cost-coronavirus/> (accessed Jul. 6, 2020); see also Mathew Herper, *Gilead announces long awaited price for Covid-19 drug remdesivir*, STAT, June 29, 2020.

112 See eg Mathew Herper, *Gilead announces long awaited price for Covid-19 drug remdesivir*, STAT, Jun. 29, 2020.

113 See eg V. Krishnah, *How Secret Deals Could Keep A Covid-19 Drug Out of Reach For Millions*, L.A. TIMES, Jul. 2, 2020.

114 There are hundreds of known types of coronavirus present in wild and domesticated animals, which have been known to have the ability to make the transition to humans, as was the case with SARS and MERS. See National Institute of Allergy and Infectious Diseases, *Coronaviruses*, <https://www.niaid.nih.gov/diseases-conditions/coronaviruses> (accessed Jul. 6, 2020).

rewarding vaccine and drug discovery in new ways, utilizing the Defense Production Act, compulsory licensing, and more.<sup>115</sup> All of these proposals are, ultimately, aimed at addressing the divergence of private incentives from public health needs on an emergency basis. Most rely simply on increasing private incentives to meet the current emergency need for vaccines and therapies. We suggest that these approaches share a failure to acknowledge and confront the structural problem with relying on the profit-driven model in general, and the way it is driving pharmaceutical innovation in particular, to satisfy public health needs, particularly in a pandemic.

While we agree that private-sector innovation is essential, and that pharmaceutical companies play an indispensable role in bringing treatments to market, this essay highlights the public health costs of relying on our current exclusively profit-driven markets for pandemic preparation and response.

At this moment, we find ourselves in the midst of frantic emergency efforts to patch up the effects of the many decades in which private incentives were allowed to diverge from public health interests. Rather than doing more of the same, public health will be best served, particularly in a pandemic-prone world, by changing incentive structures in healthcare markets to bring private incentives more closely in line with the health outcomes that are critically needed.<sup>116</sup>

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115 See eg James M. Cooper & Bashar Malkawi, *We Need to Relax Intellectual Property Rules to Fight This Virus*, THE HILL, Apr. 4, 2020, <https://thehill.com/opinion/judiciary/490742-we-need-to-relax-intellectual-property-rules-to-fight-this-virus> (accessed Jul. 6, 2020); Daniel Hemel and Lisa Larrimore Ouellette, *Want a Coronavirus Vaccine, Fast? Here's a Solution*, TIME, Mar. 4, 2020.

116 In-depth discussion of possible ways of more closely aligning private incentives and public health needs exceeds the scope of this essay. For further discussion of possible solutions, see generally *Why Healthcare Companies Should Be (come)Benefit Corporations* *supra* note 2.