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A Prescription for America's Prescriptions

Haley Gintis

A PRESCRIPTION FOR AMERICA'S PRESCRIPTIONS

INTRODUCTION

While taking questions from the audience during a town hall in Nevada in September 2019, presidential candidate Bernie Sanders was confronted by Navy veteran John Weigel who had one topic on his mind: medical costs.[1] Weigel explained that he had been diagnosed with Huntington's disease and had accumulated over $139,000 in medical debt.[2] After Sanders asked Weigel how he planned to pay for these expenses, Weigel replied "I can't. I can't. I'm going to kill myself."[3] The crowd fell silent as Sanders asked Weigel to wait for him after the event so that he could connect the veteran with needed resources.[4] Although the interaction gained headlines because of the veteran's shocking response, Weigel's plight is far from uncommon. An estimated 137 million Americans are saddled with medical debt due to the exorbitant prices of prescription drugs.[5] During the first six months of 2019, the price of more than 3,400 drugs increased an average of seventeen percent from the price just the previous year.[6] In 2015 alone, prescription drug spending within the United States totaled about $457 billion.[7] This number has continued to grow, and the Centers for Medicare and Medicaid Services (CMS) is projecting average annual increases of 6.7% through 2025.[8]

A major factor leading to the increase of drug prices is a provision in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), which includes a noninterference clause prohibiting the federal government from negotiating the price of prescription drugs with pharmaceutical manufacturers.[9] Supporters of the peculiar noninterference clause opined that the free market system would ensure that drugs were sold at

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[1] Averi Harper, *Veteran Who Contemplated Suicide Reunites With Bernie Sanders*, ABC NEWS (Dec. 9, 2019).

[2] *Id.*

[3] *Id.*

[4] Annie Grayer and Veronica Stracqualursi, *Bernie Sanders Shares Personal Moment With Veteran Struggling With $139,000 in Health Care Debt*, CNN NEWS (Sept. 14, 2019).

[5] Lorie Konish, *137 Million Americans Are Struggling With Medical Debt. Here's What to Know if You Need Some Relief*, CNBC (Nov. 10, 2019).

[6] Aimee Picchi, *Drug Prices in 2019 Are Surging, With Hikes at 5 Times Inflation*, CBS NEWS (Jul. 1, 2019).

[7] Ed Silverman, *CMS Official Says Drug Costs Are 'Unsustainable' and There Are 'Too Many' Bad Actors*, STAT (NOV. 2016), https://www.statnews.com/pharmalot/2016/11/07/medicare-medicaid-drug-prices/.

[8] *Id.*

[9] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

reasonable prices and requiring manufacturers to engage in price negotiations would suppress research and development (R&D).[10] However, prescription drugs are distinct from other products for which the competitive market can determine a reasonable price for two major reasons. First, U.S. patent law allows manufacturers to monopolize the prescription drug market, thereby decreasing the competition.[11] Second, Americans need their prescription medicines for their well-being, creating an inequality of bargaining power with individuals forced to pay prices much higher than what is reasonable or forgo treatment.[12] Recognizing the need to reform the regulatory landscape and repeal the MMA's noninterference provision, democratic and republican members of Congress have introduced legislation that would allow the federal government to negotiate with manufacturers and impose price caps on prescription drugs.[13] Yet, many of the proposals struggle with how to establish a "reasonable drug price" and how to decide which drugs to subject to price caps, which is necessary to balance drug innovation with ensuring access.[14]

Using a reasonable drug price scheme to reduce prescription drug prices is not a novel idea; in the past twenty years, the United Kingdom, India, and Germany have all established legislation that guides the government to determine a reasonable selling price for prescription drugs.[15] Because the United Kingdom, India, and Germany established such different reasonable pricing schemes, the United States can learn which policies and implementation tactics have been successful, and just as important, which regulatory mechanisms to

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[10] Rexford E. Santerre, John A. Vernon & Carmelo Giaccotto, *The Impact of Indirect Government Controls on U.S. Drug Prices and R&D*, 26 CATO J. 143, 145 (2006).

[11] *See* James T. O'Reilly, *Prescription Pricing & Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. KY. L. REV. 413, 413 (2002) ("The simplest explanation [of a drug monopoly] might be offered in basic terms: [a] patent gives the inventor a . . . monopoly, after which time any other marketer can sell the same product.").

[12] *See* Paul J. Zwier, *High Prices in the U.S. for Life-Saving Drugs: Collective Bargaining Through Tort Law*, 17 MARQ. BENEFITS & SOC. WELFARE L. REV. 203, 205–12 (2016).

[13] *See e.g.*, The We Protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. (2019); Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019); Prescription Drug Price Relief Act, S. 102, 116th Cong. (2019).

[14] *See e.g.*, Prescription Drug Price Relief Act, S. 102, 116th Cong. (2019).

[15] *See e.g.*, DEPARTMENT OF HEALTH & SOCIAL CARE, PROPOSED CHANGES TO THE STATUTORY SCHEME TO CONTROL THE COSTS OF BRANDED HEALTH SERVICE MEDICINES 2018 (Dec. 2019) (consultation response), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761015/consultation-response-statutory-scheme-to-control-costs-of-branded-health-service-medicines.pdf (UK) [hereinafter U.K. Statutory Scheme]; T.V. Padma, *India Court Ruling Upholds Access to Cheaper, Generic Drugs, Scientific American*, NATURE MAG. (Apr. 1, 2013), https://www.scientificamerican.com/article/india-court-ruling-upholds-access-to-cheaper-generic-drugs/; Richard Kingham & Joanna Wheeler, *Government Regulation of Pricing and Reimbursement of Prescription Medicines: Results of a Recent Multi-Country Review*, 64 FOOD & DRUG L.J. 101, 105 (2009).

avoid. This Comment examines five federal proposals aimed to reduce prescription drug prices through implementing a reasonable pricing scheme. This Comment then argues that the United States should leverage lessons learned from the United Kingdom, India, and Germany to establish a scheme that subjects both name brand and generic drugs to a reasonable price. The reasonable price should be determined by referencing the price of similar drugs in other countries, factoring in the value that the drug adds to the prescription drug market, and considering how much the manufacturers have invested in R&D.

This Comment is divided into four sections. The first section provides an overview of the current prescription drug regulatory system in the United States and explains why federal legislation is necessary to address the exorbitant prices of prescription drugs. The second section explores five proposals introduced to reduce prescription drug prices. The five proposals were selected for examination because they differ as to the factors used to determine the reasonability of a drug price and as to which drugs are subjected to reasonable price caps. The third section explains the reasonable drug pricing schemes implemented in the United Kingdom, India, and Germany. The fourth section explains how the United States can leverage the lessons learned from the aforementioned countries to recognize strengths and weaknesses in the recently proposed legislation. The fourth section argues that the Lower Drug Costs Now Act has the most promise in reducing prescription drug prices by combining a reference-based and value-based system, while continuing to incentivize R&D.

I. MAKING SENSE OF THE EXORBITANT PRESCRIPTION DRUG PRICES

The high costs of prescription drugs have dominated the political arena, with both presidential and congressional candidates promising to reduce drug prices as part of their 2020 campaign platforms.[16] In 2019, spending on prescription drugs in the United States was the highest to date.[17] However, the debate of how much regulatory power the government should have over the prescription drug market is not new—attempts to use federal legislation to lower drug prices have been prevalent since the 1980s.[18] After recognizing that some manufacturers and drug distributers monopolized certain pockets of the prescription drug market,

[16] Jennifer Steinhauer, *Democrats Who Flipped Seats in 2018 Have a 2020 Playbook: Focus on Drug Costs*, N.Y. TIMES (Dec. 24, 2019).

[17] Matej Mikulic, *Prescription Drug Expenditure in The U.S. 1960-2019*, STATISTA (Aug. 9, 2019), https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960/.

[18] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Congress passed legislation with the goal of increasing competition by facilitating the introduction of generic drugs into the market.[19] Yet, even with the number of generic drugs in the market at an all-time high,[20] the price of prescription drugs has not decreased.[21] Moreover, legislation passed in recent years that aimed to increase the number of American's with health insurance did little to address the price individuals were actually paying for prescription drugs.[22] Because of the failure on the federal level to decrease drug prices, states tried passing legislation to address the high price of prescription drugs but encountered issues with opponents claiming Commerce Clause and First Amendment violations.[23] The lack of success on the federal and state levels in reducing drug prices highlights the need for federal legislation mandating pharmaceutical companies sell drugs at reasonable prices.

A. The Current Prescription Drug Regulatory Landscape in the United States

In the early 1980s, congress attempted to incentivize manufacturers to create generic drugs as a way to reduce drug prices.[24] The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act ("the Act"), allowed the Food and Drug Administration (FDA) to fast track regulatory approval of generic drugs.[25] The Hatch-Waxman Act amended the former Abbreviated New Drug Application process[26] by allowing generic manufacturers to use already published clinical data.[27] The Hatch-Waxman Act changed the pharmaceutical market significantly by increasing the number of generic drugs on the market.[28] In the early 1980s, only thirty-five percent of top-selling drugs had any generic competitors following patent

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[19] *See generally id.*

[20] Press Release, FDA, Statement on Continued Progress Enhancing Patient Access to High-quality, Low-cost Generic Drugs (Oct. 16, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-progress-enhancing-patient-access-high-quality-low-cost-generic-drugs.

[21] Mikulic, *supra* note 17.

[22] Michael Callam, *Who Can Afford It: The Patient Protection and Affordable Care Act's Failure to Regulate Excessive Cost-Sharing or Prescription Biologic Drugs*, 27 J.L. & HEALTH 99, 116–17 (2014).

[23] *See* Ass'n for Accessible Medicines v. Frosh, 877 F.3d 664, 674 (4th Cir. 2018); Tara Sklar, *Affordability Boards – The States' New Fix for Pricing*, NEW ENGLAND J. MED. 1301, 1301–03 (Oct. 3, 2019).

[24] *See generally* Drug Price Competition and Patent Term Restoration Act of 1984.

[25] *Id.*

[26] The former Abbreviated New Drug Application process required companies marketing generic drugs to file information to support the safety and efficacy of the drug which was a costly and lengthy process. Garth Boehm, Lixin Yao, Liang Hana, & Qiang Zheng, *Development of The Generic Drug Industry in The US After The Hatch-Waxman Act of 1984*, DRUG PATENT WATCH, https://www.drugpatentwatch.com/blog/development-of-the-generic-drug-industry-in-the-us-after-the-hatch-waxman-act-of-1984/ (last visited Sept. 2, 2020).

[27] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[28] Boehm et al., *supra* note 26.

expiration.[29] In 2012, generic drugs were estimated to account for eighty-four percent of dispensed prescriptions.[30] Yet, critics of the Act maintain that too many loopholes exist, allowing pharmaceutical companies to extend their patent exclusivity which results in the delay of generic formulations.[31] In addition to existing loopholes, some argue that the requirements for manufacturers to demonstrate that their new drug is interchangeable with the product already on the market, thereby qualifying as a "generic" which lowers the approval process threshold, are quite demanding.[32] More concerning, however, is that the Act created a tiered scheme of additional market exclusivity provisions which extended the length of market exclusivity for some manufacturers.[33] In fact, the tiered scheme led some critics to declare that the true winner of the Hatch-Waxman Act was the pharmaceutical industry because of the additional monopoly periods.[34] Further, the Act catalyzed the prevalence of "Pay-for-Delay" schemes penetrating the market.[35] A Pay-for-Delay scheme allows the company which invented the drug to monopolize the market while imposing high drug prices.[36] Such agreements have led drug manufacturers to continue to monopolize the market long after their period of market exclusivity, thus counteracting Congress's purpose in enacting the Hatch-Waxman Act.[37]

Recognizing the need to amend the Hatch-Waxman Act to achieve the goal of reducing drug prices by increasing generics, Congress passed the MMA in 2003.[38] While the Hatch-Waxman Act granted the first generic drug entering the

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[29] Wendy H. Schact, and John R. Thomas, *Hatch-Waxman Act: A Quarter Century Later*, CONG. RSCH. SERV. (Mar. 13, 2012), https://www.everycrsreport.com/files.

[30] Boehm et al., *supra* note 26.

[31] Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 48 (2016).

[32] Abdulrazag S. Al-Jazariri, Sakra Blhareth, Iyad S. Eqtefan, & Saleh A. Al-Suwayeh, *Brand and Generic Medications: Are They Interchangeable?*, ANN SAUDI MED. (2008), https://www.ncbi.nlm.nih/gov ("Bioequivalence is defined as 'the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action.'").

[33] James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 478–79 (1986).

[34] *Id*.

[35] Pay-for-Delay settlements are "a strategic tactic in which brand-named drug manufacturers induce generic companies to agree to stay off the market by sharing portions of their monopoly profits." Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 249 (2019).

[36] Gabriele Spina Ali, *Sweetening a Bitter Pill: Of Drug Prices, Drug Delays and Data Exclusivity*, 12 ASIA PACIFIC J. HEALTH L. & ETHICS 1, 2 (2019).

[37] *See* Feldman & Misra, *supra* note 35, at 255.

[38] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

market a 180-day exclusivity period which blocked the approval of other generic formulations during this time,[39] the MMA sought to provide more stringent requirements for generic drug companies to receive such exclusivity.[40]

Prior to the MMA, a manufacturer was designated as the first applicant by filing an Abbreviated New Drug Application (ANDA).[41] The MMA changed this by designating the first applicant to be any generic drug approved on the "first day," meaning that if multiple generic drugs were approved for the first time on the same day, they would share this 180-day period of market exclusivity.[42] The MMA also added a forfeiture clause, which provided that an applicant forfeits their market exclusivity period if it fails to market its product either within seventy-five days of receiving FDA approval or thirty months after ANDA submission.[43] Though Congress passed the MMA to expand access to costly pharmaceuticals for older adults, in truth it exacerbated the issue of increasing drug prices due to its noninterference clause.[44] The noninterference clause bars the Department of Health and Human Services (HHS) from negotiating with drug manufacturers and distributors on prices for Medicare beneficiaries.[45] In addition, the MMA prohibits the government from implementing a pricing scheme to regulate drug prices.[46] Therefore, to give the government the authority to mandate that pharmaceutical companies sell prescription drugs at a reasonable price, Congress must pass legislation to amend the MMA.

Though many healthcare advocates rejoiced in the eventual enactment of the Patient Protection and Affordable Care Act (ACA**),**[47] it did little to control the actual price of prescription drugs.[48] The ACA required that healthcare plans covered essential health benefits, which includes prescription drugs.[49] Yet,

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[39] Guidance for Industry, HHS, FDA, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER) 1, 12 (Jan. 2017), https://www.fda.gov/media/102650/download [hereinafter Guidance for Industry].

[40] *Id.*

[41] Barry J. Marenberg, *Changes to the Hatch-Waxman Act Following "Medicare Prescription Drug, Improvement and Modernization Act of 2003,"* 23 BIOTECHNOLOGY L. REP. 277 (June 2004).

[42] Guidance for Industry, *supra* note 39 at 4.

[43] Aaron F. Barkoff, Understanding the 180-Day Forfeiture Provisions of The MMA, Presentation at Generic Drugs Summit, (June 19, 2008).

[44] Karen M. Wieghaus, *The Medicare Prescription Drug, Improvement, and Modernization Act of 2003: The Wrong Prescription for Our Nation's Senior Citizens*, 11 CONN. INS. L. J. 401, 402 (2004).

[45] *Id.*

[46] *Id.* at 403.

[47] *See generally* Patient Prot. & Affordable Care Act, Pub. L. No. 111-48, 124 Stat. 119 (2010).

[48] Callam, *supra* note 22.

[49] ACA § 1302, 42 U.S.C. § 18022; 45 C.F.R. § 156.110.

without regulating the actual cost of these prescription drugs, private health insurance plans recoup these high drug prices by increasing premiums and insurance costs.[50] In 2018, high drug prices were estimated to account for 23.3 cents of each dollar spent on an insurance premium.[51] While some consumers pay for the high cost of drugs in this indirect way, the ACA left many individuals to pay for prescription drug costs directly out of pocket either because they remain uninsured or because of the "grandfathering in" exception.[52] In the majority of states adopting the Medicaid expansion, only individuals earning up to 138 percent of the federal poverty level are eligible for Medicaid.[53] Therefore, individuals earning over $17,236 who are ineligible for Medicaid must rely either on their employer for health insurance, which often requires a full-time job, or they must pay for their own private health insurance, or remain uninsured.[54] Those remaining uninsured fall into what is known as the "coverage gap" and are forced to pay for prescription drugs directly out of pocket, which can result in medical debt or may result in them not receiving the drugs that they need to live healthy lives. [55] More concerning, in the fifteen states that have not adopted Medicaid expansion, parents earning forty-one percent of the federal poverty level are eligible for Medicaid but non-parents remain ineligible.[56] Many individuals are unable to afford their prescription medications because of this lack of coverage.[57] Additionally, the ACA grandfathered in health insurance plans in existence prior to 2010.[58] This allowed some plans not to cover prescription drug costs, therefore requiring individuals to pay those costs out of pocket.[59]

Despite the steps that Congress has taken in the past forty-five years to decrease excessive medical spending, U.S. prescription drug spending has

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[50] Sara Heath, *High Drug Prices Account for One-Quarter of Patient Insurance Costs*, PATIENT ENGAGEMENT HIT (May 23, 2018), https://patientengagementhit.com/news/high-drug-prices-account-for-one-quarter-of-patient-insurance-costs.

[51] *Id.*

[52] Allison K. Hoffman, Health Care Spending and Financial Security after the Affordable Care Act, 92 N.C. L. REV. 1481, 1496 (2014).

[53] *Where Are States Today? Medicaid and CHIP Eligibility Levels for Children, Pregnant Women, and Adults*, KAISER FAMILY FOUNDATION (Mar. 31, 2019), https://www.kff.org/medicaid/fact-sheet/where-are-states-today-medicaid-and-chip/ [hereinafter Where Are States Today?]

[54] Rachel Garfield, Kendal Orgera, and Anthony Damico; *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid*, KAISER FAMILY FOUND. 1, 7 (Jan. 2020).

[55] *See id.*

[56] Where Are States Today?, *supra* note 53.

[57] *See* Silverman, *supra* note 7.

[58] Hoffman, *supra* note 52.

[59] *Id.*

continued to increase at rapid rates in the past four decades.[60] In 2019, an estimated one in four Americans reported having a difficult time affording their medicine.[61] The Hatch-Waxman Act and the MMA sought to lower prescription drug pricing by increasing competition within the market.[62] Similarly, the ACA sought to provide health insurance to more Americans so they would not have to pay for medical costs directly out of pocket.[63] However, these acts did little to ensure that pharmaceutical companies and drug distributers market drugs at a reasonable price.[64]

Because increasing both the number of generic drugs on the market and the number of individuals with health insurance has proven unsuccessful in lowering drug prices,[65] the United States should consider directly regulating prescription drug prices. In the absence of federal legislation, states have tried to implement their own reasonable price schemes that appear promising but are subject to Commerce Clause and First Amendment violation claims.[66] The challenges on the state level further emphasize the need for congressional action.

B. Barriers To Implementing Reasonable Drug Price Schemes on the State Level

States, perhaps due to ineffective federal legislation to control drug prices, have tried to enact legislation at the state level to mitigate excessive drug prices for their citizens.[67] In 2019, a record number of states passed laws addressing prescription drugs, with thirty-three states enacting fifty-one laws.[68] States have faced significant roadblocks in successfully passing legislation because of Commerce Clause challenges to state power.[69]

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[60] Rabah Kamal, Cynthia Cox, & Daniel McDermott, *What Are The Recent and Forecasted Trend in Prescription Drug Spending?*, PETERSON-KAISER FAMILY FOUND. (Feb. 20, 2019), https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-nominal-and-inflation-adjusted-increase-in-rx-spending_2017.

[61] *Id.*

[62] *See generally* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[63] *See generally* ACA § 1302,42 U.S.C. § 18022; 45 C.F.R. § 156.110.

[64] *See* Mikulic, *supra* note 17.

[65] *See id.*

[66] *See, e.g.*, Ass'n for Accessible Medicines v. Frosh, 877 F.3d 664, 674 (4th Cir. 2018); Sklar, *supra* note 23, at 1301, 1302–03.

[67] *See e.g.*, Ass'n for Accessible Medicines, 877 F.3d 664, 674; Sklar, *supra* note 23, at 1301.

[68] Steven Findlay, *To Reel In Drug Prices*, KAISER HEALTH NEWS (Sept. 9, 2019), https://khn.org/news/states-pass-record-number-of-laws-to-reel-in-drug-prices/.

[69] The Commerce Clause grants the United States Congress the power to regulate interstate commerce Rachel Sachs, *Prescription Drug Policy: The Year in Review, And The Year Ahead*, HEALTH AFFAIRS (Jan. 3,

In 2017, Maryland passed An Act concerning Public Health—Essential Off-Patent or Generic Drugs—Price Gouging—Prohibition ("Price Gouging Act").[70] The Price Gouging Act prohibited price gouging for all essential off-patent and generic drugs defined as "an unconscionable increase in the price of a prescription drug."[71] The Maryland legislature passed this Act in response to Turing Pharmaceuticals acquiring the rights to Daraprim, a drug used to treat severe parasitic infections, and subsequently raising the price from $13.50 to $175.00 per dose overnight.[72] The Price Gouging Act angered manufacturers and wholesale distributors who subsequently brought suit challenging its constitutionality.[73]

In *Association for Accessible Medicines v. Frosh*, the Fourth Circuit ruled that Maryland's Price Gouging Act was unconstitutional because it violated the Dormant Commerce Clause by regulating the price of drug transactions that occur outside of Maryland.[74] In his dissenting opinion, Judge Wynn critiqued the majority's interpretation of the statute, reasoning that the statute only sought to regulate the price of drugs that are sold within Maryland.[75] The court's decision that such legislation was in violation of the Commerce Clause was a win for Big Pharma and set a precedent for questioning the constitutionality of similar state legislation.

The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents biopharmaceutical research companies, filed a complaint following a 2017 California law to increase drug price transparency.[76] The law requires drug manufacturers provide a sixty-day written notice of drug price increases for the government's review and approval for drugs with wholesale acquisition costs of greater than $40 when the price increases are above sixteen percent.[77] The notification must include a statement indicating whether the price increase follows an improvement to the drug.[78] The complaint alleged that the Bill violates the Commerce Clause because it regulates commerce beyond

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2019), https://www.healthaffairs.org/do/10.1377/hblog20190103.183538/full/.

[70] H.D. 631, 2017 Leg., 437th Sess. (Md. 2017).

[71] *Id*.

[72] *Association for Accessible Medicines v. Frosh*, 132 HARV. L. REV. 1748, 1748–49 (2019) (providing background information on the events leading up to the Act).

[73] *Id.*

[74] Ass'n for Accessible Medicines v. Frosh, 877 F.3d 664, 674 (4th Cir. 2018).

[75] *Id.* at 678–79.

[76] Rebecca E. Wolitz, *California's Drug Pricing Transparency Bill SB-17*, STAN. L. SCH. LAW & BIOSCIENCES BLOG (Sep. 21, 2019).

[77] *Id.*

[78] *Id.*

California and imposes unconstitutional burdens on interstate commerce.[79] Additionally, the complaint contends that the statute violates the First Amendment by forcing manufacturers to "speak" about drug prices, and violates Due Process because it is unconstitutionally vague.[80] The action was brought in the U.S. District Court for the Eastern District of California and was dismissed without prejudice for a lack of standing.[81]

Though state legislation to address prescription drug prices continues to increase, there is only so much states can accomplish without federal action or at least, support.[82] In 2019, Colorado, Florida, Maine, and Vermont all passed legislation establishing programs to import less expensive prescription drugs from Canada.[83] However, federal law requires that states gain approval from HHS before implementing such a program, leading many to believe it could be years before any of these programs go into effect.[84]

Even if state legislation that aims to reduce drug prices can get past the hurdle of being accused of exceeding state powers, the issue of determining a reasonable sale price remains. If federal law mandates that prescription drugs are sold at a certain price, pharmaceutical companies and drug distributers will be forced to abide by this price or risk losing the U.S. market. Conversely, implementing a fragmented state approach may allow pharmaceutical companies to select those states in which they wish to sell their drugs, leaving some U.S. consumers unable to continue their current medications, particularly those enrolled in state health programs.

Maryland could very well serve as an example of how states can determine and mandate reasonable drug prices, as a second law recently passed may be a harbinger of what's to come in drug-pricing legislation.[85] In 2019, Maryland passed a second law aimed to reduce drug prices through creating a Prescription-Drug Affordability Board.[86] The Affordability Board will have the authority to set lower prices for both patented and generic prescription drugs that it feels

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[79] *Id.*

[80] David C. Gibbons & Alan Kirschenbaum, *PhRMA's Complaint Against Enforcement of California Drug Pricing Transparency Bill SB 17 Dismissed*, FDA L. BLOG (Sept. 6, 2018), http://www.fdalawblog.net/2018/09/phrmas-complaint-against-enforcement-of-california-drug-pricing-transparency-bill-sb-17-dismissed/.

[81] *Id.*

[82] Findlay, *supra* note 68.

[83] *Id.*

[84] Sarah Owermohle, Sarah Karlin-Smith, & Gary Fineout, *Trump Plan Would Allow States to Import Drugs From Canada*, POLITICO (Dec. 18, 2019).

[85] Sklar, *supra* note 23, at 1302.

[86] *Id.* at 1301.

have unjustifiably high prices or price spikes.[87] The Affordability Board is authorized to review potential unjustifiable costs or price hikes for new brand name prescriptions with a cost of $30,000 per year, as well as treatment cost or price hikes exceeding $3,000 or more per year or course of treatment.[88] The Affordability Board can also review generic prescriptions that increase in price by $3,000 or 200 percent within one year.[89] To deter pharmaceutical companies from setting prices just below the threshold warranting review, the legislation also gives the Affordability Board the authority to review "any prescription drug that creates affordability challenges to the Maryland health care system, including [for] patients."[90] The legislation sets the factors the Affordability Board must use to determine whether the drug is "affordable" or reasonable, which includes a review of the entire supply chain.[91] Though this legislation may serve as a model for other states wishing to implement similar programs, two potential loopholes exist.[92] First, the Affordability Board will only have the authority to regulate these prices for drugs paid for through state health programs thereby leading to potential price hikes for private insurers to recoup lost profits. Second, the reference point suggested in the legislation to measure affordability is to look at the price of similar drugs sold in the state, rather than other developed economies, which may only reduce prices to a certain degree.

The need for federal legislation to address drug prices directly is illustrated in the following two ways: (1) the lack of success the federal government has had despite facilitating the entry of generic drugs into the market and increasing the number of Americans with health insurance; and (2) the precarious legality of state governments regulating prescription drug prices. By repealing the MMA's noninterference clause and allowing the government to mandate that pharmaceutical companies sell drugs at reasonable prices, the price Americans pay for prescription drugs will decrease. However, this would not take away the incentive for pharmaceutical companies to invest in drug innovation.

Five introduced federal proposals all aim to reduce drug prices by allowing the government to set a reasonable price on prescription drugs.[93] However, these

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[87] *Summary of the 2019 Prescription Drug Affordability Board HB768*, HEALTH CARE FOR ALL (Apr. 4, 2019) https://mmcp.health.maryland.gov/Documents/MMAC/2019/04_April/Summary%20of%20Prescription%20Drug%20Affordability%20Board.pdf.

[88] *Id.*

[89] *Id.*

[90] *Id.*

[91] *Id.*

[92] In 2019 a total of eight states introduced similar bills that would create an entity to review prescription drug prices. So far Maine is the only other state that has passed the legislation. Sklar, *supra* note 23, at 1302.

[93] *See* The We Protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. (2019);

five proposals all emphasize different factors for determining a reasonable price and subject a different set of drugs to the suggested pricing scheme.[94] This highlights the importance of identifying the best factors to strike the balance between ensuring drugs are affordable through reasonable price caps while still incentivizing drug innovation.

II. UNITED STATES PROPOSALS TO DECREASE DRUG PRICES THROUGH REASONABLE PRICING SCHEMES

The idea of allowing the government to intervene in determining the price of prescription drugs may seem antithetical to America's valued free market system. Yet, in reality, the prescription drug market can be viewed as lacking competition which has allowed drug prices to increase.[95] Several proposals were introduced in Congress between 2018 and 2019 aimed to reduce drug prices by authorizing the government to regulate the price at which pharmaceutical companies can sell prescription drugs.[96] This Comment focuses on the strengths and weaknesses of five proposals that vary in how they guide the government in determining a reasonable drug price and which drugs the government is authorized to subject to reasonable price caps. Though the proposals may implement different strategies, the issue of determining a reasonable price to ensure affordability, while still incentivizing R&D, manifests in each of these bills.

A. The Prescription Drug Pricing Reduction Act

The Prescription Drug Pricing Reduction Act ("Pricing Reduction Act")—which advanced out of the Senate Finance Committee in July 2019 and was introduced by Senator Chuck Grassley [R-IA] in September 2019—seeks to reduce prescription drug prices by requiring that price increases are reasonable.[97]

Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019); Prescription Drug Price Relief Act, S. 102, 116th Cong. (2019); Affordable Drug Manufacturing Act, S. 3775, 115th Cong. (2018); Press Release, Nancy Pelosi, Speaker of the House, H.R. 3 – the Lower Drug Costs Now Act (Oct. 2, 2019), https://www.speaker.gov/LowerDrugCosts [hereinafter Nancy Pelosi Press Release].

[94] *See generally* The We Protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. (2019); Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019); Prescription Drug Price Relief Act, S. 102, 116th Cong. (2019); Affordable Drug Manufacturing Act, S. 3775, 115th Cong. (2018); Nancy Pelosi Press Release, *supra* note 93.

[95] *High Drug Prices & Monopoly*, OPEN MARKETS INST., https://openmarketsinstitute.org/explainer/high-drug-prices-and-monopoly/.

[96] *See* PAID Act, S. 2387, 116th Cong. (2019); Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019); Prescription Drug Price Relief Act, S. 102, 116th Cong. (2019); Affordable Drug Manufacturing Act, S. 3775, 115th Cong. (2018); Nancy Pelosi Press Release, *supra* note 93.

[97] Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. § 128 (2019).

The legislation imposes penalties on manufacturers if the market price of drugs covered under Medicare Part D[98] increases at a faster rate than inflation.[99] As currently proposed, the Pricing Reduction Act would require HHS to determine whether the price of a drug increased faster than inflation through the use of routine audits.[100] Manufacturers who are found to have increased their price above inflation and have not submitted a required price justification to explain the price hike are subject to civil monetary penalties of $10,000 per day.[101] Additionally, the Pricing Reduction Act caps out-of-pocket spending at $3,100 a year for Medicare beneficiaries.[102]

B. Affordable Drug Manufacturing Act of 2018

The Affordable Drug Manufacturing Act (ADMA), introduced by Senator Elizabeth Warren [D-MA], aims to increase drug competition, reduce the cost of prescription drugs to government health programs and general consumers, and increase patient access to affordable drugs.[103] The ADMA would establish an Office of Drug Manufacturing within HHS that is responsible for either manufacturing a particular drug or entering into an agreement with a private company to manufacture a particular drug to reduce the drug's price.[104]

For a drug to be subject to the ADMA, it must fall within one of the following categories: a drug for which the patent has expired; a drug for which the period of regulatory exclusivity has expired; a drug that is not being marketed in the United States; or a drug that is being marketed in the United States by fewer than three manufacturers and (1) has experienced a price increase; (2) is included in the drug shortage list under the Federal Food, Drug, and Cosmetic Act; (3) is listed by the World Health Organization as an essential medicine; or (4) is determined by the HHS Secretary to have an average manufacturer price that is a barrier to patient access.[105]

The ADMA serves as an example of legislation that, while seeking to reduce the price of prescription drugs through determining a reasonable price, falls short

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98 A federal-government health program that helps cover the price of drugs deemed essential. *Drug coverage (Part D)*, MEDICARE.GOV, https://www.medicare.gov/drug-coverage-part-d.

99 Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. §160 (2019).

100 *See generally* Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019).

101 *Id.* § 1182l(f)(1).

102 *Id.* §121(a)(3)(B)(i)(VII).

103 Affordable Drug Manufacturing Act of 2018, S. 3775, 115th Cong. §§ 310B(a)(2)(A)–(C).

104 *Id.* §§ 310B(a)(4)(A)(i)–(vi).

105 *Id.* § 310B(a)(7)(e)(1).

of providing a comprehensive list of factors for consideration.[106] Though the ADMA does not require HHS to determine the "reasonable price" before manufacturing the drug or entering into an agreement to ensure its manufacturing, it does require the Secretary to engage in a fair price analysis to determine how to price the government-manufactured drug.[107] The factors for such a determination include the impact of price on patient access to the drug; the cost of the drug to government health care programs; the cost of the government's manufacturing of the drug; the administrative costs of operating the manufacturing office; the cost to manufacture the drug; and the impact of price on market competition for the applicable drug.[108]

C. The We Protect American Investment in Drugs Act

The We Protect American Investment in Drugs Act ("We PAID Act"), introduced by Senator Chris Van Hollen [D-Md.] and Rick Scott [R-Fla.] in July 2019, aims to "ensure that the prices of drugs developed using federally funded research, [such as the National Institutes of Health and the Centers for Disease Control grants,] are set at reasonable levels."[109] This legislation authorizes the National Academy of Medicine (NAM), under HHS guidance, to develop a framework for determining the reasonable cost of a new drug when R&D is supported by federal funding.[110]

The legislation proposes six factors the NAM should consider when developing the guidance, including: (1) the affordability of the drug across wide market segments; (2) the federal government's investment into development; (3) the manufacturer's R&D costs; (4) the price of the drug in similar countries; (5) the estimated global and domestic sales; and (6) the expenditures by public payers.[111] Further, the reasonable drug price analysis must be determined in time for a reasonable price to take effect in the product's second year on the market.[112] Penalties for not abiding by the determined reasonable cost include loss of market exclusivity and ineligibility for future licensing agreements for

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106 *See generally* Affordable Drug Manufacturing Act of 2018, S. 3775, 115th Cong.

107 *Id.* §§ 310B(a)(4)(A)(iv), (4)(B).

108 *Id.* § 310B (a)(4)(B).

109 Press Release, Chris Van Hollen U.S. Senator For Maryland, Van Hollen, Scott Introduce Landmark Legislation To Address Skyrocketing Prescription Drug Costs (July 31, 2019), https://www.vanhollen.senate.gov/news/press-releases/van-hollen-scott-introduce-landmark-legislation-to-address-skyrocketing-prescription-drug-costs [hereinafter Scott Introduce Landmark Legislation].

110 The We Protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. § 4(a)(1) (2019).

111 *Id.* §§ 4(a)(1)(A)–(J).

112 *Id.* § 4(a)(3).

patented technology.[113] Additionally, if the manufacturer's launch price in the first year is fifty percent higher than the determined reasonable price, the drug manufacturer is subject to a civil monetary penalty.[114] This penalty is assessed using the launch price of the drug multiplied by the number of doses sold in the United States during the first year on the market.[115]

D. The Prescription Drug Pricing Reduction Act

The Prescription Drug Price Relief Act ("Price Relief Act"), introduced by Senator Bernie Sanders [I-VT] in January 2019, would require HHS to determine whether any brand name drug is excessively priced through the use of a reference-based pricing system.[116] A reference-based pricing system requires that similar medicines are placed into groups and the "prices of these drugs are then compared to the prices for the same drugs in select international markets and set accordingly."[117] In the Price Relief Act, a price is considered excessive if the domestic average manufacturing price exceeds the median price for the drug in Canada, the United Kingdom, Germany, France, and Japan.[118] If the pricing information is unavailable in at least three of the aforementioned countries, the price is considered excessive if it is higher than reasonable in light of specified factors.[119] The factors include the cost of the drug, the value of the drug to patients, the manufacturer's revenue, and the size of the affected patient population, [120] but there is no clear guidance on how to weigh these factors. If any such drug is excessively priced, HHS must (1) void any government-granted exclusivity; (2) issue open, nonexclusive licenses for the drugs; and (3) expedite the review of corresponding applications for generic drugs.[121] However, the control mechanisms established through the Price Relief Act are applicable only to name brand drugs, not to generic drugs.[122]

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113 *Id.* § 6(b).
114 *Id.* § 6(b)(5).
115 *Id.* §§ 6(b)(1), (5).
116 Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong.
117 Marie Salter, *Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry*, 35 NW. J. INT'L L. & BUS. 413, 416 (2015).
118 Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. §§ 2(b)(1)(A)–(B).
119 *Id.* § 2(b)(2).
120 *Id.* § 2(b)(2).
121 *Id.* § 3(a)(1), (2).
122 *See generally* Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong.

E. Elijah E. Cummings Lower Drug Costs Now Act

The Elijah E. Cummings Lower Drug Costs Now Act (Lower Drug Costs Now Act) was introduced in September 2019 and passed in the House in December 2019.[123] The bill seeks to regulate drug prices by allowing CMS to negotiate prices for certain drugs. This amends the previously enacted MMA noninterference clause that prohibits HHS from directly negotiating with drug companies on prices.[124]

The bill provides a comprehensive framework to guide the government in determining a reasonable drug price, referred to as the "maximum fair price," by requiring that the government consider: (1) the drug's cost, which includes its R&D costs and the extent to which the manufacturer has recouped this cost as well as production and distribution costs; (2) the value the drug adds to the pharmaceutical market through analyzing its therapeutic advancement compared to existing therapeutic alternatives; and (3) the price of the drug in Australia, Canada, France, Germany, Japan, and the United Kingdom.[125] This legislation is unique because it sets firm guidance on how to take a reference point into account by mandating that the drug price negotiated does not exceed 120 percent of the average price in the comparable countries.[126]

In addition to a robust framework for determining a reasonable drug price, the negotiated price would apply to drugs covered by Medicare Part D and private insurers.[127] Moreover, the legislation will require the 250 highest-priced drugs, and all forms of insulin, be subject to a negotiated maximum price.[128]

Furthermore, a key strategy behind the bill is to reinvest the billions of dollars the government saves by spending less on prescription drug prices on researching new breakthrough treatments and to provide a comprehensive prescriptive framework for determining a reasonable price and subjecting a

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123 *See* Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019) (as introduced to Senate, Jan. 10, 2019 and passed by Senate, Dec. 12, 2019).

124 Juliette Cubanski et al., *What's the Latest on Medicare Drug Price Negotiations?*, KAISER FAMILY FOUND. (Oct. 17, 2019), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/.

125 *Id.*

126 *Id.*

127 *Id.*

128 Nicole Rapfogel, Maura Calysn, & Emily Gee, *House Bill Could Lower Patients' Prescription Drug Spending by Thousands of Dollars*, CTR. FOR AM. PROGRESS (Dec. 9, 2015), https://www.americanprogress.org/issues/healthcare/news/2019/12/09/478380/house-bill-lower-patients-prescription-drug-spending-thousands-dollars/.

diverse set of drugs to this analysis.[129] Though individuals are concerned that the legislation may disincentivize pharmaceutical companies from investing in R&D, in reality, even with the status quo of exorbitant drug prices, R&D has not improved in recent years.[130] Nine out of ten big pharmaceutical companies in the United States, spend more on marketing and sales than on R&D.[131] In fact, drug innovation is less reliant on big pharmaceutical companies than many claim—notably, every new drug approved between 2010 through 2016 was funded by government entities using at least some amount of tax-payer money.[132]

Though these five proposals all aim to reduce the cost of prescription drug prices by authorizing the government to intervene when prices for certain drugs are not reasonable, the proposals differ as to how a reasonable price should be determined and which drugs should be subject to reasonable price caps.[133] The Pricing Reduction Act, introduced by Senator Chuck Grassley, only authorizes the government to determine whether a price increase is reasonable, rather than whether the drug price itself is reasonable, using the rate of inflation as a guide.[134] Only drugs paid for by Medicare Part D are subject to the scheme. [135] The ADMA, introduced by Senator Elizabeth Warren, is unique in that it authorizes the government to manufacture certain drugs that HHS determines has a price that creates a barrier to patient access.[136] The We PAID Act, introduced by Senators Chris Van Hollen and Rick Scott, utilizes a reference-based pricing system, listing the price of the drugs in other countries as a factor for considering a drug's reasonable price. [137] However, the act focuses on those drugs for which the government has funded R&D costs, leaving many drugs

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129 Nancy Pelosi Press Release, *supra* note 93.

130 *See* Ana Swanson, *Big Pharmaceutical Companies Are Spending Far More on Marketing Than Research*, WASH. POST (Feb. 11, 2015).

131 *Id.*

132 Alexander Zaitchik, *Taxpayers—Not Big Pharma—Have Funded the Research Behind Every New Drug Since 2010*, OTHER98 (2018), https://other98.com/taxpayers-fund-pharma-research-development/. *Compare* Jocelyn Kaiser, *NIH Gets $2 Billion Boost in Final 2019 Spending Bill*, SCIENCE MAG. (Sep. 14, 2018, 9:55 AM), https://www.sciencemag.org/news/2018/09/nih-gets-2-billion-boost-final-2019-spending-bill ($39.1 billion in taxpayer money), *with Research & Development*, PHRMA: ADVOCACY, https://www.phrma.org/advocacy/research-development (last visited July 20, 2020) ($79.6 billion in PhRMA member money).

133 *See generally* The We Protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. (2019); Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019); Prescription Drug Price Relief Act, S. 102, 116th Cong. (2019); Affordable Drug Manufacturing Act, S. 3775, 115th Cong. (2018); Nancy Pelosi Press Release, *supra* note 93.

134 *See generally* Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019).

135 *See generally id.*

136 Affordable Drug Manufacturing Act, S. 3775, 115th Cong. § 2(e)(1)(C)(ii)(III)(aa) (2018).

137 The We Protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. § 4(a)(1)(H) (2019).

outside of the scheme.[138] The Price Relief Act, introduced by Senator Bernie Sanders, has a robust framework for determining the reasonable price of a drug, using both the manufacturing price in other countries and the value of the drug to patients.[139] This legislation, however, only applies to brand name drugs, not generic drugs.[140] The last proposal discussed, the Lower Drug Costs Now Act, first introduced by Speaker Pelosi, requires the government consider the price of similar drugs in other countries, the therapeutic value the drug adds to the existing market, and the R&D invested into the drug.[141] This legislation is unique in that it: (1) subjects the 250 highest-priced drugs to the scheme, and (2) requires that the reasonable drug price determined applies to drugs paid for by federal health insurance programs and private insurance companies.[142]

Though a majority of Americans support the idea of the government regulating prescription drug prices, the differences in these proposals demonstrate that Congress has no clear vision on the best way for the government to determine a reasonable drug price.[143] Fortunately, allowing the government to regulate the prescription drug market by implementing a reasonable pricing scheme is not new, as foreign governments have already done this.[144] Therefore, the United States can look to the successes and challenges other countries have had in implementation to determine how best to establish a reasonable drug price scheme.

III. REASONABLE DRUG PRICING SCHEMES IMPLEMENTED IN FOREIGN STATES

The implementation of a reasonable price mandate to control the cost of prescription drugs is not new. As a result, the United States is at an advantage in that it can leverage the successes and challenges that previous countries have faced in establishing a reasonable drug price scheme to inform its own policy.

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138 Scott Introduce Landmark Legislation, *supra* note 109.

139 Prescription Drug Price Relief Act, S. 102, 116th Cong. §§ 2(b)(1), (2) (2019).

140 *See generally* Prescription Drug Price Relief Act, S. 102, 116th Cong. (2019).

141 Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. §§ 1194(b)(2)(A)–(D) (2019) (as introduced to Senate, Jan. 10, 2019 and passed by Senate, Dec. 12, 2019).

142 Rapfogel et al., *supra* note 128.

143 Alison Kodak, *Poll: Americans Support Government Action To Curb Prescription Drug Prices*, NATIONAL PUBLIC RADIO (Mar. 1, 2019), https://www.npr.org/sections/health-shots/2019/03/01/699086303/poll-americans-support-government-action-to-curb-prescription-drug-prices.

144 *See* David Gross, et al., *International Pharmaceutical Spending Controls: France, Germany, Sweden, and the United Kingdom*, 15(3) HEALTH CARE FIN. REV. 127, 127 (1994) ("Four European countries that have research-based pharmaceutical industries—France, Germany, Sweden, and the United Kingdom—have each developed a set of government controls to limit the growth of prescription drug prices and expenditures.").

Since the United States is unique in its multi-payer healthcare system compared to many developed economics including Canada, the United Kingdom, Denmark, Norway, and Australia,[145] some critics are reluctant to compare the controls implemented by single-payer countries, believing that such mechanisms will not be adaptable for the United States.[146] However, regardless of whether a country utilizes a single-payer or a multi-payer health insurance system, the need to determine how best to establish a reasonable drug price remains a constant.[147] Specifically, governments must strike a balance between subjecting certain drugs to a price cap to ensure affordability, while still incentivizing R&D.

In the past two decades, the United Kingdom, India, and Germany, three distinct health care systems,[148] have all attempted to reduce prescription drug prices through legislation requiring that manufacturers sell prescription drugs at reasonable prices.[149] When first implementing a reasonable price strategy, the United Kingdom, India, and Germany utilized different schemes to determine what constitutes a reasonable price.[150] The United Kingdom determined the reasonable price of a drug through conducting a cost-effectiveness analysis, during which time it is determined whether the economic value of the drug bares a reasonable relation to the economic value it provides.[151] India emphasized the importance of the drug itself to increasing the health of the Indian population and how much the manufacturer had invested in R&D.[152] Germany implemented a value-based system that required assessing the therapeutic value the drug offers compared to similar drugs on the market, such as whether it has fewer

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[145] Ida Hellander, *International Health Systems for Single Payer Advocates*, PHYSICIANS FOR A NAT'L HEALTH PROGRAM, http://www.pnhp.org/single_payer_resources/international_health_systems_for_single_payer_advocates.php.

[146] *See* Megan McArdle, *Why U.S. Health-Care Reformers Shouldn't Use Other Countries as a Model. Swiss Miss, Anyone*, WASH. POST (Feb. 22, 2019).

[147] In addition to the United States, Germany and France are multi-payer health systems, though highly regulated by the government. Hellander, *supra* note 145.

[148] The U.K. has a national health service in which medical systems are publicly owned and operated. Germany has a highly government regulated multi-payer health insurance system in which universal health insurance is available through government-funded or private insurance. *Id*. India has publicly financed health insurance. Roosa Tikkanen et al., *India: International Health Care System Profiles*, COMMONWEALTH FUND (June 5, 2020), https://www.commonwealthfund.org/international-health-policy-center/countries/india?redirect_source=/countries/india.

[149] *See generally* U.K. Statutory Scheme, *supra* note 15; Padma, *supra* note 15; Kingham & Wheeler, *supra* note 15.

[150] *See generally* U.K. Statutory Scheme, *supra* note 15; Padma, *supra* note 15; Kingham & Wheeler, *supra* note 15.

[151] *See e.g.*, Flynn Pharma Ltd. v. Competition and Markets Authority [2018] CAT 11 Nos: 1275–1276/1/12/17, [¶¶ 255–275] (UK).

[152] Ajay Prasad & Varsha Iyengar, *Direct Price Control on Patented Drugs in India: The Probable Effects on Innovation and Access to Medicines*, 20 NAT. L. SCH. INDIA REV. 229, 233 (2008).

side effects than other drugs or has higher success rates.[153] In addition to implementing policies that emphasized different key factors to determine reasonability, the three schemes also differed as to which drugs were subjected to reasonable price caps. At first the United Kingdom's scheme only subjected generic drugs to price caps leaving name brand drugs unregulated.[154] India's scheme applied to drugs that were considered essential to the health of the population.[155] Germany's scheme applied to only generic drugs and allowed pharmaceutical companies to sell drugs under patent at any cost.[156] Understanding the prescription drug regulatory landscape in the United Kingdom, India, and Germany can help policy makers decide which current policies present the most promise in reaching the desired goal of reducing drug prices through implementing a reasonable drug pricing scheme.

A. United Kingdom's Pharmaceutical Price Regulation Scheme

The United Kingdom grants the government authority to impose price caps on prescription drugs to deter companies from selling pharmaceuticals at unreasonable prices.[157] While at first only generic drugs were subject to price regulations, the United Kingdom ultimately revised this scheme as companies took advantage of the lack of price restrictions on patented drugs by making small adjustments to former chemical compounds and increasing prices.[158]

In the past, the United Kingdom has had two main regulatory schemes to control drug prices: the Pharmaceutical Price Regulation Scheme (PPRS) and the Statutory Scheme for Pricing of Branded Medicines.[159] The PPRS regulates the profits manufacturers are allowed to make on their drug sales to the United Kingdom Department of Health's National Health Service (NHS), taking into consideration the amount the company has invested into the drug's R&D.[160] The scheme requires that manufacturers receive approval from the United Kingdom Department of Health and Social Care (DHSC) before increasing a drug's price by showing that the manufacturer's estimated profits fall below a certain level.[161]

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153 Sophia Schlette & Rainer Hess, *Early Benefit Assessment for Pharmaceuticals in Germany: Lessons for Policy Makers*, COMMONWEALTH FUND: ISSUES INT'L HEALTH POL'Y (2013).

154 U.K. Statutory Scheme, *supra* note 15, ¶¶ 3.10, 3.12, 3.14.

155 Prasad & Iyengar, *supra* note 152.

156 Schlette & Hess, *supra* note 153.

157 U.K. Statutory Scheme, *supra* note 15 ¶ 1.1.

158 Flynn Pharma Ltd. v. Competition and Markets Authority [2018] CAT 11 Nos: 1275–1276/1/12/17 [¶ 49] (UK).

159 *Id.* ¶¶ 37, 48.

160 *Id.* ¶ 38.

161 Department of Health & Social Care, *The 2019 Voluntary Scheme for Branded Medicines Pricing and*

The Statutory Scheme regulates the maximum price of the drug itself and therefore requires the government to determine a reasonable price to ensure drug affordability while still incentivizing R&D.[162]

The PPRS was established in the 1970s and expired in 2019.[163] The scheme required that the DHSC determined whether the cost of a drug was excessive. [164] An excessive price occurred when the drug had no reasonable relation to the economic value of the product supplied.[165] The DHSC, with the assistance of the National Institute for Health and Care Excellence ("NICE"),[166] determined the appropriate economic value by conducting a cost/effectiveness analysis and comparing the price of the drug with that of similar drugs on the market.[167] In using the cost/effectiveness analysis, the U.K.'s NICE measured the ability for the drug to extend and improve a patient's life, known as quality adjusted life years.[168]

Because the PPRS only applied to brand name drugs and did nothing to regulate the price of generic drugs, the scheme led to manufacturers selling generic versions at prices the Competition and Markets Authority (CMA) considered excessive.[169] Further, the PPRS gave the government no authority to counteract the pharmaceutical companies' actions.[170] In *Flynn Pharma Limited v. Competition and Markets Authority*, the U.K.'s Competition Appeal Tribunal (CAT) declined to uphold a fine imposed by the CMA pursuant to excessive drug prices.[171] In 2013 the CMA began to investigate Pfizer, a drug manufacturer, and Flynn, a drug supplier and marketer, after the price of the epilepsy drug Epanutin increased by 2,600 percent.[172] Finding that the companies "abused their dominant positions in the narrowly defined markets for manufacture and distribution" by excessively increasing their prices, the CMA

Access-Chapters and Glossary ¶¶ 5.17–5.21 (Dec. 2018).

[162] Flynn Pharma Ltd. v. Competition and Markets Authority, ¶¶ 45–48 (UK).

[163] Leela Barham, *The UK's New Medicines Pricing Deal – Opportunities and Risks For Pharma*, PMLIVE (May 10, 2019).

[164] *Understanding the 2014 Pharmaceutical Price Regulation Scheme*, THE ASS'N BRITISH PHARM. INDUS. 1 (2014).

[165] Flynn Pharma Ltd. v. Competition and Markets Authority, ¶ 405 (UK).

[166] In 1999, the UK established the National Institute for Health and Clinical Excellence (NICE) to assist the NHS in drafting clinical guidelines and technology appraisals. Kingham & Wheeler, *supra* note 15 at 106.

[167] *Understanding the 2014 Pharmaceutical Price Regulation Scheme*, *supra* note 164, at 5.

[168] *Id.*

[169] *See e.g.*, Flynn Pharma Ltd. v. Competition and Markets Authority, ¶ 4 (UK) (where the tribunal declined to uphold a fine imposed on Flynn Pharma and Pfizer for selling their generic drug at an excessive price).

[170] *See generally id.*

[171] *Id.*

[172] *Pfizer Fined for Hiking Epilepsy Drug Price 2,600%*, ASSOCIATED PRESS (Dec. 7, 2016).

fined Pfizer $84 million and Flynn nearly $7 million for charging the NHS unfair prices for Epanutin.[173] The CMA supported its decision to fine the companies based on the fact that there was an absence of data to show that there was a reasonable relation between the drug itself and its economic value.[174] However, in the CAT's decision, the tribunal explained that the PPRS profit assessment, which provides for a return on investment percentage, was not controlling, but only a relevant factor to be examined.[175] This ruling emphasized the importance of subjecting all drugs to price regulation, not just name brand drugs.

Following the *Flynn Pharma Limited* ruling, the Health Service Medical Supplies ("Costs") Act removed the loophole which exempted generic pharmaceutical companies from price control regulations.[176] The legislation was enacted after a CMA investigation found that pharmaceutical companies had engaged in a practice of de-branding medicine to make it generic and therefore no longer subject to the PPRS.[177] The Costs Act allows the DHCS to request pricing information for all drugs, whether generic or name brand, and gives the Secretary of State the authority to determine the reasonable price for generic drugs, which are exempt from the PPRS.[178]

In January 2019 the Voluntary Scheme for Branded Medicines Pricing and Access ("Voluntary Scheme") replaced the former PPRS, as the United Kingdom recognized the need to subject a larger number of drugs to regulated prices.[179] Manufacturers and suppliers now have the choice of whether to participate in the Voluntary Scheme or resort to the default Statutory Scheme.[180] However, the United Kingdom has created the voluntary scheme with the aim of having the majority of drug companies opting for this choice.[181]

Learning from the challenges the government faced with the former PPRS, the Voluntary Scheme has a number of amendments. First, the Voluntary

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173 James Killick et al., *Court of Appeal Broadly Upholds the CAT's Judgment in Phenytoin and Clarifies "Excessive Pricing" Test*, WHITE & CASE (Apr. 1, 2020), https://www.whitecase.com/publications/alert/court-appeal-broadly-upholds-cats-judgment-phenytoin-and-clarifies-excessive.

174 Flynn Pharma Ltd. v. Competition and Markets Authority, ¶ 4 (UK).

175 *Id.* ¶ 399.

176 House of Commons Committee of Public Accounts, HC 1184, Price increases for generic medications, (Oct. 2018) at ¶ 4.

177 *Id.*

178 *Id.*

179 Department of Health & Social Care, *The 2019 Voluntary Scheme for Branded Medicines Pricing and Access-Chapters and Glossary* ¶¶ 1.2, 1.10 (Dec. 2018) [hereinafter Voluntary Scheme].

180 *Id.*

181 *Spotlight on Pharmaceutical Pricing Regulation*, STEVENS & BOLTON (2017), https://www.stevens-bolton.com/cms/document/Spotlight_on_pharmaceutical_pricing_regulation.pdf.

Scheme applies to both generic and name brand drugs.[182] Second, revisions were made for how the United Kingdom should determine whether the market price of the drug is reasonable.[183] A key factor the United Kingdom must consider when reviewing a drug price for its reasonableness is the "price of therapeutically equivalent or comparable products[.]"[184] In addition to considering the cost of similar drugs already on the prescription drug market, the scheme requires the government to analyze the clinical need for the drug, the operational costs of production, and the "reasonableness" of other estimated costs, including R&D, manufacturing, and supplying cost.[185]

The United States can leverage two lessons learned from the United Kingdom. First, the United Kingdom's use of assessing the therapeutic value and cost-effectiveness of the drug when determining a reasonable price may deter the pervasive practice of manufacturers setting drug prices that do not reflect their clinical value.[186] Second, the United Kingdom's experience sheds light on the importance of subjecting drugs under patent and generic to mandatory price caps to deter pharmaceutical companies from making slight altercations to evade the price regulations.

B. India's Essential Medicine System

While the United Kingdom has implemented a voluntary scheme, India emphasizes the R&D invested to form the drug when determining a reasonable price.[187] India's heavy emphasis on R&D continues to incentivize the pharmaceutical industry to innovate.[188] Over the past five decades, India experienced a stall in drug innovation due to its patent law.[189] Before 2005 the Indian government did not grant patents on medicines, which resulted in the growth of generic drug manufacturing.[190] Consequently, prescription drugs in

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182 Voluntary Scheme, *supra* note 179, ¶ 2.38.

183 *Id.* ¶ 5.13.

184 *Id.*

185 *Id.*

186 *See* HOUSE OF PARLIAMENT PARLIAMENTARY OFFICE OF SCIENCE & TECHNOLOGY, DRUG PRICING, PostNote Number 364 (Oct. 2010), 2–4 (UK).

187 Ernst R. Berndt & Iain M. Cockburn, *The Hidden Cost of Low Prices: Limited Access To New Drugs in India*, 33:9 HEALTH AFFAIRS 1567, 1568 (Sept. 2014).

188 Prasad & Iyengar, *supra* note 152, at 233.

189 Shamnad Basheer, *India's Tryst With TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J. L. TECH. 15, 17–18 (2005).

190 Tushita Dogra, *Pharmaceutical Patents A Threat to India's Drug Industry?*, MONDAQ (Mar. 14, 2018), https://www.mondaq.com/india/food-and-drugs-law/682550/pharmaceutical-patents-a-threat-to-india39s-drug-industry.

India are very affordable, which increases access, but these tight regulations have alienated pharmaceutical companies, resulting in less innovation.[191]

In 2005 India amended the Patent Act of 1970 to incentivize innovation.[192] This amendment allowed for pharmaceutical products to receive patents, but strictly limited drugs applicable to patent protection, excluding new forms of known substances unless the new form enhanced efficacy or provided a new use.[193] The amendment required that any new pharmaceutical products were "therapeutically more beneficial than earlier versions on which patents had expired."[194] After the Indian government denied an exclusive patent to Novartis for Glivec, a drug for the treatment of leukemia, litigation commenced regarding the constitutionality of the amendment.[195] In *Novartis AG v. Union of India & Others*, the Supreme Court of India noted the importance of "strik[ing] a balance between the need to promote research and development . . . [and] keep[ing] private monopoly [of the drug market] at the minimum" and that it had been reminded "that an error of judgment . . . will put life-saving drugs beyond the reach of the multitude of ailing humanity[.]"[196] The case ultimately turned on whether Novartis could prove that its drug was effective.[197] The court chose to construe the term "effective" as narrowly as possible.[198] Instead of requiring that Novartis show that the individuals on the drug had higher success rates than those not on the drug, the manufacturer had to provide evidence that the drug was more effective than similar drugs already on the market.[199] The court found that because the drug was no more effective than others it could not qualify for a patent.[200]

The Supreme Court of India's ruling in *Novartis* is a win for affordable drug costs.[201] With fewer exclusive patents being issued, additional similar drugs can enter the market, which ultimately drives down prescription costs.[202] Yet, while India has shown its ability to "counter the abuse of monopoly on a patented

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191 *See* Berndt & Cockburn, *supra* note 187 at 1573–74.

192 Uday S. Racherla, *Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry*, *in* INNOVATION, ECONOMIC DEVELOPMENT, AND INTELLECTUAL PROPERTY IN INDIA AND CHINA 271, 285 (Kung-Chung Liu, Uday S. Racherla eds., 2019).

193 *Id.*

194 Geeta Anand & Rumman Ahmed, *Bayer Loses Drug Ruling in India*, WALL STREET J. (Mar. 13, 2012).

195 *See generally* Novartis, ¶ 3, Civil Appeal Nos. 2706-2716.

196 *Id.* ¶ 4.

197 *Id.* ¶ 171.

198 *Id.* ¶ 182.

199 *Id.* ¶ ¶ 177–88, 187–89, 190.

200 *Id.* ¶ 182 ("We have just noted that the test of enhanced therapeutic efficacy must be applied strictly.").

201 Padma, *supra* note 15.

202 *See id.*

drug," there is continuing concern that this success had led to poor R&D.[203] In an effort to spur innovation, particularly for the most severe illnesses, India implemented a reasonable drug pricing scheme that heavily incentivizes R&D.[204]

In 2013, following a change in patent policy, the Indian government implemented the Drug Price Control Order ("Order").[205] The Order implemented price ceilings for drugs deemed to be on the National List of Essential Medicines (NLEM) following the recognition of a slight increase in drug prices.[206] The drugs on the list were deemed to be those "that satisfy the primary health needs of the country's population" and must be "made available at all times in adequate quantities in the appropriate dosage forms to serve the larger public interest."[207] Unfortunately, the Order allowed the government to take into account the R&D costs of a drug when determining a reasonable price ceiling but not the manufacturing costs.[208] The price ceilings led to drug companies making unreasonable profits once R&D had been recouped.[209] Additionally, under the Order, the Indian government is unable to regulate the price of drugs that are not on the essential drug list.[210]

To ensure patient access, it would be logical and practical that all prescription drugs necessary for survival are sold at a reasonable price. Relying solely on the NLEM has become problematic for those relying on new medications because India's essential drug list is not updated on a frequent basis.[211] However, the government has faced resistance from pharmaceutical companies in an attempt to expand the list of covered drugs.[212]

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[203] Prasad & Iyengar, *supra* note 152 at 239–40.

[204] *Id.*

[205] Sakthivel Selvaraj, Habib Hasan Farooqui & Aashna Metha, *Does Price Regulation Affect Atorvastatin Sales in India? An Impact Assessment Through Interrupted Time Series Analysis*, 9(1) BMJ OPEN 1, 2 (Jan. 24, 2019).

[206] Union of India & ANR. ETC v. BGP Products Operations GMBH And Hagene Immermatt Weg. & ANR. Etc. (2019) Supreme Court of India Civil Appellate Jurisdiction, ¶ ¶ 6.1, 6.2, Civil Appeal Nos. 6588-6591.

[207] *Id.* ¶ 6.2 (internal quotations omitted).

[208] *See generally* G.S. Mudur, *Drug Price Control Overs Too Little, Riddled With Loopholes*, TELEGRAPH ONLINE (Nov. 23, 2013), https://www.telegraphindia.com/india/drug-price-control-covers-too-little-riddled-with-loopholes/cid/240824.

[209] *See generally id.*

[210] Prasad & Iyengar, *supra* note 152, at 235–36.

[211] *Id.* ("[D]irect price control has not adequately increased affordability and accessibility of medicines in India . . . because of the aforementioned flaws in the [Order] and the Pharmaceutical Policy.").

[212] Emma Boswell Dean, *Who Benefits from Pharmaceutical Price Controls? Evidence from India* 1–67, 7 (CTR. FOR GLOB. DEV., Working Paper No. 509, 2019), https://www.cgdev.org/publication/who-benefits-pharmaceutical-price-controls-evidence-india.

The United States can leverage multiple lessons from India's change in drug regulation policies from the past five decades. First, India highlights that a diverse set of drugs should be subject to price caps, as subjecting only certain drugs—such as those deemed to be essential—can lead to price hikes on other drugs as pharmaceutical companies hope to make up for lost prices. Second, the United States must strike a balance between weighing R&D investment too heavily resulting in excess pharmaceutical profits while still incentivizing investment in innovation. The latter is to ensure that new drugs continue to launch in the U.S. market.

C. Germany's Value-Based System

Unlike the United Kingdom's voluntary scheme,[213] and India's current system, which focuses on R&D investment in an effort to catalyze innovation after a period of stagnation,[214] Germany's drug price reduction scheme is a value-based system, where drug prices are determined according to the value that they add to the market by either an increase in effectiveness or a decrease in side effects when compared to drugs already on the market.[215] However, similar to the United Kingdom, Germany originally utilized a reference-based pricing system, where new drugs were grouped with those drugs previously existing on the market to determine a reasonable price.[216] The original reference system only applied to generic drugs and exempted patented products from price caps.[217] In 2011, Germany enacted the Act on the Reform of the Market for Medical Products (Arzneimittelmarkt-Neuordnungsgesetz) ("AMNOG") to replace its statutory health insurance system which allowed pharmaceutical manufacturers to set their own prices.[218] The new structure was created in response to increasing prices of brand name drugs.[219]

The AMNOG allows manufacturers to set their own initial launch price, which remains consistent for the drug's first year on the market.[220] During this time, the drug undergoes a benefit assessment.[221] If a drug is found to have no added benefit compared to other drugs on the market, which can be measured

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213 Voluntary Scheme, *supra* note 179, ¶ 1.2.

214 Dean, *supra* note 212, at 2, 25.

215 James C. Robinson, Patricia Ex & Dimitra Panteli, *Single-Payer Drug Pricing In A Multipayer Health System: Does Germany Offer A Model For The US*, HEALTH AFFAIRS (Mar. 22, 2019).

216 Kingham & Wheeler, *supra* note 15, at 105.

217 *Id.* at 104.

218 Schlette & Hess, *supra* note 153, at 1.

219 *Id.*

220 *Id.* at 4.

221 Robinson, Ex, & Panteli, *supra* note 215.

by whether the drug is more effective in treating the illness or results in fewer side effects, the price of the drug is set in reference to the price of the comparator.[222] If a drug has added therapeutic benefit, a group of health insurer representatives negotiate a price with the drug manufacturer.[223] Relevant factors for negotiation include the results of an additional benefit assessment, the cost of other comparable pharmaceuticals, and prices paid in other European countries.[224] If no price is agreed upon, the drug price is established by an arbitration panel comprised of representatives from each side, selected by the manufacturer and the insurance agency.[225] Following the arbitration panel, if the manufacturer refuses to sell the drug at the arbitrator's price, the drug is withdrawn from the German market.[226]

The added benefit assessment allows for a drug to be categorized in one of six potential levels. Level one is the *major added benefit*, which is for drugs that offer "substantial improvement not previously achieved by the current standard therapy."[227] Level two is the *considerable added benefit*, which is for drugs that offer improvement over the comparator.[228] Level three is for drugs with *minor added benefit*, which is defined as drugs that offer a moderate improvement, such as reducing non-serious symptoms of a disease.[229] The next three levels are *added benefit present but not quantifiable*; *no added benefit has been proven*; and *lower benefit than the comparator*.[230] The Federal Joint Committee, a body comprised of payers, providers, and patient representatives, performs the assessment upon the manufacture's required submission of clinical reports.[231]

The new scheme has had mixed results. From 2011 to 2019, of 230 new drugs introduced, twenty-eight were withdrawn from the market in Germany, but are still sold elsewhere.[232] Additionally, because Germany is often used as a reference country in reference-based pricing schemes, manufacturers fear that a price reduction in Germany may carry over to price reductions in other countries as well.[233]

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222 Schlette & Hess, *supra* note 153, at 4.

223 Robinson, Ex, & Panteli, *supra* note 215.

224 MARTIN WENZL & VALERIE PARIS, PHARMACEUTICAL REIMBURSEMENT AND PRICING IN GERMANY, 11 (OCED, 2018).

225 Robinson, Ex, & Panteli, *supra* note 215.

226 *Id.*

227 Schlette & Hess, *supra* note 153, at 4.

228 *Id.*

229 *Id.*

230 *Id.*

231 *Id.*

232 Robinson, Ex, & Panteli, *supra* note 215.

233 Schlette & Hess, *supra* note 153, at 5.

The downfalls of Germany's reasonable pricing scheme reveal the importance of not relying solely on a value-based system to determine price reasonability. A reasonable drug price analysis requires the consideration of R&D costs and manufacturing prices. This will ensure that pharmaceutical companies are not alienated, which may result in companies withdrawing drugs from the market.

The new regulations set in the United Kingdom, India, and Germany have had mixed results at reducing drug prices, with unexpected consequences arising as manufacturers began exploiting loopholes within the regulations.[234] Analyzing the successes and failures of previously implemented schemes can reveal certain loopholes in the current U.S. proposals that aim to establish a reasonable drug price scheme.

IV. LEVERAGING LESSONS LEARNED FOR A REASONABLE DRUG PRICE SCHEME IN THE UNITED STATES

The United States should leverage the lessons learned from the United Kingdom, India, and Germany to determine potential weaknesses with current drug pricing proposals. Specifically, the United States can determine whether the price factors laid out in each policy are best for analyzing price reasonability and which drugs should be subject to reasonable prices. Identifying the best factors to consider when determining a reasonable drug price and which drugs to subject to mandatory price caps will allow the United States to ensure that prescription drugs are affordable while not alienating pharmaceutical companies.

The Price Relief Act relies heavily on a reference-based system, in which the price of the drug is determined by comparing the manufacturing price for the drug in Canada, the United Kingdom, Germany, France, and Japan.[235] Under the Price Relief Act, an assessment of the drug's value would only be required if the price data in more than three of the reference countries were unavailable.[236] However, of concern is the fact that the R&D costs are not included in such an analysis, unless the price is already determined to not be excessive through the reference-based analysis, which may lead to a stagnation in the development of new drugs.[237] Combining the use of the Price Relief Act reference-based system with a value-based system, like that in Germany, would better incentivize the

234 *See* Robinson, Ex, & Panteli, *supra* note 215; Prasad & Iyengar, *supra* note 152, at 235–36.
235 *See* Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong., §§ 2(b)(1)(A) & (B).
236 *See id.* § 2(b)(1)(C).
237 *See id.* § 2(b)(2)(D).

pharmaceutical industry to use R&D costs to enhance the efficacy of the drug, thereby increasing its value.[238] Such an approach would require the government to negotiate drug prices while still reassuring the pharmaceutical industry that R&D costs can be recouped. If the United States were to require manufacturers to submit data on the costs associated with making the drugs, the United states could use this data to determine a reasonable price. For example, in India, pharmaceutical profits were highly inflated because while R&D was considered in determining a reasonable price, the low manufacturing cost of the drug was not. This proposal would prevent such an issue from repeating itself.[239]

While the Price Relief Act emphasizes a reference-based system, the ADMA, emphasizes the R&D investment and the manufacturing and operating costs to produce the drug, similar to the reasonable pricing scheme in India.[240] However, there is no reference-based scheme that the government can use to compare the price of the drug sold in the United States to similar foreign economies.[241] Additionally, the legislation introduces no value-based system, where the therapeutic value that the drug adds to the market compared to previously introduced similar drugs is considered, potentially limiting the incentive to innovate more effective drugs.[242]

On the other hand, the We PAID Act utilizes a reference-based pricing system by using a framework that compares the price of similar drugs in other countries, but using price comparison as one of many factors.[243] Additionally, like the pricing scheme in India, the We PAID Act also requires considering the amount of R&D costs that the company has invested.[244] However, the We PAID Act makes no mention of considering the value of the drug for determining its reasonable price.[245] The absence of such a factor disincentivizes companies from producing new drugs that are more effective than those already on the market. Also, the Pricing Reduction Act makes no mention of ensuring that drugs are sold at a reasonable price and only requires that any price hikes on drugs do not exceed the rate of inflation.[246] Though this may help stabilize prices, it will have no effect on the initial price of the drug.

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238 *See* Schlette & Hess, *supra* note 153, at 7.

239 Mudur, *supra* note 208.

240 Affordable Drug Manufacturing Act of 2018, S. 3775, 115th Cong. § 2(e)(1)(C)(ii)(III)(aa).

241 *See*. *id.*

242 *See*. *id.*

243 We protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. § 4(a)(1) (2019).

244 *See id.*

245 *Id.*

246 *Id.* § 106

The We PAID Act, the Pricing Reduction Act, and the Price Relief Act all only require a select few drugs to be regulated, which results in many drugs exempt from the legislations' purview.[247] The We PAID Act is only applicable to those drugs with R&D costs financed through federal funds.[248] The Pricing Reduction Act is only applicable to those drugs covered by Medicare Part D.[249] The Price Relief Act is only applicable to name brand drugs and does not regulate generic versions.[250] Such an approach may lead to an increase of manufacturers discontinuing development of drugs, not launching them in certain countries, or launching them at a slower rate.[251] Learning from the challenges India faced, it is therefore critical that all approved drugs are subject to reasonable prices, that manufacturers of both generic and name brand drugs abide by new regulations, and that manufacturers are still incentivized to launch in the United States.

Combining the schemes in the United Kingdom and Germany, the Lower Drug Costs Now Act uses a mixture of reference-based pricing and value-based pricing to determine the drug's reasonable price.[252] The reference-based pricing system will ensure that the prescription drug prices in the United States do not far exceed those in other developed countries. Additionally, considering the therapeutic value the drug adds to the market when determining whether its price is reasonable aims to incentivize manufacturers to produce innovative drugs rather than engage in the practice of making small chemical compound changes to existing drugs. The use of reference-based pricing can seek to deter pharmaceutical companies from dropping out of the United States market, as seen with Germany's value-based system, by ensuring that the price sold will not drop below the average price level of the drug in Australia, Canada, France, Germany, Japan, and the United Kingdom.[253] Additionally, similar to the revised scheme in the United Kingdom which subjects both name brand and generics to reasonable prices,[254] the Lower Drug Costs Now Act circumvents the issue of

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[247] *See* We Protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. (2019); Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong.; Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019).

[248] Scott Introduce Landmark Legislation, *supra* note 109.

[249] Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019), Title I, Subtitle A-Part B, § 101(a)(2)(B).

[250] Prescription Drug Price Relief Act, S. 102, 116th Cong. § 2(b)(1)(A) (2019).

[251] *See generally* Berndt & Cockburn, *supra* note 178, at 1569 ("Of the 184 new drugs launched in the United States between 2000 and 2009 that made up the study sample, 160 were available in Germany by 2010, in contrast to 111 in India.").

[252] Nancy Pelosi Press Release, *supra* note 93.

[253] *Id.*

[254] *Understanding the 2014 Pharmaceutical Price Regulation* Scheme, *supra* note 164, at 1.

manufacturers imposing price hikes by including the 250 most expensive drugs, regardless of whether the drug is generic or name brand.[255] Moreover, allowing HHS to negotiate the sale price of drugs on behalf of Medicare and Medicaid beneficiaries, but requiring that the same price be offered to those with private insurance, seeks to prevent manufacturers from recouping potential lost profits by hiking prices for drugs not covered by federally funded programs. [256]

CONCLUSION

Among the most discussed proposals currently in Congress, the Lower Drug Costs Now Act is the most promising in leveraging lessons learned from the United Kingdom, India, and Germany in regulating drug prices through imposing a reasonable drug price scheme. The Act combines the U.K.'s cost-effectiveness pricing system[257] and Germany's value-based system[258] in determining what constitutes a reasonable price, while still requiring that the pharmaceutical company's R&D investment costs are considered to not alienate the pharmaceutical industry, which may result in drug products being withdrawn from the market.[259] The Lower Drug Costs Now Act also subjects a diverse set of drugs within its purview by regulating both drugs with patent protections and generic drugs and by requiring the same reasonable prices apply uniformly rather than only applying to drugs purchased by federal or state-funded health care programs.[260] The United States must act to reduce the continuing increase in prescription drug prices to ensure that Americans remain healthy.[261] Legislation passed in the past four decades has proven ineffective in its goal of reducing prescription drug costs for American consumers through increasing the number of generic drugs entering the market and increasing the number of individuals with health insurance. This is evidenced by the fact that many individuals continue to struggle to afford the medications that they need.[262]

255 Nancy Pelosi Press Release, *supra* note 93.
256 *Id.*
257 U.K. Statutory Scheme, *supra* note 15.
258 Robinson, Ex, & Panteli, *supra* note 215.
259 Nancy Pelosi Press Release, *supra* note 93.
260 *Id.*
261 Kamal, Cox, & McDermott, *supra* note 60.
262 *Id.*

Implementing the reasonable drug price scheme in the Lower Drug Costs Now Act will begin to lower prescription drug costs and promote the health and well-being that Americans deserve.

HALEY GINTIS*

* Haley Gintis graduated from the University of Maryland in 2014, with a Bachelor of Arts Degree in Hearing and Speech Sciences and Psychology and her master's degree in Education from the Johns Hopkins School of Education in 2017. She currently serves as Executive Managing Editor of Emory International Law Review, Volume 35. The author would like to thank her advisor, Professor Liza Vertinsky, for her help in focusing her thesis and determining how best to structure her sections, and her parents for their endless support.