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### **PHARMA 101: A PRIMER**

The pharmaceutical industry is a behemoth. The global market for pharmaceuticals reached \$1.2 trillion in 2018.<sup>1</sup> Just one product—AbbVie’s Humira—had almost the same amount of sales that year as Southwest Airlines.<sup>2</sup> The U.S. accounts for more than 40 percent of the market (\$485 billion). Brand-name drugs represent just 10 percent of U.S. prescriptions but nearly 80 percent of spending.<sup>3</sup>

At its core, the brand-name business model is simple. The pharmaceutical industry uses government-funded research to help develop products that are protected by government-granted monopolies to sell to the government and other purchasers for exorbitant profits. To protect the rules tilted in its favor, the industry funnels enormous sums of money into political contributions and lobbying, employing more lobbyists than there are members of Congress.<sup>4</sup> It also uses charitable contributions and patient assistance programs to influence patient groups that might otherwise dissent.<sup>5</sup>

This primer provides an overview of the pharmaceutical industry. It uses sofosbuvir (Sovaldi), a cure for hepatitis C, as a case-study.<sup>6</sup> In 2014, Gilead set the price of drug at \$1000 a pill, or \$84,000 for a course of treatment, sparking outrage and ushering in a new era of exorbitant drug prices.

#### **KEY MESSAGES**

1. Privatizing Gains from Public Research: How Pharma Develops Drugs (Page 2)
  - Public funding plays a substantial role in the research and development of medicines
  - U.S. taxpayers are compensated by being charged the highest prices in the world
  
2. Abusing Monopoly Pricing Power: The Sale of Brand-Name Drugs (Page 3)
  - The central problem is the drug corporation’s ability to set high monopoly launch prices
  - Drug corporations increase prices for existing medicines, typically twice a year
  - Drug corporations protect their ability to price-gouge by extending monopoly privileges
  
3. Generic Competition Lowers Prices (Page 6)
  - Low-cost generic medicines have saved the health care system more than \$1 trillion
  - Making medicines affordable requires increasing government negotiating power, blocking price spikes, and curbing monopoly abuse
  - We can go further by elevating the public’s role in research and development

<sup>1</sup> IQVIA, The Global Use of Medicine in 2019 and Outlook to 2023. <https://tinyurl.com/yxptt9c9>

<sup>2</sup> Humira had sales of \$19.9 billion, compared to Southwest Airlines’ \$22.0 billion. Axios, <https://tinyurl.com/yc33ktm8>

<sup>3</sup> IQVIA, Global / US Generics and Biosimilars: Trends, Issues and Outlook (2019), <https://tinyurl.com/yysqatqy>

<sup>4</sup> Open Secrets, Pharmaceutical Industry, [https://www.opensecrets.org/lobby/induscode\\_lob.php?id=H4300&year=2018](https://www.opensecrets.org/lobby/induscode_lob.php?id=H4300&year=2018)

<sup>5</sup> See Public Citizen, Analysis Finds Misleading Claims About Patient Support in Letter Opposing Efforts to Reduce Prescription Drug Prices (finding that half the patient groups signing letter opposing Medicare Part D negotiation received industry financial support), <https://tinyurl.com/y3moa9xl>

<sup>6</sup> Truvada as PrEP—an HIV prevention drug used by less than 10 percent of those at-risk for HIV—provides another compelling case-study. See Public Citizen, Letter for the Record of House Oversight Committee Hearing on HIV Prevention Medication (2019), <https://tinyurl.com/y4oojggy>. See also, PrEP4All, Break the Patent, <https://breakthepatent.org/>

## I. PRIVATIZING GAINS FROM PUBLIC RESEARCH: HOW PHARMA DEVELOPS DRUGS

Taxpayers play a substantial role in the research and development of new medicines.<sup>7</sup> The National Institutes of Health (NIH) annually spends more than \$30 billion on medical research.<sup>8</sup> In perhaps the most common scenario, publicly-funded scientists at university labs and other institutions research how a disease works and identify viable disease targets and compounds.<sup>9</sup> If a compound shows promise, these labs work with industry to develop the candidate for clinical testing, often spinning-off into start-up biotechnology firms to receive private investment. The government facilitates this through the Bayh-Dole Act, which allows private entities to obtain patents on compounds developed with federal funds, and through tax-breaks and subsidies for clinical testing.<sup>10</sup>

With the completion of each stage of clinical testing, larger pharmaceutical companies become interested in swooping in to license the product or acquire the firm. Much “innovation” is now done through acquisition or alliances. The acquisition price is not based on the real investments made in developing the product, but rather based on the enormous expected returns were the product to be approved by the Food and Drug Administration (FDA).<sup>11</sup>

### **HOW PUBLIC FUNDING HELPED DEVELOP SOFOSBUVIR**

Sofosbuvir was initially developed by university scientists that received federal funding.<sup>12</sup> The product was spun out into a small biotechnology firm named Pharmasset. In the early stages of clinical trials, sofosbuvir was supported by federal funding. The earliest stages are the riskiest and even small federal contributions, risk-adjusted, can play a critical role. From 2007-2011, Pharmasset spent \$62.4 million developing sofosbuvir. By 2012, the promise of sofosbuvir was clear, and Gilead purchased the company for *\$11.2 billion*. Pharmasset projected that completing sofosbuvir development would cost \$216 million. After its purchase, Gilead reported spending \$880 million on R&D—likely an overestimate—for all sofosbuvir-containing regimens, which included three other products. In any case, total investment in sofosbuvir was between \$278 million and \$942 million. In the first five years on the market, sofosbuvir and related follow-on products have had global sales of \$58.6 billion.<sup>13</sup>

Drug development is risky: most compounds entering clinical testing are not approved.<sup>14</sup> But many pharmaceutical industry claims about research and development (R&D) investments fail to acknowledge

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<sup>7</sup> One study found that across high-income countries 60 percent of health research and development was funded by industry, 30 percent by the public sector, and 10 percent by private non-profits. JA Rottingen et al., Mapping of available health research and development data: what’s there, what’s missing, and what role is there for a global observatory?, S0140 *The Lancet* (2013). This figure did not account for tax credits and other subsidies, and hence likely underestimates the role of the public.

<sup>8</sup> NIH, Budget, <https://www.nih.gov/about-nih/what-we-do/budget#note>

<sup>9</sup> Aaron Kesselheim et al., The Roles Of Academia, Rare Diseases, And Repurposing In The Development Of The Most Transformative Drugs, *Health Affairs*, 34 *Health Affairs* 2 2015, <https://tinyurl.com/y3gj49pd>

<sup>10</sup> Since the enactment of the Bayh-Dole Act, the federal government has given away the fruits of the tens of billions of dollars of research it funds annually, granting corporations exclusive rights to commercialize government-funded inventions, with little commensurate benefit. The government has further sweetened the deal for pharmaceutical companies by repeatedly failing to enforce its authority to demand reasonable pricing on federally-funded inventions. See Public Citizen, Comments on NIST Bayh-Dole Reform, <https://www.citizen.org/wp-content/uploads/PC-NIST-ROI-Green-Paper-comment-FINAL.pdf>

<sup>11</sup> Notably, pharmaceutical companies sometimes include these enormous acquisition prices as part of their research and development expenses in SEC filings. In a circular logic, the high “R&D costs” then end up further justifying high prices.

<sup>12</sup> Jeff Sachs, The Drug that is Bankrupting America, *The Huffington Post*, <https://tinyurl.com/y5g5rm68>

<sup>13</sup> HepCoalition, Sofosbuvir Turns 5 Years Old (2018), <https://tinyurl.com/y4othheg>

<sup>14</sup> James Love, The 2016 Tufts Estimates of the Risk Adjusted Out-of-Pocket Costs To Develop a New Drug, *KEI* (2016), <https://www.keionline.org/23054>

the reality that industry directly builds on the knowledge funded by the taxpayer.<sup>15</sup> For example, National Institutes of Health-funded research was associated with every one of the 210 new drugs approved by the Food and Drug Administration (FDA) from 2010–2016.<sup>16</sup> U.S. taxpayers are compensated for this investment by being charged the highest medicine prices in the world.<sup>17</sup>

## II. ABUSING MONOPOLY PRICING POWER: THE SALE OF BRAND-NAME DRUGS

Drug corporations use three tactics to price-gouge: setting high launch prices, increasing prices at regular intervals, and extending their monopoly period by any means necessary.

### **High Launch Prices**

If and when the FDA approves a drug as safe and effective, it can be marketed for sale. The central problem in the U.S. drug pricing system is the drug corporation's unchecked ability to set prices. Prescription drugs are not expensive because they are costly to produce, or because of R&D investments.<sup>18</sup> A recent analysis found that prescription drug corporations receive 163 percent of their *global* research and development costs from just the revenue generated by overcharging Americans for prescription drugs compared to citizens of other countries.<sup>19</sup> Prescription drugs are expensive because patents and a complex layer of regulatory exclusivities grant brand-name companies monopoly power. In the U.S., the government does not regulate or by and large even negotiate for the monopoly price.<sup>20</sup>

In the absence of real constraints, payer access and physician demand influence pricing. To increase negotiating leverage, payers can restrict access to treatment by requiring patient co-payments or prior authorization, particularly if a substitutable product exists. Physicians can delay treatment uptake. But these strategies have largely failed to control prices and, in some cases, led to treatment rationing. Retail prescription drug spending, on a per capita basis, has nearly quadrupled since 1990, increasing from \$266 to \$1025.<sup>21</sup>

### **Price Spikes**

Prescription drug corporations continue to increase prices for medicines, even after they are on the

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<sup>15</sup> R&D estimates frequently cited by industry groups to justify high prices are drawn from studies funded by industry that use secret data, rely on assumptions that do not withstand scrutiny, and are inconsistent with other findings. *Id. See also* Public Citizen, "Pharmaceutical Research Costs: The Myth of the \$2.6 Billion Pill," Health Letter. September 2017; Mariana Mazzucato, *The Entrepreneurial State: Debunking Public v Private Sector Myths*, Chapter 3 (2014).

<sup>16</sup> Ekaterina Cleary et al., Contribution of NIH funding to new drug approvals 2010–2016, PNAS: Vol. 115: Iss. 10.

<sup>17</sup> Aaron Kesselheim et al, The High Cost of Prescription Drugs in the United States, 316 JAMA 858 (2016)

<sup>18</sup> See e.g., US Dep't of Health & Human Services, Prescription Drugs: Innovation, Spending, and Patient Access (2016), <https://tinyurl.com/y2df5563> ("Drug manufacturers often point to high drug development costs as a justification for high drug prices and understanding the R&D costs and time to develop a new drug is important. However, the relationship between R&D costs and drug prices is subject to a number of misconceptions. In reality, the prices charged for drugs are unrelated to their development costs. Drug manufacturers set prices to maximize profits. At the time of marketing, R&D costs have already occurred and do not affect the calculation of a profit-maximizing price.")

<sup>19</sup> That is, solely from the revenues obtained in the U.S. derived from the amount by which U.S. prices are higher than those in other countries. Nancy Yu, Zachary Helms, & Peter Bach. R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices. Health Affairs Blog. (Mar. 7, 2017), <https://tinyurl.com/goy26s2>

<sup>20</sup> The government does regulate the price for a small sub-section of payers, such as the Veterans Administration. In addition, even countries that regulate prices at the national level are struggling to cope with the new wave of exorbitant prices, affirming the need for fresh approaches that target monopoly power. See e.g., the United Kingdom. Robert Long, Big pharma is denying children like my son vital drugs. So I've set up a buyers club (2019), <https://tinyurl.com/y2uobqk>

<sup>21</sup> This figure is inflation-adjusted. It also likely underestimates the scope of the problem, because it excludes the vastly more expensive non-retail prescription drugs, such as those administered by a physician. Peterson-Kaiser Health System Tracker, Recent Trends, (2019), available at <https://tinyurl.com/yy8nb3md>

market—in stark contrast to the price reductions expected of a functioning market.<sup>22</sup> For the 45 top-selling drugs, more than half of all sales growth in the past three years was due to price increases.<sup>23</sup> Prescription drug corporations typically increase the price of products in their portfolios twice per year, with specialty drugs averaging an annual price increase of seven percent—or more than three times inflation.<sup>24</sup> Price spikes are a significant part of the story behind the EpiPen and insulin price scandals.<sup>25</sup>

### **Monopoly Extensions**

Drug corporations also zealously protect their ability to price-gouge by extending their monopoly privileges.<sup>26</sup> Overly broad U.S. government patent standards and interpretations enable drug corporations to construct “thickets” of patents around their product and engage in patent evergreening to prevent generic competition. Between 2005 and 2015, over 75 percent of drugs associated with new patents were already on the market, meaning most pharmaceutical patents support older medicines rather than groundbreaking new ones.<sup>27</sup>

Even industry has begun recognizing these trends. “If you have an organization that consistently relies on its price rises to increase its top line, they have no incentive whatsoever to develop new drugs to replace that old drug. And at the end of the life of the drug, the patent life, they’ll fight vigorously to protect it. We’ve seen that,” acknowledged the head of BIO, the biotechnology trade organization. “The question is, how do you change that? We’re going to have to tackle that. We can’t let that go by.”<sup>28</sup>

In short, monopolies provide harmful incentives for drug corporations. These include extracting maximal revenues through setting exorbitant launch prices, regularly increasing the prices on medicines without justification, spending tens of billions of dollars on physician detailing and direct-to-consumer advertising to influence prescribing behavior, and engaging in unlawful and criminal behavior including off-label promotion and fraudulently overcharging government health programs.<sup>29</sup>

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<sup>22</sup> See, Public Citizen, Large Majority of Prescription Drug Corporation CEOs Will Not Commit to Limiting Price Increases (2017), <https://tinyurl.com/y2x7hfnp>

<sup>23</sup> Between 2014 and 2017, U.S. sales for 45 leading products increased by about \$23 billion. \$14 billion of that increase was attributable to price increases. Price increases on top drugs drove majority of recent growth, analysis finds, BioPharma Dive (2018), <https://tinyurl.com/y2tyos5o>

<sup>24</sup> AARP, Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update.

<sup>25</sup> What makes insulin more complex is the role of pharmacy benefit managers (PBMs). These companies are employed by insurers, in part, to negotiate list prices with pharmaceutical companies. They are compensated based on the size of the discount negotiated—i.e., the size of the rebate. This can result in skewed incentives, where pharmaceutical companies *increase* list prices to give bigger discounts to PBMs, who then place the drug on preferred formularies, increasing sales.

<sup>26</sup> In addition to patent thickets and evergreening, industry also forestalls competition through abusive tactics like entering into “pay for delay” patent settlements with potential competitors, abusing regulatory rules to prevent generic firms from obtaining drug samples necessary for regulatory approval, filing spurious citizen petitions to delay approval of competing products at the FDA, and launching new products with minor modifications before patent expiration to undermine generic market.

<sup>27</sup> Robin Feldman, May your drug price be evergreen, *Journal of Law and the Biosciences* (2018). See also IMAK, Overpatented, Overpriced, How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Price (2018) (finding 125 patent applications on twelve best-selling drugs in the US), <https://tinyurl.com/yxwpubup>

<sup>28</sup> New BIO Chair Vows Crackdown on Biopharma’s “Bad Actors”, *GEN News* (June 7 2019), <https://tinyurl.com/yyo8n4ys>

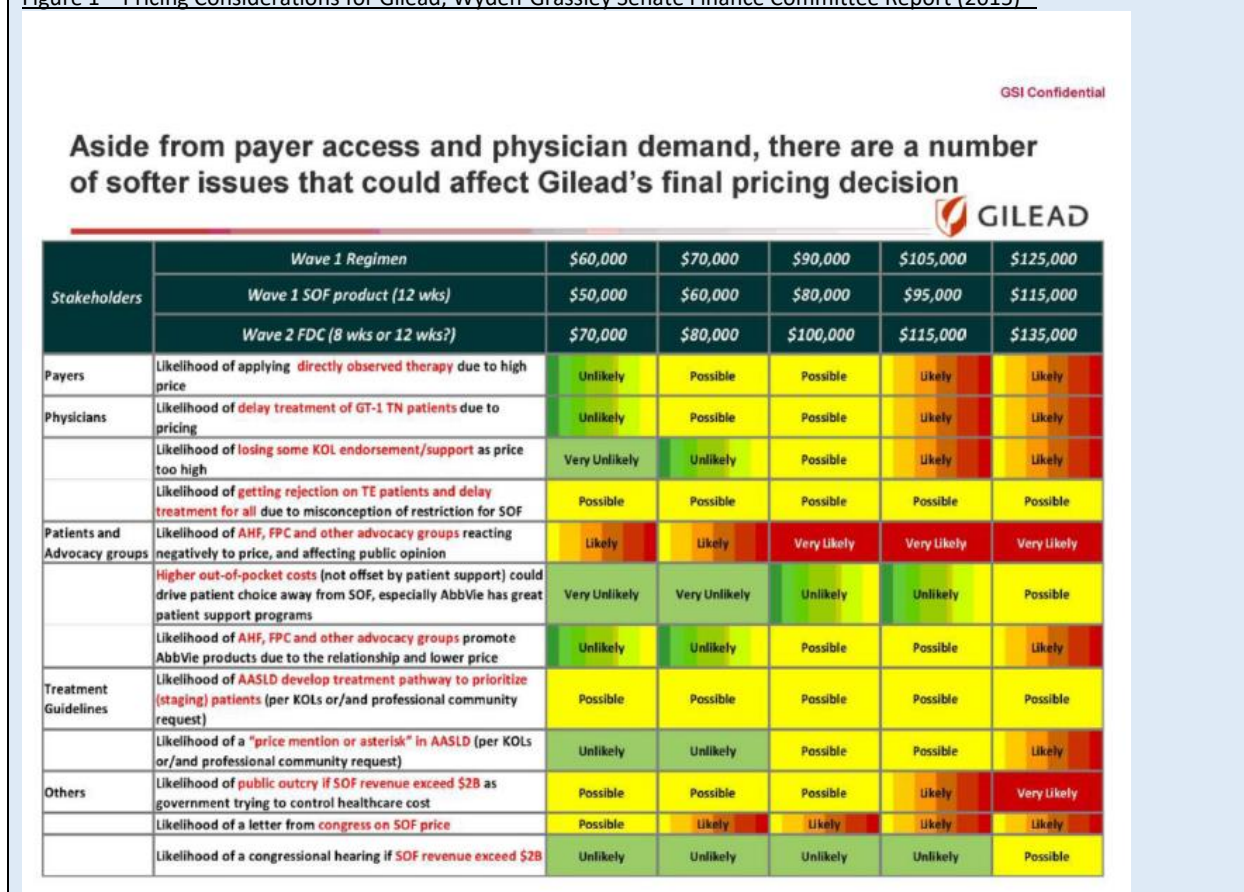
<sup>29</sup> See Lisa Schwartz et al., Interactions between physicians and the pharmaceutical industry generally and sales representatives specifically and their association with physicians’ attitudes and prescribing habits: a systematic review, *BMJ Open* (2017), <https://tinyurl.com/y3sefvak>. Public Citizen, Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2017, (2018), <https://tinyurl.com/yycvx5y7> (finding that drug corporations entered into 412 settlements totaling \$38.6 billion in criminal and civil penalties)

The industry business model is unique. But once industry has reaped its profits, it draws from the same modern corporate handbook. Pharmaceutical corporations use loopholes, like placing their intellectual property in foreign jurisdictions, to avoid paying their fair share of taxes.<sup>30</sup> They also use profits for stock buybacks to inflate shareholder value and executive compensation, instead of reinvesting it into productive uses like research and development.<sup>31</sup>

### DEVELOPING A PRICING STRATEGY FOR THE NEW HEPATITIS C TREATMENTS

When sofosbuvir was introduced, approximately 5.2 million people had hepatitis C virus. Even after significant discounts from the list price of \$84,000, universal treatment was estimated to cost hundreds of billions of dollars. The response was predictable. Payers began rationing treatment by arbitrarily restricting access, often only to the sickest patients.<sup>32</sup> The Senate Finance Committee launched an investigation, uncovering evidence of how Gilead shaped its pricing strategy.<sup>33</sup>

Figure 1 – Pricing Considerations for Gilead, Wyden-Grassley Senate Finance Committee Report (2015)<sup>34</sup>



<sup>30</sup> Oxfam, Prescription for Poverty: Drug companies as tax dodgers, price gougers, and influence peddlers (2018) [https://www.oxfamamerica.org/static/media/files/Prescription\\_for\\_Poverty\\_Full\\_Report.pdf](https://www.oxfamamerica.org/static/media/files/Prescription_for_Poverty_Full_Report.pdf)

<sup>31</sup> Roosevelt Institute, Profit Over Patients: Americans are Paying for a Financialized Pharmaceutical Industry (2018) [https://rooseveltinstitute.org/wp-content/uploads/2019/06/RI\\_Profit-Over-Patients-Financialization\\_brief\\_201906.pdf](https://rooseveltinstitute.org/wp-content/uploads/2019/06/RI_Profit-Over-Patients-Financialization_brief_201906.pdf)

<sup>32</sup> Barua et al., Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States, 163 Annals of Internal Medicine (3) 2015.

<sup>33</sup> Senator Wyden (D-OR) concluded that "Gilead knew these prices would put treatment out of the reach of millions and cause extraordinary problems for Medicare and Medicaid, but still the company went ahead." <https://tinyurl.com/y4nbmqx3>

<sup>34</sup> The Price of Sovaldi and the Its Impact on the U.S. Health Care System (2015), <https://tinyurl.com/y4nbmqx3>

### III. GENERIC COMPETITION LOWERS PRICES

Patent expiration or licensing leads to the introduction of generic competitors. Generic competition lowers prices.<sup>35</sup> Low-cost generic medicines have saved the health care system more than \$1 trillion in the past decade. One analysis in the *New England Journal of Medicine* found that medicine prices dropped by 40 percent after the introduction of three generic products.<sup>36</sup> In the case of global HIV/AIDS, generic competition lowered prices by 99% and saved twenty million lives.<sup>37</sup>

The generic market, however, is complex and has been plagued by recent scandals. A lawsuit brought by 44 states alleges price fixing between generic manufacturers.<sup>38</sup> Martin Shkreli—the infamous Pharma bro—raised prices for generic medicines produced by a single manufacturer, a strategy encouraged by some hedge funds.<sup>39</sup> A slow-growing U.S. biosimilar market, along with the rise of cell- and gene-therapies targeting small populations, raises concerns among some about relying on competition.<sup>40</sup>

But some concerns may be overstated. Competition has worked to lower prices in other countries, even for complex products like biologics.<sup>41</sup> Competition fundamentally shifts the frame of the conversation from the list price suggested by a manufacturer as the fair price, to the lowest possible price where a manufacturer is able to earn a profit. Competition has helped bring price reductions that were once unforeseeable, including for HIV drugs. While the complexity of therapies is increasing—and more support will be needed to enhance competition—many of the same arguments that were deployed forty years ago are still trotted out today. It has always been true that generic entry is not enough to bring about price reductions. Lower prices ultimately depend on a competitive generic market.

#### ***A Path Forward***

Taken together, making medicines affordable requires increasing government negotiating power, blocking price spikes, and curbing monopoly abuse. Eliminating the non-interference clause in Medicare Part D will allow the federal government to use its bargaining leverage. This should be backed up with strong government authority to induce good-faith negotiations. The federal government can use taxes and fines to block price spikes. Monopoly abuse can be curbed by allowing generic competition through competitive licensing and reducing the length of monopoly exclusivities. We can go further by elevating the public role in R&D including by asking for more in return, using grants and cash prizes instead of monopolies as incentives,<sup>42</sup> and having the public sector directly conduct more R&D.<sup>43</sup>

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<sup>35</sup> The market for new hepatitis C cures like sofosbuvir was unusual because even brand-name to brand-name competition resulted in lower list prices. One reason for this may have been the curative nature of the products, which resulted in a shrinking market and pricing pressure. In general, however, brand-name competition typically results in oligopolistic pricing. A systematic review of academic literature found no evidence that brand-name competition results in lower list prices. Ameet Sarpatwari et al., *Competition and price among brand-name drugs in the same class*, *PLoS Medicine* (2019).

<sup>36</sup> Chintan Dave et al, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, *NEJM* 377 (26) (2017).

<sup>37</sup> The global access to medicines movement made this possible through a combination of campaigning, litigation and treatment literacy. This history has been well-documented. See SECTION27 and Treatment Action Campaign, *Standing up for Our Lives: A History of the Access to Medicines Movement in South Africa*, <https://standingupforourlives.section27.org.za>

<sup>38</sup> *NY Times*, *Teva and Other Generic Drugmakers Inflated Prices Up to 1,000%, State Prosecutors Say*, 2019.

<sup>39</sup> Alexander Zaitchik, *How Big Pharma Was Captured by the One Percent*, *The New Republic*, 2018.

<sup>40</sup> Caitlin Owens, *The drug pricing debate is stuck in the past*, *Axios* (2019), <https://tinyurl.com/y4zrc8ue>

<sup>41</sup> IQVIA, *The Impact of Biosimilar Competition in Europe* (2018)

<sup>42</sup> See e.g., Jamie Love, *delinkage.org* (“Delinkage describes the idea that temporary monopolies and the associated high drug prices should not be used to fund pharmaceutical research and development, as well as a set of policy proposals that would replace monopolies and high prices with alternative incentives based upon cash rewards, and expanded funding for research, drug development, and clinical trials through a combination of grants, contracts, tax credits, and other subsidies.”)

<sup>43</sup> Dean Baker, *Drugs are Cheap: Why Do We Let Governments Make Them Expensive?*, <https://tinyurl.com/yyexfwn4>

### **INCREASING ACCESS TO HEPATITIS C TREATMENTS THROUGH LICENSING DEMANDS**

In 2014, Public Citizen asked the U.S. government to use its patent licensing authority, under Section 1498, to authorize generic competition and increase treatment access.<sup>44</sup> Yale Law School scholars joined the call, noting the economic and legal justification and showing that the law had been used repeatedly in the 1960s by the government to buy low-cost generic versions of patented drugs.<sup>45</sup>

The case was clear. Gilead had reaped billions in profit, while hundreds of thousands of people still lacked access. Generics were available abroad for under \$500 for a course of treatment. Researchers had shown that funding hepatitis C treatment would require deep cuts in state budgets for education, health, and other government services.<sup>46</sup> In 2017, Louisiana Secretary of Health and Human Services Rebekah Gee began exploring asking the federal government to use Section 1498. She then leveraged the prospect of licensing to negotiate a new discount payment model to lower hepatitis C treatment costs: under the “Netflix” model, Louisiana will have unlimited access to the treatment for a fixed annual sum.<sup>47</sup> The New York Times Editorial Board later endorsed the use of government licensing.<sup>48</sup>

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<sup>44</sup> Robert Weissman, Testimony on Hepatitis C in Veterans, The Committee on Veterans’ Affairs, U.S. Senate (2014).

<sup>45</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, Zain Rizvi, A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18 Yale J. of Law & Tech 1 (2017).

<sup>46</sup> Drug Pricing Lab at Memorial Sloan Kettering, <https://drugpricinglab.org/tools/louisiana-budget-allocator/>

<sup>47</sup> Tina Rosenberg, Treat Medicines Like Netflix Treats Shows, NY Times (2019), <https://tinyurl.com/yy95bknc>. *See also* Public Citizen, Louisiana Hepatitis C Drug Pricing Comments (2017), <https://tinyurl.com/y53svwac>

<sup>48</sup> NY Times, How the Government Can Lower Drug Prices (2018), <https://tinyurl.com/y7rbyduq>