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# Caps on Capsules: Prescription for Lower Drug Prices in the United States

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## ABSTRACT

The United States is the foremost innovator of pharmaceutical therapies in the world. That innovation, however, comes at a price—literally. Americans pay more for their medications than any other country. In a country without universal healthcare, the topics of economics, human rights, and healthcare intersect at the crossroads of pharmaceutical pricing. In contrast to most other countries, the United States has no regulations on pharmaceutical price control. One major argument against government regulation is its inherent opposition to the free market system: the heart of the American economy. Further still is the argument that profit restriction would create a chilling effect on the industry, stifling the pharmaceutical industry's cutting-edge (but expensive) innovations and jeopardizing the United States' leading position in the global pharmaceutical industry. The most basic argument for profit control is to prevent pharmaceutical price monopolization so Americans can afford the care prescribed to them. This Comment summarizes some of the unique issues in the pharmaceutical industry, major arguments for and against profit control, and the current climate in United States' politics and laws regarding this issue for a possible solution. Proposed solutions herein include policy changes to enhance Medicare's ability to negotiate drug prices with manufacturers, limiting drug companies' ability to raise prices without confines or explanation, and making reimbursement contingent on drug performance to ensure that new medications provide measurable benefits. This multipronged approach would not only make medications more affordable, but it would also increase the quality of new formularies.

## I. INTRODUCTION

The United States is arguably the world leader in both pharmaceutical development and innovation.[1] For example, the United States is credited with 43.7% of all new molecular entities (NMEs) developed between 1992 and 2004 out of all other inventor countries.[2] The United States also tops the list for having the world's highest drug

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1 *See* ROSS C. DEVOL, ARMEN BEDROUSSIAN & BENJAMIN YEO, MILKEN INST., THE GLOBAL BIOMEDICAL INDUSTRY, 6 (2011).

2 Salomeh Keyhani, Steven Wang, Paul Hebert, Daniel Carpenter & Gerard Anderson, *US Pharmaceutical Innovation in an International Context*, 100 AM. J. PUB. HEALTH 1075, 1075 (2010).

prices. On average, medications sold in the United States cost fifty percent more than in other developed countries.[3] Are these two concepts in tandem? Economists estimate that if the United States had adopted European-style price controls on medications during the 1990s–early 2000s, it would have produced 117 fewer NMEs.[4] The nation's success in the pharmaceutical industry is attributed to an array of influences, including world-class universities, research centers, and scientists, as well as groundbreaking business leadership.[5] These elements are not, of course, exclusive to the United States. However, there is one major factor that *is* exclusive: the government's commitment to the free market system. This includes the conspicuous absence of artificial limitations (i.e., government regulations) on profits pharmaceutical companies reap.[6]

The United States government and pharmaceutical industries have targeted other nations as part of the reason for the lack of American drug price controls. For example, former United States Food and Drug Administration (FDA) Commissioner, Dr. Mark McClellan, in his speech in the first-ever international colloquium on generic medicine, broadly stated that the United States shoulders most of the costs in developing new drugs worldwide.[7] He further elaborated that "some of the world's richest nations are driving the world's hardest bargains" because they are only paying to produce drugs that the United States developed.[8] He then suggested that richer countries need to shoulder related expenses to research and development of new drugs in proportion to their income.[9]

Dr. McClellan implies that the United States' domestic market is paying for the development of innovative new drugs. From this logic stems the belief that medications need freedom from governmental price controls so that the pharma industry can recoup their expenses associated with research and development. Foreign pharmaceutical companies seem to agree. While other countries are more frugal with pharmaceutical purchasing by utilizing a variety of price controls, discussed *infra*, foreign drug manufacturers take advantage of the lack of American price controls. The United States is veritably their profit haven, where they sell their products for higher prices to make up for price controls at home.[10] Even though Americans consume roughly the same amounts of medications as citizens in other countries[11] (and most

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[3] *US Price Gouging in the Pharmaceutical Industry*, IHS MARKIT (2018), https://ihsmarkit.com/solutions/us-price-gouging-pharmaceutical-industry.html [https://perma.cc/WY3D-HXTP].

[4] Joseph Golec & John A. Vernon, *Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms*, 28(8) PHARMACOECONOMICS 615, 624–25 (2010).

[5] *See generally* DEVOL ET AL., *supra* note 1.

[6] *See id.* at 32, 34.

[7] *See* Janice Kopkins Tanne, *FDA Chief Wants Other Rich Countries to Share Drug Development Costs*, 327 BRITISH MED. J 830, 830 (2003).

[8] *Id.*

[9] *Id.*

[10] *See* Alaric Dearment, *How Much Will Drug Price Controls Harm Innovation? It Depends*, MEDCITY NEWS (Feb. 19, 2020), https://medcitynews.com/2020/02/how-much-will-drug-price-controls-harm-innovation-it-depends/ [https://perma.cc/4JTS-3QT2].

[11] *See, e.g.*, Dana O. Sarnak, David Squires & Shawn Bishop, *Paying for Prescription Drugs Around the World: Why Is the US an Outlier?*, THE COMMONWEALTH FUND (Oct. 5, 2017), https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier [https://perma.cc/8L3L-X6PL]; Phill O'Neill & John Sussex, *International Comparison of Medicines Usage: Quantitative Analysis from a Swedish Perspective*, OFFICE OF HEALTH

certainly does not have the highest population), American consumers account for nearly half to seventy percent of all global pharmaceutical profits.[12]

The United States spends more on health care than all other Organisation for Economic Co-Operation and Development (OECD) countries.[13] The United States spends nearly three times per capita what the United Kingdom (UK) does, and five times per capita what Canada does—and these countries have universal healthcare for all of their citizens.[14] In a February 2019 health tracking poll, the Kaiser Family Foundation found that while most Americans (fifty-eight percent) believe prescription medicine has made their lives better, nearly eighty percent of Americans polled said the cost was "unreasonable."[15] About one in four people surveyed reported difficulty in paying for their medications, and thirty percent say that they have not taken their medications as prescribed due to cost.[16] Only twenty-five percent of survey participants believe that pharmaceutical companies actually price their medications fairly.[17]

Drug prices are not regulated in the United States. Any legal basis for taking action against excessive drug prices must be linked to a violation of established antitrust law.[18] So although raising the price of a drug is not considered illegal conduct on its own, dramatic price increases have been a catalyst for increased government inquiry. For example, in 2016, there was public outrage over the sudden, 500% price increase of EpiPens, the injectable form of epinephrine.[19] The drug's manufacturer, Mylan, publicly confirmed that it received an information request from the Federal Trade

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ECONOMICS 15 (Apr. 2015), https://www.ohe.org/publications/international-comparison-medicines-usage-quantitative-analysis-swedish-perspective# [https://perma.cc/V4XM-3D43].

[12] Exact estimates depend on the sources cited. *See, e.g.*, David Belk, *Composite Analysis of the Finances for Thirteen of the World's Largest Pharmaceutical Companies from 2011-2018*, TRUE COST OF HEALTHCARE 3, https://truecostofhealthcare.org/wp-content/uploads/2019/03/Totals-for-All.pdf [https://perma.cc/44GE-PW5T] (last accessed Aug. 29, 2020); COUNCIL OF ECON. ADVISORS, REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD (Feb. 2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf [https://perma.cc/V6AC-J4PZ].

[13] It is estimated that the United States spent 16.9% of their GDP on health care in 2018. *See* Roosa Tikkanen & Melinda K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?* THE COMMONWEALTH FUND (Jan. 30, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019 [https://perma.cc/K7TM-4B8V].

[14] *See* David U. Himmelstein, Terry Campbell & Steffie Woolhandler, *Health Care Administrative Costs in the United States and Canada, 2017*, ANNALS OF INTERNAL MED. 134–42 (2020), https://www.acpjournals.org/doi/10.7326/M19-2818 [https://perma.cc/3P22-68X6].

[15] *See* Ashley Kirzinger, Lunna Lopes, Bryan Wu & Mollyann Brodie, *KFF Health Tracking Poll - February 2019: Prescription Drugs*, KAISER FAMILY FOUNDATION (Mar. 1, 2019), https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/ [https://perma.cc/4CSG-SJYS].

[16] *Id.*

[17] *Id.*

[18] Harry First, *Excessive Drug Pricing as an Antitrust Violation*, AM. ANTITRUST INST. (Jan. 19, 2019), https://www.antitrustinstitute.org/work-product/excessive-drug-pricing-as-an-antitrust-violation/#:~:text=Harry%20First's%20%E2%80%9CExcessive%20Drug%20Pricing,82%20Antitrust%20Law%20Journal%20No.&text=Although%20high%20pharmaceutical%20drug%20prices,are%20the%20result%20of%20collusion [https://perma.cc/D7HZ-DLCE].

[19] Epinephrine is used to treat emergency conditions, such as life-threatening allergic reactions like anaphylaxis (throat swelling compromising the airway and one's ability to breathe).

Commission regarding possible antitrust violations.[20] In October that year, Mylan agreed to pay a $465 million USD settlement with the United States Department of Justice to settle claims that the company overbilled Medicaid.[21] As of the time of writing, Mylan continues to deny wrongdoing.[22]

The pharmaceutical market is unique and complicated. The *Mylan* case helps illustrate a distinct feature that deviates from standard, textbook models of competitive markets: "Merit goods," i.e., goods that should be available to all on the basis of some concept of need, rather than a basis of ability and willingness to pay.[23] As with other merit goods, pharmaceutical pricing cannot be completely left to the market. This is the veritable recipe for a monopoly: companies are free to raise prices until profits decline. Medications weigh on public budgets, which is another reason why the government should intervene in the competition process.

This Comment argues that the United States government should institute policy changes to enhance their ability to negotiate drug prices with manufacturers, limit drug companies' ability to raise prices without confines or explanation, and make reimbursement contingent on drug performance to ensure that new medications actually provide measurable benefits. Arguably, this triple-pronged approach would not only make medications sold in the United States more affordable, it would also increase the quality of new formularies.

This Comment is structured as follows. Section II is about determining the value of medicines. This includes an examination of the pharmaceutical industry's research and development burdens, the industry's economic market, and a discussion on what degrees of innovation new medications offer. Section III discusses the interplay between third party payors and the taxpayers in the United States. Section IV examines the international realm and how foreign countries balance pharmaceutical innovation and affordability. Section V reviews examples of U.S. legislation, both current and prospective-facing, as well as how some general competition law and policy framework for enforcement against excessive high prices. Section VI describes the potential downsides of curbing pharmaceutical prices at home, and Section VII discusses the government's potential role in addressing high prices in pharmaceutical markets.

## II. DETERMINING THE VALUE OF MEDICATIONS

The prices of many drugs, both novel and old "gold standard" drugs, including generics, make affordable access difficult to both patients and payors in the United States. People's willingness to pay for life-prolonging medications is high, which can lead to price-demand inelasticity.[24] This is particularly true of medications that do not

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[20] Dan Managan & Meg Tirrel, *Mylan Faces Federal Antitrust Investigation in EpiPen Business*, CNBC (Jan. 30, 2017), https://www.cnbc.com/2017/01/30/mylan-faces-federal-antitrust-investigation-in-epipen-business.html [https://perma.cc/AJ9Z-62XV].

[21] *Id.*

[22] *Id.*

[23] *Merit Goods*, TRIPLE A LEARNING: MICROECONOMICS SL, http://www.sanandres.esc.edu.ar/secondary/economics%20packs/microeconomics_sl/page_116.htm [https://perma.cc/U2FL-RP4R] (last accessed Aug. 30, 2020).

[24] ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS 2 (2014) [hereinafter OECD 2014].

have any viable alternatives.[25] Consider Erbitux, a drug used to treat metastatic colon cancer. The "sticker price" of this medication is $13,329.60 USD for one month of treatment.[26] It is incapable of curing patients; on average, it extends life just seven weeks.[27] Avastin is another colon cancer drug that is not curative.[28] On average, it extends life two to five months. Avastin's sticker price in 2008 was $90,816 USD for eighteen weeks' worth of treatment.[29] Medicare covers both of these treatments.[30] And although insurance companies and federal health insurance plans are liable for the payment of a large percentage of medications, they are limited in controlling consumption and selection.[31] In contrast, the National Institute for Health and Care Excellence (NICE), the public body of the Department of Health in England, refuses to pay for Avastin due to its high cost and perceived low value.[32]

The research and development process is inherently expensive and complicated. The resultant costs and the pricing structure of the pharmaceutical market are far from transparent, and there are valid concerns regarding the actual degree and value offered by costly new drug therapies.[33] This section analyzes market factors in the pharmaceutical industry and what degree of innovation new medications offer.

### *A. Costs of Research and Development*

The main form of competition between the largest pharmaceutical companies is the creation of new, patented, innovative therapies.[34] However, pharma research and development is expensive and risky. There is an industry saying: "The first pill can cost more than a billion dollars while the second only costs a dime."[35] Drugs are expensive to create, and failures are common. In fact, successful development of a new drug from conception to market takes an average of ten to fifteen years.[36] Even then, nearly ninety percent of all drugs entering clinical trials fail.[37] Industry approximations of research and development costs vary widely, but the most

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[25] *Id.*

[26] *How Much Should I Expect to Pay for Erbitux?*, LILLY, https://www.lillypricinginfo.com/erbitux [https://perma.cc/9YDE-93Q6] (last accessed Aug. 27, 2020).

[27] EZEKIEL J. EMANUEL, HEALTHCARE, GUARANTEED 56 (2008).

[28] *See* Tito Fojo & Christine Grady, *How Much is Life Worth: Cetuximab, Non-Cell Lung Cancer, and the $440 Billion Dollar Question*, 101 J. NAT'L CANCER INST. 1044, 1044 (2009).

[29] *See, e.g.*, EMANUEL, *supra* note 27, at 56; *see also* Fojo & Grady, *supra* note 28, at 1045.

[30] This price has started to come down, however (0.7%), in 2020 with the introduction of Pfizer's biosimilar, Zirabev. *See* Stanton Mehr, *Bevacizumab ASP Pricing Now Dropping with Biosimilar Entries*, BIOSIMILARS REV. & REP. (Jan. 27, 2020), https://biosimilarsrr.com/2020/01/27/bevacizumab-asp-pricing-now-dropping-with-biosimilar-entries/ [https://perma.cc/4X7N-EVKL]; *Cf.* EMANUEL, *supra* note 27, at 56.

[31] OECD 2014, *supra* note 24, at 2.

[32] *See* Ananya Mandal, *Avastin (Bevacizumab) Price*, NEWS-MEDICAL.NET (Feb. 26, 2019), https://www.news-medical.net/health/Avastin-(Bevacizumab)-Price.aspx [https://perma.cc/C7XA-W45R].

[33] *Id.*

[34] ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, COMPETITION AND REGULATION ISSUES IN THE PHARMACEUTICAL INDUSTRY 7 (2001) [hereinafter OECD 2001].

[35] *Preface*, *in* MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE xviii (Norman R. Augustine, Guru Madhavan & Sharyl J. Nass, eds., 2018).

[36] CLINICAL DEVELOPMENT SUCCESS RATES, BIO INDUSTRY ANALYSIS 8 (2016).

[37] *See id.* at 10.

commonly accepted estimates, after full adjustment for trial failures, are between $200 million USD and $2.9 billion USD.[38]

As mentioned *supra* in this Comment's opening salvo, it is these staggering upfront research and development costs that both the former FDA commissioner and the industry purports to be the major justification of unregulated drug price control. Like any other for-profit industry, pharmaceutical companies need to generate more income than they expend in order to remain in business. Drug developers depend on intellectual property (IP) protection to ensure that the "blockbuster" drugs (i.e., drugs that net a profit of over $1 billion USD) that make it to market provide returns on all research and development investments—not only for the innovator drug, but for all of the failures as well.[39] Following this logic, research and development should be the number one expenditure of pharmaceutical companies, but in reality, it is not. In 2015, 89 out of the top 100 pharmaceutical companies spent more on marketing than they did on research and development.[40] There are billions of dollars left over for pharma companies once research costs are covered.[41]

Additionally, pharmaceutical companies receive subsidies from American taxpayers to offset the costs of research and development,[42] which helps insulate pharmaceutical companies from clinical failures. The National Institutes of Health (NIH), a division of Health and Human Services (HHS), provided the pharma industry with more than $100 billion between 2010 and 2016 for research. All 210 drugs approved by FDA in that timeframe received NIH sponsorship.[43] Drug companies also utilize academic settings to conduct tax-deductible research and development.[44] For instance, more than a third of all new drugs approved by FDA originate from a university.[45] So in essence, American consumers pay for these drugs twice: during development, and later, consumption.

To examine the return on investment (ROI) on these drugs, the World Health Organization (WHO) analyzed ninety-nine FDA-approved cancer medications developed between 1989–2017. Cancer medications were specifically chosen for the

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[38] WORLD HEALTH ORGANIZATION, PRICING OF CANCER MEDICINES AND ITS IMPACT 27 (2018) [hereinafter WHO 2018].

[39] *See generally* OECD 2001, *supra* note 34; *see also* WHO 2018, *supra* note 38, at ix.

[40] *The R&D Smokescreen*, INST. FOR HEALTH AND SOCIO-ECONOMIC POLICY 3 (Oct. 20, 2016), https://nurses.3cdn.net/e74ab9a3e937fe5646_afm6bh0u9.pdf [https://perma.cc/PU8C-XX5A].

[41] *See* Nancy L. Yu, Zachary Helms & Peter Back, *R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, HEALTH AFFAIRS: BLOG (Mar. 7, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/ [https://perma.cc/K5Z9-LE5U].

[42] *See* Mariana Mazzucato, *How Taxpayers Prop Up Big Pharma, and How to Cap That*, L.A. TIMES (Oct. 27, 2015), https://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html [https://perma.cc/PBH6-D3NY].

[43] *See* Ekaterina Galkina Cleary, Jennifer Beierlein, Navleen Surjit Khanuja, Laura M. McNamee & Fred D. Ledley, *Contribution of NIH Funding to New Drug Approvals 2010–2016*, PROC. NAT'L ACAD. SCI. U.S. AM. (Feb. 12, 2018), https://doi.org/10.1073/pnas.1715368115 [https://perma.cc/4Q2Y-A3N5].

[44] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 15–16 (Nov. 2017), https://www.gao.gov/assets/690/688472.pdf https://perma.cc/YLA8-ZV9F].

[45] *See* Eric V. Patridge, Peter C. Gareiss, Michael S. Kinch & Denton W. Hoyer, *An Analysis of Original Research Contributions Toward FDA-Approved Drugs*, 20 DRUG DISCOVERY TODAY 1182 (June 22, 2015), https://pubmed.ncbi.nlm.nih.gov/26113307/ [https://perma.cc/5C55-44AY].

high research and development costs, as well as their steep prices.[46] The analysis found that for every $1 USD spent (after full cost adjustments of trial and error, marketing, and production), the average return rate was $14.50 USD.[47] Of the ninety-nine drugs analyzed, a solid third (thirty-three) ended up being blockbusters.

Many of the medications analyzed in the study continued to generate massive profits for the drug manufacturers long after patents and market exclusivity rights expired.[48] WHO concluded that the cost of research, development, and production bears little to no relationship regarding how the pharmaceutical manufacturers set prices, at least for oncology drugs.[49] Pharmaceutical prices, they determined, are set according to the company's commercial goals, with a special focus on extracting the maximum amount a buyer is willing to pay for medicine. It is this pricing approach that often makes cancer medication unaffordable, preventing the full benefit of the treatment modalities from being fully appreciated.[50]

While the industry focus on cancer drugs sounds like a worthy endeavor (cancer is one of the top killers in the United States),[51] it is not without criticism. Like the Avastin and Erbitux examples *supra*, many oncologic drugs are not curative; instead, they offer small, incremental gains (i.e., weeks of life versus a cure) for high prices.[52] While there may be individual benefits to patients and their loved ones, research priorities may be skewed towards making these expensive, noncurative formularies versus treatments that are less profitable.[53] To make a comparison, antibiotic resistance is an impending threat, now.[54] While there are many kinds of infections, sepsis in particular is another leading killer in the United States.[55] In fact, one in three people who die in American hospitals are septic.[56] Yet, while antibiotics are fairly cheap to create in comparison to oncology drugs, one source purports only three pharmaceutical companies are conducting trials on antibiotics.[57] Another reports that in 2018, there were only forty-

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[46] WHO 2018, *supra* note 38, at vii–ix.

[47] *Id.* at ix.

[48] *Id.* at 108.

[49] *See id.* at xii.

[50] *See id.* at ix.

[51] *National Center for Health Statistics: Leading Causes of Death*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 6, 2020), https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm [https://perma.cc/BQE7-FGPN].

[52] Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, THE ATLANTIC (Mar. 23, 2019), https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/ [https://perma.cc/P8GS-J5PG].

[53] *Id.*

[54] *Id.*

[55] Sepsis is a systemic body infection. *Sepsis*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 14, 2020), https://www.cdc.gov/sepsis/datareports/index.html#:~:text=Each%20year%2C%20at%20least%20-1.7,in%20a%20hospital%20have%20sepsis [https://perma.cc/R66W-UZGY].

[56] *Id.*

[57] *See* 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 [https://perma.cc/ZR6W-88TH]. *Contra Antibiotics Currently in Global Clinical Development*, THE PEW CHARITABLE TRUSTS (Apr. 15, 2020), https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2014/antibiotics-currently-in-clinical-development [https://perma.cc/3E5Z-2PK5].

one antibiotics in clinical development to combat the threat of a superbug (a bacterial or viral infection resistant to all known antibiotics).[58] Comparatively, there were over 600 oncology drugs in development in 2018. Glibly, this juxtaposition "seems like profit maximization, not a case of sensible research priorities that reflects value in preventing and treating disease."[59]

### *B. How Innovative is Innovation?*

Innovations are protected through intellectual property (IP) rights (a protection deemed so important, it is in the U.S. Constitution). Patents serve both to recognize and reward drug companies for the commercial success of their products.[60] Once a patent expires, the drug company loses the exclusivity for its patent, allowing generic drugs to enter the market. However, pharmaceutical companies can delay the expiration of their patents through a process colloquially known as "evergreening." The process works like this: right before the expiration of a drug's patent, the manufacturer can apply for an extension on the patent by making a slight change to the molecular structure, changing the drug delivery, or coming up with a new indication for the medication.[61] The rationale for doing so is not for any therapeutic advantage, but an economic one.[62] Evergreening thus stifles innovation by locking competitors in litigation by the patent holders as new, similar products are introduced.

Consider Lantus, a patent-protected, long-acting insulin manufactured by Paris-based Sanofi. Lantus is one of the "world's best-selling drugs."[63] Sanofi made over $5 billion USD off of Lantus alone in 2017.[64] Lantus is the number one medication expenditure for Medicaid, and number two for Medicare.[65] Total CMS expenditure on the drug increased 132% between 2012 and 2016.[66]

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[58] *Antibiotics Currently in Global Clinical Development*, The Pew CHARITABLE TRUSTS (Apr. 15, 2020), https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2014/antibiotics-currently-in-clinical-development [https://perma.cc/3E5Z-2PK5].

[59] Emanuel, *supra* note 52.

[60] *Innovation and Intellectual Property,* WORLD INTELLECTUAL PROPERTY ORGANIZATION (2007), https://www.wipo.int/ip-outreach/en/ipday/2017/innovation_and_intellectual_property.html [https://perma.cc/7UZ4-MMWX].

[61] Roger Collier, *Drug Patents: The Evergreening Problem*, CMAJ (June 11, 2013), https://www.cmaj.ca/content/early/2013/04/29/cmaj.109-4466?versioned=true [https://perma.cc/9QR3-3PRA].

[62] *Id.*

[63] Andrew Dunn, *Insulin Drugmakers Under Scrutiny for Pricing, Patent Practices*, BIOPHARMA DIVE (Nov. 2, 2018), https://www.biopharmadive.com/news/insulin-drugmakers-under-scrutiny-for-pricing-patent-practices/541275/#:~:text=Sanofi%20filed%20its%20first%20Lantus,original%20patent%20expired%20in%20201 [https://perma.cc/LG7A-KG4C].

[64] *Id.*

[65] *Drug Spending Information Product Fact Sheet*, CTRS. MEDICARE & MEDICAID SERVS. (May 15, 2018), https://www.cms.gov/index.php/es/node/52306 [https://perma.cc/224Q-8C2S].

[66] *Lantus: Overpatented, Overpriced Special Edition*, I-MAK 2 (Aug. 2018), http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf [https://perma.cc/8KC3-W7L] [hereinafter I-MAK].

Generally, patents filed after 1995 obtain twenty years of patent protection.[67] Sanofi initially filed their patent for Lantus in the United States in 1994, and the drug was first approved for sale in 2000.[68] Researchers "found that 95% of the total patent applications (69 out of 74) on Lantus in the U.S. were filed after . . . 2000."[69] Since then, the U.S. Patent and Trademark Office (USTPO) has continued to grant evergreening patents on Lantus through 2031—a full thirty-six years after initial approval.[70]

Two drug companies with competing products have attempted to market and sell their own version of long-acting insulin, only to be sued by Sanofi.[71] Lilly's FDA approval of Basaglar (another long-acting insulin) was contingent on settling their legal battle with Sanofi.[72] While Basaglar's product launch was delayed an additional year due to litigation, the insulin was out in the U.S. market December 16, 2015[73] (it was already being sold in Europe).[74] Basaglar remains Lantus' only competition in the United States.[75]

But how innovative are new drugs? There were forty-eight new drugs approved by FDA in 2019.[76] Of the forty-eight, almost half (forty-four percent) were for rare diseases and were given orphan status (more on this *infra*), almost a quarter (eleven) were for cancer, and ten were biosimilars.[77] Biosimilars are created to be similar to an existing FDA-approved reference product (any differences are not "clinically meaningful"), so they are not necessarily novel.[78] Replication is a phenomenon following successful inventions, diluting the notion of "innovation."[79] The pharma

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[67] *Drug Patent Life: How Long Do Drug Patents Last?*, DRUGPATENTWATCH, https://www.drugpatentwatch.com/blog/how-long-do-drug-patents-last/ [https://perma.cc/CUH6-YDCH] (last accessed Aug. 29, 2020).

[68] I-MAK, *supra* note 66, at 3.

[69] *Id.* at 3–4.

[70] *Id.*

[71] *Id.*

[72] M. Alexander Otto, *Lantus Competitor Basaglar Wins FDA Approval*, MDEDGE (Dec. 17, 2015), https://www.mdedge.com/diabeteshub/article/105252/diabetes/lantus-competitor-basaglar-wins-fda-approval#:~:text=The%20Food%20and%20Drug%20Administration,compete%20with%20Sanofi's%20blockbuster%20Lantus.&text=The%20approval%20was%20based%2C%20in,which%20was%20approved%20in%202000 [https://perma.cc/XJ2R-6SV5].

[73] *Basaglar Approval History*, DRUGS.COM, https://www.drugs.com/history/basaglar.html [https://perma.cc/5GZ2-W965] (last accessed Aug. 29, 2020).

[74] Otto, *supra* note 72.

[75] Merck had FDA approval on their version of long-acting insulin, but withdrew the product launch in 2018 after also being sued by Sanofi. *See* I-MAK, *supra* note 66, at 4.

[76] Lisa M. Jarvis, *The New Drugs of 2019*, CHEM. & ENG'R NEWS (Jan. 17, 2020), https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2019/98/i3 [https://perma.cc/69UX-VGYB].

[77] *FDA Approved 48 'Novel' Drugs in 2019, Down 19% From Prior Year*, PHARM. COMMERCE (Jan. 9, 2020), https://pharmaceuticalcommerce.com/cold-chain-focus/fda-approved-48-novel-drugs-in-2019-down-19-from-prior-year/ [https://perma.cc/CZ6G-26X2].

[78] *What are Biosimilars?*, BIOSIMILARS RESOURCE CTR. (2017), https://www.biosimilarsresourcecenter.org/faq/what-are-biosimilars/ [https://perma.cc/E52L-RDYY].

[79] David Kline, *Do Patents Truly Promote Innovation?* IP WATCHDOG (Apr. 15, 2014), https://www.ipwatchdog.com/2014/04/15/do-patents-truly-promote-innovation/id=48768/ [https://perma.cc/A8X9-DEW6].

industry invests in (and has been criticized for) developing "follow-on" drugs.[80] In the simplest of terms, these formularies largely duplicate the efficacy of existing medications.[81]

The criticism of follow-on drugs stems from the knowledge that if drugs have more or less the same clinical outcomes as pre-existing drugs, what value do they offer?[82] These drugs absorb resources that could have been invested into research and development, which seems inherently wasteful if they are virtually indistinguishable from the pioneer drug.[83] Additionally, these drugs require money to market. It seems counterintuitive to funnel additional resources that could have been utilized on research and development of novel formularies.[84] Evidence also suggests that follow-on drugs do not even significantly reduce the prices of the pioneering drug.[85]

Some researchers point out that many follow-on drugs are the result of parallel development rather than imitation.[86] For example, if Drug A and Drug B are concurrently in development, one of them has to reach the finish line first. The primary benefit of having two similar medications on the market is more options for patients.[87] Some patients may have a slightly better clinical outcome from Drug B even though Drug A is better for most patients.[88] The second major benefit of follow-on drugs would be competitive pricing with pioneer drugs.[89] However, in practice, there has not been any real discernable price differences between pioneer drugs before and after the introduction of follow-on drugs in the marketplace.[90] For example, researchers Lu and Comaner demonstrated that for every additional competitor in the American pharma marketplace, the price of drugs only went down, on average, by two percent.[91] Paradoxically, Azoulay's 2002 research identified examples in which the addition of follow-on drugs in the marketplace actually *increased* the prices of all of the competing medications.[92]

## III. ECONOMIC STRESS ON PAYORS AND TAXPAYERS

Third-party payor financing through health insurance or government funds strongly increases the ability of patients to pay. It should also be noted that most Americans have health insurance. The presence of health insurance insulates patients from the

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[80] AIDEN HOLLIS, ME-TOO DRUGS: IS THERE A PROBLEM?, WORLD HEALTH ORGANIZATION 1 (2005).

[81] These are not the same as generic drugs, which are instead the exact same medication as a brand name drug, but sold under a different, "generic" name. *See id.*

[82] *See id.*

[83] *Id.*

[84] *Id.* at 4.

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] *Id.* at 2.

[89] *Id.* at 2, 4.

[90] *Id.*

[91] *See generally* Z. John Lu & William S. Comaner, *Strategic Pricing of Pharmaceuticals*, 80 REV. OF ECON. AND STAT. 108 (Feb. 1998); *see also* HOLLIS, *supra* note 80, at 2.

[92] *See* Pierre Azoulay, *Do Pharmaceutical Sales Respond to Scientific Evidence?*, 11 J. ECON. & MGMT. STRATEGY 551, 567 (2004).

true cost of their medications.[93] As a result, many patients, as well as their providers, do not take into account the price of medications when making medical decisions.[94] In turn, this can lead to higher prices.

Strong buyers of care, such as national healthcare systems or large health insurance companies, should be able to negotiate prices with buyer power. A buyer's bargaining power is usually determined by two factors: (1) The ability to walk away from the deal and (2) the volume of goods they are purchasing.[95] For buyers to be able to negotiate on price, they need attractive alternatives other than the seller.[96] In the healthcare setting, this alternative could be another medication or treatment. The reality is, in the American healthcare market, alternative options are frequently limited.[97]

By law, Medicare covers medical treatments that are "reasonable and necessary," but no real, formal definition of "reasonable and necessary" exists.[98] In lieu of exact guidance, Medicare traditionally pays for medications approved by FDA.[99] FDA approval is not hinged on how incrementally more effective new medications are on existing medications. Instead, their approval (and grant of marketing exclusivity) is determinative on whether or not a drug or device is "safe and effective," which, in turn, is usually determined by a drug's ability to better treat a condition than a placebo in the drug company's own clinical trials.[100]

Basically, for the purposes of FDA, "effectiveness" does not mean that a drug is "better" than another, or even that the "improvement" in one drug over another is worth the cost. Rather, it simply means that a particular drug is better than nothing. Because Medicare cannot negotiate with drug manufacturers (see the Medicare Modernization Act, *infra)*, Medicare thus ends up paying for expensive medications without determining whether the added costs actually improve the quality or length of life.[101]

Medicare expenditure continues to be a burden on the nation's coffers. Dr. Ezekiel Emanuel put it succinctly: "The combination of continued payments for unproven tests and treatments, fraud, and uncorrected payment problems—along with the baby boom—threatens to bankrupt [the United States]."[102] In 1966, its first year of operation, Medicare covered 19 million Americans at a cost of $3.3 billion USD—less than 0.4% of the GDP.[103] By 2020, the U.S. government's insurance programs

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93 *Id.*

94 *Id.*

95 *See* CHRIS FONTEIJN, IIAN AKKER & WOLF SAUTER, RECONCILING COMPETITION AND IP LAW, AMC, 12 (2018).

96 *See id.*

97 *See id.*

98 EMANUEL, *supra* note 27, at 56.

99 *Id.*

100 It is also relevant to note that FDA does not actually test these drugs themselves; they rely on the clinical trials and studies results done and supplied by the drug manufacturer. *Cf.* EMANUEL, *supra* note 27, at 56.

101 *Id.*

102 *Id.*

103 *Id.*

consumed a quarter of the 2019 federal budget ($1.1 trillion USD).[104] Prescription drugs account for nearly $1 USD out of every $5 USD spent from the Medicare program.[105] Overall prescription drug spending in the United States was half a trillion dollars in 2016 ($477,000,000 USD).[106]

Take the example of cancer treatment, specifically early stage HER2 positive breast cancer (a type of breast cancer that represents twenty percent of all cases). A standard course of treatment is with a drug therapy combination of doxorubicin, cyclosphosphamide, docetaxel, and trastuzumab. Without insurance, the out-of-pocket cost in USD would be the equivalent of ten years' worth of the average salary in India and South Africa, or nearly two years' of the average wages in the United States.[107] And this estimation is only for the first line drug therapy: this does not include radiation or surgical treatment modalities, or supportive care like anti-emetics or blood products for transfusions. All combined, treatment for breast cancer would be unaffordable for most without health insurance. Even with insurance, patients report having financial stress to the extent that they may lower the treatment dose, only partially fill their prescriptions, or forego treatment altogether.[108]

### *A. De Facto Monopoly*

Despite undeniable advances in pharmaceutical technology, there have been a number of competition enforcement cases regarding excessive pricing in the pharmaceutical industry recently. In 2017 alone, over forty-six state attorneys general brought claims against generic drug manufacturers alleging that they collectively agreed to raise prices.[109]

Curiously, the conditions that brought these cases forward also seem to be relatively common in the pharmaceutical industry.[110] According to a September 2018 report from the American Association of Retired Persons (AARP), during 2016–2017 retail prices for 267 widely used brand name prescription medication increased another 8.4% after five straight years of double-digit average annual price increases.[111] Additionally,

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[104] *Policy Basics: Where do our Federal Tax Dollars Go?*, CTR. ON BUDGET & POLICY PRIORITIES (Apr. 9, 2020), https://www.cbpp.org/research/federal-budget/policy-basics-where-do-our-federal-tax-dollars-go [https://perma.cc/L8MU-EBVU].

[105] EMANUEL, *supra* note 27, at 56.

[106] *See* OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OBSERVATIONS ON TRENDS IN PRESCRIPTION DRUG SPENDING, 2, 8 (Mar. 8, 2016).

[107] WHO 2018, *supra* note 38, at xii.

[108] *Id.*

[109] *AG Jepsen Leads Coalition in New Expanded Complaint in Federal Generic Drug Antitrust Lawsuit*, OFF. ATT'Y GEN. WILLIAM TONG (Oct. 31, 2017), https://portal.ct.gov/AG/Press-Releases-Archived/2017-Press-Releases/AG-Jepsen-Leads-Coalition-in-New-Expanded-Complaint-in-Federal-Generic-Drug-Antitrust-Lawsuit [https://perma.cc/46QT-WTMK].

[110] *See* OECD 2014, *supra* note 24, at 2, 8.

[111] Stephen W. Schondelmeyer & Leigh Purvis, *Brand Name Drug Prices Increase Four Times Faster than Inflation in 2017*, AARP PUB. POL'Y INST. (Sept. 2018), https://www.aarp.org/content/dam/aarp/ppi/2018/09/brand-name-prescription-drug-prices-increase-four-times-faster-than-inflation.pdf [https://perma.cc/59HY-7CK6].

brand name drug prices increased four times faster than the general inflation rate in 2017.[112]

One argument cited against governmental influence on the pharmaceutical industry's pricing is that the price itself operates as a device that allows marketplaces to "self-correct."[113] If a dominant company is earning excessive profits, for example, this will send a signal to attract new entrants into the industry.[114] If a successful new competitor is likely to enter the market within a reasonable period, then, theoretically, it would not be reasonable for the government to intervene.[115]

There are various factors that explain the level prices are set, including the degree of competition.[116] In a standard market, if it is truly competitive, the price of goods will be set close to cost. With less competition in the marketplace, prices tend to be higher.[117] One way to benchmark excessive pricing is a comparison of a similar product in the industry, known as the "competitive price."[118] But how does one define the competitive price in a market that is not competitive? Another benchmark is the cost of production.[119] But what about companies such as drug manufacturers who create a number of different products? Taken together, these questions create difficulties that create risks when trying to enforce price control.[120] If the government were to over-intervene, the pharma industry argues, then it would create a chilling effect on new market entrants, thus reducing competition.[121]

MIT researchers Lu and Comaner studied competition in the pharma industry, specifically, follow-on drugs and their effects on competitive pricing.[122] Follow-on drugs typically compete with the innovator drug because they treat the same condition.[123] As discussed *supra*, Lu and Comaner concluded that each additional competitor reduces the price of the drug by two percent.[124] However, the average number of competitors for each drug in their data was about three or four, "which seems to suggest that the effect of going from [a] pure monopoly to four (competitors) . . . with very similar products is a reduction in price of only 6%."[125]

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[112] *Id.*

[113] FREDERIC JENNY, ABUSE OF DOMINANCE BY FIRMS CHARGING EXCESSIVE OR UNFAIR PRICES, ISRAELI COMPETITION AUTHORITY 21 (2016).

[114] *Id.* at 22.

[115] *Id.* at 21–22.

[116] OECD 2014, *supra* note 24, at 2.

[117] *See id.* at 16.

[118] JENNY, *supra* note 113, at 34–35.

[119] *Id.* at 32.

[120] *See id.* at 22.

[121] *See id.* at 28.

[122] Lu & Comaner, *supra* note 91, at 108.

[123] Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and the Timing of Development*, 22 PHARMACONOMICS 1, 3 (2004), https://www.who.int/intellectualproperty/submissions/Submission_DiMasi.pdf?ua=1 [https://perma.cc/L6B2-B24U].

[124] HOLLIS, *supra* note 80, at 2.

[125] *Id.*

There are also cases that with increased competition, pharmaceutical prices actually went *up*. For example, the price of Tagamet, a stomach ulcer medication, actually increased when its first competitor, Zantac, entered the marketplace.[126] The prices of both Tagament and Zantac also increased when additional competitors, Pepcid and Axid, were introduced.[127] In essence, the only effect these drugs had on the market was *market-splitting*, as opposed to *market expansion*.[128] From an economic perspective, follow-on drugs beg the question of excessive market entry. If competition is monopolistic, it can lead to too much or too little product diversity.[129] Usually, excessive market entry is not an issue for consumers. If the market is split several ways, consumers usually get the benefit of reduced pricing.[130] But this phenomenon does not appear to replicate itself in the pharma market. Follow-on drugs, for example, bring product diversity. However, they do not bring forth price reductions. The result? The competitors in the pharma industry continue to have high economic rewards with comparably little social value or scientific innovation.[131] Some researchers have even gone as far as to conclude that it is not the price of follow-ons and pioneering medications that are competing, but rather their marketing.[132]

In situations of legal or *de facto* monopoly, economic theory predicts that a *monopoly price* will be imposed; i.e., the price which the monopolist earns the most profits.[133] This approach was recently vindicated by the United States Supreme Court, which held that: "the mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free market system."[134] In the European Union (EU), on the other hand, Article 102(a) of the Treaty for the Functioning of the European Union (TFEU) prohibits conduct by companies that "directly or indirectly impos[e] unfair purchase or selling prices or other unfair trading conditions."[135] Translated, this not only prohibits prices that are unreasonably low ("predatory pricing") but also protects prices that are unreasonably high.[136] In *United Brands*, the European Court of Justice (ECJ) explained that a price is abusive if "it has no reasonable relation to the economic value of the product" and that abuse can be identified through an analysis that considers whether: (1) the price cost margin is excessive, and (2) the price imposed is either "unfair in itself or when compared to competing products."[137] This decision created a two-pronged test, which is still employed by the ECJ in excessive pricing cases.[138]

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126 *See* Azoulay, *supra* note 65, at 564–66; *see also* HOLLIS, *supra* note 80, at 3.

127 *Id.*

128 HOLLIS, *supra* note 80, at 3.

129 *Id.* at 4.

130 *See id.* at 3.

131 *Id.*

132 *Id.*

133 *Id.*

134 Verizon Commc'ns v. Law Offices of Curtis v. Trinko, 540 U.S. 398, 407 (2004).

135 Treaty on the Functioning of the European Union, art. 102, Jan. 1, 1958, 2008 O.J. (C 115) 89.

136 *See generally* ORGANISATION FOR ECON. CO-OPERATION & DEV., PREDATORY PRICING (1989), https://www.oecd.org/competition/abuse/2375661.pdf [https://perma.cc/NGE6-FW2W].

137 JENNY, *supra* note 113, at 31–32.

138 *See id.* at 6.

Given the challenges identified *supra*, it is unsurprising that excessive pricing is an area of limited (or even nonexistent) enforcement in the American pharmaceutical industry. Excessive price regulation is both underdeveloped conceptually and underused in practice.[139]

## IV. INTERNATIONAL REGULATIONS

Many countries believe that the price of medications should reflect their clinical and therapeutic value for patients and society. Other countries generally use more than one set of overlapping methods to establish prices of medications.[140] International efforts to determine the entry price of drugs include free pricing, rate-of-return regulations, international reference pricing/external price referencing, cost-plus pricing, clinical and cost-effectiveness pricing.[141] Some countries have also set maximum "ceiling" prices, while others have agreed to arrangements like discounts or rebates based on volume of sales or payment according to health outcomes.[142] These arrangements are often agreed to on confidential terms between the manufacturer and purchaser.[143]

Because IP rights are recognized on a territorial basis, each nation has established its own policy regarding imports.[144] There are flexibilities built into the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to overcome patient barriers.[145] The TRIPS Agreement set out minimum standards for the protection of IP, including pharmaceuticals.[146] Following the TRIPS Agreement, there was growing concern and evidence that patent rules might restrict access to affordable medications for people in developing countries (particularly for the treatment of HIV/AIDS, tuberculosis, and malaria).[147] This led to the Doha Declaration (2001), which stated "the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[148] The Declaration refers to a number of flexibilities, including the right to compulsory

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[139] *See id.* at 4.

[140] *See generally,* WHO 2018, *supra* note 38, at 14.

[141] *Id.* at 45.

[142] *Id.* at 11.

[143] *Id.*

[144] Emmanuel Kolawole Oke, *Territoriality in Intellectual Property Law: Examining the Tension between Securing Societal Goals and Treating Intellectual Property as an Investment Asset*, 15 SCRIPTED 313 (Oct. 2018), https://script-ed.org/article/territoriality-in-intellectual-property-law-examining-the-tension-between-securing-societal-goals-and-treating-intellectual-property-as-an-investment-asset/#:~:text=According%20to%20the%20principle%20of,of%20technological%20and%20economic%20development [https://perma.cc/TN7Y-W6CR].

[145] *Access to AIDS Medicines Stumbles on Trade Rules*, WORLD HEALTH ORG.: BULLETIN OF THE WORLD HEALTH ORG. (May 2006), https://www.who.int/bulletin/volumes/84/5/news10506/en/ [https://perma.cc/T5PA-7BP7].

[146] *Id.*

[147] *Id.*

[148] *Id.*

licenses.[149] It also extends the transition period during which the least-developed countries do not have to enforce or grant patents to pharmaceuticals.[150]

Under TRIPS, new drugs may be subject to at least twenty years of patent protection in all member nations, apart from the flexibilities for the least-developed countries and a few non-WTO members, such as Somalia.[151] Successful AIDS treatment programs, such as in Brazil or Thailand, were only possible because key pharmaceuticals were not patent protected and could be produced locally at a much lower cost than purchasing from the United States.[152] For example, when the Brazilian Government began producing generic AIDS drugs in 2000, prices dropped.[153] "The AIDS triple combination therapy, which costs $10,000 USD per patient a year in industrialized countries, can now be obtained from Indian generic drugs company, Cipla, for less than $200 USD per year."[154]

Developing countries manufacture their own generic drugs in an effort to make them more affordable for their citizens. However, they have reported being pressured by industrialized counties and the multinational pharmaceutical industry not to make the most of these provisions.[155] Even though the Doha Declaration can legally set aside patents, poorer countries are reluctant to "provok(e) the anger of the United States."[156] For example, when Brazil manufactured generic medications to treat AIDS, the United States filed a complaint to the WTO to drop the law, and then, to not use it. Brazil was successful in fighting back, but it is presumed that smaller countries would rather "give in" than fight.[157]

### *A. Caps on Capsules: Prescription from Abroad*

Despite differences globally, basically all countries do more than the American government in curbing pharmaceutical prices.[158] In countries with universal health care, their governments are motivated to help keep prescription drug costs contained (described here as "profit controls"). Thus, other nations have a lower threshold for accepting the pervasive drug pricing monopoly like in the United States.

There are several methods foreign nations employ to balance cost-containment and access to prescription drugs that should be considered stateside. For example, other countries may utilize a combination of "centralized price negotiations, national formularies, and comparative and cost-effectiveness research for determining price ceilings"[159]—the "cap" on capsules. In addition to direct price controls is another

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[149] *Id.*

[150] *Id.*

[151] *Id.*

[152] *Id.*

[153] *Id.*

[154] *Id.*

[155] *Id.*

[156] *Id.*

[157] *Id.*

[158] Sarnak et al., *supra* note 11, at 5.

[159] *Id.* at 8.

method known "external reference pricing" (ERP).[160] Under ERP, foreign governments permit sellers to set the price of pharmaceuticals by how much they are selling the same product in comparable markets. This would require price transparency. Additionally, once there is an agreement, some nations, like Canada, for example, caps the price drug manufacturers can raise it, and it has to align with national inflation rates.[161] Such a stipulation is not present in the American market.

Another method utilized by other countries is not just assessing whether a new drug is effective, but whether it is (1) *more* effective than existing therapies, and (2) if it is cost-effective.[162] For example, England's NICE, mentioned *supra* for refusing to cover Avastin, uses a quality of life formula in considering whether to cover certain medications.[163] NICE usually requires "that the cost per quality-adjusted life year (QALY) remain below 30,000 pounds ($39,000)" as a prerequisite for government coverage.[164] If the drug does not meet criteria, they would negotiate with the company for discounts and rebates.[165] Canada also pays for prescription drugs for its citizens and utilizes a similar method to the UK. The Canadian government has a quasi-judicial agency board, the Patented Medicine Prices Review Board, that will refuse to pay for medications it thinks are too excessive.[166] Drug manufacturers must either comply or be willing to lose the Canadian market.[167] Comparatively, research indicates that Americans consume more expensive drugs than their counterparts in other developed nations without any evidence of better outcomes.[168]

Another method is limiting patent protection. Introduced *supra* in the Lantus case study, patent protections and FDA marketing exclusivity in the United States, bolstered with practices like evergreening, contribute to excessive drug prices. Other countries are not as favorable to the practice. India, for example, prohibits evergreening.[169] Sanofi was also able to take advantage of the USTPO, and filed seventy-four patents in the U.S. for Lantus, compared with forty-six in all of Europe and twenty-five in Japan.[170] Additionally, "due in part to more friendly biosimilar regulatory requirements," Europe and Japan have more competitors for Lantus, two and three, respectively, compared to the United States' one.[171]

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[160] Difei Geng & Kamal Saggi, *Optimal Price Regulations in International Pharmaceutical Markets with Generic Competition*, 71 J. HEALTH ECON. 1 (Apr. 6, 2020), https://www.sciencedirect.com/science/article/abs/pii/S0167629619303844 [https://perma.cc/5YDH-W6R5].

[161] *Id.*

[162] Sarnak et al., *supra* note 11.

[163] Dearment, *supra* note 10.

[164] *Id.*

[165] *Id.*

[166] C. Michael White, *Why Cheaper Drugs From Canada Likely Won't Cure What Ails US*, THE CONVERSATION (Sept. 27, 2019), https://theconversation.com/why-cheaper-drugs-from-canada-likely-wont-cure-what-ails-us-121723 [https://perma.cc/9FAY-L93N].

[167] *Id.*

[168] Sarnak et al., *supra* note 11.

[169] India's Supreme Court refused to grant Novartis, a Swiss manufacturer, a patent extension on Gleevec and criticized Novartis' attempt to do so. *See* Collier, *supra* note 61.

[170] I-MAK, *supra* note 67, at 5.

[171] *Id.*

### *B. Does Cost-Containment Stifle Foreign Innovation?*

There is no straight-forward answer to whether cost-containment stifles foreign innovation. Because the United States has not had price controls on drug prices, it is impossible to observe the "natural experiment" of how much innovation would be stifled if both American and foreign drug manufacturers were unable to freely price their goods in the States to maximize their profits. Sanofi, for example, the French company that created Lantus, had a profit margin of 29.3% for its shareholders last year.[172] Unsurprisingly, most of that profit was made in the United States.[173]

It also should be noted that quantifying productivity with Europe versus the United States is more complicated than at first blush: a drug company's home base does not necessarily correlate with where it is developed.[174] For example, some foreign companies develop and manufacture their medications in the United States. Further complicating comparisons is the number of biosimilars approved in the United States each year, opening up, yet again, the "what is innovative" debate.

Several international biopharmaceutical companies are highly innovative and profitable in spite of being based in home countries with universal health care and profit controls. Switzerland is the home base to Roche and Novartis. AstraZeneca and GlaxoSmithKline are from England. Ireland has Allergan, Mallinckrodt, and Endo. Canada has Bausch. Bayer and Fresenius are German. The Netherlands has Mylan, and Novo Nordisk is located in nearby Denmark. Teva Pharmaceutical is in Israel. And as mentioned already, Sanofi is French.

These companies were singled out in this Comment because they were forty percent of the thirty-five pharmaceutical companies examined by Ledley et al. for *JAMA*. Researchers compared the profitability of the pharmaceutical industry with other industries with expensive, upfront research and development costs, like the technology (e.g., Google, Apple) and materials industries (e.g., 3M).[175] Altogether, the thirty-five pharmaceutical companies had a combined revenue of $11.5 trillion USD and were almost twice as profitable as the average nonpharmaceutical industry (13.8% versus 7.7%).[176] One can infer that to be competitive in the highly technical and regulated market of pharmaceuticals, these foreign companies have to be innovative.

Nevertheless, the United Kingdom was credited with being the most innovative European country in 2017 and has 2,066 biopharmaceutical companies. Germany had the highest amount of European drug patents that year (627) and has 1,201 biopharmaceutical companies.[177] There are other examples of countries "with low

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[172] *Net Income to Stockholders Margin for Sanofi*, FINBOX.COM, https://finbox.com/WBAG:SANO/explorer/ni_margin [https://perma.cc/4GWM-5GKS] (last accessed Aug. 29, 2020).

[173] Dearment, *supra* note 10.

[174] Stewart Lyman, *Which Countries Excel in Creating New Drugs? It's Complicated,* XCONOMY (Sept. 2, 2014), https://xconomy.com/seattle/2014/09/02/which-countries-excel-in-creating-new-drugs-its-complicated/ [https://perma.cc/8GLH-B4L4].

[175] Fred D. Ledley, Sarah Shonka McCoy, Gregory Vaughan & Ekaterina Galinka Cleary, *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, JAMA (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308 [https://perma.cc/8NHC-A7T9].

[176] *Id.*

[177] To view the European Top 10 list, see Alex Philippidis, *Top 10 European Biopharma Clusters*, GENETIC ENG'R & BIOTECHNOLOGY NEWS (Oct. 8, 2018), https://www.genengnews.com/a-lists/top-10-european-biopharma-clusters-5/ [https://perma.cc/6JHH-8ZSV].

domestic spending on drugs but lots of innovation."[178] Denmark and Israel, homes to Norvo Nordisk and Teva Pharmaceuticals, respectively, spend relatively little on their citizens' health care per capita ("only Costa Rica and Mexico spend less") but have "significant biopharma innovation."[179] Switzerland spends second to the United States on healthcare, but they cap out-of-pocket spending for their citizens (primary care, specialty care, and prescription drugs altogether are capped at the equivalent of $2,645 USD per adult).[180] They also boast 100% insurance coverage for their citizens. Nevertheless, Switzerland is highly innovative: two of the world's largest and highly innovative drug companies, Novartis and Roche, are based there.[181] In fact, six of the forty-eight new drugs approved in 2019 by FDA belonged to Novartis.[182] The converse is also true: Canada, with all of its healthcare protections for its citizens, is towards the bottom of all innovator countries.[183]

## V. U.S. REGULATIONS: PROTECTIONS AND LIMITATIONS

Medications are subject to dense regulatory framework. With safety and efficacy concerns, IP protection, as well as the limited ability of competition enforcement, the pharmaceutical industry is already highly regulated.[184] Nevertheless, different pharmaceutical markets are subject to different levels of regulation. This section summarizes current regulations in the American pharmaceutical industry.

### *A. Current Federal Regulations*

While there are currently no laws in the United States controlling pharmaceutical profits, the pharmaceutical industry argues that advances both in science and drug development have increased when Congress passed legislation that supports, promotes, and incentivizes innovation. "In reality, patent law and the exclusivities offered by FDA often act to inhibit innovation and confound public goals."[185] The government has also instilled measures to help the pharma industry with the assistance of federal funding.[186] Finally, the Bush Administration effectively limited CMS' ability to negotiate drug prices with the pharmaceutical companies.[187]

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[178] Dearment, *supra* note 10.

[179] *Id.*

[180] Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic & George Wharton, *International Health Care System Profiles*, COMMONWEALTH FUND (Jun. 5, 2020), https://www.commonwealthfund.org/international-health-policy-center/countries/united-states [https://perma.cc/TU5Q-CEJ5].

[181] Dearment, *supra* note 10.

[182] Jarvis, *supra* note 76.

[183] *Id.*

[184] OECD 2014, *supra* note 24, at 7.

[185] Julie Margetta Morgan & Stephanie Sterling, *Lowering Drug Prices*, GREAT DEMOCRACY INITIATIVE 9 (Nov. 2019), https://greatdemocracyinitiative.org/wp-content/uploads/2019/11/Final-Pharma-Blueprint.pdf [https://perma.cc/9CP5-EC37].

[186] *See generally id.* at 11.

[187] *See generally id.* at 12.

These policies include the Orphan Drug Act, the Hatch-Waxman Act, and the Medicare Modernization Act, among others.[188] It should be noted that this section is not meant to be inclusive of all current federal regulations (this would go beyond the scope and length of this Comment). Nevertheless, instead of regulating the pharmaceutical industry, U.S. lawmakers have instead opted to protect the pharmaceutical industry's monopolization on innovation and prices through Congress.

### *1. Orphan Drug Act*

The term "Orphan Drugs" refers to medications used in the treatment of rare diseases and conditions. The United States Orphan Drug Act (ODA) of 1983 is so-named because it refers specifically to drugs that treat rare diseases and conditions.[189] It was amended in 1984 to define rare diseases as those affecting less than 200,000 people in the United States. However, it also includes drugs for diseases affecting over 200,000 people if creating and selling the drug was not commercially viable.[190] Development of a medication is not commercially viable unless potential profits dwarf the cost of research and development. These conditions are considered "commercial orphans" because the population number of those afflicted with these conditions are too small to render commercially feasible development.[191] The Act was initially promulgated with good intentions. ODA helped the pharmaceutical industry by lowering barriers for orphan research and development, and protecting their markets with exclusivity.[192]

The major benefit of ODA is that it has been largely credited for the substantial increase of the creation of drugs for rare diseases. For example, the number of orphan designations jumped from just one in 1983 (the year the law passed), to forty in 1984, to ninety-one in 2018.[193] ODA helps protect these pioneering drugs from follow-on imitators.[194] One of the most important features of ODA is a seven-year period of marketing exclusivity for classified drugs for rare diseases. In short, a follow-on drug without any clinical benefit over an older, pioneer drug with ODA exclusivity will not be approved for sale in the United States.[195] ODA also aids drug developers by making annual grants available to either companies or academic-based researchers.[196] Along with these grants, these institutions can also enjoy a fifty percent tax credit for the research and development process.[197]

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[188] *Id.*

[189] Christopher-Paul Milne & Louis A. Cabanilla, *Orphan Drugs and Generics*, SCIENCEDIRECT (2007), https://www.sciencedirect.com/science/article/pii/B008045044X000249 [https://perma.cc/9C42-7HZB].

[190] *See* Matthew Herder, *What Is the Purpose of the Orphan Drug Act?*, PLOS MED. 2 (Jan. 14, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5207521/ [https://perma.cc/6XA2-W7M9].

[191] *Id.*

[192] *See* Milne & Cabanilla, *supra* note 189.

[193] Enrique Seoane-Vazquez, Rosa Rodriguez-Monguio, Sheryl L. Szeinbach & Jay Visaria, *Incentives for Orphan Drug Research and Development in the United States*, 3 ORPHANET J. RARE DISEASES 1, 3 (2008).

[194] *See id.* at 6.

[195] HOLLIS, *supra* note 80, at 6.

[196] *See id.* at 2, 6.

[197] *Id.* at 2.

Despite the noble purposes of ODA, the pharmaceutical industry has been exploiting this loophole. Critics insist drug manufacturers are manipulating the system and the ODA incentives need to be revisited.[198] Absent competition during the initial seven years of a drug's orphan classification, manufacturers not only have zero competition, but they can charge whatever price they want. Further, if the manufacturer can find another potentially curative effect for a different rare disease, the company can get another waiver on the same drug, in an endless Groundhog Day-esque cycle.

America's Health Insurance Plan claims that the pharmaceutical industry has "gamed the system," with manufacturers viewing ODA as a way to maximize profits by turning products that treat a small number of patients into multibillion-dollar sellers.[199] In 2017, Kaiser Health News published an investigation into orphan drug development. Their analysis suggests that pharma manufacturers milk ODA by having drugs gain orphan status after they were already approved for another disease.[200]

FDA officials have stated that before Kaiser's study was published, they did not realize how many existing drugs have been repurposed by companies, exploiting the loophole.[201] For example, a drug that can treat one cancer can be approved for multiple others. Novartis, the manufacturer for Gleevec, an effective cancer treatment for myeloid leukemia, has been awarded nine "orphan" approvals for other cancer treatments.[202] In contrast, Novartis tried to make the same argument for Gleevec to justify extending their patent in India. India's Supreme Court vehemently denied their request.[203]

Another example: Humira is a medication to treat rheumatoid arthritis. It is also the world's top-selling drug. Its 2016 revenues reached $7.6 billion USD in the third quarter in the United States and $11.8 billion worldwide. Now, it has achieved "orphan status" for juvenile arthritis, Crohn's disease, and more—giving AbbVie, its manufacturer, market exclusivity until 2023.[204] As these facts are laid open, it seems readily apparent that there needs to be policy reform. As it stands, FDA still insists on protecting the law.

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198 *See* Sarah Jane Tribble & Sydney Lupkin, *Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies*, KAISER HEALTH NEWS (Jan. 17, 2017), https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/?rel=0 [https://perma.cc/VA37-2Y7M].

199 *See How Drug Companies Game the Orphan Drug Act*, AMERICA'S HEALTH INS. PLANS (Sept. 10, 2018), https://www.ahip.org/how-drug-companies-game-the-orphan-drug-act/?rel=0 [https://perma.cc/SZK5-NEYE].

200 *See* Tribble & Lupkin, *supra* note 198.

201 *See "Orphan Drug Act" Is Turning Into a Scam*, TAHLEQUAH DAILY PRESS (Jan. 18, 2017), https://www.tahlequahdailypress.com/opinion/editorials/orphan-drug-act-is-turning-into-scam/article_1579a74d-83fc-5c39-b78d-dc6b12b3ce19.html [https://perma.cc/X69C-4BAQ].

202 *Id.*

203 Collier, *supra* note 61.

204 Susannah Luthi, *AbbVie Sued Over Humira 'Patent Thicket,'* MODERN HEALTHCARE (Mar. 19, 2019), https://www.modernhealthcare.com/politics-policy/abbvie-sued-over-humira-patent-thicket#:~:text=AbbVie%20holds%20about%20136%20patents,the%20drug%20was%20first%20introduced [https://perma.cc/E42J-C8M4].

### *2. The Hatch-Waxman Act*

The development of generic drugs was largely supported internationally by the Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act, in the United States in 1984. The Act not only defined generic drugs, but it also approved the methods by which they should be approved and regulated, thereby creating the generic drug industry as we know it today in the United States.[205] Generic drugs have been the focus in the quest for greater drug affordability, but not without the concerns that generic drugs could weaken the industry by simply producing a medication after the major research and development (along with all of the associated costs) has been finished by the brand name manufacturer.[206] Competition between generic and brand name industries is desirable for patient pockets; however, policies must maintain a delicate balance to ensure that one market does not dominate and destroy the other.[207]

The Hatch-Waxman Act was promulgated in response to *Roche Products, Inc. v. Bolar Pharmaceutical Co*.[208] Roche owned flurazepam and Bolar was planning on selling a copy of the drug after Roche's patents expired.[209] Bolar's plan was to time their approval to conveniently coincide with the expiration of Roche's patents. The essence of Roche's case was that Bolar was planning on developing and marketing flurazepam while the drug was still protected under Roche's patent.[210] The issue was that by doing preparatory efforts while the drug was still protected, Bolar was effectively infringing on Roche's patent.[211] Roche sued Bolar for patent infringement and ultimately won.[212]

From a public policy perspective, this case extended patent protection of the name brand drug manufacturers. If another manufacturer cannot begin working on a drug while the developer's patent is in full force, that means that work on the generic drug can only begin once the patent expires.[213] The approval process following patent expiration for generic purposes is around two to three years, thereby extending patent protection. Congress acted quickly after *Roche* was decided and passed the Hatch-Waxman Act.[214]

Broadly speaking, the Hatch-Waxman Act provides incentives for drug companies to challenge patents owned by innovators while simultaneously giving generics a research exemption that allows them to develop generic drugs while the branded patents are still in force—without the added liability of infringement.[215] Another feature of the act was to encourage a race to market by granting the first generic

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[205] Milne & Cabanilla, *supra* note 189.

[206] *Id.*

[207] *Id.*

[208] Flurazepam is a sedative. Roche Prod. v. Bolar Pharm., 733 F.2d 858, 860 (Fed. Cir. 1984).

[209] *Id.*

[210] *Id.*

[211] *Id.* at 865.

[212] *Id.*

[213] Andrew H. Berks, *The Hatch-Waxman Act (Simply Explained)*, BERKS IP LAW (June 10, 2019), https://berksiplaw.com/2019/06/the-hatch-waxman-act-simply-explained/ [https://perma.cc/GEP4-3GE5].

[214] *Id.*

[215] *Id.*

approval that challenges a patent listed in the "Orange Book" (a patent database of approved pharmaceuticals) with as much as 180 days of market exclusivity.[216] The generic sponsor will be able to price the drug at a premium during their 180 days.[217] This was designed to allow the first filer to earn a substantial return for both their investment in science, as well as the legal work needed when challenging a patented medication.[218] After the initial 180 days, typically other generic filers enter the market.[219]

The Hatch-Waxman Act also contains provisions that are favorable to the drug innovators. The act gave innovators FDA regulatory inclusivity (usually about five years for a new product), a period during which FDA will not approve a generic.[220] For a number of big drugs, these periods of inclusivity have been worth billions of dollars.[221]

### *3. The Bayh-Dole Act*

The Bayh-Dole Act is an unfortunate example of the United States already having the tools in its arsenal to combat pharmaceutical pricing, but never using them. Adopted by Congress in 1980, the bipartisan Bayh-Dole Act (the Patent and Trademark Law Amendments Act) allows institutions and grant recipients, such as universities, to hold the title to patents on inventions stemming from government-funded research. They are then permitted to license the rights to these inventions to the private sector, who further develop them for commercialization.[222]

Inventions conceived through federally funded research projects are required to be reported to the agency that funded the project, like NIH. The Act permits businesses (large and small) and nonprofits (including universities) to retain ownership of the inventions created with the assistance of federal funding. In turn, the organizations are expected to file for patent protection and to ensure commercialization upon licensing for the benefit of public health.[223]

Before the Bayh-Dole Act, no drug had been created from federally funded inventions.[224] Since the Bayh-Dole's inception, federal funding for drug development has been the new standard. The NIH alone, for example, supported ninety-seven percent of FDA approved drugs between 2010 and 2016.[225] As *The Economist* notes,

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[216] *Id.*

[217] Scott Gottlieb, *The HELP Committee's Fix for 180-Day Generic Marketing Exclusivity*, HEALTH AFF. BLOG (May 30, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190529.223594/full/ [https://perma.cc/ZD93-RVNA].

[218] *Id.*

[219] *Id.*

[220] Berks, *supra* note 213.

[221] *Id.*

[222] *Intellectual Property Policy*, NAT'L INSTS. OF HEALTH (Apr. 5, 2016), https://grants.nih.gov/policy/intell-property.htm [https://perma.cc/ZH4L-SARG].

[223] *Id.*

[224] Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, INFO. TECH. & INNOVATION FOUND. (Mar. 4, 2019), https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system [https://perma.cc/KLE5-Y98F].

[225] Jim Dryden, *Cutting NIH Budget Could Cripple Drug Development*, WASHINGTON UNIV. SCHOOL MED. ST. LOUIS (Nov. 16, 2017), https://medicine.wustl.edu/news/cutting-nih-budget-cripple-drug-development/ [https://perma.cc/4ND6-VU4A].

the Bayh-Dole Act "unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money."[226]

What happens to the medications once the private industry starts licensing the federally funded drugs? The companies price them however they want.[227] Congress intended to guard against such monopolization in the Bayh-Dole Act with a provision known as "march-in rights."[228] These march-in rights were intended to act as a hard stop to abuse and ensure that federally funded inventions were being used for the benefit of the public.[229] This was meant to include new medications being "available to the public on reasonable terms" or where public health or safety needs are not being satisfied.[230] Because up to half of all new medicines in the United States are invented at universities through taxpayer funding, it seems rational that the public should reap the benefits of inventions they helped fund.[231]

How many times has the United States exercised their march-in rights in nearly four decades? Exactly zero.[232] As mentioned *supra*, American taxpayers are forced to pay for federally funded pharmaceutical inventions twice: once for the research that the federal government paid for with taxpayer funds, and again as patients for monopolized and arbitrarily priced medicines.[233]

The fact that march-in rights have never been utilized by NIH/HHS means one of two things: either there have never been any abuses of publicly funded patents during this time period or that the government does not care enough to make medications affordable.[234] The NIH/HHS has repeatedly denied requests for the exercise of march-in rights because they do not believe that "reasonable terms" includes price considerations.[235] This is not likely to change any time soon, as President Trump swore in Alex M. Azar II, a senior executive at Eli Lilly for ten years, as the 24th Secretary of Health and Human Services.[236]

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[226] *Innovation's Golden Goose*, THE ECONOMIST (Dec. 14, 2002), https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose [https://perma.cc/2BLD-TA5P].

[227] Krista L. Cox, *The Government Already Has the Tools it Needs to Make Pharmaceutical Drugs Affordable—If It Really Wanted To*, ABOVE THE LAW (Dec. 7, 2017), https://abovethelaw.com/2017/12/the-government-already-has-the-tools-it-needs-to-make-pharmaceutical-drugs-affordable-if-it-really-wanted-to/ [https://perma.cc/Y4GV-6KQK].

[228] March-in rights, 35 U.S.C. § 203 (1980).

[229] *Id.*

[230] *Id.*; 35 U.S.C. § 201(f).

[231] *Id.*

[232] Cox, *supra* note 227.

[233] *Id.*

[234] Cox, *supra* note 227.

[235] *Id.*

[236] *Alex M. Azar II*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/about/leadership/secretary/alex-m-azar/index.html [https://perma.cc/PU3Z-H5TZ] (last visited Mar. 18, 2020).

### *4. The Medicare Modernization Act*

The United States Congress banned government negotiations on drug price regulation during the Bush Administration in 2003.[237] The Medicare Modernization Act (MMA) of 2003 established the Medicare Part D benefit.[238] The MMA included a provision, known as the "noninterference" clause, which stipulates that HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies . . . and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."[239] The provision effectively prohibited the United States Government from having a direct role in negotiating or setting drug prices in Medicare Part D.[240]

The Part D program allows the private insurers who provide prescription drug coverage to negotiate drug prices.[241] The private payors were given the authority to negotiate for drug prices, establish formularies, and apply utilization management tools to control costs since Medicare is not allowed to do so. This approach contrasts with how drug prices are determined in other federal programs, such as the mandatory drug price rebates in Medicaid and the use of ceiling prices and minimum discounts employed by the Department of Veterans Affairs[242] and the Department of Defense (they pay about half of retail value for medications).[243]

Since the inception of the MMA, some lawmakers have continued to press for legislation that would give the Secretary of HHS authority to negotiate drug prices for Medicare beneficiaries.[244] This policy concept has recently gained more attention in Congress because Democrats, who have historically been the strongest supporters of pharmaceutical price control regulation, now hold a majority in the United States House of Representatives. Ninety-two percent of Americans are in favor of letting the government negotiate drug prices for Medicare beneficiaries.[245] This move would mirror centralized pricing methods utilized in Europe.[246] As of this writing, the Trump Administration has not proposed any change in law nor taken a position on the

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[237] Gerard F. Anderson, Dennis G. Shea, Peter S. Hussey, Salomeh Keyhani & Laurie Zephyrin, *Donut Holes and Price Controls*, 23 HEALTH AFFAIRS (SUPPLEMENT 1) W4-396 (2004), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.W4.396 [https://perma.cc/M4GV-YQX4].

[238] *Id.*

[239] Mike McCaughan*, Prescription Drug Pricing #6 Medicare Part D*, HEALTHAFFAIRS (Aug. 10, 2017) https://www.healthaffairs.org/do/10.1377/hpb20171008.000172/full/#:~:text=%22Noninterference%22%20clause%3A%20A%20provision,formulary%20or%20institute%20a%20price [https://perma.cc/WA9D-R5VU].

[240] *See generally id.*

[241] *Id.*

[242] Juliette Cubanski, Tricia Neuman, Sarah True & Meredith Freed, *What's the Latest on Medicare Drug Price Negotiations?*, KAISER FAM. FOUND. (July 23, 2019), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/ [https://perma.cc/JS5L-94P2].

[243] Sarnak et al., *supra* note 11.

[244] Cubanski et al., *supra* note 242.

[245] Sarnak et al., *supra* note 11.

[246] *Id.*

congressional proposals to allow the government to negotiate drug prices. However, President Donald Trump expressed support for the idea prior to taking office.[247]

## *B. Proposed Federal Legislation*

Regulating pharmaceutical pricing is of concern to elected representatives. Instead of outright price controls, two senators introduced a bill in the summer of 2019 targeting manufacturers who use public funds in the creation of NMEs.

### *1. We PAID Act*

Two United States senators, Chris Van Hollen (D-Md) and Rick Scott (R-Fla), introduced bipartisan legislation to address the "skyrocketing" costs of drugs on July 31, 2019.[248] The We Protect American Investment in Drugs (We PAID) Act was created to ensure that prices of drugs developed using federal funds are set at "reasonable" levels.[249] Because taxpayers pay for the funding, the two senators argue (and as explained further *supra*), they should also be able to afford these drugs.[250]

If enacted, this act would allow the National Academy of Medicine to determine what is a reasonable price for a drug and to consider factors such as federal investment, affordability, research and development costs, the market for the drug, international and domestic sales, and public payer expenditures.[251] The act would also establish an independent committee, the Drug Affordability and Access Committee, to determine the price based on the National Academy of Medicine's study.[252] The manufacturers would have to enter licensing agreements with the government to ensure price control.[253] The two senators are hopeful that their bill will have momentum.

## *C. State Legislation*

Reducing the cost of prescription drugs is a small subset of issues that members of the House, Senate, and White House are interested in pursuing. Whether they can collectively agree on a policy solution is an entirely different matter. One tactic that some of the individual states are trying to induce is increased transparency. Because the United States is a multi-payor landscape, the actual prices of medications vary widely.[254] Their undisclosed discounts remain confidential (see MMA, *supra*), and ultimately, the general public has very little insight into the actual prices. States like

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[247] Glenn Kessler, *Trump's Truly Absurd Claim He Would Save $300 Billion a Year on Prescription Drugs*, WASH. POST (Feb. 18, 2016), https://www.washingtonpost.com/news/fact-checker/wp/2016/02/18/trumps-truly-absurd-claim-he-would-save-300-billion-a-year-on-prescription-drugs/ [https://perma.cc/KM5H-5T72].

[248] *Van Hollen, Scott Introduce Landmark Legislation to Address Skyrocketing Prescription Drug Costs*, CHRIS VAN HOLLEN, U.S. SENATOR FOR MD. (July 31, 2019), https://www.vanhollen.senate.gov/news/press-releases/van-hollen-scott-introduce-landmark-legislation-to-address-skyrocketing-prescription-drug-costs [https://perma.cc/HCD9-ZRD5].

[249] *Id.*

[250] *Id.*

[251] *See Van Hollen*, *supra* note 248.

[252] *Id.*

[253] *Id.*

[254] *See US Price Gouging in the Pharmaceutical Industry*, *supra* note 3.

California, Nevada, Maryland, and New York are all implementing legislation that seeks to provide transparency in prescription drug prices.[255]

In October 2017, California signed into law SB 17.[256] It requires drug manufacturers to notify purchasers at least sixty days before increasing the list price of a prescription drug by more than sixteen percent in a two-year period.[257] All drugs with a Wholesale Acquisition Cost or that cost more than $40.00 USD for a thirty-day supply will be subjected to the new legislation.[258] Meanwhile, health plans and insurers must self-disclose information that will be compiled in a consumer-friendly report highlighting the overall effects of drug costs on healthcare premiums. Vermont also has a drug transparency law (S.216). This law requires drug manufacturers to justify price increases exceeding fifty percent over five years or fifteen percent in a single year—if they place a substantial burden on the state—to the Attorney General's Office. They could face fines up to $10,000 USD if they fail to do so.[259]

Maryland approved a new "price gouging" law (HB 631) targeted towards essential generic and off-patent products that would cap prices for certain medications.[260] Maryland's law goes one step further than most transparency laws. Maryland's provisions essentially cap annual price increases to below fifty percent. This strategy likely would have been considered far too controversial for approval in the United States a few years earlier. Thanks to the pharmaceutical pricing landscapes' significant events during the past few years, public opinion of the industry has been markedly affected.[261]

It may not be surprising that the generic drugs trade association, Association for Accessible Medications (AAM), filed a lawsuit challenging the law's constitutionality.[262] First, AAM alleged that HB 631 violates the Commerce Clause of the United States Constitution. The Commerce Clause governs interstate commerce occurring between the states, thereby making it within the federal government's domain. The AAM was found to have standing because the law regulates commerce inside and outside of Maryland.[263]

AAM made their constitutional challenge based on several points. First, they argued that HB 631 specifically targeted transactions between pharmaceutical manufactures and wholesale distributors or retail pharmacy chains with centralized warehouses, none of which are in Maryland.[264] Furthermore, AAM alleged that pricing determinations were made on a national basis, and not within the state of Maryland.[265]

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[255] *Id.*

[256] *Id.*

[257] *Id.*

[258] *Id.*

[259] *Id.*

[260] David C. Gibbons & Jeffrey N. Wasserstein, *Maryland AG Seeks SCOTUS Review of Generics Price-Gouging Prohibition Struck Down by Fourth Circuit*, FDA LAW BLOG (Oct. 26, 2018), http://www.fdalawblog.net/2018/10/maryland-ag-seeks-scotus-review-of-generics-price-gouging-prohibition-struck-down-by-fourth-circuit/ [https://perma.cc/RWG3-24MG].

[261] *See US Price Gouging in the Pharmaceutical Industry*, *supra* note 3.

[262] *Id.*

[263] *See* Gibbons & Wasserstein, *supra* note 260.

[264] *Id.*

[265] *Id.*

AAM stated that "next to none of the largest drug manufacturers . . . reside in Maryland."[266] AAM went on to argue that price restraints imposed by HB 631 would "inevitably affect commercial transactions, pricing, and commerce in other states."[267]

The Fourth Circuit Court of Appeals agreed with AAM's argument and found that HB631 directly regulates transactions that take place outside Maryland.[268] The State of Maryland sought a writ of certiorari, concerned that this case sets "a precedent that would deprive a state of power to protect consumers from predatory commercial practices that originate out of state, even though they are directed into the state and will directly harm its citizens."[269] The writ was denied.[270]

## VI. CAPPED CAPSULES: POTENTIAL REPERCUSSIONS

If the United States were to curb the profit motive for pharmaceutical manufacturers through the myriad of options already in place overseas (i.e., limiting evergreening to measurable formulary changes, negotiating prices, capping the amount a medication's price can be raised in a given year, refusing to allow Medicare to reimburse expensive, low benefit medications, etc.), it would be naïve to think there would not be any consequences. For one, it's estimated that global profits would decrease by $134 billion USD.[271] It is also worth mentioning that price increases do not change the quantities ordered or manufacturing price; increased prices are strictly attributed to profits.[272]

Professor and economist Darren Filson describes a potential parade of horribles if the U.S. adopted European-like price controls. In a study partially funded by Pfizer, he asserts that drug corporations would fall in value by thirty-five percent, and the output of NMEs would decrease by forty percent to the detriment of consumer welfare.[273] As profit motives are decreased, drug companies may focus their attentions more on the potentiality of a drug's profit for rare diseases rather than its applicable use in more common, and less profitable, disease prevention and treatment[274] (however, there are salient arguments discussed *supra* that this is already the case).

Currently, manufacturers at home and abroad make most of their profits in the United States. The brunt of this burden is felt by Americans more than in other wealthy countries because many Americans remained uninsured or underinsured. Even those with insurance have fewer protections when compared with other countries. The CEO

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[266] *Id.*

[267] *Id.*

[268] Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 666 (4th Cir. 2018).

[269] Gibbons & Wasserstein, *supra* note 260.

[270] Jeff Barker, *U.S. Supreme Court Denies Maryland Bid to Revive Law Aimed at Preventing 'Monstrous' Generic Drug Price Increases*, BALTIMORE SUN (Feb. 19, 2019), https://www.baltimoresun.com/politics/bs-md-drug-price-gouging-decision-20190219-story.html [https://perma.cc/S69D-DRNW].

[271] *Id.*

[272] Dana Goldman & Darius Lakdawalla, *The Global Burden of Medical Innovation*, BROOKINGS (Jan. 30, 2018), https://www.brookings.edu/research/the-global-burden-of-medical-innovation/ [https://perma.cc/H9GF-Y9CH].

[273] Darren Filson, *A Markov-Perfect Equilibrium Model of the Impacts of Price Controls on the Performance of the Pharmaceutical Industry*, 43 RAND J. ECON. 110 (2012), https://www.jstor.org/stable/23209300 [https://perma.cc/D2Z4-LHMQ].

[274] White, *supra* note 166.

of French pharma company Genfit admitted "that the U.S. has been subsidizing innovation for the rest of the world."[275] Currently, other governments "get the best deal they can" from drug manufacturers because they can make up the difference from Americans.[276]

Because the U.S. government (mostly) stays out of price negotiations (current drug price negotiations are mainly between private insurers and the manufacturers), it would be a stark contrast if the government took the front seat. Say, for example, that the government decided to use Medicare bargaining power (it could be in a variety of forms, like refusing to reimburse for certain drugs that are not cost-effective, negotiate prices for vital medications like Lantus, or cap out of pocket spending for recipients), the drug industry may be forced to make profits elsewhere. Their negotiations in other countries may look different if the drug companies could not rely on making the bulk of their profits in the United States anymore and may end up raising their prices abroad.

Some researchers suggest that if prices in Europe increased, so would their innovation. With increased ability to make a profit, drug makers might be more incentivized to take the inherent risks involved in creating NMEs. Economists from the University of Southern California purport that if Europeans increased their drug prices just by twenty percent, it "would result in substantially more drug discovery worldwide," causing societal benefits that would have a global impact.[277] Europeans' lives—as well as those globally—may also be better for additional formularies.[278] Researchers concluded for every $2.5 billion of revenue, one NME could be produced.[279]

There is more to innovation than solely relying on profits. As mentioned *supra*, the United States has other methods in place to promote innovation aside from uncontrolled drug pricing, such as federally funded research, a strong patent system, and assistance from academia.[280]

## VII. CONCLUSION

Americans pay more for their medications than anywhere else on the planet.[281] Yet, despite its innovations and wealth, the United States has some of the worst healthcare outcomes of any other developed nation.[282] Pharmaceutical prices were not regulated by the federal United States government in the hopes that the industry would self-balance and self-correct as the market has for many other consumer goods. The

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[275] Dearment, *supra* note 10.

[276] White, *supra* note 166.

[277] Goldman & Lakdawalla, *supra* note 272.

[278] *Id*.

[279] Pierre Dubois, Olivier de Mouzon, Fiona Scott-Morton & Paul Seabright, *Market Size and Pharmaceutical Innovation*, 43 RAND J. ECON. 844 (Oct. 26, 2015), https://onlinelibrary.wiley.com/doi/full/10.1111/1756-2171.12113 [https://perma.cc/77AC-WJ8V].

[280] Dearment, *supra* note 10.

[281] Belk, *supra* note 12.

[282] Nisha Kurani, Daniel McDermott & Nicolas Shanosky, *How Does the Quality of the US Healthcare System Compare to Other Countries?*, PETERSON-KFF: HEALTH SYSTEM TRACKER (Aug. 20, 2020), https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/#item-start

problem, as judge and Republican Party Vice Chairman, Alex Kim, eloquently put it, "In a free market, everyone just does what's best for themselves."[283] Like modern-day conquistadors hoping to find gold in the new world, foreign drug manufacturers also reap the bulk of their profits in the United States. The pharma industry is not an altruistic one. It is a business. And because American taxes help fund the research for these drugs without ensuring universal access to them, the government should do more to regulate the industry to make pharmaceuticals more affordable.

The first concern is the circumstantial evidence of HHS' agency capture by the pharmaceutical industry. Almost a personification of this phenomenon is Secretary Azar. Prior to being a senior executive and CEO of Eli Lilly, he was an HHS attorney.[284] However, during his subsequent tenure at Eli Lilly, the price of insulin nearly doubled while he was CEO.[285] Now, as HHS Secretary, instead of regulating the industry at home, he has suggested that Americans should import their medications from Canada.[286] Without even having to make further policy changes, HHS already has march-in rights that it has never utilized. The MMA should also be repealed. Most Americans (ninety-two percent) already support the idea that Medicare should negotiate drug prices, like the large, public payors in other countries do.[287]

CMS should also institute a cost-benefit analysis when deciding whether or not to reimburse medications with little clinical value. This would also incentivize pharma to create drugs with greater efficacy, rather than focusing on the ones with the greatest price point. European-style profit controls should also be considered, including a mandate that the pharmaceutical companies reinvest a certain percentage of their profits back into research and development rather than utilize public funding. A great deal of pharmaceutical spending is on marketing, which should also be curbed. Drugs should not be advertised on television, directing consumers to ask their physicians about them.[288] This completely undermines the role physicians have in their decision-making and infringes upon the corporate practice of medicine. Further, still, is the connection between marketing and the prescribing rates of drugs. For example, between 2015 and 2017, pharmaceutical companies spent $39.7 million USD alone on opioid marketing. Researchers discovered the disturbing correlation between opioid marketing to physicians and patient deaths from overdoses.[289]

Proposed state legislation is promising. Drug companies should explain their rationale for drug increases, like the fifteen percent increase in an annual year mandated in Vermont to enhance market transparency. Price increases should stay aligned with national inflation rates versus arbitrary increases with little or no warning.

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[283] Telephone Interview with Justice Alex Kim, Vice Chairman, Tarrant Cty. Republican Party (Sept. 15, 2019).

[284] *Alex M. Azar II*, *supra* note 236.

[285] Alexandra Hutzler, *HHS Secretary Alex Azar Once Doubled the Price of Insulin. Now he Wants the Trump Administration to Import Drugs from Canada,* NEWSWEEK (Jul. 31, 2019), https://www.newsweek.com/hhs-alex-azar-import-cheaper-drugs-canada-1451931 [https://perma.cc/2TLQ-K9XZ].

[286] *Id.*

[287] Sarnak et al., *supra* note 11.

[288] Only one other country in the world, New Zealand, allows this.

[289] Bana Jobe, *Opioid Marketing Linked to Opioid Deaths*, BOS. MED. CTR. HEALTH SYS. (Jan. 19, 2019), https://www.bmc.org/healthcity/research/opioid-marketing-linked-opioid-overdose-deaths [https://perma.cc/PHV2-24G5].

While price regulation seems oppositional to the American free market system, it highlights another very American concept: choice. It's the choice between taking insulin as prescribed, or rationing a drug as essential to life as oxygen. Following price gouging by the pharmaceutical industry, the choice was already made for many Americans. Only after an overhaul of existing policies can prices be comparable to what other developed countries pay for their prescriptions. Once these means are accomplished, Americans can more freely appreciate the pharmaceutical industry's research and innovation as opposed to being victimized by it.