

# THE MEDICARE INNOVATION SUBSIDY

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*Policymakers on both ends of the political spectrum have been looking for ways to reduce prescription drug prices. Democrats have also been working on expanding healthcare coverage, including different versions of Medicare for All. All these proposals have been framed as issues of access and spending. If innovation incentives come up at all, it has primarily been because pharmaceutical companies claim that reducing drug prices will threaten innovation by lowering the returns from their patents.*

*In fact, however, pharmaceutical access and innovation incentives are intimately related. Health insurance can change the structure of market demand. And Medicare in particular does so in a way that gives a very large subsidy to patented drugs, such that current U.S. pharmaceutical profits are often higher than they would be in an unsubsidized market. Medicare reimbursement rules thus can lead to greater-than-monopoly pricing of patented drugs, dramatically expanding the incentive U.S. policy provides to pharmaceutical companies. By not recognizing the Medicare innovation subsidy, policymakers have ignored one of the largest sources of innovation incentives. That extra incentive might be a good thing or a bad thing, depending on how much incentive pharmaceutical developers need. It may well be good for some classes of drugs and bad for others. But it is important for policymakers to understand how access policies like Medicare also serve as innovation incentives. This extra innovation subsidy may open the policy space for hybrid proposals that combine expanded government insurance like Medicare for All with lower drug prices while preserving or even increasing current returns to innovation.*

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## INTRODUCTION

Lowering prescription drug costs is a policy priority across the political spectrum.<sup>1</sup> The Trump Administration’s proposals include tying some Medicare reimbursements to lower prices in other countries, while Democrats in the House of Representatives have passed a bill including a broad-based system of negotiation that would benefit privately insured Americans as well.<sup>2</sup> Many Democrats have rallied behind “Medicare for All” proposals that include government price regulations.<sup>3</sup> Notably, all of these proposals have been framed as solutions to issues of healthcare *access*.<sup>4</sup> When innovation incentives are mentioned, it is primarily by pharmaceutical companies claiming that

<sup>1</sup> See, e.g., Kate Rooney & Liz Moyer, *Health Care Topped the Economy as the Biggest Issue for Voters Now, Here’s Why*, CNBC (Nov. 7, 2018, 3:19 PM), <https://www.cnbc.com/2018/11/07/healthcare-topped-the-economy-as-the-biggest-issue-for-voters-now-heres-why.html>.

<sup>2</sup> See, e.g., Rachel Sachs, *Administration Outlines Plan to Lower Pharmaceutical Prices in Medicare Part B*, HEALTH AFF. (Oct. 26, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181026.360332/full>; Rachel Sachs, *Understanding the House Democrats’ Drug Pricing Package*, HEALTH AFF. (Sept. 19, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190919.459441/full>; Li Zhou, *The House Just Passed an Ambitious Bill to Lower Prescription Drug Prices*, VOX (Dec. 12, 2019, 2:25 PM), <https://www.vox.com/2019/12/12/21010905/house-democrats-pass-prescription-drug-price-bill>.

<sup>3</sup> See Sarah Kliff & Dylan Scott, *We Read 9 Democratic Plans for Expanding Health Care. Here’s How They Work*, VOX (June 21, 2019), <https://www.vox.com/2018/12/13/18103087/medicare-for-all-single-payer-democrats-sanders-jayapal>.

<sup>4</sup> See *infra* Section I.C.2.

any reductions in drug prices or spending will slash incentives to develop new drugs. Industry advocates have argued that “mandating price levels below market value” will “threaten U.S. innovation”<sup>5</sup> and that without pharmaceutical firms’ “ability to price to value,” the country “risks crippling our only hope of curing the many serious diseases that still plague us.”<sup>6</sup>

These advocates are right that reducing reimbursement rates will lower the returns for developing new drugs and thus may negatively impact innovation.<sup>7</sup> But it is misleading to suggest that current U.S. profits simply reflect the “market value” of a drug. A patent owner generally is entitled to exclude others from selling its invention, allowing it to charge supracompetitive prices—receiving up to monopoly profits for an invention with no ready substitutes.<sup>8</sup> Pharmaceutical companies also enjoy a number of legal incentives unavailable to other patent owners that help maintain the high prices they are able to charge. For example, they benefit from special patent-focused protections such as patent term extensions and the ability to prevent generic competitors from entering the market while the validity of the patent is disputed.

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<sup>5</sup> Jay Taylor, *Government-Imposed Price Controls Threaten Innovation and Access*, PHRMA: CATALYST (May 9, 2017), <https://catalyst.phrma.org/government-imposed-price-controls-threaten-innovation-and-access>; see also Press Release, Stephen J. Uhl, President & CEO, Pharm. Research & Mfrs. of Am., PhRMA Statement on HHS Speech and Part B Proposal (Oct. 25, 2018), <https://www.phrma.org/press-release/phrma-statement-on-hhs-speech-and-part-b-proposal>.

<sup>6</sup> Robert J. Easton, Opinion, *Price Controls Would Stifle Innovation in the Pharmaceutical Industry*, STAT (Jan. 22, 2018), <https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry>.

<sup>7</sup> See Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327 (2013) (finding significant increases in pharmaceutical research and development for therapeutic classes with higher Medicare market share). See generally Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 160–71 (2016).

<sup>8</sup> In practice, patents rarely map neatly onto monopoly markets, and patentees typically receive far less than monopoly profits. See, e.g., Robert P. Merges & Michael Mattioli, *Measuring the Costs and Benefits of Patent Pools*, 78 OHIO ST. L.J. 281, 325–27 (2017) (discussing the complex mapping from patents to technologies to products to markets). But they are more likely to do so in pharmaceuticals than elsewhere. See JAY BHATTACHARYA, TIMOTHY HYDE & PETER TU, HEALTH ECONOMICS 233–35 (2014) (modeling pharmaceutical patents as providing a monopoly); Jörg Eder et al., *The Discovery of First-in-Class Drugs: Origins and Evolution*, 13 NATURE REV. DRUG DISCOVERY 577 (2014) (analyzing the 133 first-in-class drugs approved by the FDA from 1999 to 2013, which are less likely to have direct competitors); JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 141 (2008) (estimating that the pharmaceutical and chemical industries are the only ones for which patent rents exceed litigation costs for U.S. public firms).

It isn't news that pharmaceutical patents allow above-cost pricing. That's their point. In the U.S. pharmaceutical market, however, policymakers should recognize that insurance-based public subsidies add to that incentive. As we explain in this Article, insurance allows innovating firms to receive profits even higher than the baseline monopoly level. (Or more generally, above the supracompetitive profits that would have been made in an unsubsidized market without insurance, which we will refer to as "baseline monopoly profits" as shorthand.) Rather than receiving merely a market return of the monopoly price times the quantity of the drug sold at that price in the private market, a firm can receive the monopoly price times a much higher quantity of drugs sold to patients whose purchases are subsidized through insurance.

Insurance doesn't have to work this way. Demand-side public subsidies like insurance can expand access to a patented drug while maintaining the same market-set incentive for the patentee.<sup>9</sup> But as we explain in Part I, this isn't how pharmaceutical subsidies often work in the United States. While private insurers might have some authority to limit profits to the monopoly level by refusing to cover products priced too high,<sup>10</sup> public payers like Medicare and Medicaid have little ability to decline to cover products and rein in prices. Even as Congress has expanded demand for drugs through these programs, it has often not given public payers the authority to demand and enforce meaningful price concessions for them.<sup>11</sup> For example, Medicare Part B has covered pharmaceuticals administered in outpa-

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<sup>9</sup> See Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 *YALE L.J.* 544, 559–66 (2019) (explaining how innovation incentives and allocation mechanisms can be disaggregated, and how the UK healthcare system matches IP-based pharmaceutical innovation incentives with an open-access allocation mechanism). We discuss the UK example in more detail in Section I.B.

<sup>10</sup> The extent to which they actually do this is unclear. Competition for customers puts pressure on insurers to cover most FDA-approved drugs, and state and federal laws impose some prescription drug coverage requirements. See *State Insurance Mandates and the ACA Essential Benefits Provisions*, NAT'L CONF. ST. LEGISLATURES (Apr. 12, 2018), <http://www.ncsl.org/research/health/state-ins-mandates-and-aca-essential-benefits.aspx> (listing and comparing state provisions). But some private plans do exclude drugs deemed too expensive from coverage (known as a "closed" formulary), and even plans with "open" formularies that cover all approved drugs can gain bargaining leverage by placing more expensive drugs on less desirable "tiers" for which higher copayments discourage use or by imposing administrative barriers to coverage through utilization management tools. See NAT'L ACADS. OF SCIS., ENG'G, & MED., *MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE* 47–48 (Norman R. Augustine et al. eds., 2018) (discussing bargaining power and formulary management). Lack of transparency over prices makes it difficult to determine whether these sources of leverage lead to price discounts. See *id.* at 60–62 (discussing arguments for and against transparency).

<sup>11</sup> Some payers have more leverage than others, as discussed in Section I.A.

tient settings since 1965, and the passage of Medicare Part D in 2003 greatly expanded insurance coverage for prescription drugs for Americans over the age of sixty-five.<sup>12</sup> Federal law mandates coverage for certain drugs by Part B and Part D plans, thus greatly inflating demand,<sup>13</sup> while also directly prohibiting the government from negotiating prices on those products (although private plan administrators in Part D may engage in such negotiations).<sup>14</sup> As we discuss, other countries have more freedom to engage in market-driven negotiations over pricing.

In Part II, we explain how expanding the ability of patients to pay while requiring coverage and limiting negotiation over prices changes the demand curve for drugs, creating a greater-than-baseline-monopoly reward for pharmaceutical patents. The United States has seen just that effect in the wake of Medicare Part D. The implementation of Part D in 2006 led to initial price reductions, but also increased prescription drug use, resulting in a net increase in overall U.S. pharmaceutical revenues.<sup>15</sup> Indeed, by 2017 Medicare payments accounted for thirty percent of U.S. retail prescription drug spending.<sup>16</sup> Economic theory would predict firms to be responsive to this prospect of higher profits,<sup>17</sup> and empirical work has confirmed that after Part D's passage, pharmaceutical research and development (R&D) increased in therapeutic classes with higher Medicare market shares—that is, drugs targeted toward older Americans.<sup>18</sup> The effects were strongest in drug classes for which Medicare Part D mandates coverage.<sup>19</sup>

The above-monopoly revenue provided by the combination of patent law and Medicare reimbursement was not, to our knowledge, a

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<sup>12</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101(a)(2), 117 Stat. 2072 (setting effective date for prescription drug benefit as January 1, 2006).

<sup>13</sup> See *infra* notes 41–44, 55–59 and accompanying text.

<sup>14</sup> See *infra* note 58 and accompanying text.

<sup>15</sup> See Mark Duggan & Fiona Scott Morton, *The Effect of Medicare Part D on Pharmaceutical Prices and Utilization*, 100 AM. ECON. REV. 590 (2010); see also Mark G. Duggan & Fiona Scott Morton, *The Medium-Term Impact of Medicare Part D on Pharmaceutical Prices*, 101 AM. ECON. REV. 387 (2011) (showing that these price reductions were sustained in the second and third year of the program, and perhaps in the fourth).

<sup>16</sup> *10 Essential Facts About Medicare and Prescription Drug Spending*, KAISER FAMILY FOUND. (Jan. 29, 2019), <https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending>.

<sup>17</sup> See, e.g., Darius N. Lakdawalla, *Economics of the Pharmaceutical Industry*, 56 J. ECON. LITERATURE 397, 406 (2018) (“[F]ew disagree that growth in expected market size fuels more innovation.”).

<sup>18</sup> See Blume-Kohout & Sood, *supra* note 7, at 332–33 (observing increases in Phase I testing post-legislation).

<sup>19</sup> See *id.* at 333.

deliberate policy choice to spur innovation. Rather, patent policy-makers and healthcare policymakers have set innovation policy without explicitly focusing on how the two bodies of law interact.<sup>20</sup> The United States might be over-rewarding pharmaceutical innovation, at least for drugs reimbursed by Medicare Parts B or D. And if not, that's because the preexisting combination of patent protection, regulatory exclusivity, and other innovation incentives was insufficient for those drugs before Medicare.

If Medicare for All extends these drug benefits to all Americans, it would be a significant further increase in innovation incentives—albeit also a reduced asymmetry in favor of incentives toward drugs targeting older populations.<sup>21</sup> One way to help pay for this subsidy would be to drop the reimbursement price accordingly, even if the current supra-monopoly return is the right overall incentive. In other words, discussions about expanding Medicare with “Medicare for All” should recognize that to keep the total transfer to the pharmaceutical industry the same, that market expansion would likely have to be coupled with price reductions.<sup>22</sup>

As we discuss in Part III, recognizing the interaction between innovation incentives and access allocation mechanisms opens the available policy space.<sup>23</sup> There, we describe hybrid policies that would serve different underlying values. But the goal of this Article is not to lobby for any particular policy solution. Rather, our main point is simply that policy discussions about prescription drug prices today are primarily focused on allocation without considering how efforts to increase access can affect innovation incentives. The government is in

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<sup>20</sup> This is likely due at least in part to committee structure. The committees in the House and Senate having jurisdiction over patent law (the Judiciary Committees) are separate from those with jurisdiction over health law and specifically Medicare (chiefly, the Senate Finance Committee and House Energy & Commerce and Ways & Means Committees). They do not naturally take account of one another's priorities in the policymaking process.

<sup>21</sup> There would, however, be an even greater asymmetry of increased incentives for excludable pharmacological innovations without a corresponding increase for nonexcludable innovations like lifestyle interventions. See generally Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 *YALE L.J.* 1900 (2013) (describing this distortion).

<sup>22</sup> The Affordable Care Act provides one recent example of this practice, as the Act aimed to expand Medicaid coverage to all Americans under 133% of poverty at the same time as it increased the mandatory discount pharmaceutical companies must provide to Medicaid programs. *Eligibility*, MEDICAID.GOV, <https://www.medicaid.gov/affordable-care-act/eligibility/index.html> (last visited Nov. 16, 2019).

<sup>23</sup> See Hemel & Ouellette, *supra* note 9, at 547 (disaggregating innovation policies into incentives that establish a “payoff structure for producers of knowledge goods” and allocation mechanisms that establish “the terms under which individuals and firms can gain access to knowledge goods”).

fact changing innovation incentives when it decides what to cover and the terms under which those products will be covered, even if the policy debate is framed in terms of access. Americans need policy mechanisms for weighing the tradeoffs between innovation incentives and access. Those mechanisms must consider more than just patent and regulatory policy. Now that pharmaceutical prices have the attention of the public and politicians, it is a good time to overhaul the system in a more sensible way, understanding how access affects incentives to innovate.

## I

### GOVERNMENT SUBSIDIES FOR PHARMACEUTICALS

The high cost of many prescription drugs stems in part from the intellectual property (IP) used to protect pharmaceutical R&D investments.<sup>24</sup> We will examine the interaction of this market-based reward and other innovation incentives more closely in Part II, but here we note that most users don't directly pay the monopoly price for drugs.<sup>25</sup> Rather, at least in developed countries, allocation of pharmaceuticals and other biomedical technologies is usually mediated through public or private health insurance.

Health insurance systems differ along a range of dimensions, including whom they cover, the set of services and products to which they provide access, how well patients are insulated from out-of-pocket costs, and how they interface with IP incentives. In Section I.A, we describe how different governmental programs serve as allocation mechanisms for covered medications in the United States, and in Section I.B, we examine other jurisdictions. As we explain, insurance programs can be structured in a way that maintains the same total expected profit for each covered drug as the manufacturer would receive from proprietary pricing in the private market. But health insurance can also be designed such that total expected profits increase or decrease, and that effect can vary with the drug at issue. Section I.C then explores existing proposals for reforming U.S. public health insurance systems, all of which have been focused on the allocation side of U.S. pharmaceutical innovation policy.

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<sup>24</sup> These IP policies include not just patents but also trade secrets, trademarks, and exclusivity provided through regulatory agencies like the U.S. Food and Drug Administration (FDA). See Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115, 1130–37 (2015) (describing these and other incentives in the context of biomedical research).

<sup>25</sup> See Hemel & Ouellette, *supra* note 9, at 563–66, 594–95.

### A. Public Payers in the United States

The heavily fragmented U.S. insurance system provides access to health insurance through numerous payers. These payers differ in terms of whom they cover, what benefits they cover, and how much they pay for those benefits. Policy choices along each of these dimensions affect both the allocative and incentive functions of insurance, as we explain below.

#### 1. Medicare

In the prescription drug arena, one payer looms larger than the rest: Medicare. Medicare is a federal health insurance program administered by the Centers for Medicare and Medicaid Services (CMS). Medicare was initially designed to provide healthcare benefits for essentially all Americans beginning at the age of sixty-five,<sup>26</sup> and today the program insures approximately sixty million beneficiaries.<sup>27</sup> In 2016, CMS spent almost \$130 billion on prescription drugs for Medicare beneficiaries,<sup>28</sup> far more than any other public payer.<sup>29</sup> Medicare's share of U.S. retail prescription drug spending rose to thirty percent in 2017.<sup>30</sup>

Medicare primarily covers prescription drugs under two different portions of the program, Part B and Part D. Part B covers physician services provided in outpatient settings,<sup>31</sup> including prescription drugs administered in that context.<sup>32</sup> These drugs are typically large-

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<sup>26</sup> See PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 368–70 (1982) (discussing the early history of Medicare). The program has since been expanded to cover certain categories of younger Americans with long-term disabilities, see Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329, but the primary aim of the program is to cover beneficiaries over age sixty-five.

<sup>27</sup> DEP'T OF HEALTH & HUMAN SERVS., *PUTTING AMERICA'S HEALTH FIRST: FY 2019 PRESIDENT'S BUDGET FOR HHS 60* (2018), <https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf>.

<sup>28</sup> *10 Essential Facts About Medicare and Prescription Drug Spending*, *supra* note 16; BDS. OF TRS., FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2017 ANNUAL REPORT 10, 99 (2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf> (indicating that Part D expenditures in 2016 totaled approximately \$100 billion); MEDPAC, *A DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM* 147 (2018), [http://www.medpac.gov/data-book/jun18\\_databookentirereport\\_sec.pdf](http://www.medpac.gov/data-book/jun18_databookentirereport_sec.pdf) (noting that in 2016 the "Medicare program and beneficiaries spent about \$29.1 billion on Part B drugs").

<sup>29</sup> *10 Essential Facts About Medicare and Prescription Drug Spending*, *supra* note 16.

<sup>30</sup> *Id.*; see Michael A. Carrier, Mark A. Lemley & Shawn P. Miller, *Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy*, 71 HASTINGS L.J. 307 (2020) (providing an empirical study reporting total U.S. pharmaceutical sales in 2016 of \$445 billion).

<sup>31</sup> 42 U.S.C. § 1395k(a)(2) (2012).

<sup>32</sup> *Id.* § 1395u(o)(1).



molecule, injectable or infused biologics<sup>33</sup> used for the treatment of serious conditions like cancer<sup>34</sup> or arthritis.<sup>35</sup> These drugs are also expensive: Due to large patent thickets, trade secrets, a twelve-year regulatory exclusivity period, and other barriers to entry, the U.S. biologics market has seen little price competition.<sup>36</sup> Medicare Part B drug spending has increased rapidly over the last decade, more than doubling from \$14 billion in 2006 to \$29 billion in 2016.<sup>37</sup> Over half of this total comes from anticancer drugs.<sup>38</sup> Today, Part B beneficiaries are generally responsible for monthly premiums of \$144.60, a \$198 annual deductible, and 20% of costs, without limit, once the deductible is met.<sup>39</sup> However, most seniors either are entitled to other coverage or may purchase private supplemental plans that limit their out-of-pocket exposure to these costs.<sup>40</sup>

Although Part B coverage of prescription drugs is limited by the institutional context (drugs provided in the course of a physician's ser-

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<sup>33</sup> Biologics are large-molecule drugs produced in living cells, such as monoclonal antibodies used in the treatment of autoimmune conditions. W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1026, 1028 (2016).

<sup>34</sup> In 2017, Part B spent \$1.4 billion on pegfilgrastim, a drug used in conjunction with chemotherapeutic agents to stimulate the production of white blood cells. *Medicare Part B Drug Spending Dashboard*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.html> (last updated Mar. 14, 2019); *Pegfilgrastim*, NAT'L CANCER INST., <https://www.cancer.gov/about-cancer/treatment/drugs/Pegfilgrastim> (last updated Oct. 11, 2019).

<sup>35</sup> In 2017, Part B spent \$1.3 billion on infliximab, a drug used to treat rheumatoid arthritis and other autoimmune conditions. *Infliximab*, NAT'L LIBR. MED., <https://medlineplus.gov/druginfo/meds/a604023.html> (last updated Oct. 1, 2019); *Medicare Part B Drug Spending Dashboard*, *supra* note 34.

<sup>36</sup> See Ameet Sarpatwari et al., *The US Biosimilar Market: Stunted Growth and Possible Reforms*, 105 CLINICAL PHARMACOLOGY & THERAPEUTICS 92 (2019); Price & Rai, *supra* note 33, at 1026.

<sup>37</sup> MEDPAC, *supra* note 28, at 147. In 2016, the top ten Part B drugs in terms of spending were all biologics. *See id.* at 150.

<sup>38</sup> MEDPAC, MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM: REPORT TO THE CONGRESS 119 (2016), <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf> ("In 2014, Medicare spending for anticancer drugs accounted for about 55 percent of the nearly \$21 billion spent on Part B drugs . . .").

<sup>39</sup> *Medicare Costs at a Glance*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance> (last visited Dec. 31, 2019).

<sup>40</sup> See Juliette Cubanski et al., *Sources of Supplemental Coverage Among Medicare Beneficiaries in 2016*, KAISER FAMILY FOUND. (Nov. 28, 2018), <https://www.kff.org/medicare/issue-brief/sources-of-supplemental-coverage-among-medicare-beneficiaries-in-2016> ("In 2016, eight in 10 beneficiaries in traditional Medicare (81%) had some type of supplemental insurance, including employer-sponsored insurance (30%), Medigap (29%), and Medicaid (22%) . . .").

vice), coverage within that setting is quite broad. Part B covers all services and products which are “reasonable and necessary for the diagnosis or treatment of illness or injury,”<sup>41</sup> a phrase which is defined neither by the statute nor by regulations.<sup>42</sup> Part B cannot decline to cover an FDA-approved drug, which is by definition deemed safe and effective for its intended use, merely because it is too expensive.<sup>43</sup> At present, the Part B reimbursement system is even structured to encourage physicians to prescribe more expensive products.<sup>44</sup>

Medicare Part D offers a more standard pharmacy benefit plan to seniors, providing coverage for the broad range of prescription drugs dispensed in that setting.<sup>45</sup> Relative to Part B, Part D covers more small-molecule drugs.<sup>46</sup> Although small-molecule drugs are also protected by patents and regulatory exclusivity periods, they tend to be simpler products to copy scientifically than are biologics, and thus they face far more competition after patent expiration.<sup>47</sup> Before patent expiration, Part D similarly pays high prices to provide pre-

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<sup>41</sup> 42 U.S.C. § 1395y(a)(1)(A) (2012).

<sup>42</sup> See Isaac D. Buck, *Furthering the Fiduciary Metaphor: The Duty of Providers to the Payers of Medicare*, 104 CALIF. L. REV. 1043, 1068–69 (2016) (explaining that as a consequence of the vague “reasonable and necessary” requirement, providers have “unregulated and untouchable” discretion over clinical decisions); Peter J. Neumann & James D. Chambers, *Medicare’s Enduring Struggle to Define “Reasonable and Necessary” Care*, 367 NEW ENG. J. MED. 1775, 1775–76 (2012) (describing challenges in defining the term).

<sup>43</sup> See 42 U.S.C. § 1395y(a)(1)(A).

<sup>44</sup> MEDPAC, *supra* note 38, at 118, 127. When a physician is reimbursed for providing a drug to a patient under Part B, she receives a fee based on a percentage of its price. *See id.* at 117. Scholars and policymakers have argued that this system encourages physicians to prescribe and administer more expensive drugs than may be medically necessary. *See id.* at 118 (noting that “a higher priced drug generates more revenue for the provider”); Patricia M. Danzon et al., *Alternative Strategies for Medicare Payment of Outpatient Prescription Drugs—Part B and Beyond*, 11 AM. J. MANAGED CARE 173 (2005) (describing generally how reimbursement may result in higher prices for private and public purchasers).

<sup>45</sup> Part D was not created until 2003, nearly forty years after the passage of the initial Medicare statute. KEY MILESTONES IN MEDICARE AND MEDICAID HISTORY, SELECTED YEARS: 1965–2003, HEALTH CARE FINANCING REV. 1 (2005), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research///-06Winpg1.pdf>; JANET LUNDY, KAISER FAMILY FOUND., *PRESCRIPTION DRUG TRENDS 5* (2010) (“[A]bout one-quarter (27%) of seniors age 65 and older, and one-third of poor (34%) and near-poor (33%) seniors, had no drug coverage in 2003 [when Congress passed Part D].”).

<sup>46</sup> Traditional small-molecule drugs like aspirin are produced through standard chemical synthesis techniques. Austin Frakt, *There Is No Single, Best Policy for Drug Prices*, N.Y. TIMES (July 15, 2019), <https://www.nytimes.com/2019/07/15/upshot/lower-drug-prices-no-one-cure.html> (“Until recently, the vast majority of new drugs were so-called small-molecule drugs produced through chemical processes.”); *see* Price & Rai, *supra* note 33, at 1033–34.

<sup>47</sup> See CVS HEALTH, *BASICS ABOUT BIOSIMILARS: THE SAVINGS POTENTIAL AND THE CHALLENGES* (2016), <https://payorsolutions.cvshealth.com/sites/default/files/cvs-health-payor-solutions-insights-feature-basics-about-biosimilars-april-2016.pdf>.

scription drug coverage.<sup>48</sup> However, because it covers more small-molecule drugs facing generic competition, Part D can often pay less per patient for a given drug than can Part B, particularly for commonly-prescribed medications for conditions like high cholesterol where many drugs compete.<sup>49</sup> Even though Part D enrolls about 10 million fewer beneficiaries than Part B,<sup>50</sup> total Part D expenditures are much higher, with 2016 Part D spending rising to almost \$100 billion.<sup>51</sup> Part D coverage is only partial; in 2020, after a \$435 deductible, Part D beneficiaries are responsible for 25% of costs until their out-of-pocket spending reaches \$6350, and 5% of costs thereafter, without limit.<sup>52</sup> Beneficiaries may also be responsible for additional monthly premiums and income-based premium surcharges, which may add hundreds of dollars per month for patients.<sup>53</sup>

Part D's coverage requirements are specified in both statute and regulation. Part D plans must cover at least two FDA-approved<sup>54</sup>

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<sup>48</sup> For example, the multiple-myeloma drug Revlimid cost Part D more than \$3 billion in 2017 for the treatment of roughly 37,000 beneficiaries, an average cost of over \$88,000 per patient. *Medicare Part D Drug Spending Dashboard*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html> (last updated Mar. 14, 2019). Revlimid's growing prices have caught the attention of lawmakers and illustrate how few tools the government has to limit Medicare spending. See Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic Competition Away*, NPR (May 17, 2018, 5:00 AM), <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away>.

<sup>49</sup> For instance, in 2017 Part D spent \$876 million providing rosuvastatin calcium, a drug for high cholesterol for which the branded Crestor faced generic competition beginning in 2016, to more than 2.3 million beneficiaries, at a relatively low cost of about \$375 per patient. *Medicare Part D Drug Spending Dashboard*, *supra* note 48.

<sup>50</sup> Medicare Part D enrollment is roughly 43 million beneficiaries, compared with 52 million for Part B. *Medicare Fast Facts*, NAT'L COMMITTEE TO PRESERVE SOC. SECURITY & MEDICARE, <https://www.ncpssm.org/our-issues/medicare/medicare-fast-facts> (last updated Apr. 2018). Some of these missing beneficiaries have private pharmaceutical coverage or may be dissuaded by administrative barriers. See, e.g., Brian E. McGarry et al., *Lower Hispanic Participation in Medicare Part D May Reflect Program Barriers*, 33 HEALTH AFF. 856, 860–61 (2014) (finding additional administrative barriers facing people who need to apply for the Part D low-income subsidy program).

<sup>51</sup> BDS. OF TRS., FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, *supra* note 28, at 10, 99.

<sup>52</sup> *An Overview of the Medicare Part D Prescription Drug Benefit*, KAISER FAMILY FOUND. (Nov. 13, 2019), <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit>. However, because this \$6350 includes a manufacturer discount in the coverage gap, true out-of-pocket spending can be significantly lower before catastrophic coverage begins. *Id.*

<sup>53</sup> See *id.*

<sup>54</sup> 42 C.F.R. § 423.100 (2018) defines “Part D drug” for the purposes of the program by reference to Social Security Act section 1927(k)(2)(A), which governs the Medicaid program, which is linked to drugs approved under the FDA's governing statute. See 42 U.S.C. § 1396r-8(c)(1)(C)(i) (2012) (referencing section 505(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(c) (2012)).

drugs per therapeutic class,<sup>55</sup> although plans generally cover more than two.<sup>56</sup> The ability to not cover certain drugs has enabled Part D plans to exert some downward pressure on prices,<sup>57</sup> although the government cannot itself negotiate prices under Medicare Part D, instead taking the private prices negotiated by pharmacy benefit managers (PBMs) acting on behalf of private insurance companies who sponsor Part D plans.<sup>58</sup> Further, Part D includes six “protected classes”—anticonvulsants, antidepressants, antineoplastics (cancer drugs), antipsychotics, antiretrovirals (for the treatment of HIV/AIDS), and immunosuppressants (for the treatment of transplant rejection)—in which Medicare must cover essentially all FDA-approved drugs.<sup>59</sup> As a result, for drugs that belong to these protected classes or that face little or no competition in their own class, manufacturers possess great bargaining power in their negotiations with Part D plan sponsors. The PBMs negotiating drug prices for Medicare plans cannot walk away from the table if they do not like the deal a branded company in one of these classes is offering, limiting their ability to obtain lower prices on these drugs.

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<sup>55</sup> 42 C.F.R. § 423.120(b)(2)(i).

<sup>56</sup> NAT'L COUNCIL ON AGING, MEDICARE PART D DRUG PLANS: WHAT THEY MUST, MAY, AND CANNOT COVER 1 (2017), <https://www.ncoa.org/medicare-part-d-plans-what-they-must-can-cannot-cover-2>.

<sup>57</sup> See *supra* note 15 and accompanying text.

<sup>58</sup> See 42 U.S.C. § 1395w-111(i) (2012) (stating that the agency administering Medicare “may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors” and “may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs”); John F. Wasik, *Why Medicare Can't Get the Lowest Drug Prices*, FORBES (Aug. 10, 2018), <https://www.forbes.com/sites/johnwasik/2018/08/10/why-medicare-cant-get-the-lowest-drug-prices> (describing how delegating drug price negotiation to for-profit PBMs means that beneficiaries do not get the lowest prescription costs). For a discussion of the problems with PBMs as cost-reducers, see ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES (2019); Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, HARV. J. ON LEGIS. (forthcoming) [hereinafter Feldman, *Perverse Incentives*], <https://ssrn.com/abstract=3162432>.

<sup>59</sup> 42 U.S.C. § 1395w-104(b)(3)(G)(i) (requiring plans to include drugs in these classes unless the agency creates an exception); *id.* § 1395w-104(b)(3)(G)(iv) (identifying protected classes). The CMS policy was implemented to prevent discrimination against beneficiaries with these conditions, as might be expected for patients with high-cost preexisting conditions, see Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate—Adverse Selection in the Insurance Marketplace*, 372 NEW ENG. J. MED. 399, 400 (2015) (describing how some insurers structure prescription drug benefits to deter high-cost patients from enrolling in their plans), and to “mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.” CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, ch. 6 § 30.2.5 (2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/Part-D-Benefits-Manual-Chapter-6.pdf>.

There are no legal limits on manufacturers charging much higher prices to Medicare plans than they charge to private plans, but in practice, PBMs may be able to negotiate one master agreement with each manufacturer on behalf of many public and private plans at once, giving them a strong source of leverage.<sup>60</sup> Additional negotiating leverage comes from plans' ability to place some (but not all) drugs on less desirable formulary tiers or to require prior authorization or step therapy, which imposes additional regulatory burdens on physicians and patients before providing access to particular drugs within a class.<sup>61</sup> On the other hand, the Part D benefit design limits plans' incentives to negotiate lower prices for the most expensive drugs because Medicare, not the private plans, is responsible for those costs.<sup>62</sup> Further, consumers may be inattentive to cost differences between Part D plans<sup>63</sup> or have difficulty understanding their benefits, further reducing incentives to control costs. Finally, the fact that PBMs in at least some cases are paid by insurers based on the percentage rebate they are able to obtain, not the net price that is charged for the drug, means that PBMs may have incentives to encourage plans to list drugs with greater rebates but higher net prices than drugs with smaller rebates but lower net prices.<sup>64</sup>

## 2. Medicaid

Two other large public payers<sup>65</sup> within the U.S. system—Medicaid and the Department of Veterans Affairs (VA)—serve as helpful comparisons to the Medicare program, illustrating how different policy choices in coverage both affect pricing and may create

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<sup>60</sup> See CHARLES ROEHRIG, ALTARUM INST., *THE IMPACT OF PRESCRIPTION DRUG REBATES ON HEALTH PLANS AND CONSUMERS* 8 (2018), [https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report\\_April-2018.pdf](https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf) (“Rather than negotiating separate agreements on behalf of each of their health plan customers, PBMs more typically negotiate a master agreement with each manufacturer using their combined clout.”).

<sup>61</sup> See *supra* note 10 (noting that the prevalence of such practices is difficult to determine).

<sup>62</sup> MEDPAC, *MEDICARE PAYMENT POLICY: REPORT TO THE CONGRESS* 393 (2019), [http://www.medpac.gov/docs/default-source/reports/mar19\\_medpac\\_entirereport\\_sec\\_rev.pdf](http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec_rev.pdf).

<sup>63</sup> See Kate Ho, Joseph Hogan & Fiona Scott Morton, *The Impact of Consumer Inattention on Insurer Pricing in the Medicare Part D Program*, 48 *RAND J. ECON.* 877 (2017) (estimating that if all consumers were attentive, the average savings over three years would be \$1050 per consumer and \$1.3 billion for the government).

<sup>64</sup> Feldman, *Perverse Incentives*, *supra* note 58, at 33–34.

<sup>65</sup> There are many other, smaller public payment programs with additional permutations along these lines, such as the 340B program, see *340B Drug Pricing Program*, HEALTH RESOURCES & SERVS. ADMIN., <https://www.hrsa.gov/opa/index.html> (last updated Aug. 2019), but Medicare, Medicaid, and the VA serve as three representative examples here.

potential biases elsewhere. Medicaid is a joint federal-state healthcare program for more than 65 million low-income and disabled Americans—a larger enrollment than Medicare.<sup>66</sup> All state Medicaid programs have chosen to cover outpatient prescription drugs,<sup>67</sup> a choice that requires them to cover all FDA-approved drugs with a few classes of exceptions, such as drugs used for cosmetic purposes.<sup>68</sup> In contrast to Medicare, which provides coinsurance for which beneficiaries generally are responsible for twenty to twenty-five percent of brand-name drug costs,<sup>69</sup> Medicaid provides full prescription drug coverage (with a small co-pay sometimes required).<sup>70</sup>

This untethering of prices from patient contributions removes one of the limited sources of price controls in the Medicare framework, but Medicaid constrains prices by tying them to other markets with preferred-pricing benefits. Most pharmaceutical manufacturers enter voluntary rebate agreements with CMS,<sup>71</sup> under which they must remit substantial rebates for each unit of a drug they sell to the Medicaid program: at least 23.1% of a drug's Average Manufacturer

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<sup>66</sup> *Compare July 2019 Medicaid & CHIP Enrollment Data Highlights*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html> (last visited Oct. 31, 2019) (Medicaid enrollment), *with Total Number of Medicare Beneficiaries*, KAISER FAMILY FOUND., <https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries> (last visited Oct. 31, 2019) (under 60 million enrolled in Medicare). The Affordable Care Act (ACA) was intended to increase the income threshold for coverage. *See Eligibility*, *supra* note 22 (stating that the eligibility for Medicaid under the ACA was expanded to individuals with incomes up to 133% of the poverty line). The Supreme Court effectively held that the Medicaid expansion must be optional for states. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 585 (2012). At present, thirty-seven states including the District of Columbia have opted into the expansion, *Status of State Medicaid Expansion Decisions: Interactive Map*, KAISER FAMILY FOUND. (Nov. 15, 2019), <https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map>, meaning that in fourteen states, nondisabled, childless adults still have little or no Medicaid coverage. *See JULIA PARADISE*, KAISER FAMILY FOUND., *MEDICAID MOVING FORWARD 3* (2015), <http://files.kff.org/attachment/issue-brief-medicaid-moving-forward>.

<sup>67</sup> PARADISE, *supra* note 66, at 4; *see Medicaid Benefits: Prescription Drugs*, KAISER FAMILY FOUND., <https://www.kff.org/medicaid/state-indicator/prescription-drugs> (last visited Oct. 31, 2019).

<sup>68</sup> 42 U.S.C. §§ 1396r-8(d)(2)(C), 1396r-8(k)(2) (2012).

<sup>69</sup> *See supra* note 39 and accompanying text; *see also supra* note 52 and accompanying text.

<sup>70</sup> *See Medicaid Benefits: Prescription Drugs*, *supra* note 67.

<sup>71</sup> Manufacturers that do not enter rebate agreements may still receive Medicaid payments when doctors certify the product as medically necessary, but these payments cannot be higher than “usual and customary charges to the general public.” 42 C.F.R. § 447.512(b)(2)–(c)(1) (2019). For a discussion of how this strategy was used by the manufacturer of an opioid overdose drug, see Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, J.L. & BIOSCIENCES (forthcoming 2020) (manuscript at 36–39), <https://ssrn.com/abstract=3534721>.

Price (AMP),<sup>72</sup> on top of which states are empowered to seek supplemental rebates.<sup>73</sup> If the company offers an even bigger discount to other payers (not including Medicare Part D or the VA), Medicaid is entitled by law to that “best price” for the drug.<sup>74</sup> Medicaid is also insulated from price increases on existing drugs that outpace the inflation rate.<sup>75</sup> More than half of Medicaid rebates are estimated to be due to this provision.<sup>76</sup> In 2016, Medicaid’s total drug spending net of these rebates was about \$30 billion,<sup>77</sup> less than a quarter of Medicare spending, and an even smaller fraction on a per-beneficiary basis.<sup>78</sup>

The rules linking Medicaid prices to those charged to private payers may have been successful at containing Medicaid costs relative to Medicare, but they also distort prices in the private market.<sup>79</sup> By charging higher prices to private payers, manufacturers can draw more money from the Medicaid program, and, if the number of

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<sup>72</sup> 42 U.S.C. § 1396r-8(c)(1)(B)(i)(VI); see Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2503(a)(2), 124 Stat. 310 (2010) (codified as amended at 42 U.S.C. § 1396r-8(k)(1)(A)) (redefining AMP).

<sup>73</sup> Generic companies must remit thirteen percent of the AMP per unit. 42 U.S.C. § 1396r-8(c)(3)(B)(iii).

<sup>74</sup> *Id.* § 1396r-8(c)(1)(A)(ii)(I)–(C)(i).

<sup>75</sup> *Id.* § 1396r-8(c)(2)(A).

<sup>76</sup> DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OEI-03-13-00650, MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN 8 (2015), <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

<sup>77</sup> MACPAC, JUNE 2018 REPORT TO CONGRESS ON MEDICAID AND CHIP 4 (2018), <https://www.macpac.gov/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf> (citing MACPAC, MACSTATS: MEDICAID AND CHIP DATA BOOK 80 exhibit 28 (2017), <https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-CHIP-Data-Book-December-2017.pdf>).

<sup>78</sup> Not all of these cost savings should be attributed to the pricing benefits; Medicare beneficiaries also have a higher average demand for pharmaceuticals because they are older. See Stefano DellaVigna & Joshua M. Pollet, *Demographics and Industry Returns*, 97 AM. ECON. REV. 1667, 1677 (2007) (“Older individuals demand more pharmaceutical products.”). Furthermore, as of 2010, twenty states imposed prescription limits on Medicaid beneficiaries, artificially limiting spending on prescription drugs. Daniel A. Lieberman et al., *Medicaid Prescription Limits: Policy Trends and Comparative Impact on Utilization*, 16 BMC HEALTH SERVS. RES., no. 5, 2016, at 7. For the twelve million dually eligible beneficiaries enrolled in both Medicare and Medicaid, Medicaid is the “payer of last resort,” meaning that their prescription drug costs are borne by Medicare. See CTRS. FOR MEDICARE & MEDICAID SERVS., PEOPLE DUALLY ELIGIBLE FOR MEDICARE AND MEDICAID (2019), [https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMCO\\_Factsheet.pdf](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMCO_Factsheet.pdf); *How Medicaid Interacts with Other Payers*, MACPAC, <https://www.macpac.gov/subtopic/how-medicaid-interacts-with-other-payers> (last visited Nov. 17, 2019).

<sup>79</sup> This is unlike the case for healthcare services, where Medicare and Medicaid rates are not tied to private-sector prices. In the service context, little evidence exists of cost-shifting behavior between Medicare or Medicaid and private insurers. See, e.g., Austin B. Frakt, *How Much Do Hospitals Cost Shift? A Review of the Evidence*, 89 MILBANK Q. 90 (2011).

Medicaid patients is high enough, the resulting gain can outweigh the loss of some private-sector patients. Mark Duggan and Fiona Scott Morton have shown that prescription drugs with a higher Medicaid market share have higher average prices in the private sector.<sup>80</sup> The design of demand-side subsidies is thus critically important to their effect on allocation.<sup>81</sup> And as we will discuss in the following Parts, these design differences affect innovation incentives as well.

### 3. Veterans Affairs

A third public payer in the United States, the VA, provides healthcare services to a much smaller population than either Medicare or Medicaid, covering just over nine million veterans.<sup>82</sup> Like Medicaid, the VA is entitled to a large statutory discount off of the nonfederal AMP<sup>83</sup> for a particular drug product.<sup>84</sup> But unlike either Medicare or Medicaid, the VA is further empowered to develop its own coverage requirements and is able to exclude drugs from coverage through formulary management.<sup>85</sup> This ability to set a restrictive formulary generally allows the VA to negotiate significantly better deals than Medicare<sup>86</sup> and Medicaid.<sup>87</sup> The tradeoff, of course, is

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<sup>80</sup> Mark Duggan & Fiona M. Scott Morton, *The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing*, 121 Q.J. ECON. 1 (2006).

<sup>81</sup> See Hemel & Ouellette, *supra* note 71, at 34–35 (describing the effect of demand-side subsidies on opioid proliferation).

<sup>82</sup> *Veterans Health Administration: About VHA*, U.S. DEP'T VETERANS AFF., <https://www.va.gov/health/> (last updated Feb. 19, 2020).

<sup>83</sup> The nonfederal AMP excludes any prices paid by the federal government. See 38 U.S.C. § 8126(h)(5) (2012).

<sup>84</sup> *Id.* § 8126(a)(2) (noting that the price charged may not exceed seventy-six percent of the nonfederal AMP without the Secretary's consent).

<sup>85</sup> Austin B. Frakt, Steven D. Pizer & Ann M. Hendricks, *Controlling Prescription Drug Costs: Regulation and the Role of Interest Groups in Medicare and the Veterans Health Administration*, 33 J. HEALTH POL. POL'Y & L. 1079, 1080–81 (2008).

<sup>86</sup> Estimates suggest that the VA pays on average 60% of the prices paid by Part D plans. Austin B. Frakt, Steven D. Pizer & Roger Feldman, *Should Medicare Adopt the Veterans Health Administration Formulary?*, 21 HEALTH ECON. 485, 487 (2012) (noting VA drug prices have been estimated to be between 56% and 63% of those paid by Medicaid); see also Brett Venker et al., Research Letter, *Assessment of Spending in Medicare Part D if Medication Prices from the Department of Veterans Affairs Were Used*, 179 JAMA INTERNAL MED. 431, 431 (2019) (projecting savings of 44% for a selected group of drugs).

<sup>87</sup> Estimates suggest that Medicaid pays more than the VA for a significant minority of drugs. See Thomas J. Hwang & Aaron S. Kesselheim, *Public Referendum on Drug Prices in the US: Will It Bring Relief?*, 355 BRIT. MED. J., Oct. 31, 2016, at 1, 2 (estimating that Medicaid likely pays more than the VA for 33% of drugs, by 30% on average). The VA is statutorily excluded from the calculation of the Medicaid best-price rule. 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I) (2012).



access. The VA does not cover all drugs that patients might want.<sup>88</sup> As yet, however, there has been relatively little political controversy over this issue, perhaps because VA beneficiaries are often able to access excluded drugs through supplemental insurance.<sup>89</sup> We are unaware of systematic studies of VA prescription drug benefits comparable to those that health economists have conducted for Medicare and Medicaid, but because of its smaller size, it seems unlikely that the VA's discounts have effects on private insurance markets comparable to Medicaid's, except perhaps for certain specific conditions.

### B. Models in Other Countries

Other developed countries have adopted very different methods of paying for prescription drugs and, typically, of controlling their prices. There is no single successful approach to lowering drug prices, but as summarized by a recent National Academies report, negotiating power in any market depends on a buyer's ability to walk away from the bargaining table and on the volume of goods to be purchased.<sup>90</sup> In other countries, government healthcare payers generally have far more authority than in the United States to decline coverage when a pharmaceutical manufacturer does not lower its price sufficiently, regardless of whether purchasing decisions are aggregated with a single payer or devolved to a collective of private insurance companies.<sup>91</sup> In this Section, we illustrate the ways two other countries (the United Kingdom and Germany) have achieved these goals.<sup>92</sup>

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<sup>88</sup> One study noted that although private Medicare Part D plans cover on average 85% of the top-selling 200 drugs in the country, the VA national formulary covers only 59% of these drugs. Frakt, Pizer & Feldman, *supra* note 86, at 490–91.

<sup>89</sup> Roughly thirty-two percent of VA patients report also having Medicare Part D coverage, and twenty-three percent report having a prescription benefit through a private insurance plan. GRACE HUANG ET AL., WESTAT, 2017 SURVEY OF VETERAN ENROLLEES' HEALTH AND USE OF HEALTH CARE 33 tbl.3-1 (2018), [https://www.va.gov/HEALTHPOLICYPLANNING/SoE2017/VA\\_Enrollees\\_Report\\_Data\\_Findings\\_Report2.pdf](https://www.va.gov/HEALTHPOLICYPLANNING/SoE2017/VA_Enrollees_Report_Data_Findings_Report2.pdf).

<sup>90</sup> NAT'L ACADS. OF SCIS., ENG'G, & MED., *supra* note 10, at 47.

<sup>91</sup> See David Blumenthal, Shanor Seervai & Shawn Bishop, *Three Essentials for Negotiating Lower Drug Prices*, COMMONWEALTH FUND (Aug. 22, 2018), <https://www.commonwealthfund.org/blog/2018/three-essentials-negotiating-lower-drug-prices> (“[Elsewhere,] the public is willing to delegate to informed purchasers the power to reach agreement on a price or, failing that, to walk away from the table.”).

<sup>92</sup> The United Kingdom and Germany also serve as key examples of different models for achieving universal healthcare coverage. Many countries have adopted one of these two models, although there are endless variations in between. See generally BHATTACHARYA ET AL., *supra* note 8, at 328–71 (providing an overview). The United Kingdom is a paradigmatic example of the Beveridge model of national health insurance, in which a country finances its healthcare system through taxes and provides services at the point of sale to all citizens. See Timothy Stoltzfus Jost, *Why Can't We Do What They Do? National Health Reform Abroad*, 32 J.L. MED. & ETHICS 433, 433–34 (2004) (citing

### 1. *United Kingdom*

Under the United Kingdom's Pharmaceutical Price Regulation Scheme, once a drug is approved by the relevant pharmaceutical regulators, the UK's National Institute for Health and Care Excellence (NICE) conducts a health technology assessment and makes recommendations to the National Health Service (NHS) regarding that drug's "clinical and cost effectiveness."<sup>93</sup> In conducting its assessment, NICE investigates whether the drug represents a good value for a resource-constrained healthcare system at the price offered by the manufacturer: If the drug's cost per quality-adjusted life year (QALY) gained is under £30,000, NICE is likely to recommend that the NHS provide coverage for the drug.<sup>94</sup> In the absence of a NICE recommendation, the NHS is not legally bound to cover the drug.<sup>95</sup>

The NHS's use of these health technology assessment methods, when combined with its ability to decline to pay for products if the pharmaceutical company in question does not negotiate a satisfactory price, means that the NHS typically pays far less for prescription drugs than Medicare does.<sup>96</sup> In return, patients' out-of-pocket costs are highly constrained: While a Medicare beneficiary may be asked to

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TIMOTHY STOLTZFUS JOST, *DISENTITLEMENT? THE THREATS FACING OUR PUBLIC HEALTH-CARE PROGRAMS AND A RIGHTS-BASED RESPONSE* 204 (2003) [hereinafter JOST, *DISENTITLEMENT?*]. Germany more closely resembles the Bismarck or social insurance model. Unlike national health insurance systems, these systems are not administered primarily by the government but instead by private entities, whose prices and services are tightly regulated. *Id.* (citing JOST, *DISENTITLEMENT?*, *supra* at 235). Some countries, such as Canada and Australia, have systems closer to the UK model, while others, such as Switzerland and France, align with Germany's system. *Id.* at 434. For a more detailed history of these two models, see generally Henry E. Sigerist, *From Bismarck to Beveridge: Developments and Trends in Social Security Legislation*, 13 *BULL. HIST. MED.* 365 (1943).

<sup>93</sup> NAT'L INST. FOR HEALTH & CARE EXCELLENCE, *GUIDE TO THE PROCESS OF TECHNOLOGY APPRAISAL* 6 (2018), <https://www.nice.org.uk/process/pmg19/resources/guide-to-the-processes-of-technology-appraisal-pdf-72286663351237>.

<sup>94</sup> *Cf. id.* at 31. NICE has also created a fast-track appraisal process for the most cost-effective treatments, those estimated to come in under £10,000 per QALY gained. *Id.*

<sup>95</sup> *Can I Demand a Specific Treatment?*, NAT'L HEALTH SERV., <https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/can-i-demand-a-specific-treatment> (last reviewed June 8, 2018) ("The NHS in England and Wales is legally obliged to fund medicines and treatments NICE recommends. . . . The NHS is not legally obliged to fund a medicine or treatment not recommended by NICE . . ."). For overviews of this Pharmaceutical Price Regulation Scheme, see FIN. & NHS/MEDS., PHARMACY & INDUS. GRP./17080, DEP'T OF HEALTH & ASS'N OF THE BRITISH PHARM. INDUS., *THE PHARMACEUTICAL PRICE REGULATION SCHEME 2014* (2013), [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/675465/The\\_pharmaceutical\\_price\\_regulation\\_scheme\\_2014.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/675465/The_pharmaceutical_price_regulation_scheme_2014.pdf); Hemel & Ouellette, *supra* note 9, at 564–65.

<sup>96</sup> See Jeanne Whalen, *Why the U.S. Pays More Than Other Countries for Drugs*, WALL ST. J., <https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481> (last updated Dec. 1, 2015, 9:27 PM) ("Of 40 branded drugs covered by

spend several thousand dollars out of pocket for prescription drugs,<sup>97</sup> NHS patients cannot be asked to spend more than £9 per prescription (between \$11 and \$12 in U.S. dollars), and many items are free at the point of sale.<sup>98</sup>

A system like the UK Pharmaceutical Price Regulation Scheme can be structured to approximate the profit the seller would have made on the unsubsidized UK market where the government imposes no price constraints but also doesn't subsidize the purchase price. A rational pharmaceutical firm would not offer a drug to NHS for a price that would lead to lower profits than its expected market return from the smaller number of patients willing to pay out of pocket or through private insurance.<sup>99</sup> And the NHS should not normally be willing to pay more than the actual public health benefit from the drug, although it may end up paying more for political reasons.<sup>100</sup>

The NHS's negotiating leverage is possible only because the NHS is willing to deny access to some drugs. As a result, NHS patients experience more limited access to certain medications than do Medicare patients. For example, consider the case of one of Vertex Pharmaceuticals's drugs for the treatment of cystic fibrosis, Orkambi. Orkambi's list price in the United States is \$272,000 per year, and although insurers may balk at that price when compared to the "modest[ ]" clinical value provided by the drug, Medicaid programs have been legally obligated to cover the drug since it was approved in

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Medicare Part B and also available in England in the third quarter [of 2015], 98% were more expensive in the U.S. . . .").

<sup>97</sup> See Juliette Cubanski et al., *No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending*, KAISER FAMILY FOUND. (Nov. 7, 2017), <https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending> ("The one million Part D enrollees with out-of-pocket costs above the catastrophic threshold spent more than \$3,000 out of pocket on their prescriptions in 2015, on average; 1 in 10 of them spent at least \$5,200.").

<sup>98</sup> *Help with NHS Prescription Costs*, NAT'L HEALTH SERV. BUS. SERVS. AUTHORITY, <https://www.nhsbsa.nhs.uk/help-nhs-prescription-costs> (last visited Nov. 1, 2019).

<sup>99</sup> About ten percent of the UK population has private insurance. Patrick Collinson, *Private Health Insurance Sales Surge amid NHS Crisis*, GUARDIAN (Jan. 15, 2017, 7:01 PM), <https://www.theguardian.com/business/2017/jan/16/private-medical-insurance-sales-surge-health-nhs>; see also BHATTACHARYA ET AL., *supra* note 8, at 343 (noting that private spending comprised 17.8% of UK healthcare expenditures in 2000).

<sup>100</sup> There are a number of reasons why patents' market-based proxy for social value may be imperfect, including externalities, information costs, agency costs, and gaps between willingness and ability to pay. See Hemel & Ouellette, *supra* note 9, at 575. The extent to which these factors swamp the informational value of price signals in the pharmaceutical market is an important empirical question for optimizing innovation policy in this area.

2015.<sup>101</sup> In the UK, Orkambi's list price is £105,000 (about \$133,000 per year), but NICE declared the drug not to be cost-effective at that price, declining coverage and seeking to drive a harder bargain with Vertex.<sup>102</sup> At present, few of the 10,000 cystic fibrosis patients in the UK would likely be able to afford Vertex's asking price.<sup>103</sup> However, Vertex likely feared that accepting a much lower price in the UK would jeopardize their profit margin in other countries, given both parallel importation and reference pricing.<sup>104</sup> Patients fought back, urging the government to issue a compulsory license (breaking Vertex's patents) and more recently forming buyers' clubs for generic versions of Orkambi.<sup>105</sup> In October 2019, Vertex and the NHS finally came to a confidential agreement to allow access.<sup>106</sup>

The Orkambi example illustrates that on an unsubsidized market, the profit-maximizing price will often serve a small number of very wealthy patients, and that programs like the Pharmaceutical Price Regulation Scheme can greatly decrease prices and increase access without decreasing profits. The ability to decline coverage—despite the resulting access problems—is intimately linked to the UK's ability to control prescription drug costs. But it also shows that this kind of leverage in price negotiations can lead to occasional bargaining breakdowns, with consequences for healthcare access, when a manufacturer demands more than the demonstrated health value of its product.

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<sup>101</sup> Katie Thomas, *A Drug Costs \$272,000 a Year. Not So Fast, Says New York State*, N.Y. TIMES (June 24, 2018), <https://www.nytimes.com/06/24/health/drug-prices-orkambi-new-york.html>.

<sup>102</sup> Sarah Boseley, *Calls for Action on Patients Denied £100,000 Cystic Fibrosis Drug*, GUARDIAN (Feb. 3, 2019, 6:11 PM), <https://www.theguardian.com/feb/03/nhs-cystic-fibrosis-drug-orkambi-vertex>.

<sup>103</sup> *Compare id.* (noting that there are 10,000 patients in the UK and that the drug is priced at £105,000 per year), with *Average Household Income, UK: Financial Year Ending 2018*, OFF. FOR NAT'L STAT. (Feb. 26, 2019), <https://www.ons.gov.uk/peoplepopulationandcommunity/personalandhouseholdfinances/bulletins/householddisposableincomeandinequality/yearending2018> (listing the median 2018 household disposable income in the UK as £28,400).

<sup>104</sup> It is also unclear how the price the NHS publicly offered to pay Vertex—£100 million per year for Orkambi plus its other approved drugs, Boseley, *supra* note 102, including an older cystic fibrosis drug already on the UK market—compares to the revenue Vertex was already receiving in the UK from the NHS and from private payers. See Ed Silverman, *U.K. Lawmaker Challenges the Government to Issue a Compulsory License for Vertex Drug*, STAT (Feb. 1, 2019), <https://www.statnews.com/pharmalot/2019/02/01/uk-vertex-compulsory-license> (“In effect, the [NHS] was asking [Vertex] to provide Orkambi and its future cystic fibrosis drugs at no additional cost to the NHS.”).

<sup>105</sup> Boseley, *supra* note 102; see, e.g., Robert Long, *Big Pharma Is Denying Children Like My Son Vital Drugs. So I've Set Up a Buyer's Club*, GUARDIAN (June 6, 2019, 10:12 AM), <https://www.theguardian.com/2019/jun/06/big-pharma-children-drugs-buyers-club-vertex-cystic-fibrosis>.

<sup>106</sup> See Nick Trigg, *Cystic Fibrosis Drug Given Green Light in England*, BBC NEWS (Oct. 24, 2019), <https://www.bbc.com/news/health-50144742>.

## 2. Germany

Germany's healthcare system demonstrates how similar outcomes can be achieved in a system that also includes multiple private payers. The first step in the German pharmaceutical reimbursement process is similar to the U.S. system: Once a drug comes to market in Germany, the manufacturer is guaranteed market access for one year at the reimbursed price of its choosing.<sup>107</sup> However, the similarities end there. During that year, the German Institute for Quality and Efficiency in Health Care conducts a clinical evaluation of the product in question.<sup>108</sup> If the drug displays no added benefit relative to other drugs (perhaps in the same therapeutic class), the drug is then subject to reference pricing based on the lowest price charged within the class.<sup>109</sup> If the drug does display an added benefit, the manufacturer then enters into price negotiations with the relevant regulator, with the completed comparative effectiveness assessment as one element in that negotiation.<sup>110</sup> If the negotiation fails to reach a satisfactory outcome, the parties then enter an arbitration process, in which a panel determines the product's final price,<sup>111</sup> though the pharmaceutical company may refuse to accept the negotiated or arbitrated price and opt out of the insurance market.<sup>112</sup> Although German health insurance is delivered through a more decentralized system than in the UK, these discussions and negotiations take place at the national level.

By combining elements of comparative clinical effectiveness, reference pricing, negotiation, and arbitration, German health insurers typically pay less than American payers for the same products.<sup>113</sup> Although the discounts may not be as substantial as those obtained by

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<sup>107</sup> JAMES C. ROBINSON, DIMITRA PANTELI & PATRICIA EX, COMMONWEALTH FUND, REFERENCE PRICING IN GERMANY: IMPLICATIONS FOR U.S. PHARMACEUTICAL PURCHASING 2–3 (2019), [https://www.commonwealthfund.org/sites/default/files/2019-02/Robinson\\_reference\\_pricing\\_germany\\_ib.pdf](https://www.commonwealthfund.org/sites/default/files/2019-02/Robinson_reference_pricing_germany_ib.pdf). Presumably this is subject to some political constraint—a company that demanded a billion dollars per patient might find itself in political hot water, even though the law theoretically permits it.

<sup>108</sup> *Id.* at 2–3.

<sup>109</sup> *Id.* at 3.

<sup>110</sup> *Id.* at 5.

<sup>111</sup> *Id.* (noting that, in 2017, the prices of twenty percent of new drugs submitted to GBA review were set through arbitration).

<sup>112</sup> *Id.* For more detailed explanations of this process, see *id.* and MARTIN WENZEL & VALÉRIE PARIS, ORG. FOR ECON. COOPERATION & DEV., PHARMACEUTICAL REIMBURSEMENT AND PRICING IN GERMANY (2018), <http://www.oecd.org/health-systems/-and-Pricing-in-Germany.pdf>.

<sup>113</sup> See U.S. DEP'T OF HEALTH & HUMAN SERVS., COMPARISON OF U.S. AND INTERNATIONAL PRICES FOR TOP MEDICARE PART B DRUGS BY TOTAL EXPENDITURES 3 (2018), <https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf> (finding that U.S. prices are higher than any other examined country in an analysis that included Germany).

the NHS, German plans are able to achieve a similar goal of paying more for drugs with evidence of incremental comparative effectiveness, and less for drugs without such evidence.<sup>114</sup> Importantly, German insurers also do not prevent pharmaceutical companies from charging the price of their choosing. They simply will not reimburse more than the reference price for the product, if applicable. If, however, the patient desires the more expensive drug, the patient is able to obtain it by paying out-of-pocket the difference between the reference price and the manufacturer's price.<sup>115</sup> About one-quarter of beneficiaries have private insurance to cover some of these costs.<sup>116</sup> Many patients, however, choose products priced at or below the reference limit, for which required co-pays are just a few euros.<sup>117</sup>

### C. U.S. Proposals for Reforming Pharmaceutical Access

As the previous two Sections have explained, the U.S. government's demand-side subsidies for pharmaceuticals generally involve paying higher prices and requiring higher patient cost-sharing than in other countries. To tackle these distinct issues, two very different sets of reform proposals are being considered today in the United States. First, many policymakers on both sides of the political aisle are concerned about high drug prices and are exploring ways to reduce what the government pays for drugs. Lowering drug costs is a priority at the state as well as federal level: In 2018, states considered 227 bills and passed 55 laws focused on drug costs.<sup>118</sup> Second, most Democrats (but few Republicans) are looking at ways to expand access to medicines, including proposals for "Medicare for All."<sup>119</sup> While these approaches have substantial differences, they have all been framed around improving the conditions under which consumers access drugs. They have not been framed as a way to change the incentives for pharmaceutical innovation.

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<sup>114</sup> Victoria Desiree Laurenroth & Tom Stargardt, *Pharmaceutical Pricing in Germany: How Is Value Determined Within the Scope of AMNOG?*, 20 *VALUE HEALTH* 927 (2017); see also Ariel D. Stern et al., *The Impact of Price Regulation on the Availability of New Drugs in Germany*, 38 *HEALTH AFF.* 1182, 1182, 1185 (2019) (examining drugs that entered the German market from 2012 to 2016 and finding that price regulation did not lead to significant market exits of beneficial drugs; ninety-eight percent of drugs with a positive health benefit assessment remained on the market).

<sup>115</sup> See ROBINSON, PANTELI & EX, *supra* note 107, at 4.

<sup>116</sup> *Id.*

<sup>117</sup> See *id.*

<sup>118</sup> Katherine L. Gudixsen & Jaime S. King, *The Burden of Federalism: Challenges to State Attempts at Controlling Prescription Drug Costs*, 39 *J. LEGAL MED.* 95, 98 (2019).

<sup>119</sup> Kliff & Scott, *supra* note 3.

### 1. *Reducing the Cost of Drugs*

Recent proposals to reduce Medicare prescription drug spending have come primarily from two different institutional actors: the Republican-led Department of Health and Human Services (HHS) and its subsidiary agencies, largely CMS, and Democratic members of Congress. Considering major HHS proposals for lowering Medicare spending and their Democratic congressional analogues,<sup>120</sup> and contrasting those proposals with the fundamentally different ideas put forth by most congressional Republicans, helps illustrate the range of options presently on the table for controlling drug prices and spending in the United States.

One set of drug pricing proposals involves international reference pricing, aiming to tie the price paid for a drug in the United States to the price paid abroad. Many other countries already use international reference pricing as a strategy to lower their own prescription drug costs,<sup>121</sup> but it would be a novel approach for U.S. payers. HHS under the Trump Administration has proposed using international reference pricing to reform spending for physician-administered drugs in Medicare Part B.<sup>122</sup> The novel aspect of the Advanced Notice of

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<sup>120</sup> The broader scope of congressional authority (as compared to the limited powers already vested in HHS) permits additional solutions that have no comparable administration proposal. For instance, in response to prescription drug price spikes, the administration can only offer potential formulary exclusion, and their ability to do even that is limited by statute. By comparison, congressional Democrats have suggested proposals that would tax companies who engaged in these behaviors. Stop Price Gouging Act, S. 1369, 115th Cong. (2017), <https://www.congress.gov/115/bills/s1369/BILLS-115s1369is.pdf>. They could also consider establishing an inflation-adjusted rebate to Medicare. MEDPAC, MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM: REPORT TO THE CONGRESS 34–35 (2017), [http://www.medpac.gov/docs/default-source/reports/jun17\\_reporttocongress\\_sec.pdf](http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf).

<sup>121</sup> See, e.g., PANOS KANAVOS ET AL., THE IMPLEMENTATION OF EXTERNAL REFERENCE PRICING WITHIN AND ACROSS COUNTRY BORDERS 15 (2017), <http://www.lse.ac.uk/business-and-consultancy/consulting/assets/documents/the-implementation-of-external-reference-pricing-within-and-across-country-borders.pdf>.

<sup>122</sup> International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54,546 (Oct. 30, 2018); Sachs, *supra* note 7. It was a surprise to see the Trump Administration introduce this proposal. The President has repeatedly criticized other countries for “freeloading” on the United States’ own high drug prices. See, e.g., Robert Pear, *To Lower Drug Costs at Home, Trump Wants Higher Prices Abroad*, N.Y. TIMES (May 9, 2018), <https://www.nytimes.com/2018/05/09/us/politics/trump-prescription-drug-prices.html> (“‘We’re going to be ending global freeloading,’ Mr. Trump declared at a meeting with drug company executives in his first month in office.”). Further, a Council of Economic Advisers white paper argues that foreign countries are actually “under-pricing” these drugs. COUNCIL OF ECON. ADVISERS, REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD 10–15 (2018), <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>. With this proposal, in some ways the Administration seeks to free-ride on the efforts of *other* countries to lower their own drug prices rather than engaging in those efforts directly.

Proposed Rulemaking<sup>123</sup> seeks to reduce Part B reimbursement by indexing the U.S. price to a composite of prices paid in fourteen foreign countries, including the UK and Germany (as discussed above).<sup>124</sup>

The ultimate effect of the Administration's proposal on prices is unclear, assuming it is even feasible.<sup>125</sup> Reference pricing works because it assumes some other country has set the right price. If every country does it, there may be no market price to use as a reference. Further, international reference pricing in Europe has caused firms to delay access in lower-income countries or to set higher prices in those countries than if they were not serving as references.<sup>126</sup> Companies and other countries may also attempt to prevent the United States from obtaining the information it needs to implement the program or may design their payment systems to circumvent the intent of the proposal. If the proposal is finalized, the savings to Part B thus will likely

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<sup>123</sup> The proposal actually consists of three interrelated parts—substituting private-sector vendors for Part B's current “buy and bill” system, altering Part B's average sales price reimbursement structure to a flat fee structure, and the international reference pricing system—but the first two parts recall efforts begun under both Presidents George W. Bush and Barack Obama. Sachs, *supra* note 2. Although the relationship between these three parts of the proposal does matter, we focus here on the novel part of the proposed rule, which is the only one with the potential to lower Medicare spending meaningfully, rather than simply restructure misaligned incentives.

<sup>124</sup> International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. at 54,555–57 (“CMS is considering testing an alternative payment for included drugs based on the international pricing . . . We are considering using pricing data from the following countries: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.”).

<sup>125</sup> Expert commentators have questioned whether this indexing is feasible, given the interrelated parts of the ANPRM and existing coverage requirements. *E.g.*, MedPAC, Comment Letter on Proposed Rule: Medicare Program; International Pricing Index Model for Medicare Part B Drugs 3–4 (Dec. 20, 2018), [http://www.medpac.gov/docs/default-source/comment-letters/\\_internationaldrugpricing\\_medpac\\_comment\\_v3\\_sec.pdf](http://www.medpac.gov/docs/default-source/comment-letters/_internationaldrugpricing_medpac_comment_v3_sec.pdf).

<sup>126</sup> Ulf Persson & Bengt Jönsson, *The End of the International Reference Pricing System?*, 14 APPLIED HEALTH ECON. & HEALTH POL'Y 1, 5 (2016) (“[International reference pricing] means that a price regulator's demand and acceptance of only a low price for a new product in one national market can lead manufacturers to refrain from launching their product in this market.”); *see, e.g.*, Luca Maini & Fabio Pammolli, Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market (May 6, 2019) (unpublished manuscript), [https://static1.squarespace.com/static/5b3660f9b98a78542ce0faa9/t/5cd059d36e9a7f5d06085587/1557158377685/MainiPammolli\\_ERP](https://static1.squarespace.com/static/5b3660f9b98a78542ce0faa9/t/5cd059d36e9a7f5d06085587/1557158377685/MainiPammolli_ERP) (documenting strategic launch delays in European countries due to reference pricing). The economic incentives—and the resulting welfare and distributional impact—are thus similar to those created by international patent exhaustion. *See generally* Daniel J. Hemel & Lisa Larimore Ouellette, *Trade and Tradeoffs: The Case of International Patent Exhaustion*, 116 COLUM. L. REV. SIDEBAR 17 (2016) (“[T]he adoption of a rule of international patent exhaustion would likely lower prices of patented goods in the United States and raise prices abroad. Moreover, such a rule would impose costs on foreign governments that choose to subsidize access to patented goods for their own citizens.”).



be lower than projected by the Administration, and the rule may negatively impact access in other countries.

Congressional Democrats have similarly introduced bills that involve international reference pricing, but their proposals are broader in scope than what HHS, acting under its existing statutory authority, is able to achieve. As one example, the House Democratic caucus, led by Speaker Nancy Pelosi, successfully passed a package that would use international reference pricing to set a ceiling for broad-based drug price negotiations.<sup>127</sup> The HHS Secretary would not be permitted to negotiate for a price that exceeded 1.2 times the volume-weighted average of a particular drug's price in six specified countries, including Germany and the UK.<sup>128</sup> If a drug company refused to negotiate such a price, it would be assessed a high non-compliance fee, beginning at sixty-five percent of the gross sales of the drug in question and increasing each quarter.<sup>129</sup> Importantly, the House bill envisions extending the resulting negotiated prices not only to Medicare but also to the private sector, meaning that privately insured Americans would also benefit from the lower negotiated prices (unlike under the Administration's proposals).

As another example, a bill from Senator Bernie Sanders and Representative Ro Khanna would determine whether a particular prescription drug is "excessively priced" as compared to a reference price composed of prices in five other countries (all of which are on the Administration's list for the Part B proposal).<sup>130</sup> Unlike HHS's Advance Notice of Proposed Rulemaking, which is limited to drugs dispensed in Medicare Part B, the Sanders-Khanna proposal would apply broadly.<sup>131</sup> In the event that a drug is determined to be "excessively priced," the manufacturer would forfeit "any government-granted exclusivities," presumably including both patents and FDA exclusivity periods, and the government "shall grant open, non-exclusive licenses" allowing competitors to make and sell the drug.<sup>132</sup>

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<sup>127</sup> Elijah E. Cummings Lower Drug Costs Now Act of 2019, H.R. 3, 116th Cong. § 101 (2019) ("[T]o determine the maximum fair price the Secretary shall use data relating to the [average international market] price.").

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* § 102.

<sup>130</sup> Prescription Drug Price Relief Act of 2019, H.R. 465, 116th Cong. § 2 (2019).

<sup>131</sup> *See id.* § 2(b)(1)(A) (giving the Secretary authority to declare "any brand name drug" as excessively priced).

<sup>132</sup> *Id.* § 3(a).

A second set of drug pricing proposals involves Medicare negotiation, particularly in Part D. A November 2018 CMS proposed rule<sup>133</sup> would have allowed Part D plans to limit coverage for drugs in the six protected classes described above,<sup>134</sup> although that provision was not adopted in the final rule.<sup>135</sup> Plans would have had more authority to use “utilization management tools” like prior authorization and step therapy.<sup>136</sup> Plans would have been able to exclude protected-class drugs entirely from their formulary (contrary to existing policy) if the drug in question merely reformulates an existing product,<sup>137</sup> seemingly in response to the increasing prevalence of “product hopping” behavior by firms.<sup>138</sup> And plans could exclude a drug entirely if its price increases beyond a certain amount over a particular time period, aiming to combat the problem of prescription drug price spikes.<sup>139</sup> This proposed rule would have lowered Part D spending by providing plans with greater negotiating authority within the protected classes,<sup>140</sup> but it might also have deprived patients of access to drugs that are currently available through their Part D plan.

On the Democratic side, there are a number of congressional efforts to permit HHS to negotiate Medicare drug prices. The House Democrats’ package empowers the HHS Secretary to negotiate the prices of up to 250 of the “most costly” drugs in the United States that lack “competition from at least one generic or biosimilar on the

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<sup>133</sup> Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62,152 (proposed Nov. 30, 2018) (to be codified at 42 C.F.R. pts. 422, 423).

<sup>134</sup> See *id.* at 62,184 (proposing to allow Part D sponsors to exclude protected class drugs from their formularies in some circumstances).

<sup>135</sup> In May 2019, CMS finalized this rule but did not make changes to protected-class coverage. See *Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 16, 2019), <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f> (noting that CMS did not finalize proposals that would have allowed Part D sponsors to exclude protected class drugs).

<sup>136</sup> Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. at 62,153.

<sup>137</sup> *Id.* at 62,152.

<sup>138</sup> “Product hopping” is a practice in which branded companies switch to new versions of their existing products to delay generic competition on older versions. See, e.g., Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016) (defining product hopping); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709–17 (2009) (discussing product hopping as a form of regulatory gaming).

<sup>139</sup> Recent research suggests that nearly all protected class drugs would be eligible for exclusion under this criterion. Thomas J. Hwang et al., *Price Increases of Protected-Class Drugs in Medicare Part D, Relative to Inflation, 2012-2017*, 322 JAMA 267, 268 (2019).

<sup>140</sup> See Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. at 62,184–85 (estimating potential savings for providing plans “flexibility to manage protected classes”).

market.”<sup>141</sup> To identify a target negotiating price for a particular product, below the ceiling price determined via reference pricing as above, the Secretary would consider factors including R&D costs and comparisons to existing therapeutic alternatives.<sup>142</sup> The Democrats’ bill threatens a large and escalating non-compliance fee if a company refuses to negotiate,<sup>143</sup> rather than declining to cover the drug as a first “stick” for the company. Because this bill would extend the negotiated prices to the private market, not only to Medicare, it would benefit far more patients than would the Administration’s Part D proposal.

One Democratic bill taking a different approach comes from Representative Lloyd Doggett and Senator Sherrod Brown.<sup>144</sup> Representative Doggett’s bill would also lower drug spending in Part D, although the bill is not limited to protected-class drugs. The bill instructs the Secretary to negotiate prices and provides a framework of criteria upon which that negotiation should take place.<sup>145</sup> However, if the Secretary and drug manufacturer are unable to reach an agreement, the bill pursues a “competitive licensing” approach.<sup>146</sup> In such a case, the bill instructs the Secretary to “authorize the use of any patent, clinical trial data, or other exclusivity granted by the Federal government” and permit competitors to enter the market for the product in question.<sup>147</sup> The licensing approach pursued in both the Sanders and Doggett bills seeks to lower drug spending without depriving patients of access to the drugs they may need.

Congressional Republicans largely agree on the need to lower spending through public payers, but they have generally rejected both of these approaches.<sup>148</sup> Instead, they argue for reforms that would “eliminat[e] the incentives in Medicare that reward bad actors” and

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<sup>141</sup> Backgrounder, Office of House Speaker Nancy Pelosi, H.R. 3 – The Lower Drugs Costs Now Act (Oct. 2, 2019), <https://www.speaker.gov/sites/speaker.house.gov/files/HR3%20Backgrounder%2010.2.19.pdf>; Zhou, *supra* note 2.

<sup>142</sup> Lower Drug Costs Now Act of 2019, H.R. 3, 116th Cong. § 101 (2019).

<sup>143</sup> *Id.* § 102.

<sup>144</sup> Medicare Negotiation and Competitive Licensing Act of 2019, H.R. 1046, 116th Cong. (2019); S. 377, 116th Cong. (2019).

<sup>145</sup> H.R. 1046 § 2.

<sup>146</sup> *Id.*

<sup>147</sup> *See id.* § 2(i)(3)(A) (outlining the Secretary’s competitive licensing authority and requiring reasonable compensation for “any entity making use of a competitive license”).

<sup>148</sup> During a recent markup of a drug pricing package in the Senate Finance Committee, most of the Committee’s Republican members voted to block the Administration’s international reference pricing model. Rachel Sachs, *Understanding the Senate Finance Committee’s Drug Pricing Package*, HEALTH AFF. (July 26, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190726.817822/full>.

“unleash . . . market forces.”<sup>149</sup> The bills introduced or co-sponsored by Republicans primarily focus on banning tactics used by branded firms to delay generic entry, including pay-for-delay deals with generic firms<sup>150</sup> and the restriction of sample availability.<sup>151</sup> More recently, congressional Republicans have expressed concern over other types of pharmaceutical company gaming of the patent system, and further legislation may be introduced.<sup>152</sup>

Following the lead of the pharmaceutical industry, Republicans have argued that the Democrats’ approaches would threaten pharmaceutical innovation in the way that they reduce drug prices,<sup>153</sup> and so they aim to target particular malefactors (who they see as undermining the balance struck in the patent and exclusivity systems) without affecting the incentives of other, seemingly more meritorious, firms. HHS Secretary Azar, himself a former pharmaceutical company executive, has pushed back on the argument that reforms like the ones HHS is proposing would necessarily detract from innovation incentives.<sup>154</sup> But the interactions between innovation and access in the Medicare program have yet to be explored fully by either policy-makers or scholars.

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<sup>149</sup> *Hearing on the Cost of Rising Prescription Drug Prices Before the H. Comm. on Ways & Means*, 116th Cong. (Feb. 12, 2019) (statement of Rep. Kevin Brady), [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/Corrected%20Transcript\\_3.1.19.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/Corrected%20Transcript_3.1.19.pdf).

<sup>150</sup> *See* Preserve Access to Affordable Generics and Biosimilars Act, S. 64, 116th Cong. § 2 (2019) (noting that a purpose of the Act is to “enhance competition in the pharmaceutical market by stopping anticompetitive agreements . . . that . . . delay . . . competition from generic drugs”).

<sup>151</sup> *See* Creating and Restoring Equal Access to Equivalent Samples Act of 2017, S. 974, 115th Cong. § 3(b) (2017) (allowing civil actions for failure to provide samples).

<sup>152</sup> *See, e.g.*, Peter Sullivan, *GOP Lawmaker Says Panel to Investigate Drug Company Gaming of Patent System*, THE HILL (Feb. 26, 2019), <https://thehill.com/policy/healthcare/431691-gop-lawmaker-says-panel-to-investigate-drug-company-gaming-of-patent-system> (noting that Senator Grassley supports having the Judiciary Committee further investigate gaming of the patent system).

<sup>153</sup> *See, e.g.*, Letter from Representatives Devin Nunes (R-CA) & Kevin Brady (R-TX) to Representative Lloyd Doggett (D-TX) (Mar. 5, 2019), [https://republicans-waysandmeansforms.house.gov/\\_nunes\\_drug\\_pricing\\_letter\\_sub.pdf](https://republicans-waysandmeansforms.house.gov/_nunes_drug_pricing_letter_sub.pdf) (arguing that Doggett’s proposal would “radically undermine innovation”).

<sup>154</sup> *See, e.g.*, Secretary Alex M. Azar II, *Remarks on Drug Pricing Blueprint*, HHS (May 14, 2018), <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html> (“I’ve been a drug company executive—I know the tired talking points: the idea that if one penny disappears from pharma profit margins, American innovation will grind to a halt.”); *see also* Shannon Firth, *Reactions Mixed to Part B Drug Pricing Plan*, MEDPAGE TODAY (Oct. 26, 2018), <https://www.medpagetoday.com/publichealthpolicy/medicare/75967> (describing reactions to Secretary Azar’s remarks).

## 2. *Expanding Government Insurance*

Independently, congressional Democrats are also introducing bills that would dramatically expand public health insurance, predominantly under the banner of “Medicare for All.” The goal is to provide universal access to health insurance for all Americans, although existing plans differ in the benefits package they would provide and on how exactly they plan to expand access.<sup>155</sup> Several proposals would provide a publicly available buy-in to a program closely approximating existing Medicare coverage,<sup>156</sup> which has the benefits and cost-sharing features described in Section I.A.1. Other proposals would create a *Medicaid* buy-in,<sup>157</sup> incorporating Medicaid’s cost-control features described in Section I.A.2, but would permit greater cost-sharing obligations for higher-income individuals than are currently permitted in the low-income Medicaid population.

Other proposals would provide universal access to a more generous version of Medicare than currently exists, including far more generous coverage of prescription drugs. However, they also contain provisions that aim to lower overall drug prices dramatically. Three bills—Senator Sanders’s Medicare for All, Representative Pramila Jayapal’s Medicare for All, and Representatives Rosa DeLauro and Jan Schakowsky’s Medicare for America—provide helpful examples of these two aspects of the proposals.

Senator Sanders’s Medicare for All bill provides coverage for all prescription drugs,<sup>158</sup> but it does largely permit cost-sharing obligations of \$200 per year per individual.<sup>159</sup> The bill provides that drug prices “shall be negotiated annually” by HHS but does not provide details as to how such negotiation should be conducted and what criteria should be used.<sup>160</sup> Representative Jayapal’s Medicare for All bill on behalf of the House Progressive Caucus is even more generous, providing coverage for all prescription drugs with no cost-sharing.<sup>161</sup> The Jayapal bill would also require the Secretary of HHS to negotiate prescription drug prices, but it is more specific about how to do so,

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<sup>155</sup> See Kliff & Scott, *supra* note 3 (comparing Democratic proposals to expand healthcare).

<sup>156</sup> See *id.* (describing the structure and benefits of the proposed Medicare buy-in); see also Choose Medicare Act, S. 1261, 116th Cong. (2019) (proposing the establishment of “Medicare part E plans” in which U.S. residents could enroll).

<sup>157</sup> See Kliff & Scott, *supra* note 3 (describing the structure and benefits of the Medicaid buy-in); see also State Public Option Act, S. 489, 116th Cong. (2019) (proposing a Medicaid buy-in option).

<sup>158</sup> Medicare for All Act of 2019, S. 1129 § 201, 116th Cong. (2019).

<sup>159</sup> *Id.*

<sup>160</sup> *Id.* § 614.

<sup>161</sup> Medicare for All Act of 2019, H.R. 1384 § 202, 116th Cong. (2019).

providing for criteria very similar to those identified in Representative Doggett's bill, in which the HHS Secretary would be required to issue licenses if negotiations were to fail.<sup>162</sup> The Medicare for America bill introduced by Representatives DeLauro and Schakowsky is similar, providing broad coverage of prescription drugs generally<sup>163</sup> with no cost-sharing<sup>164</sup> and incorporating the negotiation and licensing authority from Representative Doggett's bill as a means to bring down prices.<sup>165</sup>

Unlike for drug prices, there is no bipartisan consensus around expanding social health insurance. To the contrary, the Trump Administration has recommitted to rolling back the insurance protections of the Affordable Care Act (ACA)<sup>166</sup> and has shown no interest in expanding government-funded healthcare, much less Medicare for All. Nonetheless, the Jayapal and DeLauro–Schakowsky bills are particularly interesting for our purposes because they aim to connect the two different access mechanisms under discussion. The coupling of lower unit prices for pharmaceuticals through the process of negotiation and licensing with much greater access to those same pharmaceuticals may or may not result in lower pharmaceutical spending overall.<sup>167</sup> But the juxtaposition sets the stage for our discussion in the remainder of this Article of how access and pharmaceutical innovation relate.

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<sup>162</sup> See *id.* § 616 (authorizing annual negotiations and competitive licensing authority).

<sup>163</sup> See Medicare for America Act of 2019, H.R. 2452 § 2203(a)(6), 116th Cong. (2019) (providing coverage for “[p]rescription drugs approved by the Food and Drug Administration”).

<sup>164</sup> See *id.* § 2205(a)(3) (setting reimbursement rate for generic drugs and “medically necessary” prescription drugs to one hundred percent).

<sup>165</sup> See *id.* § 2206(d) (allowing the Secretary to negotiate prices and issue competitive licenses).

<sup>166</sup> See Jan Hoffman & Abby Goodnough, *Trump Administration Files Formal Request to Strike Down All of Obamacare*, N.Y. TIMES (May 1, 2019), <https://www.nytimes.com/2019/05/01/health/unconstitutional-trump-aca.html> (noting that striking down the ACA “could end health insurance for some 21 million Americans”).

<sup>167</sup> The ACA itself coupled lower unit prices for pharmaceuticals through an increase in the mandatory minimum Medicaid rebate, with a broad Medicaid expansion. See Patient Protection and Affordable Care Act of 2010, 42 U.S.C. § 1396r-8(c)(1)(B)(i)(VI) (2012); Ramsey Baghdadi et al., *Medicaid Best Price*, 7 HEALTH AFF. 1, 2 (Aug. 2017), [https://www.healthaffairs.org/doi/10.1377/hpb20171008.000173/full/healthpolicybrief\\_173.pdf](https://www.healthaffairs.org/doi/10.1377/hpb20171008.000173/full/healthpolicybrief_173.pdf) (noting that the ACA increased the rebate from 15.1% to 23.1%); see also LARISA ANTONISSE ET AL., KAISER FAMILY FOUND., THE EFFECTS OF MEDICAID EXPANSION UNDER THE ACA: UPDATED FINDINGS FROM A LITERATURE REVIEW 3 (2019), <http://files.kff.org/attachment/Issue-brief-The-Effects-of-Medicaid-Expansion-under-the-ACA-Findings-from-a-Literature-Review> (discussing Medicaid expansion under the ACA generally and noting that “[s]everal studies identified larger coverage gains in expansion versus non-expansion states for specific vulnerable populations, including . . . prescription drug users”).

## II

## PHARMACEUTICAL SUBSIDIES AS INNOVATION INCENTIVES

Governments have created the complex array of prescription drug allocation mechanisms described in Part I because those drugs are costly and public payers face tradeoffs about how to allocate scarce resources. As noted above, the ability of drug manufacturers to set prices well above the cost of production stems from the IP used to protect R&D investments.<sup>168</sup> This ex post, market-set incentive is provided not only through patent law, but also through other forms of IP, including trade secrets, trademarks, and regulatory exclusivity.<sup>169</sup> It is hard to disentangle the effects of these different forms of IP, but companies generally report that the pharmaceutical industry is the sector in which patents are most effective,<sup>170</sup> and scholars often agree.<sup>171</sup>

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<sup>168</sup> See *supra* note 24 and accompanying text. Making drugs is expensive, see Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 302 & nn.10–12 (2010), and private firms regularly drop clinically promising projects from development pipelines if they do not expect sufficient market exclusivity to recoup their investments. See Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545–47 (2009); see also Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044 (2015) (showing a distortion in R&D away from cancer drugs with shorter effective patent terms). It is far from obvious that leaving responsibility for clinical trials to the private sector is optimal, but the government currently plays little role in funding the later stages of drug development. See Hemel & Ouellette, *supra* note 9, at 570–71.

<sup>169</sup> See *supra* note 24 and accompanying text. For example, pharmaceutical patents co-exist with a regulatory scheme that includes an automatic thirty-month bar on generic entry until a patent dispute is resolved and five years of data exclusivity restricting competitors from piggybacking on the patent owner's FDA submissions for any drug with a new active ingredient. 21 U.S.C. § 355(c)(3)(C), (c)(3)(E)(ii), (j)(5)(B)(iii), (j)(5)(F)(ii) (2012). Several works consider the importance of regulatory exclusivity. See generally Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007) (explaining the FDA's role in motivating biopharmaceutical investments); Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357 (2019) (explaining data exclusivity and advocating for an additional period of exclusivity in all markets where the innovator does not seek patent protection); John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39 (2015) (discussing the growing role of regulatory exclusivities and its implications for innovation policy). On the role of trade secrecy, see generally W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769 (2016), which describes the interaction between regulation and trade secrecy and advocating for regulatory-enforced disclosure.

<sup>170</sup> See, e.g., Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1286 (2009) (noting that biotechnology companies report that patents provide "moderate" incentives, while software companies report that patents provide "slight" incentives to innovate); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 12 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), <http://www.nber.org/papers/w7552> ("[A]mong large firms, patents have the highest effectiveness scores in a number of industries,

But patents and other forms of IP come with significant drawbacks. They raise prices, impose administrative costs, and can discourage follow-on innovation. As discussed below, market-based IP rewards are misaligned from social value for a variety of biomedical innovations, including for goods that generate positive externalities or for which the social value exceeds consumers' ability to pay. Governments can offset these IP-related biases with other innovation policies, including R&D tax incentives, direct funding through grants and research at national labs, and prizes.<sup>172</sup>

Here, we focus on one such policy tool—one that policymakers have rarely seemed to think of as implementing innovation policy at all: government subsidies for particular drugs through health insurance programs like Medicare and Medicaid. From an incentive perspective, reimbursement programs can function as market-based prizes, in which the reward incorporates both a government assessment of social value and market information based on consumer choices.<sup>173</sup> For example, suppose policymakers decide that the expected IP-based market reward is insufficient for incentivizing a vaccine for a particular disease.<sup>174</sup> The government could offer an

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including drugs.”); *see also* Heidi L. Williams, *How Do Patents Affect Research Investments?*, 9 ANN. REV. ECON. 441, 448–50 (2017) (reviewing 1980s survey evidence that patents are viewed as most effective in the pharmaceutical and chemical industries).

<sup>171</sup> *See, e.g.*, BESSEN & MEURER, *supra* note 8, at 108–09, 108 tbl.5.3 (studying the contribution of U.S. patents issued in 1991 to the market value of U.S. public firms and estimating that two-thirds of the value is provided in the chemical and pharmaceutical industries and one-half is captured by about twenty-five large drug companies); DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 64–65 (2009) (noting that the value of patents is highest in the pharmaceutical industry and that “it seems clear that both pharmaceutical and biotech R&D spending is heavily dependent on patent protection”).

<sup>172</sup> *See generally* Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303 (2013) (developing a framework for comparing these incentives and explaining why no incentive is uniformly optimal). These incentives vary based on both the degree of technology-specific tailoring by the government and the timing of the award, with intermediate solutions existing along either of these dimensions. *See id.* at 327–45; *see also* Hemel & Ouellette, *supra* note 9 (discussing the potential efficiency gains from intermediate solutions on both the incentive and allocation side of innovation policy).

<sup>173</sup> Sachs, *supra* note 7; *see also* Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1011–14 (2014) (“[M]ost developed countries already accomplish (or could accomplish) the same basic objectives of the [proposed] prize system through their national prescription-drug insurance programs.”). *See generally* Heidi Williams, *Innovation Inducement Prizes: Connecting Research to Policy*, 31 J. POL’Y ANALYSIS & MGMT. 752 (2012) (describing other market-based prizes, including in the health context).

<sup>174</sup> Again, we note that this decision can be independent from whether that reward is transferred through proprietary pricing or through an alternative allocation mechanism, such as an effective patent buyout coupled with open-access allocation (as in the UK Pharmaceutical Price Regulation Scheme example).



additional fixed prize—say, \$1 billion for the first firm to develop a cure. But to encourage distribution of the vaccine and to tie the reward to some measure of patient preference, policymakers could also offer a market-based prize—say, \$100 per patient vaccinated. Particularly for interventions with positive externalities or high disparities between patients' ability and willingness to pay, administering this kind of additional incentive through government health insurance programs improves the alignment between the returns to innovation and social value.

The incentive effect of demand-side healthcare subsidies depends critically on details of institutional design. Section II.A shows how Medicare-like programs can provide a significant subsidy to drug manufacturers beyond expected profits in an unsubsidized market. Section II.B discusses the effect of this kind of subsidy on overall pharmaceutical innovation. Finally, Section II.C examines how subsidies from government insurance can bias innovation incentives in favor of particular biomedical technologies. But those details should not obscure the larger point, to which we turn in Part III: Healthcare reimbursements *are* innovation incentives. Indeed, they may be among the largest innovation incentives in the pharmaceutical sector.

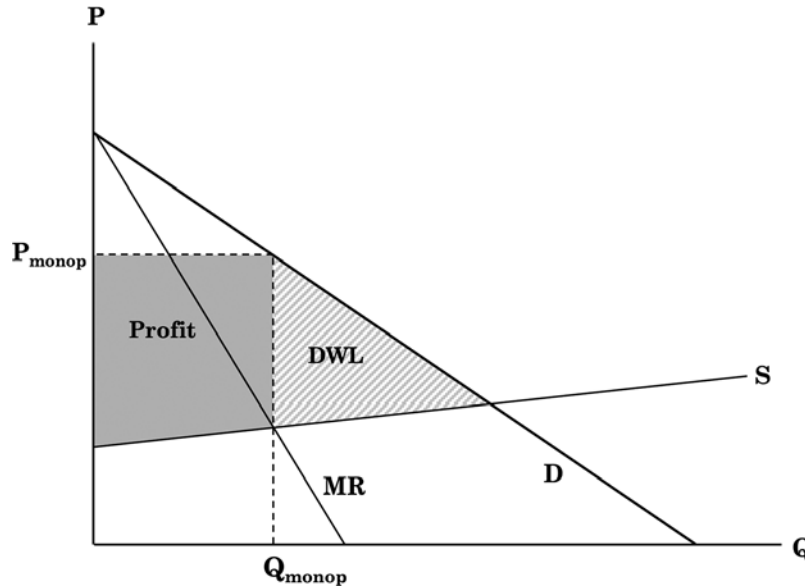
#### A. *The Medicare Innovation Subsidy*

To illustrate how pharmaceutical profits under Medicare reflect more than the “market value” of a drug, we begin with an ordinary, unsubsidized market in which a seller has monopoly power, as illustrated in Figure 1. The demand curve (D) represents how much quantity of the drug (Q) consumers will purchase at a given price (P); an ordinary market has a downward-sloping demand curve because more consumers are typically able to purchase a good at lower prices.<sup>175</sup> The supply curve (S) represents the quantity of drug that will be sold at a given price. Monopoly pricing involves reducing sales in order to increase the price.

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<sup>175</sup> The slope of the demand curve is referred to as the price elasticity of demand. For an essential medicine with no direct substitutes, demand is relatively inelastic: Significant changes in price will have only small effects on the number of consumers who purchase the drug, so the demand curve will be steeply sloped. For a lifestyle drug such as a treatment for baldness, demand is more elastic: Price increases will deter more consumers from purchasing the drug, as represented by a more gradually sloping demand curve. For an overview, see BHATTACHARYA ET AL., *supra* note 8, at 19–22; David Henry & Andrew Searles, *Pharmaceutical Pricing Policy*, in *MANAGING ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES* 9.2–9.3 (Marian Ryan et al. eds., 2012).

FIGURE 1. PROFIT AND DEADWEIGHT LOSS (DWL) IN A MONOPOLY MARKET



Why do monopolists reduce output while increasing prices? The key to this “normal” monopoly is the absence of price discrimination. The patentee would like to sell to everyone who is willing and able to pay more than it costs to sell them a drug: that is, everyone for whom the demand curve is higher than the supply curve. But if they lower the price to reach those who can afford to pay less, they also lower the price for all the other buyers, too, reducing the marginal revenue from adding a new sale. Monopolists, then, price not where the supply curve meets the demand curve (the competitive market price),<sup>176</sup> but instead where the supply curve meets the marginal revenue curve (MR), resulting in a higher price ( $P_{\text{monop}}$ ) and lower quantity ( $Q_{\text{monop}}$ ) than in a competitive market. If they cut the price any further, the money they would lose from existing customers would counteract the additional sales, making the additional sale unprofitable.

If this monopoly price is used to allocate access to the drug, consumers who value the drug above the cost of production but below the monopoly price are unable to access the drug. The social loss due to these lost transactions is known as deadweight loss (DWL), represented by the striped triangle in Figure 1. In the context of essential

<sup>176</sup> In a competitive market, if any producer attempted to raise prices above the competitive price, it would lose sales to lower-price suppliers. And if a producer attempted to lower prices below the competitive price to capture the market, it would not be profitable due to insufficient demand.

medicines, this represents patients who will be unable to access the treatments they need. IP policy tolerates this allocative inefficiency on the theory that it will be exceeded by gains in dynamic efficiency: The prospect of monopoly profits will incentivize a producer to create this drug in the first place. In other words, the development of the drug is necessary to provide any access at all. IP policy is thus typically described as representing a tradeoff between short-term access and longer-term innovation.<sup>177</sup>

The full interaction between IP and pharmaceutical access is more complicated than this simple model suggests. One of us has recently questioned the conventional view that the fundamental tradeoff in IP is between dynamic and allocative efficiency: IP-facilitated market power does create incentives to restrict quantity and thus decrease consumption, but it also has consumption-expanding effects.<sup>178</sup> But for our purposes, the standard monopoly-pricing model suffices to illustrate the basic effect of insurance and demand-side subsidies.

In Figure 2 we add the effect of coinsurance, in which an insurer covers a fixed percentage of medical costs. Compared to a market without insurance, a coinsurance system expands demand, moving the demand curve to the right. The curve pivots rather than simply shifting because coinsurance pays a percentage of the total cost, so it magnifies the effect of a consumer's existing willingness and ability to pay. If insurance pays 80% of the cost, a consumer who can pay \$100

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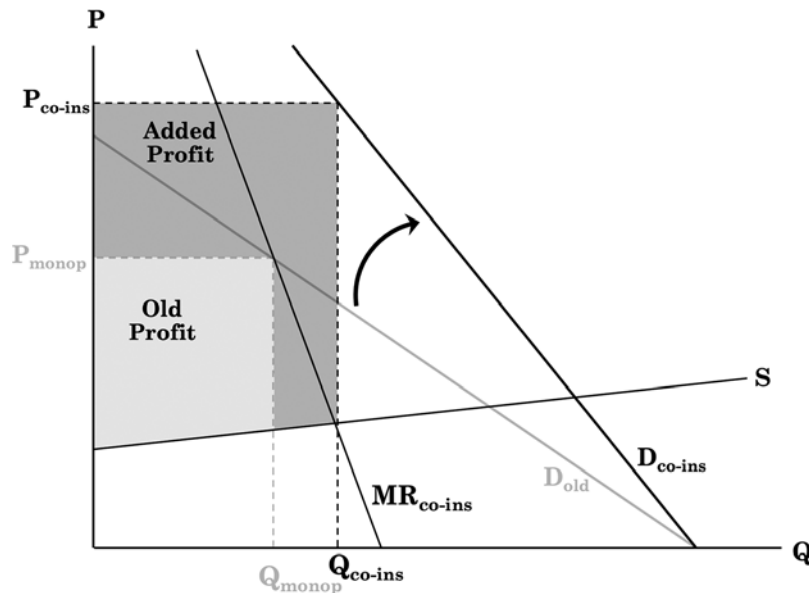
<sup>177</sup> See, e.g., Bhaven Sampat & Heidi L. Williams, *How Do Patents Affect Follow-on Innovation? Evidence from the Human Genome*, 109 AM. ECON. REV. 203, 204 (2019) (“[O]ptimal patent policy design has traditionally been framed as a trade-off between this benefit of providing incentives for the development of new technologies and the cost of deadweight loss from higher prices during the life of the patent.”).

<sup>178</sup> See Hemel & Ouellette, *supra* note 71 (discussing the role of IP policy in the opioid crisis and asserting that some patents have consumption-expanding effects). Most significantly, market power creates stronger incentives to invest in demand creation through commercialization and marketing expenses. Studies of the pharmaceutical market have found that the decline in marketing expenditures after patent expiration have a negative effect on consumption that is roughly equivalent to the positive effect from lower prices. See Gautier Duflos & Frank R. Lichtenberg, *Does Competition Stimulate Drug Utilization? The Impact of Changes in Market Structure on US Drug Prices, Marketing and Utilization*, 32 INT'L REV. L. & ECON. 95, 95 (2012) (“Price and marketing expenditure both decline by about 50–60% in the years immediately following generic entry, but the number of prescriptions remains essentially constant during those years.”); Darius Lakdawalla & Tomas Philipson, *Does Intellectual Property Restrict Output? An Analysis of Pharmaceutical Markets*, 55 J.L. & ECON. 151, 151 (2012) (“[I]n the short run, patent expirations reduce output and consumer welfare by decreasing marketing.”).

out of pocket can buy a \$500 drug. But a consumer who can pay \$1000 (\$900 more than her neighbor) can buy a \$5000 drug.<sup>179</sup>

The effect of adding insurance is to expand the patent owner's profits beyond the monopoly profit without insurance. Because consumers effectively can pay more (with the help of their insurers), a monopolist can charge each consumer more and can also sell to more consumers.

FIGURE 2. ADDED PROFIT IN MONOPOLY MARKET WITH COINSURANCE AND NO PRICE NEGOTIATION



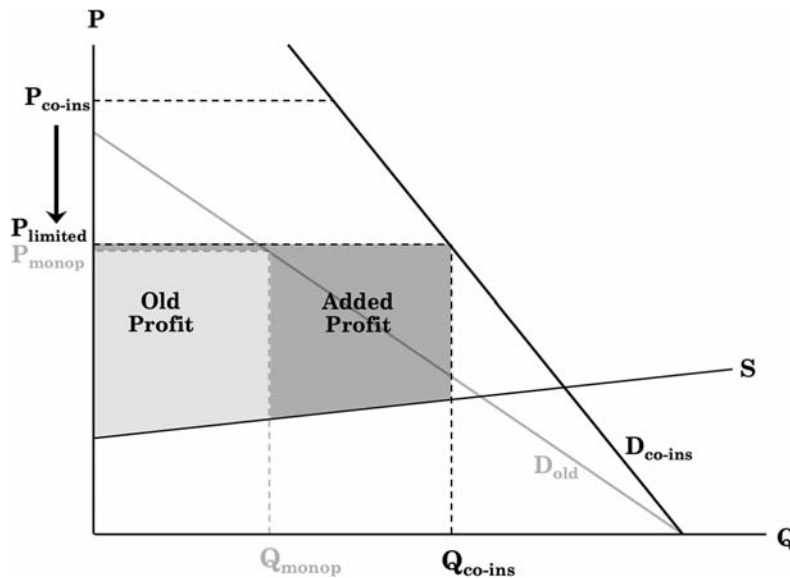
Note that as patients' share of costs decreases, the demand curve pivots further to the right, and more consumers gain access to the drug. This effect is generally framed in the health economics literature in terms of the resulting moral hazard problem in which patients may

<sup>179</sup> In at least some cases, patients can obtain additional help from pharmaceutical companies (typically referred to as "coupons") to decrease their out-of-pocket responsibilities. Although these coupons can indeed help patients afford their out-of-pocket costs for particularly expensive drugs, scholars have expressed concern that they may have the effect of encouraging patients to purchase expensive branded products over generic drugs, which are less expensive for the healthcare system. See, e.g., FELDMAN, *supra* note 58, at 53–54 (noting that coupons can block lower-cost competitors, distort economic effects, and encourage overconsumption); Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 27 (Hutchins Ctr., Working Paper No. 30, 2017), [https://www.brookings.edu/wp-content/uploads/2017/05/wp30\\_scottmorton\\_competitioninpharma1.pdf](https://www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf) (explaining how coupon cards work and summarizing a study that found coupons "reduce[] the ability of generic drugs to penetrate markets dominated by a brand-name drug").

choose treatments that are more expensive than the value they actually receive.<sup>180</sup> But there has been less attention to the way insurance greatly increases prices and profits for a seller with market power. If patients’ share of costs declines to zero (such as through insurance that requires only a flat copayment), then there would be no upper bound on price. That’s why, as a practical matter, public or private insurance systems providing free or low-cost care must have some other mechanism to contain costs. For example, as described in Part I, Medicaid links prices to private markets, the VA and UK systems can exclude drugs from coverage, and the German system will only reimburse up to a reference price. Coinsurance systems in which insurers cover a large percentage of costs typically also have some cost-control mechanism, including copayments, deductibles, and formulary management tools.

But even if there is some mechanism for limiting price, the patient may still receive additional profits in a market in which all patients have coinsurance as compared with the “normal” monopoly market, as we illustrate in Figure 3.<sup>181</sup>

FIGURE 3. ADDED PROFIT IN MONOPOLY MARKET WITH COINSURANCE PLUS SOME MECHANISM FOR LIMITING PRICE

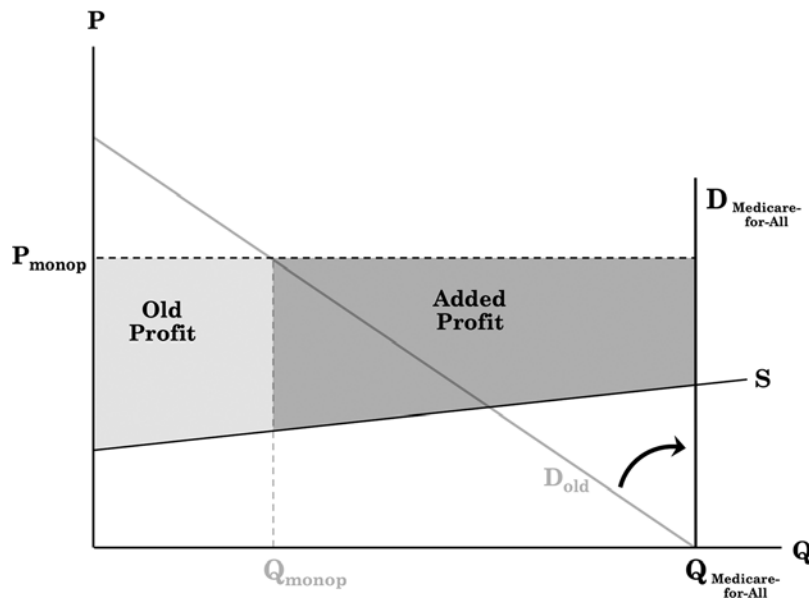


<sup>180</sup> See, e.g., BHATTACHARYA ET AL., *supra* note 8, at 209 (noting that when an insurer offers full coverage for enrollees, “each consumer will demand all the health care that provides him any positive utility at all”).

<sup>181</sup> The marginal revenue line has been removed for simplicity because it is no longer setting the price.

A mechanism for limiting prices is particularly necessary if the model moves from one in which all consumers have coinsurance (requiring them to pay some percentage of the price) to one in which all consumers have generous access to drugs with no cost-sharing, as suggested by some Medicare for All proposals.<sup>182</sup> As we illustrate in Figure 4, even if prices are limited to the original monopoly price, providing coverage for all patients with no cost-sharing leads to a substantial additional profit for the patentee.<sup>183</sup>

FIGURE 4. ADDED PROFIT IN MARKET WITH MEDICARE FOR ALL  
IN WHICH ALL PATIENTS RECEIVE ACCESS AT ORIGINAL  
MONOPOLY PRICE



Real-world pharmaceutical markets are substantially more complex than any of the simplified models shown in Figures 1–4. The important conceptual point, however, is that when insurance-related policies effectively shift demand upward or to the right, the seller of a drug with market power can receive higher profits for that drug. These added profits grow as patients' share of pharmaceutical costs shrinks, particularly in the absence of robust cost-containment mechanisms.

<sup>182</sup> See *supra* notes 162–64 and accompanying text (describing Medicare for All proposals).

<sup>183</sup> For a discussion of how other forms of government mandates, such as those governing accessibility for the disabled, can alter the market for innovations in that field, see Christopher Buccafusco, *Disability and Design*, 95 N.Y.U. L. REV. (forthcoming 2020).

To some degree, this is what Medicare's prescription drug benefits do. Medicare beneficiaries generally are responsible for only twenty to twenty-five percent of brand-name drug costs under Parts B and D,<sup>184</sup> and millions of patients receive government subsidies lowering these amounts.<sup>185</sup> Many of these are people who didn't have private insurance or who had insurance that was less generous,<sup>186</sup> who can now effectively pay much more for drugs than they used to. Medicare also increases overall demand for drugs by causing beneficiaries to live longer.<sup>187</sup> These factors tend to push the demand curve upward to the right, artificially adding to the number of people who can pay the monopoly price. And unlike private insurers, who have greater legal authority to negotiate prices freely and to refuse to cover drugs that cost too much, Medicare Parts B and D often impose coverage requirements with little ability for the government to negotiate prices beyond the price set in the private market, giving drug manufacturers significant leverage in setting prices.<sup>188</sup> Expanding the demand curve in this way increases the patentee's profits even further beyond what they would make without government insurance. The patentee no longer has to worry about cutting prices to match demand for customers who can pay less; some combination of the government and supplemental private insurance will pay the monopoly price for almost everyone.

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<sup>184</sup> See *supra* notes 39, 52 and accompanying text.

<sup>185</sup> SUZANNE M. KIRCHHOFF, CONG. RESEARCH SERV., MEDICARE PART D PRESCRIPTION DRUG BENEFIT 1 (2018), <https://fas.org/spp/crs/misc/R40611.pdf> (noting that 12.9 million Part D beneficiaries would receive low-income subsidies in 2018).

<sup>186</sup> See Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D of Medicare? And if So, How?*, 27 HEALTH AFF. 33, 34 (2008) ("The drug benefit offered under Part D of Medicare has given millions of low-income elderly Americans the ability to obtain drugs that are vital to their health and continued longevity."); LUNDY, *supra* note 45, at 5 (noting that twenty-seven percent of seniors had no drug coverage in 2003).

<sup>187</sup> See David Card, Carlos Dobkin & Nicole Maestas, *Does Medicare Save Lives?*, 124 Q.J. ECON. 597, 598 (2009) (noting that "we find a clearly discernible drop in mortality once people become eligible for Medicare" and concluding that "differential treatment afforded to those with Medicare coverage has an important impact on patient survival"); Frank R. Lichtenberg, *The Effects of Medicare on Health Care Utilization and Outcomes*, in 5 FRONTIERS IN HEALTH POLICY RESEARCH 27 (Alan M. Garber ed., 2002) (finding that Medicare eligibility increases healthcare utilization rates and leads to a slower growth in the probability of death).

<sup>188</sup> See *supra* notes 41–44, 54–59 and accompanying text (describing the reimbursement policies of Medicare Parts B and D). Sharat Ganapati and Rebecca McKibbin estimate that allowing the government to negotiate drug prices as a purchaser, without other changes such as compulsory licensing, would reduce overall drug prices by as much as eighteen percent even once the patents have expired. Sharat Ganapati & Rebecca McKibbin, *Non-Tariff Barriers and Bargaining in Generic and Off-Patent Pharmaceuticals* (Mar. 2019) (unpublished manuscript), <http://ssrn.com/abstract=3313630>.

Medicare does expand access to consumers who value the drug more than its cost of production but less than the unsubsidized monopoly price (the striped DWL triangle in Figure 1). But it also transfers a great deal of additional profit to the patent owner. The scope and duration of the patent hasn't changed, but it is generating a lot more profit for the simple reason that, thanks to the government subsidy, there are many more customers who can pay and they all pay the monopoly price or close to it, even if they value the drug at less than that price. We call this added profit the Medicare innovation subsidy.

The real world has more complications than this stylized model, of course. Here are four important ones:

First, not all pharmaceutical patents confer market power, though they are more likely to than patents in other fields.<sup>189</sup> Even where drugs face quite a lot of competition, as with antidepressants, patentees may not face effective price competition if doctors don't view the drugs as substitutes for any given patient or if Medicare must cover all FDA-approved drugs for certain illnesses.<sup>190</sup>

Second, Medicare plans and the PBMs that negotiate on their behalf do have some bargaining leverage, including threatening to cover only certain drugs for non-protected classes, using prior authorization or step therapy, and threatening to move drugs to less desirable formulary tiers.<sup>191</sup> This leverage has allowed them to lower prices for drugs with competition in a particular therapeutic class, although their bargaining power is limited by the government's inability to directly negotiate and by the plans' inability to walk away from the table in most cases.<sup>192</sup> As Figure 3 illustrates, however, patentees still receive substantial additional profits even with tools for limiting price.

Third, Medicare Part D covers primarily Americans aged over sixty-five. For drugs that affect only the elderly, the model just described is accurate. But it doesn't apply to drugs for diseases that only affect children, and it applies only partially to drugs taken by

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<sup>189</sup> See *supra* note 8 and accompanying text (discussing the relationship between patents and monopoly market power).

<sup>190</sup> See *supra* note 59 and accompanying text (explaining Medicare's protected classes).

<sup>191</sup> See *supra* notes 10, 55 and accompanying text. When a drug is on a higher tier in the formulary, it means the patient typically faces higher out-of-pocket costs before they can access the drug. Higher out-of-pocket (OOP) costs may lead patients to abandon their drugs at the pharmacy, though, even in cases of serious conditions like cancer. See, e.g., Jalpa A. Doshi et al., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, 36 J. CLINICAL ONCOLOGY 476, 476 (2018) ("Higher OOP costs were associated with higher rates of oral prescription abandonment and delayed initiation across cancers.").

<sup>192</sup> See *supra* notes 15, 58 and accompanying text.



patients of all ages. We discuss the biases this may cause in more detail in Section II.C.

Finally, the above graphs assume that Part D was created against a baseline in which seniors did not have prescription drug insurance. This was true for twenty-seven percent of seniors,<sup>193</sup> creating a demand expansion effect among this population. Before Part D implementation, sixty-six percent of Medicare-eligible seniors already had some prescription drug insurance plan.<sup>194</sup> However, at least some of those patients also increased pharmaceutical returns when substituting into Medicare—nine million patients moved from lower-reimbursement Medicaid coverage to higher-reimbursement Part D coverage.<sup>195</sup> Effects may be more variable for the beneficiaries substituting from private insurance into Medicare.

Despite these complications, the Medicare innovation subsidy is real. It has significantly increased the returns to pharmaceutical patent owners. Medicare now accounts for thirty percent of U.S. retail prescription drug spending,<sup>196</sup> even though it applies primarily to people over sixty-five, who make up just thirteen percent of the population,<sup>197</sup> and not all of whom even opt-in to Medicare. Medicare, then, is a big source of additional money for drug companies, both because it increases the number of people who can afford drugs and because it may increase the price companies can charge for those drugs.

### B. Effect on Innovation

Above-baseline-monopoly profits aren't necessarily bad. Few dispute that higher profits for certain innovations increase incentives to produce those knowledge goods,<sup>198</sup> and a number of empirical studies have found increases in private-sector R&D investment following legal changes that increased market size in the contexts of vaccines and orphan drugs.<sup>199</sup> Based on analysis of time-series data of drugs entering clinical development, Margaret Blume-Kohout and Neeraj

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<sup>193</sup> LUNDY, *supra* note 45, at 5.

<sup>194</sup> Patricia Neuman & Juliette Cubanski, *Medicare Part D Update—Lessons Learned and Unfinished Business*, 361 NEW ENG. J. MED. 406, 407 (2009).

<sup>195</sup> *Id.* at 410.

<sup>196</sup> See *supra* note 16 and accompanying text.

<sup>197</sup> LINDSAY M. HOWDEN & JULIE A. MEYER, U.S. CENSUS BUREAU, U.S. DEP'T OF COMMERCE, C2010BR-03, 2010 CENSUS BRIEFS: AGE AND SEX COMPOSITION: 2010, at 2 tbl.1 (2011), <https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf>.

<sup>198</sup> See generally Lakdawalla, *supra* note 17, at 405–06 (reviewing this literature).

<sup>199</sup> E.g. Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q.J. ECON. 527, 528 (2004) (finding that policies designed to increase use of vaccines led to a 2.5-fold increase in vaccine clinical trials); Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060, 1061 (2008) (finding that the Orphan Drug Act increased production of drugs for rare diseases).

Sood conclude that “passage and implementation of Medicare Part D is associated with significant increases in pharmaceutical R&D for therapeutic classes with higher Medicare market share.”<sup>200</sup> They found that this was largely new investment, not substitution away from other drugs, and that the effect was smaller for drugs that had been previously covered under Part B and larger for drugs in protected Part D classes.<sup>201</sup> (In contrast, the original introduction of Medicare in 1965—without the prescription drug benefit—didn’t increase drug use among the elderly or induce significant pharmaceutical innovation,<sup>202</sup> though it did increase medical-equipment patenting.)<sup>203</sup> True, increases in R&D alone do not necessarily enhance patient welfare. Subsequent work focused on biologics found a similar incentive effect from Part D implementation, but also concluded that “most of this effect is concentrated among products aimed at diseases that already have multiple existing treatments,”<sup>204</sup> and the net welfare impact of such drugs is ambiguous.

Even though the size of the Medicare subsidy is large, its net innovation benefit might be relatively modest. The United States offers a huge array of innovation incentives in the pharmaceutical industry already, including not just patents but also direct research funding through grants and national laboratories, prizes, tax incentives, regulatory exclusivities, data exclusivities, and special incentives for orphan drugs and pediatric research.<sup>205</sup> Pharmaceutical “lifecycle management” through secondary patents and regulatory gaming mean that companies keep market power for years and even decades after

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<sup>200</sup> Blume-Kohout & Sood, *supra* note 7, at 327.

<sup>201</sup> *Id.* at 333.

<sup>202</sup> See Daron Acemoglu, David Cutler, Amy Finkelstein & Joshua Linn, *Did Medicare Induce Pharmaceutical Innovation?*, 96 AM. ECON. REV. 103, 103 (2006). The market for drugs in 1965 was different than it is today in a few ways. First, there were many fewer products dispensed in physician settings, so it may not have been seen as a significant effect on the market. Second, the FDA didn’t start regulating drugs for safety and efficacy until 1962, and the current generic system didn’t take its major form until 1984, so it was much easier and cheaper for brand owners to bring drugs to market (and harder for generic substitutes). Further, there was no regulatory exclusivity to serve as a barrier.

<sup>203</sup> See Jeffrey Clemens, *The Effect of U.S. Health Insurance Expansions on Medical Innovation* 1 (Nat’l Bureau of Econ. Research, Working Paper No. 19761, 2013), <https://www.nber.org/papers/w19761>.

<sup>204</sup> David Dranove, Craig Garthwaite & Manuel Hermsilla, *Pharmaceutical Profits and the Social Value of Innovation* (Nat’l Bureau of Econ. Research, Working Paper No. 20212, 2014), <https://www.nber.org/papers/w20212>. On the other hand, another recent paper finds that pharmaceutical “firms respond to a plausibly exogenous positive shock to their net worth by developing more of these riskier novel candidates.” Joshua L. Krieger, Danielle Li & Dimitris Papanikolaou, *Missing Novelty in Drug Development* (Nat’l Bureau of Econ. Research, Working Paper No. 24595, 2019), <https://www.nber.org/papers/w24595>.

<sup>205</sup> See *supra* note 24 and accompanying text.

initial patent expiration.<sup>206</sup> For at least some drugs, patent-owner returns for pharmaceuticals seem to far exceed the risk-adjusted R&D costs.<sup>207</sup> Greatly increasing this innovation subsidy through expansion of government insurance may thus lead to limited innovation gains—although, as discussed in the following Section, existing incentives appear to be insufficient for at least some kinds of socially valuable innovation.

Even so, perhaps we should celebrate the expansion of patent owner profits above the baseline monopoly level, since it seems to spur at least some additional R&D investment. If Medicare Part D is justified solely for the access benefits it provides for the elderly, the fact that there is also an innovation subsidy that leads to the production of even some new drugs is an extra benefit for the world. It is found money. And more drugs to treat diseases for no extra cost seems like an unambiguously good thing.

Things are more complicated if the question is whether to expand Medicare (or if you think Medicare Part D wasn't justified by the expansion of coverage). But here, too, recognizing the Medicare innovation subsidy can help evaluate the question. From a social welfare perspective, the relevant question is whether the benefits of expanding Medicare outweigh the costs. The traditional benefit policymakers have focused on is giving more people access to life-saving drugs. But the Medicare innovation subsidy suggests that expanding Medicare would have an additional benefit: Society would get some additional R&D which would lead to some new drugs beyond those provided by the existing combination of patents, grants, subsidies, market exclusivities, and private insurance. Those new drugs would benefit both Medicare recipients and others who aren't on Medicare but can now pay for the drug, including patients outside the United States whose countries invest less in biomedical R&D.<sup>208</sup> So while it might or might not make the difference, the existence of

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<sup>206</sup> See Carrier & Shadowen, *supra* note 138, at 168; Dogan & Lemley, *supra* note 138, at 687; Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 614–18 (2018), <https://doi.org/10.1093/jlb/lisy022>; see *supra* text accompanying note 138.

<sup>207</sup> See Kiu Tay-Teo, André Ilbawi & Suzanne R. Hill, *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, 2 JAMA NETWORK OPEN 1 (2019) (estimating a return of \$14.50 per \$1 of risk-adjusted R&D spending for 99 cancer drugs); Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 278, 328 (2016) (estimating that Gilead's blockbuster hepatitis C drugs brought in forty times the development cost in just the first twenty-seven months).

<sup>208</sup> On the ways national innovation policies subsidize foreign consumption of the resulting inventions, see Daniel J. Hemel & Lisa Larrimore Ouellette, *Bayh-Dole Beyond Borders*, 4 J.L. & BIOSCIENCES 282, 291–93 (2017).

some social benefit from the Medicare innovation subsidy helps make the case for expanding Medicare.

We don't want to take that argument too far, however. Even though society benefits if all cost-justified projects are pursued, there seems to be finite political will for raising additional taxes, particularly in the current political climate. Policymakers should thus also consider what else might be accomplished if this subsidy were not paid through the Medicare program—including whether subsidies for non-pharmaceutical interventions or non-Medicare populations would have a larger net social benefit.

We can't definitively answer the question of whether the overall level of pharmaceutical innovation is currently too high or too low.<sup>209</sup> If innovation incentives were roughly "right" before the government created the Medicare innovation subsidy, Congress should have balanced Part D's additional incentive effects by either reducing the price paid for drugs or reducing other innovation incentives (tax, regulatory exclusivity, etc.) to compensate. On the other hand, if there weren't enough incentives to produce new drugs before 2006, Medicare Part D might have moved innovation policy in the right direction by supplementing an insufficient patent-regulatory incentive system. The answer will depend in part on whether one considers welfare outside the United States. If the focus is global value, the benefits from a given U.S. innovation become significantly larger.<sup>210</sup> It seems improbable, however, that Part D moved innovation incentives to the optimal point, in large part because policymakers were not focused on Part D's innovation-enhancing qualities. Additionally, optimal incentives differ depending on the type of drug and disease at issue and the alternatives already on the market, as the next Section explores.

At a minimum, policymakers need to recognize that Medicare Part D *is* an innovation subsidy. The same is true of future changes. If innovation incentives are now sufficient after the addition of Medicare Part D, a further expansion of Medicare would create an additional, excessive incentive that would need to be balanced with some changes to price or a reduction in other incentives, as the leading Medicare for All proposals do. If, on the other hand, we still aren't funneling enough money into the pharmaceutical industry, versions of Medicare

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<sup>209</sup> See Lakdawalla, *supra* note 17, at 444 (calling this "a first-order—perhaps *the* first-order—policy question in the economics of the pharmaceutical industry").

<sup>210</sup> See generally Daniel J. Hemel & Lisa Larrimore Ouellette, *Knowledge Goods and Nation States*, 101 MINN. L. REV. 167 (2016) (explaining that because knowledge goods are usually nonrivalrous across borders and are hard to exclude entirely, the total global benefit is greater than that of the benefit to a single country, as people across the world may use and enjoy the innovation).

for All that would significantly increase pharmaceutical industry revenues might be desirable. We discuss these issues further in Part III.

### C. Innovation Asymmetries

Even if we can't answer the overall question of whether the additional incentive Medicare expansion provides is good or bad for either domestic or global welfare, we can note asymmetries in the incentives resulting from the Medicare innovation subsidy that seem difficult to justify on public policy grounds. Paying extra for drugs that primarily benefit the elderly may encourage new R&D, but only R&D on drugs that benefit the elderly. Indeed, Blume-Kohout and Sood found that Medicare Part D drove R&D on drugs with a large Medicare market share, but not on other drugs.<sup>211</sup> These differences can have real-world consequences. For example, Eric Budish, Benjamin Roin, and Heidi Williams have demonstrated that R&D money is less likely to be invested in drugs for early-stage cancers with longer commercialization times (and thus shorter effective patent protection) compared to later-stage drugs that get faster approval, even though the early-stage drugs would save many more life-years.<sup>212</sup>

Firms may also underinvest in pharmaceutical innovations that cannot be easily protected using IP, including new uses for old drugs.<sup>213</sup> Even for patentable products with short commercialization lags, market-based rewards underestimate social value for drugs with positive externalities (such as vaccines, drug addiction treatments, or innovations generating technological spillovers), and for drugs with a social value greater than consumers' ability to pay (that is, when the average income of target patients is low).<sup>214</sup> And there is likely underinvestment in both preventatives and in single-use products (including prophylactic vaccines) relative to the repeated-use treatments that

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<sup>211</sup> Blume-Kohout & Sood, *supra* note 7, at 334–35.

<sup>212</sup> Budish et al., *supra* note 168, at 2045–46, 2081.

<sup>213</sup> See Eisenberg, *supra* note 169, at 347; Hemel & Ouellette, *supra* note 71, at 5; Kapczynski & Syed, *supra* note 21, at 1903; Rachel E. Sachs, Paul B. Ginsburg & Dana P. Goldman, *Encouraging New Uses for Old Drugs*, 318 JAMA 2421, 2421 (2017); Benjamin N. Roin, *Solving the Problem of New Uses 1* (Oct. 1, 2013) (unpublished manuscript), <https://ssrn.com/abstract=2337821>. How big a problem this is in practice as opposed to theory is unclear. There are many drugs on the market with significant new uses, approved or off-label.

<sup>214</sup> See Hemel & Ouellette, *supra* note 9, at 575 (discussing the “numerous reasons that the net present value of future monopoly profits may diverge from the social value of a new knowledge good,” including generating positive externalities “such that a consumer’s willingness to pay will be less than the good’s social value”).

dominate scholarly and industry attention.<sup>215</sup> This is to say nothing of the innovation bias in favor of pharmaceuticals as compared to other interventions, including surgery, psychological services, or lifestyle interventions, many of which may be as or more effective for particular conditions than are prescription drugs.<sup>216</sup>

U.S. innovation policy does sometimes deliberately try to influence R&D incentives for only certain types of innovation. Patent law as a whole is such a distortion, for instance.<sup>217</sup> And in the pharmaceutical industry, there are stronger incentives for orphan diseases than ones that affect a larger population, on the theory that diseases affecting smaller markets will have smaller market incentives that may be insufficient to spur their development.<sup>218</sup> Pediatric exclusivity is designed to encourage more research on drugs targeted to children.<sup>219</sup> But in those cases Congress has intentionally tried to privilege some forms of R&D over others. There is little evidence that Congress intended to give stronger incentives to develop treatments for diseases affecting the elderly (Medicare Part D recipients) than for diseases affecting adults under sixty-five. Indeed, pediatric exclusivity points in the opposite direction.

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<sup>215</sup> See Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729 (2019); Lisa Larrimore Ouellette & Q. Claire Xue, *Innovation Policy and the Market for Vaccines 1* (Sept. 20, 2019) (unpublished manuscript).

<sup>216</sup> See Kapczynski & Syed, *supra* note 21, at 1930–38 (detailing some of the alternative interventions, their efficacy and obstacles to wider investment, and implementation).

<sup>217</sup> See Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1033–36 (2005) (explaining the shift in terminology and ideology surrounding patent law and how conceptions of real property have influenced the understanding of IP rights and exclusions).

<sup>218</sup> Starting in 1983, the Orphan Drug Act added three new incentives for drugs treating rare diseases—additional grants, a seven-year market exclusivity period, and a new tax credit for clinical trial expenses—which led to a thirteen-fold increase in orphan drug approvals. See Hemel & Ouellette, *supra* note 172, at 379 (summarizing the legal mechanisms and empirical studies). While noneconomic factors may help explain the orphan drug rules, as Congress may be motivated to act on behalf of ignored diseases, one possible economic explanation for the orphan drug rules may be the minimum cost required for the FDA process, so drugs with a small demand need an extra bump. On the other hand, the FDA has been willing to accept smaller trial sizes to demonstrate the safety and efficacy of orphan drugs, leading to somewhat lower R&D costs. See Kavisha Jayasundara et al., *Estimating the Clinical Cost of Drug Development for Orphan Versus Non-Orphan Drugs*, 14 ORPHANET J. RARE DISEASES 12 (2019) (estimating capitalized clinical costs to be thirty percent lower). Orphan drugs are also able to command premium prices, now into the millions of dollars per patient, unlike drugs for conditions affecting large populations. The optimal incentive size or policy mix is far from obvious. Perhaps from a concern that incentives were too strong, the 2017 tax reform cut the value of the orphan drug credit from fifty to twenty-five percent of clinical trial expenses. See Tax Cuts and Jobs Act, Pub. L. No. 115-97, § 13401(a) (2017) (codified at I.R.C. § 45C(a)).

<sup>219</sup> Drugs or biologics that undergo certain pediatric studies can receive an additional six months of exclusivity. See 21 U.S.C. § 355a (2012); 42 U.S.C. § 262(m)(3) (2012).

Other pharmaceutical innovation asymmetries stem from the decision of the United States, alone among developed countries, to allocate access to drugs in significant part based on price.<sup>220</sup> Using price as an allocation mechanism means that U.S. policy already privileges drugs desired by rich people over drugs desired by poor people, who are more likely to be uninsured and may have little ability to pay. As one example, the parasitic Chagas disease likely causes greater social loss to Americans (and an even greater loss to the world) than many other conditions,<sup>221</sup> but if the people who need Chagas treatment are disproportionately poor, firms will conduct (from a social perspective) not enough research into Chagas relative to other conditions with similarly sized but higher-income patient populations. Policymakers might want to distort market results to compensate for this, giving extra incentive to drugs that wouldn't get enough support in the existing market, and less incentive to drugs that the market overvalues. For this reason, we might distinguish Medicare from Medicaid. Medicaid provides insurance primarily for low-income Americans, and because Medicaid typically pays lower rates for the same drug than does Medicare, there might be reason to worry that there is not enough investment in drugs that disproportionately benefit the Medicaid population. This suggests both that the incentive bump Medicaid provides is more likely to offset an existing distortion based on inability to pay and that the remaining disparity between Medicare and Medicaid rates may perpetuate innovation biases.<sup>222</sup>

The Medicare innovation subsidy also distorts away from the market outcome, but not in a way that seems targeted to correct some existing distortion. Encouraging innovative drugs is very important, but it is not the only important thing. Moving more money into drugs that benefit the elderly encourages public spending on those drugs but can also limit public spending on other aspects of healthcare.<sup>223</sup> That is a good idea only if we think that drugs are underprovided relative to

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<sup>220</sup> To be sure, the United States does have numerous policies, including Medicare and Medicaid, through which it matches IP innovation incentives with allocation mechanisms not fully based on proprietary pricing. See Hemel & Ouellette, *supra* note 9, at 594–95, 598–99. But as discussed in Section I.B, other countries have moved more fully toward open-access allocation mechanisms for pharmaceuticals.

<sup>221</sup> See Sachs, *supra* note 7, at 154 (noting Chagas disease afflicts eight million people worldwide, including 300,000 people in the United States, but that it primarily affects poor Americans).

<sup>222</sup> See Hemel & Ouellette, *supra* note 9, at 594–95; Sachs, *supra* note 7, at 201–02 (discussing Medicaid reimbursement as innovation policy). Medicaid is also a much smaller distortion. In 2016, Medicaid drug spending was about \$30 billion, compared with almost \$130 billion for Medicare Parts B and D. See *supra* notes 28, 77 and accompanying text.

<sup>223</sup> See Kapczynski & Syed, *supra* note 21, at 1930–38 (noting differences between behavioral and pharmaceutical approaches to cardiovascular disease).

other forms of healthcare, such as surgery, holistic treatment, and prevention. There is no reason to think that is the case across the board. The innovation subsidy also contributes to growth in the portion of U.S. GDP spent on pharmaceuticals.<sup>224</sup> This may be desirable now, but at some point, it may become unaffordable to continue to move resources from other sectors of the economy to producing more pharmaceuticals. And policymakers certainly shouldn't do so accidentally, as they seem to have done with Medicare Part D.

### III

#### BRINGING AN INNOVATION PERSPECTIVE TO PHARMACEUTICAL ACCESS REFORM

Current interest across the political spectrum in reducing drug prices provides a good opportunity to overhaul our existing system of pharmaceutical incentives. But policymakers should do so in a sensible way, with recognition of how allocation mechanisms affect incentives. Here, we bring an innovation incentive perspective to the access-focused reform ideas that have recently gained attention in the United States. Recognizing Medicare drug spending as an additional form of innovation incentive expands the policy space available for reform. Society has, quite inadvertently, created an additional incentive to produce drugs. Reasonable people can differ on what to do with this information; indeed, we might not agree ourselves. The point is that considering pharmaceutical allocation mechanisms as an innovation incentive provides additional policy options that may be more or less attractive depending on the perceived adequacy of existing pharmaceutical R&D.

#### *A. Expanding Government Insurance*

One popular U.S. policy proposal is to increase demand-side government subsidies, such as by expanding the Medicare or Medicaid framework to all Americans.<sup>225</sup> Doing so would reduce the current bias Medicare creates in favor of incentives to treat diseases that primarily affect the elderly. But as Part II showed, expanding government insurance would add some additional incentive to produce new drugs (what we call the Medicare innovation subsidy). If U.S. innovation policy doesn't provide enough incentive to pharmaceutical com-

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<sup>224</sup> For a graph of the increasing portion of GDP spent on healthcare in the United States and some other high-income countries compared with the world average, see *Current Health Expenditure (% of GDP)*, WORLD BANK, <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=US-1W-JP-GB-DE-CH> (last visited Nov. 4, 2019).

<sup>225</sup> See *supra* Section I.C.2.



panies now, that increase would be a good thing. But if the policymakers advocating for proposals like Medicare for All aim to maintain the healthcare system's current transfer to pharmaceutical companies rather than increase it, they will need to either (1) reduce drug prices to offset the increased Medicare innovation subsidy, or (2) offset that additional incentive by cutting incentives elsewhere in the system.

To be clear, we are not advocating for maintaining existing incentives—we think it highly unlikely that the existing incentive structure is optimal. Reasonable policymakers might think that the incentives our healthcare system already provides, including the Medicare innovation subsidy described here, are too high, and that we should reduce those incentives in an effort to reduce the cost of healthcare. Others might think that we don't have enough innovation incentive, and that expanding the Medicare innovation subsidy is good precisely because it means more money for drug companies and hopefully correspondingly more innovation.<sup>226</sup> Our goal here is not to take a position on how the Medicare innovation subsidy should be spent. Nonetheless, laying out the different options for how incentives might be preserved provides a useful illustration of the different policy levers Congress could adjust, including increasing or decreasing incentives from the current baseline.

### 1. *Maintaining Incentives with Price Reductions*

As one of us has explained in prior work with Daniel Hemel, increasing access to patented goods does not require changing the innovation incentive provided to producers of those goods. Instead, producers can still receive an ex post, market-set incentive even when consumers receive a good for free, through open-access allocation.<sup>227</sup> The UK's Pharmaceutical Price Regulation Scheme may be the closest real-world example of this kind of matching of IP incentives with a non-IP allocation mechanism.<sup>228</sup>

In the Medicare for All context, the goal would be to hold monopoly profit for a given drug constant while expanding access, which we refer to as “monopoly profit maintenance.” To do this, the government would need to negotiate a price that was lower than the insurance-adjusted monopoly price but above the competitive price.

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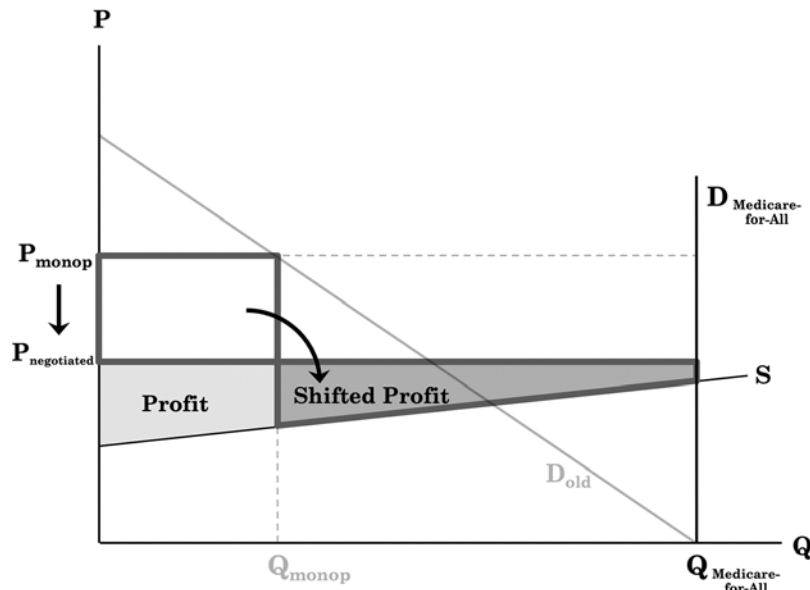
<sup>226</sup> For example, there appear to be insufficient incentives to develop drugs to treat early-stage cancers. See Budish et al., *supra* note 168, at 2045–46.

<sup>227</sup> Hemel & Ouellette, *supra* note 9, at 563–66, 594–95, 598–99.

<sup>228</sup> See *id.* at 564–65; *supra* Section I.B.1 (describing how the Pharmaceutical Price Regulation Scheme works in the UK and its major benefits, including lower costs for prescription drugs).

Ideally, that lower price would reduce the patentee's profit from pre-expansion sales just enough to balance the extra profit from demand expansion, as illustrated in Figure 5. Any such policy would involve some errors in estimating future profits, but from an incentive perspective, what matters is the patentee's ex ante expected profits, not the actual profits.

FIGURE 5. MONOPOLY PROFIT MAINTENANCE



Scholars and companies have generally reacted to proposals for pharmaceutical price negotiation with the concern that these policies would reduce profits and thus depress innovation. Some amount of downward pricing pressure has been shown to affect pharmaceutical firms' revenues and behaviors. For instance, firms are less likely to enter price-controlled countries,<sup>229</sup> and as we explain above, a number of studies have documented the link between expected profits and R&D investment in other biomedical innovation contexts.<sup>230</sup> It is less clear what impact price negotiation has on pharmaceutical *innova-*

<sup>229</sup> See Margaret K. Kyle, *Pharmaceutical Price Controls and Entry Strategies*, 89 REV. ECON. & STAT. 88, 88 (2007); see also Iain M. Cockburn, Jean O. Lanjouw & Mark Schankerman, *Patents and the Global Diffusion of New Drugs*, 106 AM. ECON. REV. 136, 136 (2016) (demonstrating that although “[p]rice regulation delays launch . . . more extensive patent rights accelerate it”).

<sup>230</sup> See *supra* notes 199–200 and accompanying text. For a review of other studies showing that pharmaceutical price regulations cause declines in pharmaceutical revenues, see Lakdawalla, *supra* note 17, at 407–08.

tion.<sup>231</sup> In any case, the kind of price negotiation we contemplate shouldn't even have an effect on revenues, because the goal is just to maintain innovation incentives as we expand access.

Policymakers implementing such a system would face many additional policy choices. Price negotiation can occur through diverse institutional structures, as illustrated by the different approaches of the UK and Germany described in Section I.B. But effective negotiation requires some form of enforcement authority, often including the buyer's ability to walk away from the table if the patentee is unwilling to pay the proposed price.

U.S. policymakers might look to the VA system as an example of how a public payer can use negotiating authority and meaningfully decline coverage (as is also true in the UK example), without the label of compulsory licensing.<sup>232</sup> Alternatively, the government could gain leverage by limiting reimbursement of amounts higher than the proposed price, as in Germany.<sup>233</sup> Policies like these can lead to access limitations when negotiations fail, and a desire to avoid the resulting political and public health costs may be one explanation for the popularity of compulsory licensing in Democratic proposals to reduce drug prices.<sup>234</sup> However, because the goal of this system would be to provide patentees with the same *ex ante* expected profits, rational firms should be willing to accept the negotiated price in exchange for the ability to supply a larger market.<sup>235</sup>

## 2. *Offsetting Reductions in Other Incentives*

Alternatively, expected profits per drug could be maintained by using the additional expected incentive through the Medicare for All innovation subsidy to reduce other incentives. This reduction could be accomplished in two different ways.

First, Congress could decrease non-patent incentives for drug manufacturers such as R&D tax incentives, direct support, and regulatory exclusivities.<sup>236</sup> The government would pay pharmaceutical firms

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<sup>231</sup> See Lakdawalla, *supra* note 17, at 408 (“Although the evidence on the effects of price regulation on pharmaceutical revenues is fairly substantial and convincing, the evidence on the effects of price regulation on pharmaceutical *innovation* is not as well developed.”).

<sup>232</sup> See *supra* notes 85–89 and accompanying text.

<sup>233</sup> See *supra* notes 111–18 and accompanying text.

<sup>234</sup> See *supra* notes 132–33, 147 and accompanying text.

<sup>235</sup> That doesn't mean they won't lobby for more, of course. But in a political environment in which government regulation of drug prices is realistically on the table, expanding demand and keeping profits constant may be a political tradeoff they are willing to accept.

<sup>236</sup> See *supra* note 172 and accompanying text.

a higher amount through Medicare because of the expanded pool of beneficiaries, but a lower amount through these other policy instruments, resulting in no net change in expected profits or in the burden on the public fisc.

Alternatively, Congress could reduce the duration of the effective period of IP protection for pharmaceuticals, such as by limiting regulatory exclusivity or “lifecycle management” practices like product hopping and extending effective patent terms through patent evergreening.<sup>237</sup> The government would still pay drug manufacturers a higher amount through Medicare, but over a shorter time period, again with the goal of maintaining *ex ante* expected profits.

At first glance, either of these approaches to reducing other incentives might seem less efficient than negotiating prices because higher prices in a monopoly market generally entail a greater deadweight loss in social welfare.<sup>238</sup> Under either approach, the proprietary price would not be used as an allocation mechanism. The deadweight loss in pharmaceutical markets stems from denying access to many patients for whom the value of a drug exceeds its marginal cost of production, and this loss is avoided if the Medicare for All system provides access to these patients.<sup>239</sup>

A more important distinction between the different approaches to maintaining incentives is feasibility. For example, the size of all non-IP incentives may not be sufficient to offset the additional Medicare for All innovation subsidy. And reducing the duration of effective IP protection may be effective in markets for small-molecule drugs that regularly see generic entry, but not for biologics that have so far faced little competition.<sup>240</sup> Further, the effect of Medicare for All may vary for different drugs, and it is hard to reduce the term of exclusivity for some drugs but not others in a way that matches the innovation subsidy for those drugs. In these cases, price reductions may be the more desirable approach.

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<sup>237</sup> See *supra* notes 24, 169, 208 and accompanying text.

<sup>238</sup> See Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 987 (1999); Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 529 (2001).

<sup>239</sup> See Hemel & Ouellette, *supra* note 9, at 563 (explaining that creating an *ex post*, market-set innovation incentive without the deadweight loss of IP-based allocation is the best justification for this kind of policy matching).

<sup>240</sup> See generally Preston Atteberry et al., *Biologics Are Natural Monopolies (Part 1): Why Biosimilars Do Not Create Effective Competition*, HEALTH AFF. (Apr. 15, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190405.396631/full> (noting the limited number of biosimilars on the market).

### B. *The Incentive Side of Cost-Reduction Proposals*

The other pharmaceutical policy priority for U.S. politicians across the political aisle is lowering drug costs. Section I.C.1 described current cost-reduction proposals, including international reference pricing, Medicare negotiation, and compulsory licensing. Policy discussions around these proposals have focused largely on the allocation side of pharmaceutical innovation policy. Bringing the incentive side of innovation policy into these discussions illuminates two points.

First, as we explained in Section II.B, reducing drug prices without expansions of the market or other policy changes—that is, reducing profits—likely would reduce innovation. But that doesn't mean these proposals are bad ideas. Cost-reduction proposals generally aren't mandating rewards below market value. Rather, they would move otherwise-inflated profits closer to the reward from a “normal” market for patented inventions and may address innovation-related biases in the system.

Second, pharmaceutical price reductions don't mean that overall incentives need to decrease. The government savings from cost reductions could be used to fund more innovation directly, through grants and national labs.<sup>241</sup> Ideally, policymakers would focus these new incentives on areas under-incentivized by market rewards to correct for biases embedded in the patent system. As we described in Section II.C, scholars have identified numerous fields of biomedical research in which current market rewards seem insufficient, including drugs with short effective patent protection, treatments for patients with limited ability to pay, non-pharmacological interventions, and interventions with positive externalities. Investing the savings from drug price reductions in non-IP incentives in these fields would be a substantial improvement in U.S. innovation policy.<sup>242</sup>

### C. *Improving Incentives Through Access Policies*

Finally, we think it is worth considering whether drug access policies such as Medicare and Medicaid can be adjusted on a more fine-grained level to improve social welfare.

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<sup>241</sup> The House Democrats' drug pricing package envisions using at least some of the savings it achieves for this purpose. See Backgrounder, *supra* note 141, at 2.

<sup>242</sup> We recognize, however, that it is easier to diagnose institutional deficiencies than to correct them. For example, in an analysis of the role of innovation institutions in the opioid epidemic, one of us argues that “[t]he failure of America's innovation institutions to encourage the development and dissemination of nonaddictive pain treatments arose not only from errors of institutional design but also from deficiencies of political will—deficiencies that non-patent institutions came to reflect.” Hemel & Ouellette, *supra* note 71, at 54–55.

Innovation incentives could also be improved by adjusting Medicaid policy levers.<sup>243</sup> For example, the rebate manufacturers are required to remit to CMS could be reduced for drugs treating diseases that primarily impact low-income populations, including mental health conditions and neglected tropical diseases.<sup>244</sup> The effect would be to pay more for certain classes of drugs prescribed primarily through the Medicaid program, mitigating the innovation distortion caused by the price differentials between Medicare and Medicaid.

It also may be worth considering new cost-control mechanisms for public payers. One alternative policy that could help control costs is the kind of cost-effectiveness analysis (also known as health technology assessment) used in most other countries' healthcare systems, as explained in Section I.B.<sup>245</sup> Health technology assessment organizations around the world often consider the cost-effectiveness of new therapies as well as their comparative clinical effectiveness, asking whether a new drug provides additional benefit beyond existing treatments and using the resulting analysis to inform reimbursement decisions.<sup>246</sup>

The goal of health technology assessment is to align the price of drugs with the value those drugs provide. Countries may choose to pay more for drugs that provide more health benefits, and less or not at all for drugs that provide fewer benefits or which are no better than existing treatments. These choices might encourage pharmaceutical companies to alter the set of projects they choose to invest in, but the new set of projects is likely to provide more societal benefit.<sup>247</sup> As noted in Section III.B, there are many areas of research which do not provide market returns commensurate with their social value, often due in part to misaligned innovation incentives. Reimbursement strat-

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<sup>243</sup> See Sachs, *supra* note 7, at 201–08 (demonstrating how altering the structure of Medicaid rebates can influence global innovation).

<sup>244</sup> *Id.* at 202.

<sup>245</sup> See Adrian Towse, Michael Drummond & Corinna Sorenson, *Measuring Value: Pharmacoeconomics Theory and Practice*, in THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 394, 427 (Patricia M. Danzon & Sean Nicholson eds., 2012) (reviewing the use of cost-effectiveness analysis and noting that it “is the most efficient form of regulation in theory and also in practice, if done well—and that, of course, is the challenge”).

<sup>246</sup> See Steven D. Pearson, Len Nichols & Amitabh Chandra, *Policy Strategies for Aligning Price and Value for Brand-Name Pharmaceuticals*, HEALTH AFF.: POL'Y OPTIONS PAPER (Mar. 15, 2018), <https://www.healthaffairs.org/doi/10.1377/hpb20180216.92303/full>.

<sup>247</sup> Rachel E. Sachs & Austin B. Frakt, *Innovation–Innovation Tradeoffs in Drug Pricing*, 165 ANNALS INTERNAL MED. 871, 871 (2016) (explaining the goal of reorganizing innovation and its efforts, “which would reduce some types of innovation we have now and encourage other types that would yield greater social value”).

egies that use health technology assessment can help address those misalignments.

To be clear, health technology assessment is formally agnostic as to whether society spends more or less on prescription drugs. It may be that there are many classes of drugs where the system should spend more, not less, particularly if spending on other healthcare services can be avoided as a result. In general, other countries' use of health technology assessment tools in paying for prescription drugs results in prices that are lower than those in the United States, across the board. Within the United States, public concern about government rationing of healthcare has so far sunk efforts to introduce such a system,<sup>248</sup> causing most biomedical innovation decisions to be outsourced to private markets.<sup>249</sup> Perhaps growing public concern about the existing U.S. healthcare system in general and drug prices in particular will change the current aversion to alternative models.

#### CONCLUSION

Innovation institutions—including patent law, tax law, and government funding agencies—expend enormous effort to optimize incentives to innovate, encouraging new ideas and products but not making them so costly that consumers can't have access to them. In the pharmaceutical industry, where these incentives arguably matter most to human welfare, policymakers have ignored one of the largest sources of innovation incentives: the Medicare innovation subsidy. Understanding how reimbursement through Medicare and related programs funds innovators opens up the policy space for both innovation and healthcare policy, offering everything from a way to get more drugs produced to a way to pay for Medicare for All. Whatever policymakers do with those levers, they should make innovation and healthcare policy with an awareness of how they affect each other and with full knowledge of the accidental subsidy Medicare provides to innovation.

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<sup>248</sup> See Towse et al., *supra* note 245, at 395.

<sup>249</sup> See Amy C. Madl, Note, *Using Value-Agnostic Incentives to Promote Pharmaceutical Innovation*, 71 STAN. L. REV. 1305, 1305, 1312 (2019).