

# Pharmaceutical Pricing When Success Has Many Parents

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*Pharmaceutical companies claim that high prices for drugs are needed to offset the costs and risks associated with research and development. In most instances, though, the initial (basic) research that leads to new discoveries is conducted at public institutions and paid for with public funds. Drugmakers tend to take over the process of bringing new drugs to market when the prospects for gaining regulatory approval seem good.*

*Because the public helps cover the cost of research, many people believe that it pays twice for drugs—once when tax dollars support research and a second time when patients buy drugs for personal use. This Article takes a hard look at this “paying-twice” critique. We present case studies of two expensive drugs, Sovaldi and PrEP, that were developed with a combination of public and private support. We then survey the broader literature that attempts to quantify and assess the relative importance of both contributions. We then discuss the general problem of evaluating the importance of multiple contributions to productive activities in the absence of market-based allocations of the resulting revenue streams. Finally, we discuss the possibility of protecting consumers from high drug prices and deadweight losses by using prizes instead of patents to incentivize drug development. A prize regime would take the sting out of the paying-twice critique as well.*

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## Introduction

Count Caleazzo Ciano, the Italian diplomat and son-in-law of Mussolini, was the first to observe that “success has a hundred fathers.”<sup>1</sup> Anyone who has worked hard on a team project and then seen others claim undeserved credit will understand what Count Ciano meant.

When pharmaceutical companies bring new drugs to market, they invariably take credit for the discoveries and routinely charge thousands, tens of thousands, hundreds of thousands, or even millions of dollars for them. But in most instances, pharmaceutical companies are not solely responsible for the research and development that results in new drugs. The initial (basic) research is typically conducted at public institutions and paid for with public funds from the National Institutes of Health (NIH) or other public sources. For example, two new cancer drugs, Kymriah and Yescarta, were introduced in 2018. Kymriah cost \$475,000 and Yescarta cost \$373,000. Both drugs “grew out of research conducted and supported” by the NIH.<sup>2</sup> Were Novartis and Kite Pharma, the companies that make them, claiming more credit than they were due?

Many people seem to believe that pharmaceutical companies are overclaiming. In a representative op-ed from 2002 bearing the headline *Paying Twice for the Same Drugs*, two professors noted that “the American public pumps more than \$20 billion a year in taxpayers funds into health-related research and development, making it the single largest investor in the pharmaceutical industry.”<sup>3</sup> After observing that “[w]e’ve already paid for the

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1. “Success Has Many Parents,” PHRASE FINDER, [https://www.phrases.org.uk/bulletin\\_board/59/messages/906.html](https://www.phrases.org.uk/bulletin_board/59/messages/906.html). [<https://perma.cc/YMC9-NG4B>] A more accurate and more complete version of Count Ciano’s aphorism is: “victory finds a hundred fathers but defeat is an orphan.” At a 1961 press conference held in the wake of the Bay of Pigs fiasco, President John F. Kennedy ruefully recast Count Ciano’s quip, noting “there’s an old saying that victory has a hundred fathers and defeat is an orphan.” WILLIAM SAFIRE, SAFIRE’S POLITICAL DICTIONARY 777-79 (2008); see also *Origin of ‘No Jack Kennedy’ Comment Disputed*, NAT’L PUB. RADIO (June 6, 2007), <https://www.npr.org/templates/story/story.php?storyId=10785989>. [<https://perma.cc/HV7T-PMP3>] Over time, various commentators have re-framed “victory” into “success” and “father” into “parents.”

2. Robert Pear, *‘Paying Twice’: A Push for Affordable Prices for Taxpayer-Funded Drugs*, N.Y. TIMES (May 28, 2018), <https://www.nytimes.com/2018/05/28/us/politics/drug-prices.html>. [<https://perma.cc/XXS6-8GS3>]

3. Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, WASH. POST (Mar. 27, 2002), <https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931> [<https://perma.cc/Q6DZ-BSAA>] (arguing that the federal government should use its powers under the Bayh-Dole Act to make drugs more affordable); see also Peter S. Arno & Michael H. Davis, *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631 (2001) (same).

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cost of research,” the authors ask “[w]hy [a]ren’t we seeing lower drug prices?”<sup>4</sup> Many patient advocates similarly contend that the public “pays twice” for drugs—first when tax dollars pay for research and second when patients buy the drugs for personal use.<sup>5</sup>

Are drug companies taking more credit than they deserve? How involved is the government in developing new drugs, and in what ways? How often are patients actually paying twice for their pharmaceuticals, and what does paying twice actually mean? Is paying twice a problem, and if it is, what should we do about it? To answer these questions, one must work through complicated factual, legal, and philosophical puzzles. In this Article, we lay out some basic facts and highlight these difficulties.

In Part I, we document the prevalence of the “paying-twice” critique in the debate over pharmaceutical pricing. Part II presents case studies of two drug regimens (Sovaldi and PrEP), which help illustrate the diverse ways in which the government is involved in pharmaceutical R&D. Part II also reviews the empirical evidence on the role of government funding in the development of new drugs and medical devices. Part III provides a theoretical framework for analyzing the dynamics when two or more parties contribute to the creation of a valuable asset and discusses the possibility of using prizes instead of patents to incentivize drug development—thereby protecting consumers from high drug prices and deadweight losses. Finally, we offer a brief conclusion.

### I. The Paying-Twice Critique

In the pharmaceutical context, the paying-twice critique surfaced during debates over the Bayh-Dole Act. Bayh-Dole was enacted in response to the perception that government-funded research was being commercialized too slowly—if at all.<sup>6</sup> Bayh-Dole authorized nonprofit institutions (including colleges and universities) to retain ownership of inventions that resulted from government-funded research. The government retained a nonexclusive license for its own use and “march-in” rights under four specified circumstances.<sup>7</sup> One of the four specified circumstances involves the failure to take “effective steps to achieve practical application of the subject invention”<sup>8</sup>—with practical application defined, in part, as requiring that the “benefits are, to the extent

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4. *Id.*

5. See *infra* Section I.A. For a detailed discussion of the complexities of the paying-twice critique, see Rebecca E. Woltz, *The Pay-Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. LEGAL MED. 177 (2019).

6. WENDY H. SCHACHT, CONG. RESEARCH SERV., RL32076, THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 2 (2012).

7. JOHN R. THOMAS, CONG. RESEARCH SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT (2016).

8. 35 U.S.C. § 203(a) (2018).

permitted by law or Government regulations, available to the public on reasonable terms.”<sup>9</sup>

Bayh-Dole effectively privatized the rewards of research done by universities at public expense. That strategy was controversial from the Act’s development. Senator Russell Long expressed concerns on the Senate floor:

There is . . . absolutely no reason why the taxpayer should be forced to subsidize a private monopoly and have to pay twice: First for the research and development and then through monopoly prices . . . This proposed legislation is one of the more radical, far-reaching giveaways that I have seen in many years.<sup>10</sup>

Subsequent evaluation of Bayh-Dole has highlighted this criticism.<sup>11</sup> Other analysts have focused on the substantial increase in technology transfer by colleges and universities following the enactment of Bayh-Dole and have proclaimed the legislation a success on that basis.<sup>12</sup>

In fairness, the paying-twice critique prompted the government to require “reasonable” pricing of products that relied on a subset of government-funded basic research from 1989 through 1995. More specifically, for products that resulted from Cooperative Research and Development Agreements between NIH and private parties, this policy required “a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.”<sup>13</sup> Six years later, the government abandoned the policy,<sup>14</sup> despite the now-familiar criticism from Senator Ron Wyden that taxpayers would be “forced to pay twice for their medicines—through their taxes and again at the pharmacy.”<sup>15</sup>

9. 37 C.F.R. § 401.2(e) (2019); *see also* Steven Ezell, *THE BAYH-DOLE ACT’S VITAL IMPORTANCE TO THE U.S. LIFE-SCIENCES INNOVATION SYSTEM*, INFO., TECH. & INNOVATION FOUND. 30 (Mar. 2019), <https://itif.org/sites/default/files/2019-bayh-dole-act.pdf> [<https://perma.cc/R2ZM-BRAX>] (explaining that the NIH has never exercised its march-in rights, nor has any other federal agency).

10. 126 CONG. REC. 8738-39 (1980) (statement of Sen. Long).

11. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1666 (1996) (“[B]y allowing private firms to hold exclusive rights to inventions that have been generated at public expense, it [Bayh-Dole] seems to require the public to pay twice for the same invention—once through taxes to support the research that yielded the invention, and then again through higher monopoly prices and restricted supply when the invention reaches the market.”); Daniel J. Hemel & Lisa Larrimore Ouellette, *Bayh-Dole Beyond Borders*, 4 J.L. BIOSCIENCES 1 (2017); Wolitz, *supra* note 5.

12. SCHACHT, *supra* note 6, at 8.

13. *See* Wolitz, *supra* note 5, at 193-98.

14. Warren E. Leary, *U.S. Gives Up Right to Control Drug Prices*, N.Y. TIMES (Apr. 12, 1995), <https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html?mcubz=1> [<https://perma.cc/BK9C-VNPP>]; *see also* NAT’L INSTS. OF HEALTH, NIH RESPONSE TO THE CONFERENCE REPORT REQUEST FOR A PLAN TO ENSURE TAXPAYERS’ INTERESTS ARE PROTECTED 10 (2001), <https://www.ott.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf> (“Shortly after the policy of ‘reasonable pricing’ was introduced, industry objected to it, considering it a form of price control. Many companies withdrew from any further interaction with NIH because of this stipulation. Both NIH and its industry counterparts came to the realization that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act.”).

15. *Id.*

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The paying-twice critique has become quite common of late, appearing in statements by politicians,<sup>16</sup> the executive director of Doctors Without Borders,<sup>17</sup> opinion journalists, historians,<sup>18</sup> and progressive economists.<sup>19</sup> The policy implications of this critique are straightforward: we should stop paying twice. But how should we go about accomplishing that goal?

Professors Peter Arno and Michael Davis argue that the solution “does not involve new legislation but already exists in the unused, unenforced march-in provision of the Bayh-Dole Act.”<sup>20</sup> Senators Bayh and Dole have disputed the suggestion that the legislation bearing their names authorizes the imposition of pricing constraints on pharmaceuticals merely because drugs are expensive.<sup>21</sup> Although the Department of Health and Human Services (HHS) and NIH have had several opportunities to revisit the issue, to date they have sided with Senators Bayh and Dole,<sup>22</sup> despite pressure from multiple members of Congress.<sup>23</sup>

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16. Wolitz, *supra* note 5, at 178 n.1 (referencing a tweet from Rep. Ocasio-Cortez complaining that “tax dollars are helping big pharma companies get rich.”); Bernie Sanders, Opinion, *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> [<https://perma.cc/Y9KQ-NXNT>] (“Under this insane system, Americans pay twice. First we pay to create these lifesaving drugs, then we pay high prices to buy those drugs.”).

17. Jason Cone, *Pharmaceutical Corporations Need to Stop Free-Riding on Publicly-Funded Research*, HILL (Mar. 3, 2018), <https://thehill.com/opinion/healthcare/376574-pharmaceutical-corporations-need-to-stop-free-riding-on-publicly-funded> [<https://perma.cc/H5WM-9MLS>]

18. Steven Conn, *You're Paying Twice for Your High-Priced Drugs*, DAYTON DAILY NEWS (Mar. 21, 2019), <https://www.daytondailynews.com/news/opinion/commentary-you-paying-twice-for-your-high-priced-drugs/4DWHU5PKRCuZMXRqIgPn2O> [<https://perma.cc/PVC2-NUUH>] (“[T]he very technology that makes Humalog possible, and every other product manufactured through genetic engineering, was paid for by you, and not just if you were paying taxes back in 1973. The same could be said of almost every drug for which Big Pharma is gouging patients. The basic research, plus the FDA trials and approvals, have been publicly funded while the huge profits that have resulted have been entirely private . . . unless Congress acts to rein in these prices, we will all keep paying for our prescriptions twice over.”).

19. Marianna Mazzucato, *How Taxpayers Prop up Big Pharma, and How to Cap That*, L.A. TIMES (Oct. 27, 2015), <https://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html> [<https://perma.cc/M45Q-PQLT>] (“Everyone knows that Americans pay high prices for drugs. But there is more to this story. The taxpayer not only shells out at the pharmacy but often plays a critical role in funding these drugs in the first place. In other words, the public pays twice.”).

20. Arno & Davis, *Why Don't We Enforce Existing Drug Price Controls?*, *supra* note 3, at 631.

21. See *Statement of Senator Birch Bayh to the National Institutes of Health*, in NAT'L INSTS. OF HEALTH, NIH PUBLIC MEETING ON NORVIR/RITONAVIR MARCH-IN REQUEST 2-4 (May 25, 2004) (statement of Sen. Birch Bayh), <https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf> [<https://perma.cc/QK83-RL6F>] (asserting that Bayh-Dole does not authorize the government to use its march-in rights to set reasonable drug prices, and that Arno & Davis had misrepresented the legislative history to argue to the contrary); Birch Bayh & Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST, Apr. 11, 2002, at A28.

22. Wolitz, *supra* note 5, at 205; see also Letter from Sylvia Burwell, Sec'y, U.S. Dep't of Health & Human Servs., to Sen. Lloyd Doggett, U.S. Congress (Mar. 2, 2016), <http://freepdfhosting.com/be7532cfc0.pdf> [<https://perma.cc/DB6X-ZPGH>] (declining the invitation to issue regulatory guidance on when HHS/NIH would assert its march-in rights, but noting that such rights are “strictly limited and can only be exercised if the agency conducts an investigation and determines

Are Americans actually paying twice for pharmaceuticals? In Part II, we examine the extent of government involvement in drug development, and in Part III, we provide a framework for analyzing the paying-twice critique and propose several strategies for addressing the underlying problem.

## II. Government Involvement in Drug Development

We begin with case studies of two high-profile medications whose histories illustrate the complex interaction of public and private institutions during the drug-development process. We follow these case studies with a broader review of the literature. Both approaches highlight the difficulty of disentangling public and private contributions to pharmaceutical development.

### A. Case Studies

#### 1. Sovaldi

As we have described in detail elsewhere, Sovaldi, a breakthrough treatment for hepatitis C, exemplifies the complexities of quantifying the risks that pharmaceutical companies bear and of determining whether those risks justify the prices that pharmaceutical companies demand.<sup>24</sup> When Gilead Sciences (Gilead) introduced Sovaldi, it charged \$84,000 for a course of treatment that required 84 pills, each of which cost about \$1 to make.<sup>25</sup> This staggeringly large difference between the list price and the manufacturing cost might well be justified, depending on the amount of risk the companies (in this case, Pharmasset and Gilead) incurred in the course of inventing the drug and bringing it to market. As we have noted previously: “[E]normous risks justify enormous rewards when ambitious undertakings succeed. *If* Pharmasset/Gilead took big risks by inventing and testing Sovaldi, then big rewards are warranted, just as they are when companies invent and bring to market other new products, like electric cars, smartphones, or flat screen TVs.”<sup>26</sup>

Whether Pharmasset and Gilead actually incurred enormous risks is, however, an open question. At times, the public bore the risks associated with Sovaldi’s development because public funds helped pay for the research. For example, from 2000 to 2006, Pharmasset received NIH grants totaling

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that specific criteria are met, such as alleviating health or safety needs or when effective steps are not being taken to achieve practical application of the inventions”).

23. Ed Silverman, *NIH Asked to Fight Price Gouging by Overriding Drug Patents*, STAT (Jan. 11, 2016), <https://www.statnews.com/pharmalot/2016/01/11/nih-drug-costs-patents> [<https://perma.cc/74X4-HFX9>].

24. CHARLES M. SILVER & DAVID A. HYMAN, *OVERCHARGED: WHY AMERICANS PAY TOO MUCH FOR HEALTH CARE* 58 (2018).

25. Richard Knox, *\$1,000 Pill for Hepatitis C Spurs Debate over Drug Prices*, NPR, (Dec. 30, 2013), <https://www.npr.org/sections/health-shots/2013/12/30/256885858/-1-000-pill-for-hepatitis-c-spurs-debate-over-drug-prices> [<https://perma.cc/ZYR8-4QWF>].

26. SILVER & HYMAN, *supra* note 24.

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\$2,460,171.<sup>27</sup> Neither Pharmasset nor Gilead deserves credit for costs that taxpayers covered.

Although \$2.5 million over seven years isn't chicken feed, publicly supported research on hepatitis C is far more extensive and far more longstanding, dating back to the 1990s with the development and commercialization of tools for testing antiviral compounds.<sup>28</sup> Should we include those expenditures when counting the public's contribution to the development of Sovaldi? In practice, all discoveries of new treatments take advantage of scientific knowledge and tools developed by others.<sup>29</sup> Quantifying the public's financial contribution to Sovaldi's development requires deciding when the process of developing it started and what prior and contemporaneous research to include—a process that is both arbitrary and subjective.

One approach is to include all public expenditures devoted to research on hepatitis C and other hepatitis-related matters. Although data limitations prevent us from developing a complete picture, from 2008 through 2014, NIH doled out \$752 million for hepatitis-C research and over \$2.6 billion for all forms of hepatitis research combined.<sup>30</sup> But even if figures for years prior to 2008 were available, the numbers alone would not show whether Pharmasset's scientists benefitted from other researchers' work—or if so, by how much.

It is tempting to use Pharmasset's founding in 1998 as the point after which a private entity began covering the costs and bearing the risks associated with developing Sovaldi. However, that approach might be overinclusive. Pharmasset first reported spending money on preclinical studies for PSI-7977 (the molecule that became Sovaldi) in SEC filings in 2008.<sup>31</sup> During the first decade of Pharmasset's existence, the company was focused on other drug candidates. Research on those candidates may have helped with the study of PSI-7977, but again, the magnitude of the overlap cannot be assessed with precision.

A report by the Senate Finance Committee states that “Pharmasset spent \$62.4 million researching and developing PSI-7977” from 2008 to 2011.<sup>32</sup> Only a small fraction of these costs, less than \$250,000, was covered by a

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27. See *NIH Awards by Location & Organization*, NIH RES. PORTFOLIO ONLINE REPORTING TOOLS (REPORT), <https://report.nih.gov/award/index.cfm?ot=&fy=2000&state=&ic=&fm=&orgid=3938601&distr=&rfa=&om=n&pid=#tab2> [https://perma.cc/G3HU-3R8U] (searching “PHARMASSET, INC.” as an organization for fiscal years 2000-2006 in the database).

28. Victor Roy & Lawrence King, *Betting on Hepatitis C: How Financial Speculation in Drug Development Influences Access to Medicines*, BRIT. MED. J. 354, 354-59 (2016).

29. For an example, see John D. Westbrook & Stephen K. Burley, *How Structural Biologists and the Protein Data Bank Contributed to Recent FDA New Drug Approvals*, 27 STRUCTURE 211 (2019), which discusses the use of an open-access databank by drug innovators.

30. See *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, NIH RES. PORTFOLIO ONLINE REPORTING TOOLS (REPORT) (Feb. 24, 2020), [https://report.nih.gov/categorical\\_spending.aspx](https://report.nih.gov/categorical_spending.aspx) [https://perma.cc/5YWX-5H9J].

31. STAFF OF THE S. COMM. ON FINANCE, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM 13 (Comm. Print 2015).

32. *Id.*

federal grant.<sup>33</sup> Presumably, the latter figure reflects only public funds that were specifically tied to studying PSI-7977 rather than to all grants that Pharmasset may have received, and the former reflects private monies used for that purpose. However, for already explained reasons, these allocations may be arbitrary for determining how public and private support affected the risks associated with Sovaldi. Before focusing on PSI-7977, Pharmasset spent money on other candidate treatments for hepatitis C.<sup>34</sup> If one conceptualizes the search for new drugs in terms of diseases targeted rather than molecules tested, then the cost of creating Sovaldi should include all money spent on candidates that did not pan out.

So when should we start counting? By 2010, Pharmasset insiders had determined that PSI-7977 was “less risky than other drugs at this stage of development.”<sup>35</sup> In 2011, they concluded a successful Phase 2 trial, received encouraging feedback from the Food and Drug Administration (FDA), and became the target of a bidding war among larger pharmaceutical companies. The war ended on November 21, 2011, when Gilead announced Pharmasset’s acquisition at a price of \$11.2 billion.

Interestingly, “many investors believed Gilead had overpaid, taking umbrage at the eighty-nine percent premium to Pharmasset’s stock price.”<sup>36</sup> The stock market agreed. Gilead’s shares fell nine percent the day of the announcement. But Gilead had the last laugh; “[i]n 2014, the first year that Gilead marketed Sovaldi and Harvoni,” a drug that combined Sovaldi with another ingredient, “the company reported \$12.4 billion in worldwide HCV sales.”<sup>37</sup> Gilead recouped the cost of buying Pharmasset in less than a year and reaped billions of dollars in profits thereafter.

Pharmasset’s owners may have sold the company too cheaply, but they still enjoyed a spectacular return on their investment. Gilead’s acquisition of Pharmasset reflects the modern business model of large pharmaceutical companies, which tend to acquire promising molecules from smaller start-ups rather than doing the original, highly risky research themselves. “A 2014 study found that companies deemed to be ‘winners’”—the ten that consistently outperformed the average for the pharma sector—“earned more than 70% of their sales from products developed by other companies.”<sup>38</sup>

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33. *Id.*

34. Merrill Gozner, *Why Sovaldi Shouldn’t Cost \$84,000*, MOD. HEALTHCARE (May 3, 2014), <https://www.modernhealthcare.com/article/20140503/MAGAZINE/305039983/why-sovaldi-shouldn-t-cost-84-000> [<https://perma.cc/5QES-AMH7>].

35. STAFF OF THE S. COMM. ON FINANCE, 114TH CONG., *supra* note 31, at 13.

36. Charley Grant, *Deal Iron Too Hot for Gilead to Strike*, WALL ST. J. (May 1, 2015), <https://www.wsj.com/articles/deal-iron-too-hot-for-gilead-to-strike-1430496777> [<https://perma.cc/WUE8-FGK8>].

37. *Id.* at 14.

38. Roy & King, *supra* note 28, at 354-59 (citing Nils Behnke et al., *New Paths to Value Creation for Pharma*, BAIN & CO. (Sept. 24, 2014), <https://www.bain.com/insights/new-paths-to-value-creation-in-pharma> [<https://perma.cc/23YU-ARUX>]).

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Gilead was one of those companies. Over a 20-year period, its total annual shareholder return reportedly averaged about 22%.<sup>39</sup> By comparison, the average for similarly sized pharmaceutical companies was about 9%.<sup>40</sup> Gilead's decision to acquire Pharmasset fit the business model that generated this performance. Commenting on the acquisition of Pharmasset in a 2015 earnings call, John Martin, Gilead's CEO, reportedly stated: "We typically like things where we can have impact on phase III and where we can accelerate those products either into the approval process or into greater indications after the approval process."<sup>41</sup> Phase III, which follows discovery and development in the laboratory and preclinical research, is the stage for testing drugs' safety and effectiveness on humans.<sup>42</sup>

Gilead pegged the cost of bringing Sovaldi to market at \$880 million (on top of the cost of acquiring Pharmasset), but this figure is almost certainly exaggerated. Before being acquired, Pharmasset estimated that the remaining cost to bring Sovaldi to market was \$125.6 million.

Even if Gilead's figures are correct, the price it set for Sovaldi does not reflect the risks and costs incurred by the company. The Senate Finance Committee's report on Sovaldi identifies the considerations that drove the decision to charge \$1,000 per pill:

Gilead considered a number of factors in determining a price point for Sovaldi, including costs for the existing standard of care for HCV treatment and setting a high baseline for the next wave of HCV drugs. In addition, during the pricing process, Gilead looked at a range of impacting factors to gauge the likelihood of various "softer issues" at different pricing points—ranging from professional societies including price "asterisks" in their therapy recommendations, to protests from the AIDS Health Foundation or Fair Pricing Coalition, to losing "key opinion leader" endorsements, and even to the likelihood of congressional hearings or letters concerning the price of Sovaldi.<sup>43</sup>

The factors mentioned in Gilead's internal deliberations had nothing to do with the costs and risks the company incurred and everything to do with the price the market could bear. In its public statements, Gilead has tried to

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39. Behnke et al., *supra* note 38.

40. *Id.*

41. Roy & King, *supra* note 28, at 354-59.

42. *The Drug Development Process*, U.S. FOOD & DRUG ADMIN (Jan. 4, 2018), <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process> [<https://perma.cc/KMA2-E3MS>].

43. STAFF OF THE S. COMM. ON FINANCE, 114TH CONG., *supra* note 31, at 29.

emphasize Sovaldi's "value",<sup>44</sup> even though value actually has little to do with the price at which goods and services change hands in competitive markets.<sup>45</sup>

Gilead's internal pricing calculus is unsurprising. Costs and risks matter *ex ante*—when drug companies are deciding whether to invest in research, to acquire other companies with promising products, and so forth—but they do not affect the prices pharmaceutical companies charge *ex post*, after the research is complete and FDA approval is secured. Then, rational businesses always charge as much as they can for their goods. That is how they maximize their profits or, when production costs exceed prices, minimize their losses.

Pressure to keep prices low comes from external sources. Chief among them are competition from other suppliers and consumers' willingness to pay. When it comes to name-brand drugs, however, neither matters much. Patents effectively confer a time-limited monopoly. Thus, when patented drugs lack close substitutes, the sky is the limit when it comes to pricing, particularly when third-party payers bear most of the costs.

The question becomes how much money payers will part with and, as we explain in *Overcharged*, those payers often have little power to resist pharmaceutical companies' demands.<sup>46</sup> It is easy to see why prices for branded drugs like Sovaldi and Harvoni seem to defy gravity.

Sovaldi and Harvoni also show some of the complications of disaggregating the relative contributions of public and private efforts to the development of new drugs. Depending on when one starts counting and what one counts, the degree of public contribution is either overwhelming or quite modest—and the extent to which taxpayers are paying twice varies, accordingly.

## 2. Pre-Exposure Prophylaxis (PrEP) Regime

Gilead Sciences also makes Truvada, a treatment for HIV. Truvada combines two previously discovered antiretroviral drugs, emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF), into a single pill. In 2004, the FDA approved Truvada as a treatment for HIV. When used for this purpose, Truvada reduces the amount of HIV in patients' bloodstreams by preventing the virus from replicating.

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44. *Innovating and Expanding Access to Hepatitis C Treatments*, GILEAD SCIS. (Oct. 2014), <https://www.gilead.com/~media/Files/pdfs/Policy-Perspectives/ExpandingAccessToHCVTreatments10214.pdf> [<https://perma.cc/PH9U-HH9G>] (“[T]he price of Gilead’s hepatitis C treatments reflects the significant clinical, economic and public health value that Sovaldi and Harvoni offer to patients, their families and healthcare systems, and is comparable to, or in many cases less than, the cost of older, less effective regimens.”).

45. As we explain in *Overcharged*, “value” to the purchaser places a ceiling on the price that buyers will pay—but marginal cost actually drives prices in competitive markets. SILVER & HYMAN, *supra* note 24, at 56-57. The repeated invocation of “value” by Gilead and its apologists is a clumsy attempt to deflect attention from this reality. *Id.*

46. *Id.* at 54.

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Eight years later, the FDA approved Truvada in the same dosage form and strength as a Pre-Exposure Prophylaxis (PrEP) regime. When used for this purpose, Truvada reduces the likelihood that the virus will gain a foothold in the body of a person who is not already infected. The estimated effectiveness of Truvada as PrEP is 99%. In 2019, Americans who purchased Truvada domestically paid about \$2,000 a month for the drug.<sup>47</sup> That is substantially more than the \$1,200 the drug cost in 2012.<sup>48</sup> And by comparison to the marginal cost of making the pills—about \$0.20<sup>49</sup>—both prices are astonishingly high.<sup>50</sup>

A chorus of voices, including advocates for the LGBTQ+ community and several U.S. Senators, have accused Gilead of profiting off research on the effectiveness of the FTC/TDF combination done by the Centers for Disease Control (CDC). Unlike the debate over Sovaldi, the dispute over PrEP has recently morphed into a legal battle. The CDC patented the use of FTC and

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47. Natalie Grover, *Under Fire for Truvada US Pricing at House Hearing, Gilead Chief O'Day Touts R&D Costs, Asserts Governments Patents are Void*, ENDPOINTS NEWS (May 17, 2019), <https://endpts.com/under-fire-for-truvada-us-pricing-at-house-hearing-gilead-chief-oday-touts-rd-costs-asserts-governments-patents-are-void> [<https://perma.cc/956U-6A2R>]. In other countries, generic versions sell for much less; for example, only about \$250 per month in Canada and Mexico. Bobby Box, *Why Is Prep So Inaccessible in Canada?*, IN MAG. (June 18, 2019), <http://inmagazine.ca/2019/06/why-is-prep-so-inaccessible-in-canada> [<https://perma.cc/8A44-N4JC>]; Mexico, *First Latin American Country with AIDS Pills for Sale*, MAZATLÁN POST (Apr. 7, 2019), <https://themazatlanpost.com/2019/04/07/mexico-first-latin-american-country-with-aids-pills-for-sale> [<https://perma.cc/LE35-869H>] (\$4,599 pesos equaled about \$250 in 2019). The Yale Global Health Justice Partnership reports that “pills . . . cost less than \$6 per month abroad.” *GHJP Joins PrEP4All in Calling on CDC to Use Its Patents for PrEP*, YALE L. SCH. TODAY (Mar. 27, 2019), <https://law.yale.edu/yls-today/news/ghjp-joins-prep4all-calling-cdc-use-its-patents-prep> [<https://perma.cc/NB3G-NKRT>].

48. Tim Fitzsimons, *Following Court Ruling, Generic Truvada Could Soon Be Available in U.K.*, NBC NEWS (Sept. 21, 2018), <https://www.nbcnews.com/feature/nbc-out/following-court-ruling-generic-truvada-could-soon-be-available-u-n911586> [<https://perma.cc/HM7Z-NQDV>].

49. Letter from Amy Kapczynski & Christopher Morten, Yale Global Health Justice Partnership, to Rep. Elijah Cummings & Rep. Jim Jordan, U.S. Congress, Re: May 16, 2019 Hearing on “HIV Prevention Drug: Billions in Corporate Profits after Millions in Taxpayer Investments” (May 16, 2019), [https://law.yale.edu/sites/default/files/area/center/ghjp/documents/2019.05.16\\_ghjp\\_letter\\_to\\_house\\_oversight\\_committee\\_final.pdf](https://law.yale.edu/sites/default/files/area/center/ghjp/documents/2019.05.16_ghjp_letter_to_house_oversight_committee_final.pdf) [<https://perma.cc/7PLD-8WKD>].

50. Gilead has sought to distract attention from the total cost of Truvada by emphasizing the small amounts that insured patients pay out of pocket for the drug. See *Gilead Statement on Petitions to US Patent and Trademark Office on HIV PrEP Patents*, GILEAD SCIS. (Aug. 21, 2019), <https://www.gilead.com/news-and-press/company-statements/petitions-to-us-patent-and-trademark-office-on-hiv-prep-patents> [<https://perma.cc/HD8V-4N4S>] (“Today, a person with Medicare typically pays between \$0 and \$5 per month for Truvada for PrEP®; a person with Medicaid typically pays between \$4 and \$9 per month; and a person with insurance through an employer or private party typically pays between \$0 and \$35 per month.”).

That same tactic has been used by many pharmaceutical companies, see SILVER & HYMAN, *supra* note 24, at 293, and by the *Wall Street Journal's* editorial board in defending Gilead, The Editorial Board, *Opinion, Trump's Patent Trolls*, WALL ST. J. (Nov. 15, 2019), <https://www.wsj.com/articles/trumps-patent-trolls-11573777498> [<https://perma.cc/7SRZ-WVKA>] (noting that “Truvada has a list price of about \$2,000 per month, though almost no one pays that,” that in 2018 Gilead “covered the out-of-pocket costs for nearly 170,000 privately insured patients,” and that because the U.S. Preventive Services Task Force recently recommended adding Truvada to the menu of preventive services that insurers must provide subscribers without charge, “virtually everyone who wants Truvada in the U.S. will soon be able to get it for free”).

TDF for PrEP,<sup>51</sup> and Gilead's critics argued that it should have to obtain a license from the U.S. government.<sup>52</sup> The government could condition granting that license on Gilead paying royalties or agreeing to lower Truvada's price. Gilead, however, has no license. And the Department of Justice (DOJ) recently filed a patent-infringement case against Gilead.<sup>53</sup>

Although the editorial board of the *Wall Street Journal* accused the DOJ of being a patent troll, there is evidence that the DOJ's case has merit.<sup>54</sup> Mylan, which sells a generic version of Truvada in Europe and Australia, challenged the CDC's patents. The European Patent Office rejected Mylan's claim, and Mylan now pays royalties to the United States.<sup>55</sup>

Gilead has denied the allegations in the DOJ complaint and sought to open a second front by asking the U.S. Patent and Trademark Office to reexamine the patent issued to the CDC.<sup>56</sup> Gilead's position is that the patent should not have been issued since "medical professionals were widely discussing Truvada . . . for prevention of [HIV] before the government filed its patent claim in 2006."<sup>57</sup>

It is true that the CDC's researchers were not the first to recognize the possibility of using antiretroviral drugs to prevent HIV transmission; that idea dates back to the 1990s.<sup>58</sup> Nor were they the first to think of using tenofovir prophylactically. In 1995, *Science* published a study where researchers at the University of Washington demonstrated the potential of tenofovir, referred to as PMPA, to protect uninfected monkeys from the Simian Immunodeficiency Virus (SIV), a virus similar to HIV that is used in tests performed on

51. *US Government Sues Gilead Over Patents for HIV PrEP*, Healio News (Nov. 7, 2019), <https://www.healio.com/news/infectious-disease/20191107/us-government-sues-gilead-over-patent-for-hiv-prep> [<https://perma.cc/YX7T-XS92>].

52. Statement, Treatment Action Grp., Advocates Must Press the CDC to Enforce Its PrEP Patents in Order to End HIV as an Epidemic, Treatment Action Group (Mar. 28, 2019), <https://www.treatmentactiongroup.org/statement/advocates-must-press-the-cdc-to-enforce-its-prep-patents-in-order-to-end-hiv-as-an-epidemic/#:~:text=New%20York%2C%20March%2028%2C%202019,mysteriously%20failed%20to%20enforce%20them> [<https://perma.cc/G3F6-JPHF>].

53. Press Release, U.S. Dep't of Justice, No. 19-1212, United States Files Complaint against Pharmaceutical Company Gilead for Patent Infringement Related to Truvada® and Descovy® For Pre-Exposure Prophylaxis of HIV (Nov. 7, 2019), <https://www.justice.gov/opa/pr/united-states-files-complaint-against-pharmaceutical-company-gilead-patent-infringement> [<https://perma.cc/D2AW-79WW>]. The government's lawsuit against Gilead also applies to a second drug, Descovy, that is also used as PrEP.

54. The Editorial Board, *supra* note 50.

55. *US: AIDS Activists Skewer CDC for Conflicting Stance on Collecting HIV Drug Royalties*, EQUAL EYES (Apr. 16, 2019), <https://equal-eyes.org/database/2019/4/16/us-aids-activists-skewer-cdc-for-conflicting-stance-on-collecting-hiv-drug-royalties> [<https://perma.cc/2VVF-G9TU>].

56. *Gilead Files Challenge to Government Patents for HIV Prevention Pill*, AVAC: GLOBAL ADVOC. FOR HIV PREVENTION (Aug. 21, 2019), <https://www.avac.org/news/gilead-files-challenge-government-patents-hiv-prevention-pill> [<https://perma.cc/358J-BD62>].

57. *Id.*

58. John Cohen, *Untangling the Trump Administration's Lawsuit over an HIV Prevention Drug*, SCI. MAG. (Nov. 8, 2019), <https://www.sciencemag.org/news/2019/11/untangling-trump-administration-s-lawsuit-over-hiv-prevention-drug> [<https://perma.cc/BY6V-S6C8>].

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monkeys.<sup>59</sup> The 1995 study also noted the possibility that tenofovir “may [] have an important role in combination therapies or strategies against HIV.”<sup>60</sup>

Obviously, that observation is unspecific. It does not say, for example, whether the study’s authors considered pairing FTC with TDF/PMPA. It seems unlikely that they did. The FDA only approved FTC as a treatment for HIV in humans eight years after the *Science* study appeared.<sup>61</sup> Even if the general idea of combining TDF with other drugs was not novel, the more specific idea of coupling it with FTC may have been.

Gilead could have beaten the CDC to the punch by exploring the possibility of using FTC and TDF together. It supplied the quantities of both drugs that the CDC’s researchers used in their studies.<sup>62</sup> But Gilead did not pursue this angle. The company even declined to test TDF alone as PrEP. It had “no interest in pursuing PrEP because of fears that uninfected people who take tenofovir and still become infected might sue the company.”<sup>63</sup> Nor did Gilead discover FTC. Scientists at Emory University, one of whom was Dr. Raymond Schinazi, the head researcher at Pharmasset, did that, and their research was funded by the NIH.<sup>64</sup> That is why Emory University held a royalty interest in the drug—an interest that Gilead paid \$525 million to acquire.<sup>65</sup>

The DOJ contends that the idea of combining TDF and FTC for use as PrEP was novel. It points out that studies conducted through 2006, which employed single drugs, including TDF and FTC, were disappointing. “Based on these results,” the DOJ asserts, “no one in the field expected a tenofovir prodrug in combination with FTC, or any other type of PrEP regimen, to have the superior effectiveness that the FTC/tenofovir prodrug regimens are known to have today.”<sup>66</sup> Nor had the two-drug regimen been studied. “Prior to CDC’s

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59. Che-Chung Tsai et al., *Prevention of SIV Infection in Macaques by (R)-9-(2-Phosphonylmethoxypropyl)adenine*, 270 SCI. 1197 (1995).

60. *Id.*

61. Dennis C. Liotta & George R. Painter, *Discovery and Development of the Anti-Human Immunodeficiency Virus Drug, Emtricitabine (Emtriva, FTC)*, 49 ACCT. CHEMICAL RES. 2091 (2016).

62. Complaint ¶ 103, United States v. Gilead Sci., Inc. (D. Del. 2019) (No. 119 Civ. 02103), <https://www.mintz.com/sites/default/files/media/documents/2019-12-09/19-cv-02103%20Complaint%20USA%20v.%20Gilead%20Sciences%20Inc.pdf> [<https://perma.cc/NP7F-VGGZ>].

63. Jon Cohen, *Prevention Cocktails: Combining Tools To Stop HIV’s Spread*, 309 SCI. 1002, 1004 (2005).

64. Christopher J. Morten & Amy Kapczynski, United States v. Gilead: *Can a Lawsuit Yield Better Access to PrEP?*, HEALTH AFF. BLOG (Nov. 18, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20191118.218552/full>; see also Rick Mullin, *Emory Gets \$525 Million for AIDS Drug*, CHEMICAL ENGINEERING NEWS (July 25, 2005), <https://cen.acs.org/articles/83/i30/Emory-525-Million-AIDS-Drug.html> [<https://perma.cc/8GMP-7W37>] (stating that “[much of the research on emtricitabine was done with NIH funding”); Tsai et al., *supra* note 59, at 1199 n.25 (acknowledging grants received from NIH).

65. Press Release, Emory Univ., Gilead Sciences and Royalty Pharma Announce \$525 Million Agreement with Emory University to Purchase Royalty Interest for Emtricitabine (July 18, 2005), <http://www.emory.edu/news/Releases/emtri> [<https://perma.cc/NZH8-JYGU>].

66. Complaint, *supra* note 62, ¶ 91.

patented work, no preclinical or clinical PrEP studies during the mid-2000s were conducted using the combination of FTC and TDF []. Only the CDC researchers focused their studies on a two-drug regimen.”<sup>67</sup>

To explore the two-drug regimen’s potential for preventing infection, the CDC’s researchers created a new protocol for exposing macaques to SIV. Instead of giving them “a single high dose” exposure, as had been done in prior experiments, “the virus was painstakingly administered into rhesus macaques in repeated and precise low doses, by applying it vaginally or rectally, with the intent to more accurately model the conditions by which HIV is sexually transmitted in humans.”<sup>68</sup> That protocol for testing effectiveness in macaques seems to have been a noteworthy innovation. Without it, studies of the effectiveness of drug combinations as PrEP may have continued to produce unimpressive findings.<sup>69</sup>

Hoping to give the government the leverage needed to force Gilead to sell Truvada more cheaply, advocacy groups have taken pains to show that the government’s patents are valid.<sup>70</sup> The Global Health Justice Partnership at the Yale Law School produced a report authored by Christopher J. Morten, a patent attorney, who opined that the CDC’s patents for PrEP “appear to be valid and enforceable.”<sup>71</sup> Morten and Amy Kapczynski, one of the Partnership’s codirectors, also published a *Health Affairs Blog* column defending the patents at length.<sup>72</sup> Both the column and the report were part of “a wave of pressure . . . from a coalition of activists, HIV care providers, and civil society groups organized by the PrEP4All Collaboration [], urging HHS and its constituent agency, the Centers for Disease Control and Prevention (CDC), to assert government-owned ‘patents for PrEP’ against Gilead.”<sup>73</sup>

Eventually, the validity of the CDC’s patents—and claims of Gilead’s infringement of them—will be determined authoritatively. Either way, it will continue to be true that taxpayers bore a large portion of the cost of demonstrating the safety and effectiveness of Truvada as PrEP. Thus, it will also be true, as HHS asserts, that “Gilead has profited from research funded by hundreds of millions of taxpayer dollars and reaped billions from PrEP

67. *Id.* ¶ 92.

68. *Id.* ¶¶ 97-98.

69. The researchers overcame other technical problems too. For example, they determined the dosages of FTC that, when given to macaques, would mimic the effectiveness of FTC in humans. *Id.* ¶¶ 100-104.

70. Morten & Kapczynski, *supra* note 64. Although a judgment in a patent-infringement action could only require Gilead to pay damages, a settlement with the government could contain a price cap. See Donald G. McNeil & Apoorva Mandavilli, *Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says*, N.Y. TIMES (Nov. 8, 2019), <https://www.nytimes.com/2019/11/08/health/hiv-prevention-truvada-patents.html> [<https://perma.cc/2WUF-N9PJ>].

71. Yale Global Health Justice Partnership, *Summary of Statement on CDC’s Patents for PrEP*, YALE L. SCH., <https://law.yale.edu/sites/default/files/area/center/ghjp/documents/ghjp2-pagestatement.pdf> [<https://perma.cc/YF9K-2KLM>] (summarizing the findings of Morten’s report).

72. Morten & Kapczynski, *supra* note 64.

73. *Id.*

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through the sale of Truvada[].”<sup>74</sup> The creation of an effective prophylactic against HIV “was a public health triumph that was spurred by years of government-funded research.”<sup>75</sup>

It seems clear that the returns Gilead has earned on sales of Truvada as PrEP bear no relation to the costs and risks it bore in bringing the drug to market for that purpose. Although Gilead reportedly “spent \$1.1 billion to develop the drug, which was first approved in 2004 for treatment of patients who already have the HIV virus,” the returns on that investment are generated by Truvada sales for its prior purpose: curing HIV.<sup>76</sup> The costs and risks at issue in the litigation are those borne by Gilead in connection with Truvada’s use as PrEP, which appear to be quite small. CDC researchers tested Truvada on both humans and macaques to establish the efficacy of Truvada for HIV prevention.<sup>77</sup>

So what was Gilead’s role in the development of PrEP? According to testimony from Robert M. Grant, the lead author on the study in question, “Gilead’s role was limited to donating study medicine and placebos,” and Gilead was “‘a reluctant partner’ in the research, until demand for the prevention use increased in 2013.”<sup>78</sup> At a hearing before the House Committee on Oversight and Reform, Daniel O’Day, Gilead’s CEO, countered Grant’s assertion by stating that “two Gilead researchers were co-authors on the 2010 prevention trial.”<sup>79</sup> Regardless, it seems clear that the returns on sales of Truvada as PrEP are massively disproportionate to the costs and risks borne by Gilead.

We noted above that the federal government rarely sues drug companies for infringing CDC-held patents; its lawsuit against Gilead is an exception attributable to pressure exerted by advocacy groups. In view of the government’s customary reluctance to challenge infringements, one may wonder why the CDC bothers to acquire patents in the first place.

The history of government-owned patents is short. Professor Kapczynski reports that laboratories participating in a multinational network studying influenza initially operated without patenting discoveries.<sup>80</sup> The CDC became

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74. Press Release, U.S. Dep’t of Health & Human Servs., United States Files Patent Infringement Lawsuit Against Gilead Related to Truvada® and Descovy® For Pre-Exposure Prophylaxis of HIV (2019), <https://www.hhs.gov/about/news/2019/11/06/us-files-patent-infringement-lawsuit-against-gilead-pre-exposure-prophylaxis-hiv.html> [<https://perma.cc/MV9G-ZS4R>].

75. Robert Langreth & Kristin V. Brown, *Gilead’s \$21,000 Drug Is Being Blamed for a Plateau in HIV Prevention*, BLOOMBERG NEWS (May 17, 2019), <https://www.bloomberg.com/news/articles/2019-05-17/gilead-s-21-000-drug-gets-blame-for-a-plateau-in-hiv-prevention> [<https://perma.cc/LTH2-UC5N>].

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017).

“one of the few labs to hold such patents.”<sup>81</sup> Its decision was “defensive,” seeking “to prevent private firms from taking unfair advantage of” publicly supported research.<sup>82</sup>

But it seems unlikely that the motives underlying government-owned patents are wholly defensive. For one thing, under existing law, a private entity cannot obtain a patent on a discovery made at the CDC or at any other laboratory in the network. To obtain a patent, a private entity that took advantage of publicly available research findings would have to innovate, and any patent it secured would be limited to the innovation. For another, before Bayh-Dole, the government controlled patents on inventions that were created with public funds. As noted in Part I, Senators Bayh and Dole believed that this arrangement discouraged private companies from using publicly supported inventions to create commercially viable products. They proposed the Act “to promote collaboration between commercial and non-profit concerns; and to enhance the commercialization and public availability of the inventions.”<sup>83</sup> Congress later reinforced this object by passing the Federal Technology Transfer Act of 1986,<sup>84</sup> which gave federal laboratories a “mandate to ensure that new technologies . . . are transferred to the private sector and commercialized in an expeditious and efficient manner.”<sup>85</sup> In keeping with this mandate, the official policy of the U.S. Public Health Service is:

[to] seek patent protection on biomedical technologies only when a patent facilitates availability of the technology to the public for preventive, diagnostic, therapeutic, or research use, or other commercial use. Generally a patent is necessary to facilitate and attract investment by commercial partners for further research and commercial development of the technology, such as where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However, a patent might also be necessary to encourage a commercial partner to make available for research use important materials or products.<sup>86</sup>

In short, giving the NIH and other government agencies the power to hold patents serves to encourage private companies to use publicly sponsored research to develop and commercialize useful products and services. There is no hint in any of these materials that doing so takes “unfair advantage” of the publicly sponsored research.

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81. *Id.* at 1623.

82. *Id.*

83. *The Bayh-Dole Act at 25*, BAYHDOLE25, INC. 19 (Apr. 17, 2006), [https://ipmall.law.unh.edu/sites/default/files/BAYHDOLE/BayhDole25\\_WhitePaper.pdf](https://ipmall.law.unh.edu/sites/default/files/BAYHDOLE/BayhDole25_WhitePaper.pdf) [<https://perma.cc/B9A9-RZPR>].

84. Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785, (codified at 15 U.S.C. § 3701 (2018)).

85. NAT’L INSTS. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS (1998), [https://www.mmrc.org/about/NIH\\_research\\_tools\\_policy](https://www.mmrc.org/about/NIH_research_tools_policy) [<https://perma.cc/BS6B-XV5Y>].

86. *Id.* at app. D.1

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Indeed, if empowering the NIH to hold patents facilitates the use of publicly supported inventions by private entities, the DOJ's lawsuit against Gilead is hard to explain. After scientists at the NIH discovered that TDF and FTC effectively prevent people from contracting HIV when used in combination, Gilead gained FDA approval for the treatment and started selling Truvada. Gilead thus did what the sponsors of the Bayh-Dole Act wanted: it quickly turned a technology created with public support into a commercial product.

The DOJ's lawsuit stands the Bayh-Dole Act on its head. Instead of celebrating the rapid commercialization of the idea behind PrEP, the lawsuit seeks to punish Gilead for violating the government's patents. That reversal is politically motivated. Truvada is too expensive for millions of Americans to afford, and advocacy groups want the government to force Gilead to sell it more cheaply by threatening to demand billions of dollars in royalties unless the company complies. Meanwhile, the Trump administration has prioritized reducing drug prices and likely would celebrate a decision to cut Truvada's price. The lawsuit represents an instance of agreement between groups on opposite sides of the partisan divide.

Lawsuits are a clumsy way to address the paying-twice critique. Filings are rare and politically motivated. Their outcomes are hard to predict. Even if the government obtains a judgment against Gilead or settles, the likelihood is low that the amount transferred will bear any relation to the number of dollars that taxpayers provided or to the risks borne by Gilead in bringing the product to market. Damages for patent infringement are typically based on either a reasonable royalty or on lost profits—not on the patent holders' development costs.<sup>87</sup>

Replacing patents with prizes would better address the paying-twice critique, as we discuss in Section III.C. The paying-twice critique has some surface plausibility only because patents enable inventors to gouge the public by giving them time-limited monopolies on sales.<sup>88</sup> Because a prize system would reward inventors without conferring monopolies, drugs would be priced at market rates, and the critique would lose its force. The need for lawsuits like the one the DOJ filed against Gilead would also disappear.

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As these two case studies indicate, the government can contribute in a variety of ways to drug research and development. It can conduct the research itself, and it can (but need not) patent the resulting inventions. It can help fund

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87. See Rebecca Wolitz, *Recent Litigation Developments Regarding Drug Pricing and Access*, STAN. L. SCH.: SLS L. & BIOSCIENCES BLOG (Jan. 3, 2020), <https://law.stanford.edu/2020/01/03/recent-litigation-developments-regarding-drug-pricing-and-access> [<https://perma.cc/4SFC-BUPR>] (noting the complexities of valuing early stage contributions in a patent infringement case).

88. In theory, the government-conferred patent-based monopoly may not actually result in pricing power if there are adequate substitutes, switching costs are low, and market entry is easy. In practice, these preconditions are often not met. SILVER & HYMAN, *supra* note 24, at 30-39.

basic or applied research in an area, and any resulting invention might be patented by a private entity. It can invest a little or a lot in any given disease, molecule, or drug regimen. And the government's investments can be tightly linked to a given treatment, or quite remote. We now turn to the extent to which our two case studies are representative of the broader universe of approved drugs and medical devices.

*B. The View from 10,000 Feet*

The conventional wisdom is that “the upstream, pre-competitive, basic science research that so many new drugs depend on is . . . predominantly funded by public support, while clinical trials are . . . predominantly funded by the pharmaceutical industry.”<sup>89</sup> This belief supports the policy of allowing pharmaceutical companies to secure the exclusive right to sell new medicines because it implies that private companies shoulder the substantial cost of “translational research”: “the ‘bench-to bedside’ enterprise of harnessing knowledge from basic sciences to produce new drugs, devices, and treatment options for patients.”<sup>90</sup>

In reality, financial responsibility for basic research and translational research is divided less neatly than the conventional wisdom posits. Businesses have long sponsored a good deal of basic research, and in recent decades their share of the burden has increased:

Data from ongoing surveys by the National Science Foundation (NSF) show that federal agencies provided only 44% of the \$86 billion spent on basic research in 2015. The federal share, which topped 70% throughout the 1960s and '70s, stood at 61% as recently as 2004 before falling below 50% in 2013.<sup>91</sup>

Pharmaceutical companies have stepped up their investment in basic research: Drug-company investment in basic research soared from \$3 billion in 2008 to \$8.1 billion in 2014, according to the most recent NSF data by business sector. Spending on basic research by all U.S. businesses nearly doubled over that same period, from \$13.9 billion to \$24.5 billion.<sup>92</sup> Funding by universities and private foundations has also increased.<sup>93</sup>

The second component of the conventional wisdom—that the private sector bears the cost of translational research—appears to be sounder. In 2015, \$316 billion was spent on development, “[a]lmost all” of which was

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89. Rahul K. Nayak, Jerry Avorn & Aaron S. Kesselheim, *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study*, BRIT. MED. J. 367, 367 (2019).

90. Steven H. Woolf, *The Meaning of Translational Research and Why It Matters*, 299 JAMA 211 (2008).

91. Jeffrey Mervis, *Data Check: U.S. Government Share of Basic Research Funding Falls Below 50%*, SCI. MAG. (Mar. 9, 2017), <https://www.sciencemag.org/news/2017/03/data-check-us-government-share-basic-research-funding-falls-below-50> [<https://perma.cc/EW3D-6WWJ>].

92. *Id.*

93. *Id.*

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funded by industry and done in house, as companies try to convert basic research into new drugs, products, and technologies that they hope will generate profits. (The pharmaceutical and biotech industry, for example, spent a total of \$102 billion on research and development in 2015, according to Research!America, an Arlington, Virginia–based advocacy group.)<sup>94</sup>

The public sector’s contribution to translational research on drugs may be more important than these figures indicate, however. Public funding tends to be supplied at key moments in the development process, to support essential academic research on specific drugs, and is associated with drugs of special therapeutic value.

Researchers have used patents to study the contributions made by public funding to the creation of new drugs, and found a trend toward increasing public-sector involvement<sup>95</sup>—consistent with “large manufacturers investing proportionally less in internal basic and translational research” as their business models shifted toward “purchasing drugs developed in start-up companies, many spun out of public sector research institutions.”<sup>96</sup>

A recent study focused on 248 novel drugs that received FDA approval from 2008 to 2017. In addition to scouring patents for signs that public-sector institutions were involved in late-stage research, they compiled their own drug-discovery histories and identified spin-off companies whose origins included publicly supported research. Their efforts revealed that 62 (25%) of the novel drugs

had documented late stage research contributions from a publicly supported research institution or spin-off company. Forty eight products (19% of all new drug approvals) had evidence of direct publicly supported research (table 1 and table 2). For all but one, the contributions were related to the drug’s initial discovery, synthesis, or other key intellectual property leading to a patentable invention. For 30 of these drugs, publicly supported research institutions directly held one or more of the key patents. Another seven drugs had direct publicly supported research origins, although the patents [] were held by a spin-off company.<sup>97</sup>

The drugs with late-stage public involvement included “the hepatitis C treatment sofosbuvir (Sovaldi) and other sofosbuvir-containing combination drugs [that] originated at Pharmasset, a spin-off company based on federally funded research performed at Emory University.”<sup>98</sup>

The same study found that public support was concentrated on drugs with special therapeutic importance. Drugs created with help from publicly supported research “were substantially more likely to receive FDA approval

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94. *Id.*

95. Nayak et al., *supra* note 89, at 368 (noting that “earlier analyses found public sector research institutions to be associated with the patents covering 4.6% of new molecular entities approved in 1981-90, 6.7% of new drugs approved in 1990-99, 9.0% of new molecular entities approved in 1988-2005, and . . . 13.6% of new molecular entities approved between 1990-2007”).

96. *Id.*

97. *Id.* at 371.

98. *Id.* at 372.

through one or more expedited development or review pathways . . . and to be first in class.”<sup>99</sup> They attributed the “flow of publicly funded research knowledge into the private sector for commercialization” to an increase in public funding for biomedical research and to Bayh-Dole.<sup>100</sup>

A different group of researchers assessed the importance of public support by studying the contribution NIH funding made to published research associated with 210 new molecular entities that received FDA approval from 2010 to 2016.<sup>101</sup> They located more than 2 million publications relating to these drugs, found that 600,000 “were associated with NIH-funded projects,” and further determined that the relevant projects received more than \$100 billion in funding. Their efforts showed that NIH funding contributed to the discovery of every new molecular entity, including the 84 that were first-in-class treatments.

Another study focused on the various models of public-private collaboration for 113 molecular and biologic drugs approved by the FDA between 2006 and 2016.<sup>102</sup> They also examined the same information for 39 failed drugs that the same companies pursued during the same time period. Approved drugs had an average of 60 original research papers. Failed drugs averaged only 13. The authors inferred that “approved drugs are often associated with a more robust data set provided by a large number of institutions.”<sup>103</sup> When they examined the affiliations of the researchers who produced the publications, they found that academics contributed significantly to 79% of the publications associated with newly launched biologics and to 76% of those associated with new molecular entities.<sup>104</sup>

This major contribution by “academics” held true for all companies and across all therapeutic areas. Conversely, top pharmaceutical companies published only 10% of the papers for biologic approvals and 13% for NME approvals, while all other institute types contributed 5% or less of the publications for biologics and NMEs. For failed drugs, academics contributed 72% of the pre-termination publications on biologic drugs and 60% on NMEs. The lower percent as compared to approved NMEs was largely made up by top pharmaceutical- and other pharmaceutical/biotech-company contributions with 19% and 16% for NMEs, respectively.<sup>105</sup>

By focusing on drugs rather than drug targets, the authors showed that academic researchers contribute significantly to translational research and are especially likely to focus on new drugs that are eventually approved.

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99. *Id.* at 373.

100. *Id.* at 374.

101. Ekaterina G. Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010–2016*, PROC. NAT’L ACAD. SCI. U.S. 1 (2018).

102. Xiong Liu, Craig E. Thomas & Christian C. Felder, *The Impact of External Innovation on New Drug Approvals: A Retrospective Analysis*, 563 INT’L J. PHARMACEUTICS 273 (2019).

103. *Id.* at 274.

104. *Id.* at 276.

105. *Id.* at 280.

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The studies summarized in this section describe a complicated state of affairs in which both public and private organizations make important contributions to the discovery of new medications. Although businesses appear to spend more dollars on research overall, the public's contribution is sizeable, and the research it supports is disproportionately important.

Given this factual background, how should we think about the merits of the paying-twice critique? What, if anything, needs to be done about this situation? Part III turns to that issue.

### III. A Framework for Thinking About the Paying-Twice Critique

The paying-twice critique has considerable intuitive appeal, which helps explain why it has been a policy perennial. Yet that intuitive appeal does not necessarily translate into well-founded policy because there are additional considerations that the paying-twice critique obscures or ignores.<sup>106</sup> To clarify those issues, we begin with a short parable. We then discuss the inherent difficulty of quantifying the importance of contributions from multiple sources in the absence of a market where *ex ante* bargaining can occur. Finally, we offer a prize system as a possible solution to the problem of high drug prices—a solution that would incentivize drug development, address the paying-twice critique, and avoid the deadweight losses that monopolies create.

#### *A. Parable of the Austin Convention Center*

While working on this Article, one of us happened to walk past the Austin Convention Center—a handsome building that was built from 1990 through 1992 and subsequently renovated from 1999 through 2002 using only public funds. In May 2019, the Austin City Council unanimously approved spending \$1.2 billion more to expand the Convention Center yet again.

Like all convention centers, the Austin facility is surrounded by hotels and restaurants, including some very expensive offerings. The presence of the Convention Center obviously increases the demand for these hotels and restaurants. A large number of people will converge on Austin to attend events held at the Convention Center, each looking for places to stay and to eat. In economic terms, the city of Austin created a positive externality by building the Convention Center, as well as some negative externalities due to traffic and congestion. Alternatively, to the extent the Convention Center is nonrival and nonexcludable, the city of Austin was simply investing in a public good.<sup>107</sup>

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106. See Wolitz, *supra* note 5, at 185-89 (noting the complexities of the paying-twice critique, and offering three distinct lenses for thinking about the issue).

107. To the extent the city of Austin is able to exclude, the Convention Center is more properly viewed as a club good, rather than a public good. On the difference between public goods and club goods, see Patrick McNutt, *Public Goods and Club Goods*, in *ENCYCLOPEDIA OF LAW AND ECONOMICS* § 0750, at 927 (Boudewijn Bouckaert and Gerrit De Geest eds., 1999), <https://reference.findlaw.com/lawandconomics/literature-reviews/0750-public-goods-andamp-club->

What should we make of the fact that Austin taxpayers paid for the Convention Center? More specifically, do these circumstances provide a valid basis for capping the amounts that hotels and restaurants near the Convention Center can charge for their wares? For requiring those hotels and restaurants to offer a lower price to residents of Austin? For taxing people who stay in hotels and eat at restaurants near the convention center? For taxing people who stay in hotels and eat in restaurants in Austin more generally—or in Travis County, where Austin is located? Or should the city of Austin view a convention center as an infrastructure investment to be funded solely by the taxpayers?

As it happens, Austin partially funds the Convention Center by imposing a dedicated tax on all hotel stays, whether near the Convention Center or not.<sup>108</sup> By contrast, Austin does not impose a dedicated tax on restaurants to fund the Convention Center. More importantly, Austin does not impose a price cap on the amounts that hotels and restaurants can charge or attempt to ensure that they are charging only reasonable amounts, even when the customers are only in town because of an event being held at the Convention Center.

Why do we open this Section with a case study of the Austin Convention Center? Our parable makes several important points:

(1) For pure public goods, which are nonrival and nonexcludable, the public should not expect users to materially contribute to funding.<sup>109</sup> Stated differently, for such goods, there is likely to be one principal payer—i.e., the taxpayers.

(2) For products and services that have elements of a public good but are to varying degrees rivalrous and excludable (like the Austin Convention Center), there are likely to be multiple payers, with the precise details of their contributions varying depending on institutional dynamics and politics.

(3) If we want to ensure that the public receives a fair return on whatever funds it has invested in nonpublic goods (and we should), it is unlikely that the optimal strategy for doing so is to require reasonable pricing of the products and services that benefit directly or indirectly from those investments. Imposing and enforcing a reasonable-pricing constraint requires taxpayers to fund a complex administrative system to monitor and adjust prices. The history

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goods.html [<https://perma.cc/NNH6-JUKV>]. However, in our experience, convention centers and sports stadiums are largely or entirely publicly funded. This suggests that ordinary citizens and sports fans (but not economists) think of these facilities as public goods, which are appropriately funded entirely with public funds.

108. A fight is currently brewing over whether Austin has gobbled up more than its share of hotel-stay taxes, at the expense of Travis County, which wants to expand its own exposition center. Cindy Widner, *City Tackles Convention Center Expansion with Hotel Tax Rate Hike*, CURBED AUSTIN (Aug. 12, 2019), <https://austin.curbed.com/2019/8/12/20802030/austin-hotel-tax-rate-increase> [<https://perma.cc/Z7DC-PSC2>].

109. Although the Austin Convention Center is a club good, most people seem to believe such facilities are public goods. *See supra* note 107.

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of price-setting is not one that inspires confidence, even if one does not factor technological change and the public-choice dynamics into the equation.<sup>110</sup>

It is not an accident that we do not observe government-imposed price constraints on either hotels or restaurants, even in the area immediately surrounding the Austin Convention Center.

Our parable also points to a plausible set of regulatory responses to the circumstances we confront when the government contributes to the development of a valuable product or service. One approach (exemplified by Austin's tax on hotels) is to allow the market to set prices for the desired goods and services and then tax the producers to secure a reasonable return on the government's investment.<sup>111</sup> An alternative approach (exemplified by Austin's nontaxation of restaurants) is to treat the Convention Center as a public good that must be funded by the government if it is to exist at all, and the benefits to the restaurants as a positive externality that need not be recouped.

Of course, we should not be naïve about the larger context in which these cost-allocation decisions are being made. Austin opts for one approach (taxing hotel stays) when dealing with people who are from out-of-town and another (not taxing meals bought at restaurants) when people are more likely to be residents who vote in local elections.<sup>112</sup> Regardless, both of these approaches

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110. ROBERT L. SCHUETTINGER & EAMONN F. BUTLER, FORTY CENTURIES OF WAGE AND PRICE CONTROLS: HOW NOT TO FIGHT INFLATION (2014).

111. Cf. Wolitz, *supra* note 5, at 185 (noting that from a transactional perspective, the paying twice critique could be addressed by imposing "additional fees, royalties, or the repayment of the government's initial investment," rather than through pricing control).

112. Of course, these patterns are not unique to Austin, nor to the funding of convention centers. In California, pursuant to Proposition 13, residential property tax valuation for newcomers is based on the market price of the property. For incumbents, valuation may not increase more than a specified amount per year, regardless of actual market prices. In practice, this approach dramatically increases the property tax burden on newcomers—which is why it is called the "welcome stranger" approach. Gale A. Norton, *The 'Welcome Stranger' Provision of Prop. 13 Clearly Is Unwelcome*, L.A. TIMES (Feb. 9, 1989), <https://www.latimes.com/archives/la-xpm-1989-02-09-me-2894-story.html> [<https://perma.cc/KR2R-TSUT>] ("[C]onsider two homes that were each worth \$100,000 in 1975. One home has frequent turnovers while the other remains in the same ownership. Assuming that home prices increase 7% per year, the transferred house would have a taxable value of more than \$750,000 in the year 2005. The assessed value of the other house, increasing at only 2% a year, would be listed on the assessment rolls at about \$180,000."). The Supreme Court upheld California's "welcome stranger" approach in *Nordlinger v. Hahn*, 505 U.S. 1 (1992).

There are similar disparities with the price of car rentals at airports versus in-town:

I've covered the travel industry for quite a few years, and am well aware that airport rental car counters gouge customers with high rates and even higher taxes and mandatory fees. The blame for this doesn't necessarily fall on greedy rental car companies. Instead, a big part of the explanation for this situation is that the most (only?) popular tax is one that's not paid by the people approving of it. Politicians and voters around the country routinely approve new or higher taxes and fees on airport rental cars and hotel rooms—which, by and large, hit visiting travelers rather than locals in the pocketbook.

It's a different story at neighborhood rental car locations, however. In these spots, the typical customer is someone who lives in the area—and who would be outraged and have an earful to give to the local lawmakers if the taxes and fees were insane.

Brad Tuttle, *The Surprising Way I'm Saving \$1,800 on My Rental Car This Summer*, MONEY (June 23, 2016), <https://money.com/save-money-rental-car-airport> [<https://perma.cc/F88Y-8Y79>].

are far easier to administer and to adjust to changing circumstances than the reasonable-pricing model envisioned by proponents of the paying-twice critique.

Of course, the Austin Convention Center is not a drug, let alone a lifesaving one. But even for goods and services that are necessities of life, the same basic analysis should apply. Believing otherwise will not work out well for anyone involved—least of all those who want to obtain the next generation of lifesaving drugs. Section III.B situates this problem in a broader theoretical framework.

### *B. Theoretical Framework*

Stepping back from the details of our case study of the Austin Convention Center, there are endless examples of multiple parties contributing to the creation of a valuable asset. Some of these assets are trivial while others are vital contributors to human health and wealth.

How should the law go about sorting out the relative contributions of each of these parties, thereby ensuring that they receive what they are due? Contracts provide the most obvious solution, at least when the parties are able to negotiate *ex ante*. Individuals that are starting a business together can choose their corporate form (e.g., corporation, partnership or LLC, for-profit or nonprofit) and allocate ownership interest based on their *ex ante* agreement of the relative value of the assets contributed by each party. For some transactions and circumstances, sweat equity or political connections will be highly valued, while for others, it is cash or hard assets that are more important to the success of the enterprise. Some individuals will want equity, while others will prefer debt. Some employees will want stock options, while others will prefer salary. Salary may be tied to success, to hours worked, or to both. And so on.

If the parties have not negotiated a binding agreement, or if the agreement they negotiated is silent on the issue in question, the law has developed various default rules for sorting out such matters. For example, the Uniform Commercial Code (UCC) provides gap-fillers in the event the parties did not explicitly contract as to any element other than quantity.<sup>113</sup> More broadly, the law of restitution is designed to prevent unjust enrichment of one party at the expense of the other.<sup>114</sup>

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113. Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 *YALE L.J.* 87, 95-96 (1989) (“Although price and quantity are probably the two most essential issues on which to reach agreement, the U.C.C. establishes radically different defaults. If the parties leave out the price, the U.C.C. fills the gap with ‘a reasonable price.’ If the parties leave out the quantity, the U.C.C. refuses to enforce the contract.”); Omri Ben-Shahar, *‘Agreeing to Disagree’: Filling Gaps in Deliberately Incomplete Contracts*, 2004 *WIS. L. REV.* 389, 389 (observing that the UCC “aggressively supplements the parties’ agreement with reasonable or average terms, including price terms”).

114. RESTATEMENT (THIRD) OF RESTITUTION AND UNJUST ENRICHMENT § 1 (AM. L. INST. 2011) (“A person who is unjustly enriched at the expense of another is subject to liability in restitution.”).

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Once again, as with our parable of the Austin Convention Center, the takeaway is simple. When parties are able to negotiate with one another in advance, they reach terms that reflect the relative value of their anticipated contributions to the joint enterprise. In the absence of an *ex ante* contract that speaks to the issue, the legal system has developed various default rules—again seeking to capture the terms the parties would have negotiated if transaction costs were low and they had thought about the issue. In the context of the drug-pricing issue, it is simply implausible that the government could insist on reasonable pricing for all drugs where the government had any involvement whatsoever in the underlying R&D process.

Worse still, history shows conclusively that price controls create shortages which governments then try to fix by ad hoc means, such as subsidizing the discouraged activity. In the case of the pharmaceutical industry, these subsidies go to research and development. . . . Again, however, the difficulty arises in choosing the level of the subsidy, deciding whether and how to award it to for-profit corporations, and avoiding inefficient lobbying and corruption. In practice, these are very difficult issues to manage in a way that benefits consumers.<sup>115</sup>

It is not an accident that the NIH's attempts to insist on a reasonable-pricing term from 1989 to 1995 prompted many pharmaceutical companies to walk.<sup>116</sup> Their departures led the NIH to drop this term from its contracts, observing that its inclusion was detracting from the goals set by Bayh-Dole.<sup>117</sup>

If the government wants a better deal than the one struck by Bayh-Dole, the obvious solution (as long as we are maintaining the current patent-based system) is to demand a royalty reflecting the risk-adjusted value of the licensed technology. Those funds can be used to defray the cost of future publicly funded research (reducing the paying-twice problem going forward) or to subsidize the treatment costs of everyone who needs the drug in question. Alternatively, the government can take the royalty in the form of a price reduction for beneficiaries of government-funded programs. Finally, the money could be deposited into the general fund and be used for whatever purpose Congress desires. Any of these royalty-based strategies are far more achievable and administrable than the reasonable pricing model proposed by the paying-twice crowd.

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115. Fiona M. Scott Morton, *The Problems of Price Controls*, CATO INST. (June 20, 2001), <https://www.cato.org/publications/commentary/problems-price-controls> [<https://perma.cc/PDS8-CEDU>].

116. See NAT'L INSTS. OF HEALTH, *supra* note 14 ("Many companies withdrew from any further interaction with NIH because of this stipulation.").

117. *Id.* ("Both NIH and its industry counterparts came to the realization that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act.").

*C. A Better Alternative: Prize-Based Reform*

As we explain in more detail in *Overcharged*, the existing patent-based system has both strengths and weaknesses.<sup>118</sup> Its main strength is that patents encourage inventors to bear the costs and risks associated with discovering new drugs. Its main weaknesses are two. First, because the strength of the incentive to innovate depends on the volume of sales, patents fail to incentivize drugmakers to create therapies for illnesses suffered by small populations. Second, the patent-created sales monopolies often enable inventors to charge supra-competitive prices and impose substantial deadweight losses, as many consumers who value drugs above the marginal cost of production are excluded from the market.

Existing arrangements for paying for prescription drugs create additional problems. Because Medicare, Medicaid, and private insurers have difficulty refusing to pay for therapies approved by the FDA, drugmakers can set prices above the monopoly level that would prevail if consumers purchased drugs directly. The absence of a ceiling on prices encourages drugmakers to create new medicines that are only marginally better than existing treatments yet extremely expensive.

Like other authors, we believe that prizes can ameliorate these problems and the option of replacing the patent-based system, including the Bayh-Dole Act, the Orphan Drug Act, and the Unapproved Drugs Initiative, with a system based on prizes should be seriously considered.<sup>119</sup> Prizes would “separate the market for products from the market for innovations by removing the link between R&D incentives and product prices.”<sup>120</sup> In the latter market, all companies would be free to manufacture and sell newly discovered drugs, just as they are able to produce generic medicines today. Competition would reduce drug prices to their lowest sustainable levels, eliminating the deadweight losses associated with patents.

The competition spurred by a prize regime would also make it much harder for drug companies to set inflated prices. When Gilead introduced Sovaldi, it could charge \$84,000 for a course of treatment because it had a guaranteed market.<sup>121</sup> Medicare had to buy Sovaldi for seniors with hepatitis C and could not bargain over the price.<sup>122</sup> Private insurers and Medicaid had somewhat greater leverage, especially when alternatives like the Viekira Pak became available, but they too paid through the nose.<sup>123</sup> Under a prize regime, Gilead wouldn't have been able to charge more than the marginal cost of

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118. SILVER & HYMAN, *supra* note 24, at 27-30, 35, 40.

119. For sources, see James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANN. HEALTH L. 155, 156 n.3 (2009).

120. *Id.* at 159.

121. See SILVER & HYMAN, *supra* note 24, at ch. 2.

122. *Id.* at 55.

123. *Id.* at 56.

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production since any other company could supply the drug. Payors could even run an auction to determine which manufacturer would have the right to supply Sovaldi to their beneficiaries.

Substituting prizes for patents would also make it possible to rationalize the financial incentives for developing new drugs. Currently, expected prices and sales volumes determine the strength of these incentives. This arrangement encourages pharmaceutical companies to create new cancer treatments that retail for hundreds of thousands or even millions of dollars despite extending patients' lives only briefly.<sup>124</sup> By contrast, it gives them little reason to develop new antibiotics with the potential to save lives because doctors will use these new drugs only when all existing antibiotics fail.<sup>125</sup> By linking rewards to “the impact of innovations on health care outcomes,” prizes could focus researchers' energies on drugs that are needed.<sup>126</sup>

A prize system also would eliminate the need for programs which use the prospect of earning monopoly rents, tax breaks, and other emoluments to encourage researchers to develop treatments for uncommon diseases (i.e., the Orphan Drug Act (ODA)) and establish the efficacy and safety of drugs that were on the market before testing requirements were imposed (i.e., the FDA's unapproved drugs initiative (UDI)). The ODA entitles manufacturers to seven years of marketing exclusivity on drugs prescribed for the orphan indication; the UDI gives them three for all prescriptions.

Pharmaceutical companies have gamed both programs. In the case of colchicine, an ancient treatment for gout (a common illness) that also helps patients with familial Mediterranean fever (a rare one), a drugmaker secured 3 years of marketing exclusivity under the UDI and 7 years under the ODA after conducting a small controlled trial on gout sufferers. After the FDA ordered all other manufacturers to stop producing colchicine, the monopoly-holder raised the price from \$0.09 per tablet to \$5—illustrating the adverse (but almost entirely off-budget) consequences of casually handing out market exclusivity. The government could have completely avoided these consequences by offering a small prize for running tests on colchicine.<sup>127</sup>

Drug companies routinely game the ODA by using it to obtain monopolies on drugs that are eventually sold to large populations. For example, Reckitt Benckiser is said to have used the ODA in an “alarming” manner by

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124. Alice Chen & Dana Goldman, Opinion, *Accounting for Hope: Using 'Mean Survival Gain' to Price New Cancer Drugs*, STAT NEWS (Oct. 14, 2019), <https://www.statnews.com/2019/10/14/mean-survival-gain-pricing-cancer-drugs> [<https://perma.cc/P8WL-FNJJ>]; Meghana Keshavan, *Fixing a 'Market Failure': To Develop New Antibiotics, Upend the Incentive Structure, Experts Urge*, STAT NEWS (May 2, 2019), <https://www.statnews.com/2019/05/02/fixing-a-market-failure-to-develop-new-antibiotics-upend-the-incentive-structure-experts-urge> [<https://perma.cc/A3TP-AGL3>].

125. *Id.*

126. Love & Hubbard, *supra* note 119, at 159.

127. Aaron S. Kesselheim et al., *Reductions in Use of Colchicine After FDA Enforcement of Market Exclusivity in a Commercially Insured Population*, 30 J. GEN. INTERNAL MED. 1633 (2015).

misleading the FDA about the potential profitability of a treatment for Opioid Use Disorder.<sup>128</sup> It reportedly obtained seven years of marketing exclusivity by telling the FDA that “its Subutex (buprenorphine) and Suboxone (buprenorphine-naloxone) tablets wouldn’t recoup their costs of development.”<sup>129</sup> In fact, both drugs were so profitable that, in response to complaints from generic pharmaceutical companies, the FDA revoked their orphan status.<sup>130</sup>

More recently and appallingly, Gilead gamed the ODA by obtaining orphan status for remdesivir, a drug being studied as a treatment for COVID-19. “Orphan status is generally reserved for companies that may not recoup their research costs and for drugs which treat conditions affecting fewer than 200,000 people.”<sup>131</sup> The number of Americans alone who might eventually contract COVID-19 could easily run into the millions, the worldwide market for remdesivir could be far larger, and analysts at Bank of America predicted that remdesivir would generate \$2.5 billion in revenue.<sup>132</sup> But at the time Gilead applied, fewer than 200,000 Americans had been diagnosed with the disease, so remdesivir satisfied the technical regulatory requirement.<sup>133</sup> Even so, and not at all surprisingly, the FDA’s approval of Gilead’s application sparked widespread outrage. Some critics lodged the paying-twice complaint, pointing out that “Gilead developed remdesivir with at least \$79 million in government funds.”<sup>134</sup> The firestorm of criticism was so intense that Gilead quickly capitulated and withdrew its application. In its public statement, the company claimed to have sought orphan status for remdesivir so that it would not have to conduct “a pediatric study plan prior to the submission of a New Drug Application—a process that can take up to 210 days to review.”<sup>135</sup>

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128. Rebecca L. Haffajee & Richard G. Frank, *Abuses of FDA, Regulatory Procedures — The Case of Suboxone*, 382 NEW ENG. J. MED. 496 (2020).

129. *Id.*

130. *Id.*

131. Julia Conley, ‘Big Win’: Caving to Pressure Campaign, Gilead Sciences Relinquishes Monopoly Claim for Promising Coronavirus Treatment, COMMON DREAMS (Mar. 26, 2020), <https://www.commondreams.org/news/2020/03/26/big-win-caving-pressure-campaign-gilead-sciences-relinquishes-monopoly-claim> [<https://perma.cc/3LFU-2UU7>]. For background on the ODA, see *Developing Products for Rare Diseases and Conditions*, U.S. FOOD & DRUG ADMINISTRATION (Dec. 20, 2018), <https://www.fda.gov/industry/developing-products-rare-diseases-conditions> [<https://perma.cc/D9B2-V7QT>].

132. Drew Armstrong & Bailey Lipschultz, *Gilead Stock Surges After WHO Comments on Its Coronavirus Drug*, ALJAZEERA IMPACT (Feb. 24, 2020), <https://www.aljazeera.com/ajimpact/gilead-stock-surges-comments-coronavirus-drug-200224194452522.html> [<https://perma.cc/V8KW-322H>].

133. Matthew Brown, *Fact Check: Drugmaker Gilead Sciences Claimed Right to a Possible COVID-19 Treatment*, USA TODAY (Mar. 27, 2020), <https://www.usatoday.com/story/news/factcheck/2020/03/27/fact-check-coronavirus-gilead-sciences-received-withdrew-fda-orphan-status-remdesivir/2922115001> [<https://perma.cc/WM92-25M5>].

134. Conley, *supra* note 131.

135. Company Statement, Gilead Scis., 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> [<https://perma.cc/2P3Y-H3GZ>].

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Manufacturers also game the ODA by obtaining “multiple orphan drug designations for the same drug in different diseases.”<sup>136</sup> They then stack their “seven-year monopolies on top of each other and protect their exclusivity in the initial disease indication for far longer than the statute originally intended.”<sup>137</sup> Another tactic is to use ODA to lengthen the normal duration of exclusivity on patented drugs. “[M]any companies find new applications for major drugs that have been around for a long time and then seek the extension. One example, Rituxan, has obtained seven orphan approvals—meaning seven additional uses—and now has exclusivity until June 2025.”<sup>138</sup> An investigation by Kaiser Health News “found that popular mass-market drugs such as cholesterol blockbuster Crestor, Abilify for psychiatric conditions, cancer drug Herceptin and rheumatoid arthritis drug Humira, the best-selling medicine in the world, all won orphan approval yet were already on the market to treat common conditions.”<sup>139</sup>

By employing tactics like these, manufacturers have generated enormous revenues. In 2015, 7 of the 10 drugs that achieved blockbuster status with sales exceeding \$1 billion were approved as orphans but were then routinely prescribed by physicians for off-label uses.<sup>140</sup> “Scholars at Johns Hopkins estimate that in 2015, revenue from orphan drugs totaled \$107 billion, representing one-quarter of all U.S. drug revenues []. They project that share to approach one-third of drug spending in 2020, representing \$176 billion in orphan sales.”<sup>141</sup> By eliminating marketing exclusivity and rendering pharmaceutical companies’ stratagems useless, a prize system could bring down drug costs significantly.<sup>142</sup>

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136. Avik Roy, *The Competition Prescription: A Market-Based Plan for Affordable Drugs*, FOUND. FOR RES. ON EQUAL OPPORTUNITY 12 (May 16, 2017), <https://freopp.docsend.com/view/cfaqar8> [<https://perma.cc/MPB4-CDHN>].

137. *Id.*

138. Erik Sherman, *Big Pharma Companies Use Loophole on Old Drugs for New Profits*, FORTUNE MAG. (Feb. 19, 2019), <https://fortune.com/2019/02/19/orphan-drug-loopholes> [<https://perma.cc/2P6J-RBB4>].

139. Sarah J. Tribble & Sydney Lupkin, *Government Investigation Finds Flaws in the FDA’s Orphan Drug Program*, KAISER HEALTH NEWS (Nov. 30, 2018), <https://khn.org/news/government-investigation-finds-flaws-in-the-fdas-orphan-drug-program> [<https://perma.cc/U7S8-U88D>]; see also Sarah J. Tribble & Sydney Lupkin, *Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies*, KAISER HEALTH NEWS (Jan. 17, 2017), <https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies> [<https://perma.cc/NF5R-7GXR>].

140. Michael G. Daniel et al., *The Orphan Drug Act: Restoring the Mission to Rare Diseases*, 39 AM. J. CLINICAL ONCOLOGY 210, 211 (2016).

141. Roy, *supra* note 136, at 12 (citing Daniel et al., *supra* note 134, at 211).

142. We have focused on the ways that pharmaceutical companies have gamed the UDI and UDA, but there is no shortage of similar examples of strategic behavior in other contexts (e.g., reverse payments, product hopping, authorized generics, Orange Book listings, citizens petitions, and the like). As these examples individually and collectively reflect, pharmaceutical companies expertly manipulate our regulatory system to extend the functional life of their patents. A prize system would eliminate the incentive and opportunity to engage in such behavior. It would also eliminate the need for patent-infringement suits by disposing with the patents that are the subject of such litigation.

A prize system could also encourage the development of medicines that are not needed currently but that would be valuable to have available for a possible epidemic. Remdesivir, discussed above, provides an example. Remdesivir is a multipurpose antiviral developed to combat dengue fever, West Nile virus, Zika, MERS, SARS, and Ebola.<sup>143</sup> However, remdesivir was never approved by the FDA, apparently because Gilead, the patent holder, saw too little financial gain to warrant the cost of applying. Had a prize regime been in place, the NIH might have motivated Gilead to perform clinical trials on remdesivir's effectiveness against a variety of coronaviruses. The NIH might also have incentivized other drug companies to develop other, more effective molecules. From this perspective, the paying-twice critique has some bite. But consumers' second payment is not at the pharmacy counter. Instead, consumers pay the opportunity costs of drugs and other treatments that never come to market—or come to market too late—because our patent-based system provides inadequate incentives to do so.

The idea of using government-sponsored prizes to spur innovation is an old one. The most famous example, memorialized in Dava Sobel's bestselling book *Longitude: The True Story of a Lone Genius Who Solved the Great Scientific Problem of His Time*, is the prize the government of Great Britain offered for the development of an instrument that would enable mariners to determine their longitude at sea.<sup>144</sup> Other instances include the Food Preservation Prize, which led to the invention of canning, and the French government's offer of cash to anyone who discovered a cure for Phylloxera, a disease that ravaged vineyards.<sup>145</sup> Private philanthropies and businesses have offered prizes for achieving progress toward a diverse array of goals, including “ending human trafficking, reducing American dependency on foreign oil, reducing smoking and obesity rates, improving African governance, providing clean water in the developing world, inspiring and educating children about technology, and improving collaboration among nonprofits.”<sup>146</sup>

There is much that can be learned by studying these efforts. Mission-driven private philanthropies and businesses can resist the efforts of influence-

143. See Brown, *supra* note 133; Lee Fang, *Banks Pressure Health Care Firms to Raise Prices on Critical Drugs, Medical Supplies for Coronavirus*, INTERCEPT (Mar. 19, 2020), <https://theintercept.com/2020/03/19/coronavirus-vaccine-medical-supplies-price-gouging> [<https://perma.cc/EW34-4HUV>].

144. DAVA SOBEL, *LONGITUDE: THE TRUE STORY OF A LONE GENIUS WHO SOLVED THE GREATEST SCIENTIFIC PROBLEM OF HIS TIME* (1995).

145. For a list of prizes of historical interest, their sponsors, and their winners, see William A. Masters & Benoit Delbecq, *Accelerating Innovation with Prize Rewards: History and Typology of Technology Prizes* (Int'l Food & Policy Research Inst., IFRI Discussion Paper 00835, 2008), <http://cdm15738.contentdm.oclc.org/utills/getfile/collection/p15738coll2/id/15644/filename/15645.pdf> [<https://perma.cc/QW3H-XWQJ>].

146. “*And the Winner Is . . .*”: *Capturing the Promise of Philanthropic Prizes*, MCKINSEY & CO. 11-12 (2009), <https://www.mckinsey.com/~media/McKinsey/Industries/Social%20Sector/Our%20Insights/And%20the%20winner%20is%20Philanthropists%20and%20governments%20make%20prizes%20count/And-the-winner-is-Philanthropists-and-governments-make-prizes-count.ashx> [<https://perma.cc/L2C5-NZ87>].

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peddlers more readily than governments and are strongly motivated to design prizes that generate desired effects.

What about prizes for improvements in health care? In medicine, privately funded prizes “have been used since the 1800s to incentivize and/or reward R&D.”<sup>147</sup> Many were offered to stimulate research on treatments for tuberculosis. Drugmaker “Eli Lilly developed a program of small prizes to address discrete challenges that were part of larger efforts on drug development. This was later spun off as InnoCentive, a for-profit entity that currently manages hundreds of prize competitions, many of which involve biomedical inventions.”<sup>148</sup> In addition to tuberculosis, the research areas targeted include cancer, sexually transmitted infections, aging, ALS, and genome sequencing.

What about pharmaceuticals? Proposals for a pharmaceutical prize-based system have gained traction in recent years. In 2007, Professor Joseph Stiglitz floated the idea in a two-page paper.<sup>149</sup> Senator Bernie Sanders then proposed a bill in 2012 to use prizes, rather than patents, for AIDS drugs.<sup>150</sup> In 2017, Ohio State Representative Jim Butler advocated for a general prize-based system. He “proposed having Ohio take the lead in creating a new multi-state compact that would offer billions in cash prizes to those who develop actual cures for major diseases.”<sup>151</sup> The compact would tie the amount offered for a drug to the money that drug saved over a period of years.<sup>152</sup> For example, the inventor of a cure for Alzheimer’s Disease might receive \$12 billion to \$25 billion.<sup>153</sup> Ingeniously, Rep. Butler suggested that the money needed to fund the prizes should come from the states’ Medicaid programs, which would redirect to inventors the money previously spent on services for patients.<sup>154</sup> This would both eliminate the need for a new appropriation and protect the participating states from losses. They would pay out only when they saved money, and the amount paid would never exceed the amount saved.

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147. *Treating Rare and Neglected Pediatric Diseases: Promoting the Development of New Treatments and Cures: Hearing on Examining Treating Rare and Neglected Pediatric Diseases, Focusing on Promoting the Development of New Treatments and Cures Before the S. Comm. on Health, Educ., Labor & Pensions*, 111th Cong. 125 (2010) (statement of Suerie Moon, Bd. Member, Doctors Without Borders USA).

148. *Id.*

149. Joseph E. Stiglitz, *Prizes, Not Patents*, 42 *POST-AUTISTIC ECON. REV.* 46, 46-47 (2007).

150. Brian Vastag, ‘Radical’ Bill Seeks to Reduce Cost of AIDS Drugs by Awarding Prizes Instead of Patents, *WASH. POST* (May 19, 2012), [https://www.washingtonpost.com/national/health-science/radical-bill-seeks-to-reduce-cost-of-aids-drugs-by-awarding-prizes-instead-of-patents/2012/05/19/gIQAEGfabU\\_story.html](https://www.washingtonpost.com/national/health-science/radical-bill-seeks-to-reduce-cost-of-aids-drugs-by-awarding-prizes-instead-of-patents/2012/05/19/gIQAEGfabU_story.html) [<https://perma.cc/8DDQ-HVER>].

151. Jim Siegel, *Ohio Lawmaker Wants to Offer Billions for Cure of Cancer, Other Major Diseases*, *COLUMBUS DISPATCH* (Sept. 12, 2017), <https://www.dispatch.com/news/20170912/ohio-lawmaker-wants-to-offer-billions-for-cure-of-cancer-other-major-diseases> [<https://perma.cc/6ZGS-8257>].

152. *Id.*

153. *Id.*

154. *Id.*

There is strong support for publicly sponsored prizes. In 1999, the National Academy of Engineering “recommended that Congress encourage federal agencies to experiment more extensively with inducement prize contests in science and technology.”<sup>155</sup> Soon thereafter, the Pentagon’s Defense Advanced Research Projects Agency offered a \$1 million prize for the development of self-driving vehicles.<sup>156</sup> NASA picked up the baton in 2005 and created its Centennial Challenges program, which seeks “to directly engage the public in the process of advanced technology development.”<sup>157</sup> In 2011, the America Competes Reauthorization Act, “which allowed all federal agencies to set up challenges,” led to the creation of *Challenge.gov*. As of 2017, federal agencies had established more than 770 competitions, several of which, such as those for creating vascular tissue *in vitro* and for producing an app for reading medical records, related to health care.<sup>158</sup>

HHS actively sponsors prizes. Between 2011 and 2017, it ran 140 competitions spawning a variety of inventions, including:

apps that speed identification of dangerous pathogens or respond to asthma attacks, [] wearables that collect health data, and improve[d] patient matching through electronic records. The competitions have fostered dozens of new companies and partnerships. A Breast Cancer Startup Challenge, funded partly by the Avon Foundation and private NGOs, encouraged inventors to develop products from the National Institutes of Health’s collection of patents related to the disease. Eleven companies have been started as a result. An NIH Debut challenge, aimed at firing up undergraduate scientists, led to a prototype device for measuring lung function that plugs into a smartphone. . . . The U.S. Agency for International Development provided \$2 million to its Fighting Ebola Grand Challenge, which drew 1,500 proposals and led to development of new diagnostics, tracking apps and protective equipment for health workers, including cool packs allowing them to comfortably treat Ebola patients while wearing hazmat suits.<sup>159</sup>

There is plenty of opportunity for new prizes as well. In 2017, the NIH announced a \$1 million prize for creating a process to grow human retinal tissue.<sup>160</sup> In 2020, the NIH is running a \$100,000 challenge to generate ideas for the treatment of Substance Use Disorders.<sup>161</sup>

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155. NAT’L ACADS. OF SCIS., ENG’G & MED., CONCERNING FEDERALLY SPONSORED INDUCEMENT PRIZES IN ENGINEERING AND SCIENCE: REPORT OF THE STEERING COMMITTEE FOR THE WORKSHOP TO ASSESS THE POTENTIAL FOR PROMOTING TECHNOLOGICAL ADVANCE THROUGH GOVERNMENT-SPONSORED PRIZES AND CONTESTS 1 (1999).

156. Arthur Allen, *Government by Prize*, POLITICO (June 8, 2017), <https://www.politico.com/agenda/story/2017/06/08/federal-government-innovation-challenge-gov-000450> [https://perma.cc/2S6T-K5Q4].

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

161. Nat’l Insts. of Health, *\$100,000 for a Start a SUD Startup Challenge, 2020 Spring Edition*, CHALLENGE.GOV (2020), <https://www.challenge.gov/challenge/2020-1000000-start-a-sud-startup-challenge> [https://perma.cc/TWF5-XGN4].

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Although we have concentrated in this Article on using prizes for pharmaceuticals, these examples show that the potential is far broader and could encompass all the areas currently covered by Bayh-Dole. Indeed, a prize system has the potential to revolutionize the way public and private funds are used across the board, for all types of inventions. Because universities would no longer be able to patent discoveries made with public funds, as they have since the enactment of the Bayh-Dole Act in 1980, grants funded with tax dollars could require open access to all results, thereby eliminating trade-secret protections as well. Expensive acquisitions of spinoffs, like Gilead's \$11 billion purchase of Pharmasset, would disappear and with them, those acquisitions' effects of driving up drug prices and providing whopping private returns on research undertaken with public funds. The change would also facilitate cooperation among scientists because there would be little to gain by keeping secrets from others.

Prizes would pick up where grants leave off. With all publicly funded basic research in the public domain, private entrepreneurs would be free to take advantage of new discoveries when trying to develop the treatments for which prizes are on offer. Presumably, prizes would offer lucrative compensation to talented researchers who reach the goal before others. But researchers would have only their talents to sell, and private entities would bear costs and risks associated with the process of turning basic research into marketable drugs. Consumers would continue to fund research, but they would buy the resulting drugs far more cheaply.

Careful division of grants from prizes would also prevent researchers and pharmaceutical companies from working together to force third parties to carry the largest possible share of research costs. Under the current system, grants are all upside for the private sector. When experiments fail, they need not return the money, and when they succeed, researchers and drug companies can patent the discoveries. Even if we move to a prize system, researchers and pharmaceutical companies will have every incentive to milk the grant system for additional support. To address their use of "heads I win, tails you lose" strategies, grants and prizes would have to be coordinated.

Making a single government agency responsible for both grants and prizes would facilitate coordination. The NIH is the obvious candidate. It already sponsors both grants and prizes and has ready access to the information necessary for deciding which prizes to offer and how large they should be. Deciding which prizes to offer, fixing their amounts, defining their conditions, and evaluating success are complicated tasks requiring experts' informed judgments. For present purposes, though, the important point is that a prize regime could eliminate the concern that the prices charged for new medications compensate drug companies for costs and risks that taxpayers bore by funding relevant research. Prizes would be the only source of remuneration for inventors. Consequently, the burden of avoiding overcompensation would fall

to the agency charged with fixing the amount of the prize. All such decisions would be public—and paid out of the public fisc.

Because prizes would be funded with taxpayers' dollars, it is an open question whether the public's total financial contribution to drug development and consumption would fall if the patent system for pharmaceuticals was replaced. Although the likely answer is yes, the matter is too complicated to be resolved here. One must know, for example, how many prizes will be offered and how large they will be.<sup>162</sup> One must also attach dollar values to the deadweight losses that patents produce and reduce the cost of prizes accordingly. Finally, one would have to compare drug prices under the two regimes and decide how to account for the fact that a prize system makes the cost of pharmaceutical R&D the responsibility of the taxpayers, while our current patent-based system forces patients and their insurers (both public and private) to foot the bill. These matters require sophisticated assessments that have yet to be made and would be based on data that are not readily available.

That observation points to a final—but larger—problem. As with most areas of law and policy, we don't have the data to evaluate fully the consequences of abandoning the Bayh-Dole regime in favor of plausible alternatives. With a modest amount of work, anyone with an internet connection can figure out how much we are spending on federal funding of research and development. But it is much more difficult to figure out the returns on those expenditures. Is Bayh-Dole still a good deal for the taxing

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162. Even if we constitute an expert body to set the prizes, we should anticipate that they will make mistakes, sometimes offering too much and other times not offering enough. And the criteria for obtaining the prize will sometimes be too lax and other times too strict. All these targets will be set based on an assessment of the value of drug innovation (both in general and in particular areas), which are all highly contested judgments. If these decisions are left to the political process, there will be different (and likely additional) complications and error costs. Of course, hindsight is 20/20, but the reality is that we are dealing with comparative institutional imperfection. To believe otherwise is to indulge in the nirvana fallacy. See Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. ECON. 1, 1 (1969) ("The view that now pervades much public policy economics implicitly presents the relevant choice as between an ideal norm and an existing 'imperfect' institutional arrangement. This *nirvana* approach differs considerably from a *comparative institution* approach in which the relevant choice is between alternative real institutional arrangements.").

For those who want more concrete evidence on the difficulties with relying on experts, we have a one-word response: COVID-19. For those who prefer citations to the literature, we suggest Nicola Davis, *Report on Face Masks' Effectiveness for Covid-19 Divides Scientists*, GUARDIAN (May 4, 2020), <https://www.theguardian.com/world/2020/may/04/scientists-disagree-over-face-masks-effect-on-covid-19> [<https://perma.cc/4UJ6-RKCU>] (discussing disagreement among scientists regarding the efficacy of face coverings in preventing the spread of disease); John P.A. Ioannidis, Sally Cripps & Martin A. Tanner, *Forecasting for COVID-19 has Failed*, INT'L INSTITUTE FORECASTERS (June 14, 2020), <https://forecasters.org/blog/2020/06/14/forecasting-for-covid-19-has-failed> [<https://perma.cc/47NX-R2DP>] ("[D]espite involving many excellent modelers, best intentions, and highly sophisticated tools, forecasting efforts have largely failed. . . . Failure in epidemic forecasting is an old problem. In fact, it is surprising that epidemic forecasting has retained much credibility among decision-makers, given its dubious track record."); and Liz Essley Whyte, *Scientists Say New, Lower CDC Estimates of COVID-19 Severity Are Optimistic*, CTR. FOR PUB. INTEGRITY (May 22, 2020), <https://publicintegrity.org/health/coronavirus-and-inequality/scientists-say-new-lower-cdc-estimates-of-covid-19s-severity-are-optimistic> [<https://perma.cc/3247-8JAM>] (discussing changes over time in the CDC's "best-guess" estimates of the number of deaths from COVID-19 and disagreements among experts concerning the accuracy of its predictions).

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public? Without the necessary data, we have no idea. It is an old joke that the invariant finding of all studies is the need for more studies,<sup>163</sup> but in this instance, that observation happens to be right.

### Conclusion

The paying-twice critique is simultaneously far more complex and far less compelling than its proponents have acknowledged. Some publicly funded research is basic research that qualifies as true public goods. Other publicly funded research does not involve public goods, but even here the relative contribution of all parties (including the risks that each one bears) must be considered. Given these dynamics and past unhappy experiences with regulatory price setting, it is wholly implausible that the efficient solution to this complex problem is to require reasonable pricing for all comers.

That is not to say that all is well with the pharmaceutical market, for reasons that go well beyond the paying-twice problem. However, if we want to address the paying-twice problem, the obvious solution is to require the payment of a royalty reflecting the contribution of publicly funded research to the drug in question, with the precise details varying depending on the nature of those contributions and the risks borne by each of the parties.<sup>164</sup>

For those who favor more radical strategies, we argue in *Overcharged* that given our flawed patent and payment systems, even a flawed prize system is likely to do better.<sup>165</sup> “You pays your money and takes your choice.”<sup>166</sup>

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163. Editorial, *More Research Is Needed*, 9 ANNALS EPIDEMIOLOGY 17, 17 (1999) (“An old joke in epidemiology is that research papers always conclude with some variation of the statement, ‘more research is needed.’”).

164. See *supra* notes 117-118 and accompanying text.

165. SILVER & HYMAN, *supra* note 24, at 359.

166. William Safire, *On Language; You Pays Yer Money*, N.Y. TIMES (Feb. 28, 1988), <https://www.nytimes.com/1988/02/28/magazine/on-language-you-pays-yer-money.html> [<https://perma.cc/UW4U-DHBM>].