

AN EASIER PILL TO SWALLOW: SUBSCRIPTION MODEL AGREEMENTS AS A SOLUTION TO THE GOVERNMENT’S PRESCRIPTION DRUG PRICING CRISIS

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I. INTRODUCTION

Vyera Pharmaceuticals, formerly known as Turing Pharmaceuticals, manufactures the drug Daraprim.¹ Daraprim is approved by the U.S. Food & Drug Administration (“FDA”) to treat acute malaria and toxoplasmosis, the latter of which is a parasitic infection that often strikes patients with HIV or AIDS.² The patent term for Daraprim has expired,³ but no generic drug equivalent exists in the United States market today.⁴

In the fall of 2015, Turing raised the price of Daraprim from \$13.50 per pill to \$750 per pill—an increase of over 5,000%.⁵ The public backlash was fierce amidst stories of reduced access to the drug; many refused to believe the price hike was necessary to fund research and development efforts for future drugs.⁶

Fortunately for Turing, brand-name drug manufacturers are uniquely protected from bad press associated with price hikes. This protection exists, in part, because the market for breakthrough drugs is monopolistic. A typical brand-name drug manufacturer distributing within the United States is granted a utility patent for its drug, which lasts twenty years.⁷ This may be extended for an additional five years due to a drawn-out regulatory review process.⁸ There is also no guarantee that a cheaper generic equivalent will be

¹ Beth Mole, *The 5,000% Price Hike That Made Martin Shkreli Infamous is No Longer Paying Off*, ARS TECHNICA (July 19, 2018), <https://arstechnica.com/tech-policy/2018/07/shkreli-former-company-is-now-losing-money-even-with-the-5000-price-hike>.

² *Id.*; FDA, DARAPRIM® PRESCRIBING INFORMATION (2003), https://www.accessdata.fda.gov/drugsatfddocs/label/2003/08578slr016_daraprim_lbl.pdf.

³ See Mole, *supra* note 1 (stating Daraprim is “off-patent”).

⁴ Alternative toxoplasmosis treatments are available but lack robust clinical data showing safety and effectiveness. See *Daraprim Prices Still an Obstacle for Patients*, HEALIO (Mar. 26, 2018), <https://www.healio.com/infectious-disease/hiv-aids/news/online/%7B90a0d411-0033-4269-ba41-89986411071d%7D/daraprim-prices-still-an-obstacle-for-patients>.

⁵ Mole, *supra* note 1. Turing’s then-CEO, Martin Shkreli, became infamous as a result of this price hike. See *id.*

⁶ *Id.*

⁷ See 35 U.S.C. § 154(a)(2) (2012).

⁸ 35 U.S.C. §§ 156(a)(4), (g)(6)(A) (2012). While the maximum extension is five years, a 2019 study found that utility patents for drugs are extended by a median of 2.75 years. Michael Mezher, *Study: Patent Term Restoration Extends Drug Patents by About 3 Years*, REGUL. AFFS. PROS. SOC’Y (Feb. 14, 2019), <https://www.raps.org/news-and-articles/news-articles/2019/2/study-patent-term-restoration-extends-drug-patent>.

developed once a drug's patent term expires.⁹ Lastly, drug manufacturers can often guarantee a customer pool due to the life-saving or life-altering nature of their products. Alternative treatments to patented drugs, if they exist, are much less attractive to physicians because they are generally less studied, which exposes the patient to more risk.¹⁰

Daraprim is just one drug within an industry-wide trend spanning the past decade. A federal government study found that 351 drug prices increased by at least 100% between 2010 and 2015.¹¹ As of September 2019, the twenty most expensive drugs range from list prices of \$26,000 to \$64,859 per month.¹²

Those who enroll in government insurance plans¹³ only pay a fraction of the drug list price.¹⁴ While this is essential to keep high-cost specialty drugs accessible to public healthcare enrollees, it shifts an enormous financial burden onto the government; net Medicaid outpatient prescription drug spending in 2017 was \$29.1 billion,¹⁵ and net Medicare Part D spending in 2018 was \$82 billion.¹⁶

These multi-billion-dollar figures reflect poor negotiating power on behalf of the state and federal governments when entering into supply agreements with drug manufacturers. This Note identifies the root causes behind the current drug pricing dilemma. Then, it explores a range of mechanisms to increase government negotiating power and it comments on their legal and legislative feasibility, ethical implications, and possible market responses from the pharmaceutical industry. Ultimately, this Note recommends broader adoption of subscription-based contracts which will result in increased fairness in government-manufacturer drug pricing negotiations and increased drug accessibility to plan enrollees.

⁹ See *Generic Drugs Undergo Rigorous FDA Scrutiny*, FDA (Oct. 8, 2014), <https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny> (stating that not every brand-name drug has an approved generic); see also *Daraprim Prices Still an Obstacle for Patients*, *supra* note 4 (citing raw material shortages, manufacturing challenges, company consolidation, and a backlog of new drug applications as barriers to entry in the drug industry).

¹⁰ See *Daraprim Prices Still an Obstacle for Patients*, *supra* note 4 (arguing that “[i]t is ridiculous that we have to search for other [lower-priced] options when we have a drug that works well.”).

¹¹ *Id.*

¹² Two of the drugs on this list are associated with patents that have expired. See Tori Marsh, *The 20 Most Expensive Prescription Medications in the U.S.*, GOODRX RSCH. (July 2019), https://www.goodrx.com/blog/wp-content/uploads/2019/10/The-20-Most-Expensive-Prescription-Medications-in-the-U.S.-Q2_-2019.pdf.

¹³ Private insurance plans independent from Medicare and Medicaid are not considered in this Note.

¹⁴ Marsh, *supra* note 12.

¹⁵ MEDICAID & CHIP PAYMENT & ACCESS COMM'N, MEDICAID DRUG SPENDING TRENDS 1 (2019), <http://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf>.

¹⁶ CONG. BUDGET OFF., MEDICARE—CBO'S MAY 2019 BASELINE 1 (2019), https://www.cbo.gov/system/files/2019-05/51302-2019-05-medicare_0.pdf.

II. FACTORS INFLUENCING THE LIST PRICES OF PRESCRIPTION DRUGS

A. THE PHARMACEUTICAL INDUSTRY

“[T]he healthcare industry is an odd market.”¹⁷ Novel drugs are difficult to place on American pharmacy shelves, and a manufacturer’s peak opportunity to capitalize on high drug prices ends when generic counterparts are permitted to enter. As a result, drug manufacturers tend to price their products at a premium to recapture costs and bring in profits during their twenty-year window of patent protection.

Prescription drug manufacturers incur substantial monetary and time costs in bringing novel drugs to the United States market. Costs range up to \$2.5 billion for a single drug¹⁸ with “an average of 10 to 20 years” to take a drug from the laboratory to the pharmacy.¹⁹ These costs reflect the mountain of data necessary to satisfy FDA’s regulatory requirements. While “every drug takes a unique route” to FDA approval, a drug is generally proven safe and effective for human use only after it is subjected to in vitro studies, animal studies, and several separate human clinical studies totaling over three thousand enrollees.²⁰ Regulatory requirements continue to accumulate after FDA approves a drug, commonly in the form of post-approval studies and surveillance activities, which alone may add another \$300 million in expenses.²¹

Embarking on a novel drug project is also an extremely risky business venture. Approximately ninety percent of all novel drug projects fail as a result of either ineffectiveness or an unacceptable risk-to-benefit ratio.²² Alarming, forty percent of drug projects fail in the third and final stage of human clinical trials, which occurs after spending years of human capital and millions of dollars of investment capital.²³

Additionally, the time for a manufacturer to generate returns on novel drugs is often limited by the drug’s patent term. Once the patent term expires, generic drug manufacturers are free to copy the drug’s formulation and sell it at a significantly lower price, which, on average, is seventy-five percent to

¹⁷ ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES 6 (2019).

¹⁸ *Id.* at 5.

¹⁹ Joe Kennedy, *The Link Between Drug Prices and Research on the Next Generation of Cures*, INFO. TECH. & INNOVATION FOUND. (Sept. 9, 2019), <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures>.

²⁰ *FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA (Nov. 24, 2017), <https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective>.

²¹ Kennedy, *supra* note 19. Post-approval regulatory requirements are necessary to ensure that a drug’s safety and effectiveness profile is maintained in real-world use, and that its manufacturing conditions remain acceptable. This real-world use often encompasses a wider range of patients than those enrolled in the drug’s pre-approval clinical trials. *See generally Postmarketing Surveillance Programs*, FDA (Apr. 2, 2018), <https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs> (explaining the purpose of postmarket requirements).

²² Derek Lowe, *I Do Hate to Tell You This, But . . .*, SCI. TRANSLATIONAL MED.: IN THE PIPELINE (Jan. 23, 2017), <https://blogs.sciencemag.org/pipeline/archives/2017/01/23/i-do-hate-to-tell-you-this-but>.

²³ *Id.* Imperfect models and methods during the earlier stages of drug development may factor into this late-stage high failure rate.

ninety percent below the price of the original branded drug.²⁴ While the brand-name drug may stay on the market beyond its patent term, the presence of a generic drug will inevitably reduce its sales because of the generic's superior affordability.

When a novel drug succeeds, drug manufacturers require returns proportionate to its high risk and temporary market dominance—one which may be less than the twenty-year patent term. These returns do not translate to pure profits. Rather, returns are used to recoup the costs of failed projects and the years of delay between the drug's initial conception and initial sale in the market.²⁵ Returns are also used to support significant investments into innovative drug research, as the typical research and development budget for a large pharmaceutical company in 2018 was around twenty percent of its sales revenue.²⁶ Without a strong pipeline of next generation drugs, investors may lose faith in a pharmaceutical company and move their money elsewhere.²⁷

B. THE MEDICAID FRAMEWORK

1. Member Eligibility and Care Plan Options

Generally speaking, Medicaid is the principal source of long-term care coverage for over 72.2 million low-income Americans and nonelderly adults with disabilities who otherwise lack access to health insurance.²⁸ The program covers approximately one in five Americans.²⁹ Its built-in federal and state partnership operates as follows: a state guarantees specified mandatory healthcare benefits to all eligible individuals, and the federal government guarantees uncapped funding to the state, dependent on the healthcare services provided.³⁰ Prescription drug coverage is not a mandatory

²⁴ FELDMAN, *supra* note 17, at 6.

²⁵ See Kennedy, *supra* note 19 (explaining the prescription drug manufacturer's need to recoup costs of drug development).

²⁶ Ben Adams, *The Top 10 Pharma R&D Budgets in 2018*, FIERCEBIOTECH (June 3, 2019), <https://www.fiercebiotech.com/special-report/top-10-pharma-r-d-budgets-2018> (showing pharmaceutical companies' research and development budgets in relation to their revenue). Specifically, research and development spending in the pharmaceutical industry in 2018 totaled \$181 billion globally. Matej Mikulic, *Total Global Spending on Pharmaceutical Research and Development Spending From 2012 to 2026*, STATISTA (Sept. 4, 2020), <https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals>. For comparison, advertising expenditures and chief executive compensation were \$6.4 billion and \$2.6 billion, respectively. See Bob Herman, *Health Care CEOs Took Home \$2.6 Billion in 2018*, AXIOS (May 16, 2019), <https://www.axios.com/health-care-ceo-pay-compensation-stock-2018-0ed2a8aa-250e-48f1-a47a-849b8ca83e24.html>; Alison Kanski, *Nielsen: Pfizer Tops List of Biggest Advertisers in 2018*, MED. MKTING & MEDIA (Apr. 2, 2019), <https://www.mmm-online.com/home/channel/nielsen-pfizer-tops-list-of-biggest-pharma-advertisers-in-2018>.

²⁷ Kennedy, *supra* note 19.

²⁸ *November 2020 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 Apr. 12, 2021).

²⁹ Robin Rudowitz et al., *10 Things to Know About Medicaid: Setting the Facts Straight*, KAISER FAM. FOUND. (Mar. 6, 2019), <https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight>.

³⁰ The federal government's funding to a state is ordinarily a minimum of fifty percent of the cost of qualified healthcare services. In other words, the federal government will at least match state contributions toward these expenses. See *id.*; see also 42 U.S.C. § 1396-1 (2012) (enabling states to receive federal funding for specified medical assistance).

benefit.³¹ Nevertheless, all fifty states and the District of Columbia provide some level of prescription drug coverage as part of their Medicaid programs.³²

Most Medicaid enrollees are placed by their state in a privately managed care plan, known as a Managed Care Organization (“MCO”),³³ that contracts with the state to provide certain services.³⁴ MCOs are responsible for the health of a large pool of enrollees and serve as a conduit between patients and physicians through clinical management systems.³⁵ These clinical management systems may influence the treatment decisions of in-network physicians.³⁶ The minority of Medicaid enrollees are placed into a fee-for-service plan, in which there is no MCO conduit.³⁷ In fee-for-service plans, the patient initiates all contact with healthcare providers, and in-network physicians make fully-independent treatment decisions.³⁸

Since most Medicaid enrollees are economically disadvantaged, enrollee out-of-pocket costs are “limited to nominal or minimal amounts.”³⁹ The costs vary by state and typically consist of copayments, deductibles, and other similar charges.⁴⁰ States are also free to impose additional cost-sharing methods for specified services, such as prescription drugs. For instance, states may establish lower copayments for generic or preferred drugs than for brand-name or non-preferred drugs.⁴¹

2. Medicaid and Prescription Drugs

MCOs are required to justify their healthcare pricing schedules as “actuarially sound,” which equates to a reasonableness standard.⁴² This provides MCOs and brand-name drug manufacturers leeway to explain away high treatment costs. However, the Medicaid Drug Rebate Program (“MDRP”) imposes a major check on how much the government will pay for prescription drugs.

Among other requirements, the MDRP compels drug manufacturers to enter into national rebate agreements with the Secretary of the Department

³¹ *Mandatory & Optional Medicaid Benefits*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/benefits/list-of-benefits/index.html> (last visited Jan. 15, 2021).

³² See *Medicaid Benefits: Prescription Drugs*, KAISER FAM. FOUND., <https://www.kff.org/medicaid/state-indicator/prescription-drugs> (last visited Jan. 15, 2021) (showing that all fifty states and the District of Columbia provide prescription drug coverage as part of their Medicaid program).

³³ Two types of MCOs exist: Health Maintenance Organizations (“HMOs”) and Preferred Provider Organizations (“PPOs”). *Managed Care Organization (MCO)*, INT’L RISK MGMT. INST., <https://www.irmi.com/term/insurance-definitions/managed-care-organization> (last visited Jan. 15, 2021).

³⁴ Rudowitz et al., *supra* note 29.

³⁵ See David M. Eddy, *Balancing Cost and Quality in Fee-For-Service Versus Managed Care*, 16 HEALTH AFFS. 162, 163–64 (May 1997) (describing standard characteristics of MCOs).

³⁶ *Id.*

³⁷ *Id.* (describing standard characteristics of fee-for-service plans); see Rudowitz et al., *supra* note 29 (stating that less than one-third of Medicaid beneficiaries receive their care through fee-for-service plans).

³⁸ Eddy, *supra* note 35, at 163 (describing standard characteristics of fee-for-service plans).

³⁹ *Cost Sharing Out of Pocket Costs*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/cost-sharing/out-of-pocket-costs/index.html> (last visited Jan. 15, 2021).

⁴⁰ See *Cost Sharing*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/cost-sharing/index.html> (last visited Jan. 15, 2021) (explaining the types of out-of-pocket costs for Medicaid enrollees).

⁴¹ *Id.*

⁴² See 42 C.F.R. § 438.4(a) (2019) (defining “actuarially sound”). See generally Jeff C. Goldsmith et al., *Medicaid Managed Care: Lots of Unanswered Questions (Part 2)*, HEALTH AFFS. (May 4, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180430.510086/full> (explaining the Center for Medicare and Medicaid Services’ (“CMS”) “actuarially sound” requirement).

of Health and Human Services (“HHS”) in exchange for Medicaid coverage of the manufacturer’s drugs.⁴³ Drug manufacturers pay these rebates quarterly to the state, and the state shares the payment with the federal government.⁴⁴ The national rebate agreements specify a minimum rebate amount based on statutory formulas accounting for the type of drug offered and the existing market for the drug’s equivalents, if one exists.⁴⁵ For instance, “innovator drugs” require a rebate amounting to the greater of 23.1% of the “average manufacturer price” per unit for similar drugs,⁴⁶ or the difference between the “average manufacturer price” per unit and the lowest price for the drug available to any entity (also called the “best price”).⁴⁷ Average manufacturer price is defined as the average price paid to the manufacturer by both wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.⁴⁸ This ensures that Medicaid receives discounts, for any given drug, at least as large as that for any other insurance plan. The maximum total rebate for an innovator drug is equivalent to its average manufacturing price.⁴⁹

In addition to the mandatory rebate, states may also negotiate supplemental rebate agreements with drug manufacturers.⁵⁰ When a drug manufacturer agrees to a supplemental rebate, the state may reward the manufacturer by placing its drug on a preferred drug list, thereby increasing the drug’s sales volume.⁵¹ As with the mandatory rebate, states share the payments with the federal government.⁵²

Medicaid relies on a unique give-and-take system between drug manufacturers and the government. Drug manufacturers must participate in Medicaid to qualify for Medicare, which presents a more lucrative market for drug manufacturers.⁵³ Manufacturers therefore tend to negotiate with state Medicaid departments and accept smaller profits within the low-income Medicaid population, because doing so unlocks larger profits within the elderly Medicare population. Though the Medicaid rebate scheme is designed to protect state governments, its relationship with the average manufacturer price has become a pain point in recent years. The combination of average manufacturer price increases and a fixed mandatory minimum

⁴³ *Medicaid Drug Rebate Program*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (last visited Jan. 15, 2021).

⁴⁴ See Daniel R. Levinson, DEP’T OF HEALTH & HUM. SERVS., STATES’ COLLECTION OF OFFSET AND SUPPLEMENTAL MEDICAID REBATES 2–3 (2014), <https://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf> (explaining the Medicaid Drug Rebate Program process).

⁴⁵ See 42 U.S.C. § 1396r-8(c) (2012) (defining criteria for rebates).

⁴⁶ *Id.* Innovator drugs are defined as drugs that are marketed under a new drug application approved by the FDA. 42 U.S.C. § 1396r-8(k)(7)(A)(ii) (2012).

⁴⁷ See 42 U.S.C. §§ 1396r-8(c)(1)(A)(ii), (c)(1)(C) (2012) (defining innovator drug rebates and “best price”); see also Levinson, *supra* note 44, at 3 (summarizing innovator drug rebates).

⁴⁸ 42 U.S.C. § 1396r-8(k)(1) (2012).

⁴⁹ Levinson, *supra* note 44, at 2.

⁵⁰ *Id.* at 5.

⁵¹ *Id.* at 6.

⁵² *Id.*

⁵³ CHARLES ROHRIG, THE IMPACT OF PRESCRIPTION DRUG REBATES ON HEALTH PLANS AND CONSUMERS 10 (2018), https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf (explaining a drug manufacturer’s exclusion from Medicare if that manufacturer refuses to participate in Medicaid).

rebate has shifted more costs onto state governments. In response, several states have implemented novel drug pricing schemes within their Medicaid programs. These are discussed in the sections to follow.

C. THE MEDICARE FRAMEWORK

1. Member Eligibility and Federal Government-Provider Contracts

Generally speaking, Medicare is the federal health insurance program for people who are at least sixty-five years of age.⁵⁴ The most popular portions of the program are Part A, inpatient coverage, and Part B, outpatient coverage, which together are referred as Original Medicare.⁵⁵ Part D was added in 2006 to provide prescription drug plans (“PDPs”).⁵⁶ Part C covers Medicare Advantage, which offers an alternative means for individuals to obtain Parts A, B, and D coverage.⁵⁷ The overall program currently covers around sixty million people.⁵⁸ Individuals can be enrolled in both Medicare and Medicaid simultaneously—this is known as dual eligibility. When dual-eligible individuals file claims, Medicare pays first and Medicaid pays last.⁵⁹

As with Medicaid, Medicare offers both MCOs and fee-for-service plans. Specifically, Original Medicare offers fee-for-service plans,⁶⁰ and Medicare Advantage offers both fee-for-service plans and MCOs.⁶¹ PDP coverage is available under both options; one can either enroll in a standalone PDP provided through Part D coverage, or enroll in a Medicare Advantage plan that includes prescription drug coverage.⁶² Original Medicare and Medicare Advantage plans without prescription drug coverage are contracted between the government and insurer through a system of bidding and rebates. Part I.C.2 of this Note discusses the contracting process when prescription drug coverage is included.

Medicare shifts substantially more costs onto enrollees than Medicaid. These costs are typically in the form of premiums, deductibles, coinsurance, and copayments. Enrollees pay greater fees as their income increases; for example, in 2019, Part D enrollees with a yearly income of \$85,000 paid a

⁵⁴ *What's Medicare?*, MEDICARE.GOV, <https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/whats-medicare> (last visited Jan. 15, 2021); *see also* 42 U.S.C. §§ 1395c, 1395j, 1395w-21(a)(3)(A), 1395w-101(a)(3)(A) (2018) (defining eligibility requirements for Medicare Parts A, B, C, and D).

⁵⁵ *See The Parts of Medicare (A, B, C, D)*, MEDICARE INTERACTIVE, <https://www.medicareinteractive.org/get-answers/medicare-basics/medicare-coverage-overview/original-medicare> (last visited Jan. 15, 2021).

⁵⁶ *Id.*

⁵⁷ *See id.*

⁵⁸ *An Overview of Medicare*, KAISER FAM. FOUND. (Feb. 13, 2019), <https://www.kff.org/medicare/issue-brief/an-overview-of-medicare>.

⁵⁹ Josh Schultz, *Can I Be Enrolled in Medicare and Medicaid at the Same Time?*, MEDICARE RES. CTR. (May 31, 2020), <https://www.medicareresources.org/faqs/can-i-be-enrolled-in-medicare-and-medicare-at-the-same-time>.

⁶⁰ *What is Original Medicare (Part A and Part B)?*, CIGNA, <https://www.cigna.com/medicare/understanding-medicare/part-a-part-b> (last visited Jan. 15, 2021) (defining Original Medicare as a fee-for-service plan); *see supra* notes 38–39 and accompanying text.

⁶¹ *What is Medicare Advantage (Part C)?*, CIGNA, <https://www.cigna.com/medicare/understanding-medicare/part-c> (last visited Jan. 15, 2021) (defining Medicare Advantage as either a fee-for-service plan or MCO plan); *see supra* notes 35–37 and accompanying text.

⁶² *What is Medicare Part D Prescription Drug Coverage?*, CIGNA, <https://www.cigna.com/medicare/understanding-medicare/part-d> (last visited Jan. 15, 2021) (defining the two ways to enroll in Part D prescription drug coverage).

set monthly premium, while enrollees in the same plan with a yearly income of \$500,000 paid the set premium plus an additional \$77.40 per month.⁶³

2. Medicare and Prescription Drugs

The legislation that created Medicare Part D included a noninterference clause.⁶⁴ The clause prohibits the federal government from participating in negotiations between drug manufacturers, pharmacies, and PDP sponsors, and also from requiring drug manufacturers to pay rebates to the government.⁶⁵

The noninterference clause leaves PDP sponsors in complete control of their plans, allowing them to negotiate drug prices, determine the drugs covered, and the amounts enrollees pay.⁶⁶ This was enacted to create a competitive private market in which Medicare beneficiaries may choose from a wide variety of PDPs with varying drug prices, and to incentivize PDP sponsors to keep plan costs low to promote beneficiary enrollment.⁶⁷ For instance, Medicare beneficiaries are free to reject plans that, while carrying cheaper premiums, restrict access to specific drugs. Affordability aside, beneficiaries have had a consistently large selection of PDPs; there were 901 nationwide PDP offerings in 2019, and there have been over 1,000 nationwide PDP offerings each year from 2006 to 2015.⁶⁸

Medicare PDPs impose substantial costs on the federal government. This is due to two main factors. First, the standard PDP benefit design exposes the government to a high amount of monetary risk. There are four zones of coverage in a standard PDP: a deductible zone, an initial coverage zone, a “coverage gap” zone, and a catastrophic coverage zone.⁶⁹ The enrollee progresses through these zones as they incur more prescription drug costs throughout a calendar year, beginning in the deductible zone and ending in the catastrophic coverage zone.⁷⁰ The catastrophic coverage zone is entered into after the enrollee incurs \$8,140 in total drug costs.⁷¹ In this zone, the

⁶³ *Medicare Costs at a Glance*, MEDICARE.GOV, <https://www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance> (last visited Jan. 15, 2021) (tabulating Part D premiums by income).

⁶⁴ See 42 U.S.C. § 1395w-111(i) (2018) (“In order to promote competition . . . the Secretary (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.”). The noninterference clause was established by the Medicare Modernization Act of 2003, and the clause was used as a “bargaining chip to attract market-oriented Republican votes.” Theodore T. Lee, et al., *The Politics of Medicare and Drug-Price Negotiation*, HEALTH AFFS. (Sept. 19, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160919.056632/full>. The pharmaceutical industry had a “major role” in writing the noninterference clause in 2003, and the industry’s presence remains prevalent in Congress. *Id.* It spent over \$230 million in lobbying efforts in 2015, and also spent more on lobbying than any other industry from 1998–2015. *Id.*

⁶⁵ See 42 U.S.C. § 1395w-111(i) (2018).

⁶⁶ *Medicare Part D: The Noninterference Clause*, SENATE REPUBLICAN POL’Y COMM. (May 22, 2019), <https://www.rpc.senate.gov/policy-papers/medicare-part-d-the-noninterference-clause> (explaining the purpose of the noninterference clause).

⁶⁷ See *id.*

⁶⁸ *An Overview of the Medicare Part D Prescription Drug Benefit*, KAISER FAM. FOUND. (Oct. 14, 2020), <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit> (listing PDP offerings in the United States since 2006).

⁶⁹ See *id.* (listing Medicare Part D standard benefit parameters).

⁷⁰ See *id.*

⁷¹ See *id.*

government typically pays eighty percent of all costs.⁷² Given the current state of high-end drug prices, in which one month of treatment may cost at least \$26,000,⁷³ the catastrophic coverage zone can be entered into quickly, creating a significant burden on the government.

The government is also burdened by the lack of drug manufacturer competition for high-priced brand-name drugs. When there is only one form of treatment available, PDP sponsors have little bargaining power against drug manufacturers, leading PDP sponsors to accept high drug prices. PDP sponsors then pass these high costs onto the government via catastrophic coverage when the plans are accepted into Medicare.

D. THE COVERED PATIENT

Since most people place a very high value on their own life, buying decisions for healthcare are financially irrational.⁷⁴ As a result, the high cost of a particular method of care may not deter a patient from pursuing it, despite a low likelihood of success or a mere marginal benefit to their life.⁷⁵

Additionally, patients are not always adequately informed of their treatment options and therefore suffer from an informational disadvantage.⁷⁶ This knowledge gap exists, in part, because it is difficult for physicians to avoid both under-informing a patient on treatment options and flooding a patient with too much information.⁷⁷ This problem leads to physicians making the ultimate decision for medical treatment, in which the decision to treat with high-cost brand-name drugs may dominate due to existing relationships with drug manufacturers⁷⁸ and superior clinical data supporting safety and efficacy.

When noneconomic factors dominate both a patient's choice to use a high-cost drug and a physician's decision to prescribe a high-cost drug, the drug will likely be chosen regardless of the list price. As a result, manufacturers do not face the usual market incentives to lower drug prices in order to increase sales.

⁷² Insurance providers pay fifteen percent of all costs, and enrollees pay the remaining five percent of all costs. *See id.*

⁷³ *See supra* note 12 and accompanying text.

⁷⁴ FELDMAN, *supra* note 17, at 7.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *See id.*

⁷⁸ *See id.*

III. ASSESSING SEVERAL EXISTING METHODS FOR REDUCING PRESCRIPTION DRUG COSTS

A. LEGISLATIVE PRICE CEILINGS

“From a global perspective, many countries limit how much they pay for prescription drugs by . . . implementing national formularies and price ceilings.”⁷⁹ Though the current United States public healthcare system promotes a passive government during drug pricing negotiations, public and political winds are shifting. On the federal level, the Trump administration voiced support for legislative price ceilings as a solution for rising prescription drug costs, and the House of Representatives approved a bill that would empower the HHS Secretary to negotiate the prices of specified prescription drugs.⁸⁰ On the state level, forty-five drug-cost-control bills were passed by twenty-eight states in 2018, mostly focusing on the relationship between pharmacy benefit managers and pharmacists.⁸¹ Maryland passed a law pertaining to its health plans for government employees in 2019, which required drug manufacturers to justify high prices or price spikes for both patented and generic drugs.⁸² If the state rejected the justification, it could set a lower price.⁸³

Legislative price ceilings are a much more direct solution to governments’ healthcare burdens than the innovative pricing models discussed in the sections to follow. The forthcoming material will explore a price ceiling’s potential impact on the citizens and economy of the United States, as well as its legal feasibility.

1. Ethical Benefits

The most profound benefit that legislative price ceilings would have on American public healthcare would be to make some drugs more accessible to enrollees, provided that the manufacturers of drugs affected by the price ceilings remain in the public healthcare market. The government’s negotiating power in setting prescription drug prices would be superior to that of drug manufacturers because of the large share of the total market covered by government health insurance. As a whole, this would result in better deals for the government in the form of lower prescription drug prices for Medicare and Medicaid programs. Lower drug costs will free up some funds in state and federal healthcare budgets, which could be spent to cover more drugs (and other medical services) and to lower treatment thresholds for already-covered drugs, which in turn will expose public healthcare enrollees to a wider range of treatments. Due to the stark negotiating power shift mentioned above, the level of accessibility brought by legislative price

⁷⁹ Tara Sklar & Christopher Robertson, *Affordability Boards—The States’ New Fix for Drug Pricing*, 381 NEW ENG. J. MED. 1301, 1301 (2019).

⁸⁰ See *infra* note 163.

⁸¹ Specifically, bills lifted prohibitions on pharmacists from informing patients about lower-priced generic drugs. See Sklar & Robertson, *supra* note 79, at 1301.

⁸² *Id.*

⁸³ *Id.*

ceilings would surpass that unlocked by any other payment model discussed in this Note.⁸⁴

2. Repairing the Public Image of the Pharmaceutical Industry

Brand-name drug manufacturers are offered unique market protections for their products with the existing regulatory frameworks of patents and public healthcare. Industry supporters believe that these protections are a fair reward for the massive risks undertaken in prescription drug research and development.⁸⁵ But a skeptic would argue that the protections allow drug manufacturers to exploit patients by setting their own price on an extremely valuable commodity.

Legislative price ceilings remove the skeptic's concerns by eliminating perceived drug price exploitation. The prices of prescription drugs would be tied to a metric deemed fair by state or federal legislatures, rather than manufacturers. Proposed metrics of fairness include an international price index,⁸⁶ tying maximum drug price hikes to the rate of domestic inflation,⁸⁷ and mandatory manufacturer justifications for price increases.⁸⁸ These metrics would eliminate Daraprim-like price hikes.⁸⁹

These price ceilings would provide a much-needed boost to the reputation of the pharmaceutical industry. "Big pharma" has an overwhelmingly negative connotation today, and high drug pricing is largely to blame.⁹⁰ An industry comparison poll conducted by Gallup showed that the pharmaceutical industry is "the most poorly regarded industry in Americans' eyes."⁹¹ At times, poor reputations can contribute to poor corporate financial statements by "rattl[ing] shareholder confidence, hamper[ing] employee recruitment, and caus[ing] a company to lose credibility."⁹² Shifting drug pricing schemes onto the government would shield the pharmaceutical industry from a great deal of negative press and its financial consequences. As a result, prescription drug manufacturers' lost

⁸⁴ In contrast, the subscription model and other payment models are efforts to level the bargaining power between the government and drug manufacturers.

⁸⁵ See discussion *supra* Part I.A.

⁸⁶ See Rachel Sachs, *Understanding the House Democrats' Drug Pricing Package*, HEALTH AFFS. (Sept. 19, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190919.459441/full> (defining the international price index as "1.2 times the volume-weighted average of the drug's price in six countries: Australia, Canada, France, Germany, Japan, and the United Kingdom.").

⁸⁷ See Emmarie Huetteman, *GOP Senators Distance Themselves from Grassley and Trump's Efforts to Cut Drug Prices*, KAISER HEALTH NEWS (July 25, 2019), <https://khn.org/news/gop-senators-distance-themselves-from-grassley-and-trumps-efforts-to-cut-drug-prices>.

⁸⁸ See Sklar & Robertson, *supra* note 79, at 1301.

⁸⁹ See *supra* note 5 and accompanying text.

⁹⁰ The pharmaceutical industry's role in the recent opioid crisis is another significant factor in its poor reputation. See Justin McCarthy, *Big Pharma Sinks to the Bottom of U.S. Industry Rankings*, GALLUP (Sept. 3, 2019), <https://news.gallup.com/poll/266060/big-pharma-sinks-bottom-industry-rankings.aspx>.

⁹¹ Fifty-eight percent of polled consumers had a negative view of the pharmaceutical industry, while twenty-seven percent had a positive view of it. *Id.* This perception is the continuation of a recent trend; in 2016, just nine percent of polled consumers believed pharmaceutical companies valued patients over profits. See *Only Nine Percent of U.S. Consumers Believe Pharma and Biotechnology Put Patients Over Profits; Only 16 Percent Believe Health Insurers Do*, HARRIS POLL, <https://theharrispoll.com/only-nine-percent-of-u-s-consumers-believe-pharmaceutical-and-biotechnology-companies-put-patients-over-profits-while-only-16-percent-believe-health-insurance-companies-do-according-to-a-harris-poll> (last visited Jan. 15, 2021).

⁹² Meagan Parrish, *Pharma's Damaged Reputation*, PHARMA MFG. (Mar. 18, 2019), <https://www.pharmamanufacturing.com/articles/2019/pharmas-damaged-reputation>.

profits resulting from legislative price ceilings could be partially offset by a repaired public perception.

3. Risking Reduced Innovation

“Developing these [prescription drugs] is time-consuming and costly, and their value—their ability to save lives—is in some ways immeasurable.”⁹³ Imposing legislative price ceilings necessarily means capping a drug manufacturer’s reward for making it through a tortuous development process.

Limiting profits may decrease pharmaceutical breakthroughs by shifting an established pharmaceutical company’s research and development budget. Broadly speaking, pharmaceutical companies pursue either “incremental improvements” or “innovative therapies” in their next generation product pipeline.⁹⁴ A 2018 study found that when these companies suffered a decrease in profits, they were more likely to pursue incremental improvements than innovative therapies.⁹⁵ One possible explanation for this correlation is that innovative therapies are too high-risk to pursue with limited research and development resources, which in turn drives companies to choose lower-risk incremental improvement projects. This study suggests that a landscape of reduced profits to established drug manufacturers under a regime of legislative price ceilings could result in a greater industry bias toward incremental improvement projects and away from innovative therapy projects.

Limiting profits may also decrease the attractiveness of starting or acquiring a pharmaceutical startup company. Potential founders may choose to pursue an idea with greater promise for profits, and established pharmaceutical companies may decide against acquiring a startup with a capped potential for profits. Today’s pharmaceutical industry relies heavily on startups, as startups have created sixty-three percent of novel drugs approved in the United States from 2013 to 2018.⁹⁶ Legislative price ceilings may ultimately impose a chilling effect on this startup ecosystem in the forms of fewer pharmaceutical startup formations and fewer acquisitions of existing startups.

Pharmaceutical breakthroughs are a massive benefit to society. The current United States healthcare system generally allows breakthrough brand-name manufacturers twenty years of market control before their drug is undercut by generic counterparts. While there are short-term ethical

⁹³ Robin Feldman, *The Perils of Value-Based Pricing for Prescription Drugs*, WASH. POST (Apr. 11, 2019), <https://www.washingtonpost.com/outlook/2019/04/11/perils-value-based-pricing-prescription-drugs>.

⁹⁴ Incremental improvements exist in the form of minor changes to existing drugs. These are generally risk-averse investments, given their higher research and development success rate and lesser amount of clinical data necessary to gain FDA approval. See Joshua Krieger et al., *Everyone Wants Pharmaceutical Breakthroughs. What Drives Drug Companies to Pursue Them?*, KELLOGGINSIGHT (Sept. 6, 2018), <https://insight.kellogg.northwestern.edu/article/everyone-wants-pharmaceutical-breakthroughs-what-drives-drug-companies-to-pursue-them> (arguing that “financial frictions may be limiting innovation”).

⁹⁵ *Id.*

⁹⁶ Lori Ioannou, *Big Pharma’s Billion-Dollar Scramble to Invest in Start-Ups to Fuel Innovation*, CNBC (Mar. 28, 2018), <https://www.cnbc.com/amp/2018/03/26/big-pharmas-scramble-to-invest-in-start-ups-to-fuel-innovation.html>.

concerns of access during the periods of brand-name market control, these concerns subside in the long term as generics increase accessibility. Legislative price ceilings ease these short-term ethical concerns by increasing accessibility from the start, but consequently pose a long-term practical risk. By limiting the drug manufacturer's upside when pursuing high-risk innovative development projects, legislative price ceilings discourage this risk-taking and may jeopardize the creation of innovative therapies.

However, amidst predictions that legislative price ceilings will hinder pharmaceutical innovation, competing data suggest this fear is overstated. One study published in 2010 compared the degree of pharmaceutical innovation between the United States and major international countries, most of which employ stricter drug price regulation than the United States, in proportion to each country's gross domestic product and prescription drug spending.⁹⁷ The study failed to find a definitive correlation between high drug spending and high levels of innovation.⁹⁸ Specifically, "[h]igher prescription drug spending in the United States does not disproportionately privilege domestic innovation, and many countries with drug price regulation were significant contributors to pharmaceutical innovation."⁹⁹

The accuracy of pharmaceutical development cost estimates has also come under criticism. Andrew Witty, the former chief executive officer of GlaxoSmithKline,¹⁰⁰ has stated that billion-dollar price estimates of drug development are the result of cherry-picking the drugs that were particularly expensive to develop. If drug development costs are in fact lower than the pharmaceutical industry advertises, the risk in pursuing an innovative drug project is lower as well. This would decrease a price ceiling's adverse effects on innovation.

4. Constitutional Conflicts Impede Widespread State Adoption

State governments face a difficult legal path in establishing meaningful legislative price ceilings within their Medicaid programs. One recent state government's attempt to regulate drug pricing conflicted with the interstate commerce clause of the United States Constitution.¹⁰¹ Maryland passed the Anti-Price Gouging Act in 2017, which prohibited unconscionable price increases on the part of prescription drug manufacturers.¹⁰² In 2018, in *Ass'n for Accessible Medicines v. Frosh*, the Fourth Circuit Court of Appeals struck down the law as unconstitutional on the grounds that it interfered with

⁹⁷ The amount of "innovation" was measured by an inventor's development of a new molecular entity. Each qualified invention was assigned to an inventor country. See Salomeh Keyhani et al., *US Pharmaceutical Innovation in an International Context*, 100 AM. J. PUB. HEALTH 1075, 1076 (2010).

⁹⁸ *Id.* at 1078.

⁹⁹ *Id.* at 1075.

¹⁰⁰ GlaxoSmithKline is a global healthcare company whose pharmaceutical business generated approximately \$19 billion in 2018. See generally *Pharmaceuticals*, GLAXOSMITHKLINE, <https://www.gsk.com/en-gb/about-us/pharmaceuticals> (last visited Dec. 19, 2019).

¹⁰¹ The interstate commerce clause gives Congress the power "to regulate commerce with foreign nations, and among the several states." U.S. CONST. art. 1, § 8.

¹⁰² See Sklar & Robertson, *supra* note 79, at 1301. For the entire text, see generally MD. CODE ANN. HEALTH-GEN. §§ 2-801 to 2-803 (West 2020).

interstate commerce.¹⁰³ Specifically, “the fundamental problem with the Act [was] that it ‘regulate[d] the price of [an] out-of-state transaction,’” because upstream sales between drug manufacturers and any third party were within the act’s scope as long as downstream sales took place within Maryland.¹⁰⁴

The Fourth Circuit’s decision reiterated the states’ limited power to initiate substantive drug pricing reform. In its wake, several states have passed bills establishing “drug cost commissions” which shy away from interstate commerce challenges.¹⁰⁵ For example, in 2018, Maryland passed a bill creating a drug affordability board that can only recommend reimbursement level changes based on manufacturer pricing justifications and spending targets for certain categories of drugs.¹⁰⁶ The board has no direct authority to implement changes.¹⁰⁷ While these state bills represent good faith efforts to reduce the burden of high drug prices on their Medicaid budgets, constitutional law restrictions will likely prevent them from enacting effective prescription drug price controls. Reform is needed on the federal level.

5. Political Barriers Impede the Required Substantial Federal Reform

Governments must strike a delicate balance when imposing price controls. They gain favor with voters and constituents when contributing to lowering the price of popular goods but gain favor with lobbyists and firms when contributing to raising prices to promote the health of the industry.¹⁰⁸

Federally imposed price ceilings for prescription drugs would represent a shift away from industry interests and toward the perceived public good. This shift would radically depart from a cornerstone of United States healthcare: minimal government intervention. Such a shift is prone to fierce political resistance, and it would receive more political resistance than the proposition of government involvement in drug pricing negotiations through the pricing models discussed in the sections to follow. Divisive solutions are difficult to pass into law. Legislative price ceilings for prescription drugs are divisive, resulting in strong feasibility concerns.

B. CLINICAL OUTCOME PAYMENT MODELS

Clinical outcome payment models link the payment of a drug to its clinical effectiveness. Under these models, a government and drug manufacturer measure the drug’s effectiveness through a clinical benchmark and agree upon separate rebates for when the benchmark is either met or not met.¹⁰⁹ This entitles the government to a higher rebate when a drug is deemed

¹⁰³ See generally *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018), *cert. denied* 139 S. Ct. 1168 (2019).

¹⁰⁴ *Id.* at 672.

¹⁰⁵ See Sklar & Robertson, *supra* note 79, at 1302.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Fiona M. Scott Morton, *The Problems of Price Controls*, CATO INST. (June 20, 2001), <https://www.cato.org/publications/commentary/problems-price-controls> (discussing the various interests involved when setting price controls).

¹⁰⁹ See Press Release, Marc Williams, *CMS Approves Colorado Medicaid Plan for Value-Based Pharmaceutical Contracts*, COLO. DEP’T HEALTH CARE POL’Y & FIN. (Feb. 26, 2019),

clinically ineffective for a given patient. In 2018, Oklahoma incorporated clinical outcome payment models for two antipsychotic drugs, a drug for treating skin infections, and a product for seizures into its Medicaid program.¹¹⁰ The contracting parties agreed to reevaluate the clinical outcome benchmarks either annually or semi-annually.¹¹¹

This payment model is a means of increasing access to high-cost brand-name drugs by acting as a quasi-insurance policy for the government. However, clinical outcomes are often difficult to assess. “[M]any disease areas don’t have a strict biological outcome that can readily serve as an assessment metric for drug performance.”¹¹² This uncertainty may ultimately discourage the model’s broader adoption. Indeed, domestic clinical outcome payment model contracting activity has slowed in recent years.¹¹³

C. INDICATION-SPECIFIC PAYMENT MODELS

Indication-specific payment models link the payment of a drug to the condition for which it was prescribed.¹¹⁴ Accordingly, drug manufacturers are paid more when their drug is used to treat an indication with a higher agreed-upon value than an indication with a lower agreed-upon value.¹¹⁵ The agreed-upon values may be determined by the drug’s effectiveness within the indicated mode of treatment.¹¹⁶

In theory, these models should result in payments to drug manufacturers proportionate to the drug’s perceived value. They should also cause drug manufacturers to pursue high-value indications with future drug projects, resulting in a wider pool of desirable drugs for patients.¹¹⁷ However, a major ethical disadvantage exists. Patients or providers with healthcare budget constraints may not be able to afford the higher-valued treatment, thereby forcing the use of lower-valued treatments.¹¹⁸ In this scenario, economically

<https://www.colorado.gov/pacific/hcpf/news/cms-approves-colorado-medicaid-plan-value-based-pharmaceutical-contracts>

[<https://web.archive.org/web/20200804091924/https://www.colorado.gov/pacific/hcpf/news/cms-approves-colorado-medicaid-plan-value-based-pharmaceutical-contracts>].

¹¹⁰ See Harris Meyer, *As a Cure for High Drug Prices, Outcomes-Based Deals Aren’t Delivering Yet*, 49 MOD. HEALTHCARE 22, 23 (2019) (summarizing Oklahoma’s clinical outcome payment model contracts). Michigan and Colorado Medicaid programs have also received CMS approval to enter into clinical outcome agreements with drug manufacturers. See David Lim, *CMS Approves Michigan Medicaid Drug Value-Based Payment Plan*, BIOPHARMA DIVE (Nov. 14, 2018), <https://www.biopharmadive.com/news/cms-approves-michigan-medicaid-drug-value-based-payment-plan/542280> (summarizing Michigan’s clinical outcome agreement approval); Williams, *supra* note 109 (summarizing Colorado’s clinical outcome agreement approval).

¹¹¹ Meyer, *supra* note 110, at 23.

¹¹² Ben Comer, *Six Drug Pricing Models Have Emerged to Improve Product Access and Affordability*, PRICEWATERHOUSECOOPERS (Sept. 23, 2019), <https://www.pwc.com/us/en/industries/health-industries/library/6-drug-pricing-models.html>.

¹¹³ Meyer, *supra* note 110, at 22.

¹¹⁴ Ryan Knox, Note, *More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States*, 18 YALE J. HEALTH POL’Y L. & ETHICS 191, 199 (2019) (defining indication-specific pricing).

¹¹⁵ *Id.* A drug’s “indication” is a term with regulatory origin. FDA defines an indication as a notification “for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition.” See Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products, 83 Fed. Reg. 31,760 (July 9, 2018), <https://www.regulations.gov/document/FDA-2018-D-1895-0001>.

¹¹⁶ Comer, *supra* note 112 (defining indication-specific pricing).

¹¹⁷ Knox, *supra* note 114, at 200.

¹¹⁸ See *id.* at 224–25 (discussing the ethical issues of indication-specific pricing).

disadvantaged individuals suffer reduced access to treatments deemed most effective by society. A practical disadvantage is also present due to extensive “off-label” use of prescription drugs.¹¹⁹ Off-label uses likely cannot find their way into indication-specific payment models because they lack sufficient clinical effectiveness data to justify a price point.¹²⁰ This off-label exclusion impacts a substantial portion of prescribed drugs, as off-label prescribing accounts for approximately twenty percent of all prescriptions issued in the United States.¹²¹

D. MORTGAGE PAYMENT MODELS

Mortgage payment models allow prescription drug purchasers to spread the cost of an expensive therapy over a period of time.¹²² Similar to a home mortgage system, in which the homeowner agrees to set costs over time rather than paying the entire property value up front, prescription drug mortgage payment models in public healthcare allow the government to reimburse the drug manufacturer over time rather than paying the entire treatment cost up front.

The mortgage payment model reduces the “sticker shock” of particularly high-priced brand-name drugs that face no competition or treat rare diseases.¹²³ This is particularly useful for gene-editing treatments, which have limited patient populations and are one-time, rather than recurring, treatments. In 2017, the total costs for the first and second FDA-approved gene therapy drugs were \$475,000 and \$850,000, respectively.¹²⁴ These prices compare well with the cost of existing drugs that require long-term, recurring treatments.¹²⁵ However, mortgage payment models have practical disadvantages. First, the model essentially pushes healthcare costs down the road without effectively lowering them.¹²⁶ Extremely high price tags may still be too steep for governments to cover within their healthcare programs. This would not increase public access to desired drugs. Second, patients will likely bring complexities into the reimbursement scheme. If the patient has any financial obligation in the payment model with respect to co-payments or deductibles, it is unclear what would happen if the patient changes insurance plans or defaults on scheduled payments.¹²⁷

¹¹⁹ “Off-label” use is defined by FDA as an “[u]napproved use of an approved drug.” This generally refers to the use of an approved drug that falls outside the scope of its indications. See *Understanding Unapproved Use of Approved Drugs “Off Label”*, FDA (Feb. 5, 2018), <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>.

¹²⁰ See Knox, *supra* note 114, at 219.

¹²¹ *Id.*

¹²² Comer, *supra* note 112 (defining mortgage payment models).

¹²³ *Id.*

¹²⁴ Laura Hercher & Anya E.R. Prince, *Gene Therapy’s Field of Dreams: If You Build It, Will We Pay?*, 97 N.C.L. REV. 1463, 1474–75 (2019).

¹²⁵ *Id.* at 1475.

¹²⁶ *Id.* at 1489 (discussing the impracticalities of mortgage payment models).

¹²⁷ *Id.* at 1488.

IV. ASSESSING SUBSCRIPTION MODEL AGREEMENTS AS A BETTER MEANS TO REDUCE PRESCRIPTION DRUG COSTS

As the federal and state governments continue to search for additional solutions to rising drug prices, creative contract agreements between the government, plan providers, and drug manufacturers continue to grow in popularity. One such agreement is known as the “subscription model.”¹²⁸ This is a subscription-based payment model in which the government or plan provider pays the drug manufacturer a fixed monthly or annual fee in exchange for unlimited access to a specific drug.¹²⁹ The forthcoming section discusses the limited use of the subscription model both in the United States and abroad, and the benefits and repercussions of its broader incorporation into United States public health insurance.

A. ORIGINS AND RECENT INTRODUCTION INTO STATE MEDICAID PROGRAMS

In 2015, Australia was the first government to incorporate a subscription model agreement into its healthcare program.¹³⁰ Under Australia’s healthcare system,¹³¹ prescription drugs are largely paid for by the government.¹³² The nation signed a joint deal with Gilead, AbbVie, Bristol Myers Squibb, and Merck, all of which manufacture hepatitis C treatments, worth approximately \$766 million USD in exchange for a five-year unlimited volume of the treatment.¹³³ Though the five-year term has not yet expired, estimates indicate that Australia will realize substantial cost savings. Predictions for hepatitis C drug treatment range from approximately 60,000 patients to 100,000 patients within the five-year term, yielding a price-per-patient range from approximately \$7,300 USD to \$10,700 USD.¹³⁴ An

¹²⁸ The subscription model is commonly nicknamed the “Netflix model,” as it reflects the Netflix business model of unlimited content streaming at a fixed monthly rate. However, a disparity exists between the streaming service industry and the prescription drug industry; the former is a repeat-use industry, while the latter is a single-use industry. There are no additional production costs to Netflix (outside of licensing fees) once a piece of content is available for streaming, regardless of the number of users consuming the content. On the other hand, there are substantial manufacturing and distribution costs to pharmaceutical companies once a prescription drug is included in the subscription plan. Thus, while the “Netflix model” is used by authors in some of the source material, the term “subscription model” is used exclusively in the text of this Note.

¹²⁹ See Ipsita Smolinski, *More States Consider ‘Netflix Model’ to Access Life-Saving Medications*, MORNING CONSULT (May 1, 2019), <https://morningconsult.com/opinions/more-states-consider-netflix-model-access-life-saving-medications> (defining subscription models).

¹³⁰ See Alyssa Rege, *Can the Netflix Model Help Curb Healthcare Costs?*, BECKER’S HOSP. REV. (Mar. 7, 2019), <https://www.beckershospitalreview.com/strategy/can-the-netflix-model-help-curb-healthcare-costs.html> (discussing Australia’s first subscription model deal).

¹³¹ Australia has a universal healthcare system for which all Australian and New Zealand citizens qualify. It includes a Pharmaceutical Benefits Scheme (“PBS”), similar to Medicare Part D and Medicaid, which “makes some prescription medicines cheaper.” See generally *The Australian Health System*, AUSTRAL. GOV’T DEP’T HEALTH, <https://www.health.gov.au/about-us/the-australian-health-system> (last updated Aug. 7, 2019).

¹³² Suerie Moon & Elise Erickson, *Universal Medicine Access Through Lump-Sum Remuneration—Australia’s Approach to Hepatitis C*, 380 NEW ENG. J. MED. 607, 607 (2019) (explaining the Australian government’s role in paying for prescription drugs).

¹³³ See *id.* The details regarding drug manufacturing responsibilities of each company and payment distribution to each company is not public.

¹³⁴ See *id.* at 607–08.

identical drug treatment is sold in the United States for \$72,756 USD per patient.¹³⁵

The subscription model's success in Australia eventually caught the attention of state lawmakers in the United States. In July 2019, Louisiana became one of two states to implement a subscription model agreement within its Medicaid program. As with Australia, Louisiana crafted the deal around hepatitis C medications.¹³⁶ Hepatitis C is a massive problem for Louisiana; an estimated 39,000 people in the state's Medicaid program or in its prisons have hepatitis C, which kills more Louisianans than all other infectious diseases combined.¹³⁷ Historically, Louisiana was only able to treat the most severe cases of hepatitis C because it did not have the budget to increase access to high-priced prescription drugs.¹³⁸ The state signed a five-year deal with Gilead Sciences worth \$58 million annually, under which it would provide Medicaid patients with unlimited access to Gilead's hepatitis C treatment, plus a copayment that would be no more than three dollars.¹³⁹ This contract was the outcome of a competitive bidding process in which three drug manufacturers submitted proposals to Louisiana.¹⁴⁰ By reducing this cost barrier, the state expected to treat 10,000 of the estimated 39,000 Medicaid patients and prisoners with hepatitis C by the end of 2020, and 31,000 by the end of 2024.¹⁴¹ Effective state-driven campaigns to inform Medicaid enrollees of this new treatment option could drive these figures up. By comparison, the state of Louisiana treated just 1,100 patients under the traditional per-patient payment model in 2018.¹⁴²

Washington took a similar approach. In July 2019, the state signed a deal with AbbVie in which the state would provide set annual payments in exchange for an unlimited supply of hepatitis C treatment through June 2023.¹⁴³ This contract is the hallmark of Washington's effort to eliminate hepatitis C in the state by 2030, a disease that currently affects 65,000 Washingtonians.¹⁴⁴

¹³⁵ *Id.* at 608.

¹³⁶ See Melinda Deslatte, *Louisiana Reaches 'Netflix-Model' Deal to Tackle Hepatitis C*, AP NEWS (June 26, 2019), <https://www.apnews.com/bc074b5c06024926a5c58163de8bab9d> (summarizing Louisiana's subscription model contract).

¹³⁷ Les Masterson, *Louisiana Launching 'Netflix Model' in Medicaid for Hepatitis C Drugs*, HEALTHCARE DIVE (Jan. 14, 2019), <https://www.healthcaredive.com/news/louisiana-launching-netflix-model-in-medicare-for-hepatitis-c-drugs/545945>.

¹³⁸ See Deslatte, *supra* note 136 (explaining that access to hepatitis C medication was restricted for Louisiana Medicaid enrollees due to the high drug cost).

¹³⁹ *Id.*

¹⁴⁰ Smolinski, *supra* note 129 (stating Louisiana also received competitive bids from AbbVie and Merck).

¹⁴¹ Deslatte, *supra* note 136.

¹⁴² *Id.*

¹⁴³ *Washington Finalizes Volume-Based Alternative Payment Model Contract with AbbVie for Hepatitis C Virus Treatment*, OPEN MINDS (July 28, 2019), <https://www.openminds.com/market-intelligence/news/washington-finalizes-subscription-model-contract-with-abbvie-for-hepatitis-c-virus-treatment>. AbbVie's bidding documents have not yet been made public, so Washington's annual payments to AbbVie are currently unknown. See generally JoNel Aleccia et al., *Pharma Sells Washington State and Others on 'Netflix Model' to Wipe Out Hep C. But the Cost is Being Kept from the Public*, SEATTLE TIMES (Oct. 29, 2019, 6:00 AM), <https://www.seattletimes.com/seattle-news/health/pharma-sells-washington-state-and-others-on-netflix-model-to-wipe-out-hep-c-but-the-cost-is-being-kept-from-the-public>.

¹⁴⁴ See *Eliminating Hepatitis C*, WASH. STATE HEALTH CARE AUTH., <https://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/eliminating-hepatitis-c> (last visited Dec. 19, 2019).

B. BENEFITS OF EXPANSION INTO MEDICARE AND MEDICAID

1. Ethical Implications

The ethical benefit of the subscription model is increased access to life-altering or life-saving drugs. The cost of prescription drugs is becoming increasingly burdensome for both the federal and state governments, adversely affecting those who qualify for Medicare and Medicaid, particularly the elderly and financially disadvantaged. As Louisiana's history with hepatitis C shows,¹⁴⁵ governments simply cannot afford to treat all diseases and conditions under per-patient payment models. Louisiana had resorted to a "rationing" approach in which only Medicaid patients with the most severe cases received treatment.¹⁴⁶ For a communicable disease such as hepatitis C, failing to treat all infected patients allows the infection to spread more rapidly and extensively in the population. Rationing therefore creates a cycle of low-volume, expensive per-patient treatments coupled with a growing number of cases. Subscription models instead unlock unlimited access to a drug for a specified time period, reducing a disease's prevalence in the population and potentially eradicating it outright.

The subscription model's increased access also enables greater patient autonomy. When patients have the ability to choose from a complete range of treatments, including historically high-priced options, they have a better chance to make fully informed decisions free from coercion.¹⁴⁷ Without a subscription model, patients are prone to financial coercion in which their treatment decisions are limited by a budget, whether personal or public. Louisiana's Medicaid enrollees were burdened by this coercion prior to the state implementing its solution for hepatitis C treatment. One enrollee commented, "I was always told that unless I was at stage 4 [of hepatitis C progression], I couldn't be treated. At stage 4, you're dying. So that wasn't helpful."¹⁴⁸

2. Benefits to Both Contracting Parties

Both governments and drug manufacturers have something to gain by including subscription models in drug price negotiations. Financially, governments likely receive the better end of the deal because they can provide treatment to patients at a much lower per-patient cost than traditional pricing agreements allow.¹⁴⁹ Governments also receive more predictable total spending on the drugs in the subscription agreement, which helps to create accurate healthcare budgets. Finally, subscription models are a smart political move for governments, because increased access to high-priced prescription drugs can lead to increased constituent support.

¹⁴⁵ See *supra* notes 141–42 and accompanying text.

¹⁴⁶ See Moon & Erickson, *supra* note 132, at 609 (explaining the concept of drug rationing).

¹⁴⁷ While the patient must also be adequately informed of each treatment's risks and benefits to make a fully informed decision, this topic is out of scope for this Note.

¹⁴⁸ Selena Simmons-Duffin, *Louisiana's Novel 'Subscription' Model for Pricey Hepatitis C Drugs Gains Approval*, WLRN (June 26, 2019, 5:28 PM), <https://www.wlrn.org/2019-06-26/louisianas-novel-subscription-model-for-pricey-hepatitis-c-drugs-gains-approval>.

¹⁴⁹ See Smolinski, *supra* note 129 (comparing the benefits of subscription models for governments and drug manufacturers).

While subscription models generally lower a drug's per-unit cost, drug manufacturers benefit from increased sales volume and predictability.¹⁵⁰ Both of these benefits are reflected in the deal between Gilead and Louisiana.¹⁵¹ Louisiana's Medicaid budget did not allow the state to purchase large volumes of Gilead's drug because the per-patient price was too high. The subscription model unlocked the Louisiana Medicaid market, guaranteed Gilead a set sum of cash, and avoided an across-the-board lowering of Gilead's drug price for other purchasers. Several years of expected, high-volume sales provide substantial value to a brand-name drug manufacturer, whose drugs typically experience short-term success in the drug market, before generic versions of the drug are developed. This is supported by the level of competitive manufacturer interest in the executed subscription model deals—Australia signed an agreement with four manufacturers, and three manufacturers submitted bids to Louisiana.

3. Potential to Expand the Model to Other Drugs

The subscription model is currently used in drug pricing contracts for hepatitis C treatments, but there is room for the model's incorporation beyond this specific collection of drugs. The model is not a universal solution for all prescription drugs, but the scheme can play an effective role when the following three conditions are met.¹⁵²

First, "the payer must be able to reasonably predict volumes in order to identify a lump sum [payment] that will yield adequate benefits over the traditional [per-patient payment]."¹⁵³ In other words, a disease must be well known, and its effects on the government's constituents must be well studied. Second, "[t]he manufacturing cost must be a relatively small proportion of the price."¹⁵⁴ Drug manufacturers will generally be less willing to enter into bulk agreements if profit margins are small. Third, the manufacturer must be capable of producing mass quantities of the drug to meet the expected high demand.¹⁵⁵

The three conditions above suggest that subscription models are not ideal options for drugs that treat new, unstudied, or rare diseases; drugs sold with small profit margins; and drugs manufactured under limited production capabilities. This leaves many potential candidates to push the boundaries of the subscription model. For example, treatments for opioid overdoses and pre-exposure prophylaxis for HIV are two categories of drugs that are expensive and well-studied.¹⁵⁶ The government is additionally incentivized to enter into subscription model agreements for these drugs because the increased access would help address substantial public health issues in HIV and opioid-overdose-related deaths. Expansion of the subscription model to drugs beyond hepatitis C is feasible and likely imminent rather than distant.

¹⁵⁰ *Id.*

¹⁵¹ See *supra* notes 139–142 and accompanying text.

¹⁵² See Moon & Erickson, *supra* note 132, at 609 (explaining the conditions necessary for prescription drug subscription model agreements to take place).

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ Smolinski, *supra* note 129.

4. Ease of Incorporation into Medicaid

The Louisiana and Washington Medicaid programs demonstrate that subscription models can be compatible with a state's existing Medicaid framework. As stated above, the MDRP compels drug manufacturers to enter into national rebate agreements with the federal government, and states may also negotiate supplemental rebate agreements with drug manufacturers.¹⁵⁷

Whenever states wish to enact or modify a supplemental rebate, they must submit a proposal to the Center for Medicine and Medicaid Services ("CMS") for approval.¹⁵⁸ The Louisiana and Washington proposals have taken the following form: the state's subscription payment approach is classified as a supplemental rebate, and the drug manufacturer's sales from the agreement are exempt from the Medicaid "best price" rule.¹⁵⁹ The best price exemption is necessary to prevent a free rider problem in which non-contracting states benefit from lower subscription model drug prices without entering into long-term supply contracts.¹⁶⁰

CMS has expressed deference to states when states put forth proposals to address high drug prices in their Medicaid programs. CMS has specifically noted that "[t]he high cost of prescription drugs is one of the greatest challenges in our healthcare system," and also that "[s]tates are best positioned to meet the needs of their Medicaid beneficiaries."¹⁶¹ Thus, it is no surprise that Louisiana's and Washington's proposals were readily accepted by CMS.

5. Potential to Incorporate into Medicare

Medicaid's experimental successes with subscription models should hint at the model's legitimacy within Medicare.¹⁶² However, Republican and Democratic lawmakers have disagreed over the level of participation the federal government should have in negotiating drug prices, creating a stalemate that has preserved the original noninterference clause.

This partisan disagreement is reflected in two recent bill proposals. On December 12, 2019, the Democrat-controlled House of Representatives, led by House Speaker Nancy Pelosi, passed the Elijah E. Cummings Lower Drug

¹⁵⁷ See discussion *supra* Part I.B.2.

¹⁵⁸ Submissions are officially classified as State Plan Amendments ("SPAs"). See *Financial Management*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/financial-management/index.html> (last visited Apr. 12, 2021). The purpose of CMS review for SPAs is to ensure state compliance with the requirements of the Social Security Act and any applicable agency regulations. CMS aims to approve SPAs within ninety days of the submission date. See Bulletin from Timothy B. Hill, Acting Dir. Ctrs. for Medicare & Medicaid Servs., *Update on State Plan Amendment and Section 1915 Waiver Process Improvements* (Aug. 16, 2018), <https://www.medicaid.gov/federal-policy-guidance/downloads/cib081618.pdf>.

¹⁵⁹ See *CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid*, CMS.GOV (June 26, 2019), <https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified>.

¹⁶⁰ See *supra* note 47 and accompanying text.

¹⁶¹ *CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid*, *supra* note 159.

¹⁶² Trish Riley & Sarah Lanford, *States on the Front Line: Addressing America's Drug Pricing Problem*, 39 J. LEGAL MED. 81, 85 (2019) (claiming that states function "as laboratories of experimentation, inform[ing] federal policy and influenc[ing] national policy change").

Costs Now Act.¹⁶³ The proposal would effectively repeal the noninterference clause. Specifically, it would require CMS to negotiate maximum prices for at least twenty-five brand-name drugs that do not have generic competition and are among the 125 drugs that account for the greatest national spending.¹⁶⁴

On December 9, 2019, Congressional Republicans countered with a bill proposal of their own—the Lower Costs, More Cures Act of 2019.¹⁶⁵ The proposal aims to lower prescription drug costs while preserving the noninterference clause. Specifically, it would cap out-of-pocket healthcare costs for seniors in Medicare Part D, and end “pay for delay” industry practice, in which generic drug manufacturers are paid by brand-name counterparts to postpone the introduction of the generic drug.¹⁶⁶

These proposals both have a predictable future. The Lower Drug Costs Now Act is too aggressive to garner Republican support in the Senate, and the Lower Costs, More Cures Act of 2019 is too moderate to garner Democratic support in the House. Alternatively, the subscription model bypasses this positional impasse and provides a realistic bipartisan compromise; it gives the federal government a seat at the Medicare drug pricing negotiation table—effectively lowering brand-name drug prices—without imposing legislative price ceilings on pharmaceutical companies.

C. THE DISADVANTAGES OF SUBSCRIPTION MODELS

1. Risk of Treatment Estimation Errors

Subscription models do not guarantee cheaper prescription drugs for the government. To reach an agreement, both the drug manufacturer and the government must make multi-year treatment estimations. If the government significantly overestimates treatment volumes, it could end up paying higher per-patient drug prices than it would have under a traditional payment model and risk locking in this higher rate for multiple years.

The limited treatment volume data resulting from subscription model contracts exposes the government to a small amount of risk relative to the potential benefits. Australia’s hepatitis C treatment predictions result in a per-patient cost of over \$60,000 USD less than the per-patient cost in the United States.¹⁶⁷ Nevertheless, erratic patient behavior can factor into overestimation errors. Poor decision-making or understanding, poor communication from physicians, and mistrust of the medical community can each lead a patient to refuse treatment subsidized by the subscription

¹⁶³ H.R. 3, 116th Cong. 319 (2019). Voting House Democrats were unanimously in support 228–0, while voting House Republicans almost entirely opposed it 2–191. *H.R. 19: Lower Costs, More Cures Act of 2019*, GOVTRACK, <https://www.govtrack.us/congress/bills/116/hr19/summary> (last updated Feb. 11, 2020). The bill has “almost no chance to be taken up by the Republican-controlled Senate.” Stephanie Armour, *House Passes Bill to Reduce Drug Prices*, WALL ST. J. (Dec. 12, 2019), <https://www.wsj.com/articles/house-passes-bill-to-reduce-drug-prices-11576177896>.

¹⁶⁴ H.R. 3, at 13–14. The negotiated maximum price could not exceed 120% of the average international market (“AIM”) price. *Id.* at 31; see Sachs, *supra* note 86 (defining AIM pricing).

¹⁶⁵ H.R. 19, 116th Cong. 1 (2019).

¹⁶⁶ See *H.R. 19: Lower Costs, More Cures Act of 2019*, *supra* note 163.

¹⁶⁷ See *supra* notes 134–135 and accompanying text.

model.¹⁶⁸ Patient autonomy preserves the patient's right to refuse treatment, but governments will likely seek to minimize the risk of purely erratic patient behavior. For example, Louisiana and its healthcare providers are proactively reaching out to their Medicaid enrollees to inform them of the program's newly available hepatitis C treatment and its benefits.¹⁶⁹

2. Not a "One-Size-Fits-All" Solution

Subscription models are not appropriate for all prescription drugs.¹⁷⁰ Absent future academic and industry research on the drugs best suited for subscription model agreements, governments may spend considerable resources gathering this information on their own.

Further, a limited application of subscription models likely will not substantially reduce Medicaid and Medicare budgets. The average state Medicaid budget in fiscal year 2018 was near \$10 billion,¹⁷¹ and the Medicare Part D budget in fiscal year 2018 was \$96.8 billion.¹⁷² Sparse adoption of subscription models may go unnoticed in these massive budgets, and this may sway state and federal legislators to pursue broader-sweeping healthcare changes.

3. Limits on the Choices of Public Healthcare Enrollees

While subscription models generally increase access to life-altering or life-saving prescription drugs, cases may theoretically arise where the models leave public healthcare enrollees with fewer viable treatment options. When a government enters subscription contracts with drug manufacturers for specific drugs, it will seek to maximize those treatment volumes, possibly reducing access to alternative treatments in the process.

However, an access reduction problem is very unlikely to become associated with subscription models. This payment model has gained popularity because it bypasses the high list price of a brand-name drug that already has a patent-protected monopoly in the United States. Patients cannot be deprived of alternate, equivalent treatment methods when none are available.

¹⁶⁸ See S.F. Tong & Chen Robert, *A Patient Who Refused Medical Advice: The Doctor and the Patient Should Look for a Common Ground*, 2 MALAY. FAM. PHYSICIAN 110, 112 (2007) (discussing reasons why patients may decide against medical advice).

¹⁶⁹ See Deslatte, *supra* note 136.

¹⁷⁰ See *supra* notes 152–55 and accompanying text.

¹⁷¹ See generally *Total Medicaid Spending*, KAISER FAM. FOUND., <https://www.kff.org/medicaid/state-indicator/total-medicaid-spending> (last visited Jan. 15, 2021) (tabulating each state's Medicaid spending in fiscal year 2018).

¹⁷² *HHS FY 2018 Budget in Brief - CMS - Medicare*, HHS.GOV (May 23, 2017), <https://www.hhs.gov/about/budget/fy2018/budget-in-brief/cms/medicare/index.html>.

V. CONCLUSION

The status quo of prescription drug pricing in United States public healthcare is widely considered unacceptable. States are exploring a variety of solutions through Medicaid programs that provide greater government presence in pricing negotiations, and this sentiment is growing within Congress as a solution for Medicare. Courts appear sympathetic to the government as well. In the *Frosh* decision, which barred Maryland's version of prescription drug price controls, the Fourth Circuit noted, "[W]e in no way mean to suggest that . . . states cannot enact legislation meant to secure lower prescription prices for their citizens."¹⁷³

The solution to this drug pricing problem lies in identifying the fair price for prescription drugs. It is important to distinguish that high drug prices are neither necessarily unfair nor unethical. The pharmaceutical industry has its reasons for selling drugs at high prices, and insurance providers have their reasons for seeking to purchase drugs at low prices. Fair prices—achieved through negotiations between a seller and a buyer, both of whom have similar bargaining power—likely lie somewhere between the two ends of the spectrum. Currently, the insurance company buyer under the noninterference regime is not a typical self-protecting actor, and predictably shifts a substantial portion of the negotiated costs onto the passive government. The high governmental costs proceed to limit availability.

Subscription models provide an attractive means of reaching a fair drug price. These models have substantially reduced per-patient treatment costs when integrated into healthcare systems abroad, and similar benefits are predicted amongst the several states that have recently enacted such a plan. CMS has voiced strong support for state implementation of subscription models for Medicaid programs. Most importantly, these models allow for predictable and lower prescription drug budgets and permit governments to feasibly eradicate diseases through increased treatment access.

Furthermore, subscription models are better equipped than legislative price ceilings for widespread implementation into public healthcare. State governments do not have to worry about constitutional conflicts between their Medicaid programs and interstate commerce. Medicare reform is more likely to pass in the form of moderate federal government involvement in drug pricing negotiations than in the form of aggressive government price controls. Lastly, while legislative price ceilings skew negotiating power in favor of the government, subscription models represent a mutually beneficial deal: the government secures prescription drugs at a lower per-patient cost, and the drug manufacturer secures long-term sales volume. This optimal cost-spreading supports the feasibility and longevity of the subscription model as a solution to the growing government public healthcare burden.

¹⁷³ Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 674 (4th Cir. 2018), cert. denied 139 S. Ct. 1168 (2019).