CAUSE AND EFFECT: A COMPARATIVE ANALYSIS ON HOW ALLOWING MEDICARE PHARMACEUTICAL PRICE NEGOTIATIONS COULD IMPACT RESEARCH AND THE GREATER PHARMACEUTICAL INDUSTRY

Jordan A. Huffman

TABLE OF CONTENTS

ABSTRACT

The costs of prescription medicines in the United States remain significantly higher than in most other developed nations. As part of this problem, the Medicare program, which purchases 17% of the pharmaceuticals sold in the United States, is prohibited by law from leveraging its purchasing power to negotiate the prices of the pharmaceuticals it purchases. This causes Medicare to pay exceptionally high prices for medicines sold elsewhere for much less—at a great cost to American taxpayers. While many feel that allowing the government to negotiate Medicare pharmaceutical prices would lead to a drastic reduction in innovation and investment in research and development spending, this belief

largely rests on speculation about the pharmaceutical industry itself. Much has been written on the impact that allowing the federal government to negotiate Medicare pharmaceutical prices might have. The current literature has yet to comparatively analyze the effects government price negotiations have had on research spending in countries which do negotiate the prices of their medicines. This note offers a comparative analysis between the pharmaceutical policies of the United States, the United Kingdom, and Australia. It looks to draw on the best practices of those countries to show the thoughtful implementation of governmental price controls on pharmaceutical drugs could effectively reduce prices while simultaneously maintaining research spending and positive patient outcomes in America.

I. INTRODUCTION

A. Understanding the Pharmaceutical Industry

In the broadest sense, people have studied medicine and pharmacology since ancient times.[1] Consider one example from Egypt: the Ebers papyrus. The Ebers papyrus described over 700 medicinal formulations as early as 1550 B.C.E.[2] Pharmaceutical companies as we know them today began to form during the industrial revolution, when local apothecaries moved into the wholesale production of drugs.[3] As of 2013, the global pharmaceutical company market was a 989 billion dollar industry; it is expected to reach 1.3 trillion dollars by 2018.[4] As a major member of the pharmaceutical market, the United States leads the world in pharmaceutical spending, accounting for 340 billion dollars of the global market in 2013.[5] This amounts to nearly 35% of the market share.[6] One study even showed that prescription drug use among Americans is higher than it has ever been, with over 48% of the American population having taken at least one

---

[1] *See generally, From Bench to Boardroom: Historical Developments in the Pharmaceutical Industry,* ENTREPRENEURSHIP REVIEW (Mar. 23, 2010), http://miter.mit.edu/articlebench-boardroom-historical-developments-pharmaceutical-industry/ (discussing the historical background of the pharmaceutical industry).

[2] *Id*.

[3] *See Emergence of the Pharmaceutical Science and Industry: 1870-1930,* CHEMICAL & ENGINEERING NEWS (Jan. 18, 2016 3:15 AM*),* http://pubs.acs.org/cen/coverstory/83/8325/8325emergence.html (regarding the rise of large scale drug production in the late 1800's).

[4] *See* IMS INST. FOR HEALTHCARE INFORMATICS, GLOBAL OUTLOOK FOR MEDICINES THROUGH 2018 1 (2014), http://static.correofarmaceutico.com/docs/2014/12/01/informe_ims.pdf [hereinafter GLOBAL OUTLOOK] (regarding the current size and expected growth of the global pharmaceutical industry).

[5] *Id*. at 12.

[6] *Id*.

prescription drug in the last month.[7] These facts understandably make our nation's pharmaceutical policy an issue of substantial concern, both to the American voter and to companies within the pharmaceutical industry.[8]

The pharmaceutical companies in many cases are multinational and multibillion-dollar corporations, with the twenty largest pharmaceutical companies accounting for over $461 billion of sales in 2013, or 64.3% of the combined industry market share.[9] One factor encouraging such market concentration is developing a new medicine for sale often takes years of research and millions, if not billions of dollars of investment.[10] Furthermore, even with such great investment, there is no guarantee that a company's research will discover a new medicine, or that a medicine being researched will not be developed by a competitor before the research is complete.[11] Yet, despite the great risk involved, companies that are able to develop new medicines enjoy patent exclusivity in the market, a market that remains one of the most profitable in the United States' economy.[12] The vast revenues of these pharmaceutical companies allow them to exert significant political power, contributing an industry total of more than $50.7 million to political campaigns in 2012, making any legislative action affecting the industry a contentious issue.[13]

B. Conflicting Interests—Consumer Protection and Free Market Capitalism

Unfortunately, because these pharmaceutical companies are profit driven like any other business, their interests do not always align with those of the general public. This is not always the case, though, because meeting consumers'

---

[7] Qiuping Gu et. al*., Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007–2008*, 1 (Sept. 2010), https://www.cdc.gov/nchs/data/databriefs/db42.pdf.

[8] *See generally Importance of Issues—Voters List Economy, Health Care, Spending as Top Issues*, RASMUSSEN REP. (June 16, 2014), http://www.rasmussenreports.com/public_content/politics/mood_of_america/importance_of_issues (showing 67% of survey respondents considered healthcare a very important issue for upcoming elections).

[9] EVALUATE PHARMA, WORLD PREVIEW 2014, OUTLOOK TO 2020 12 (2014), http://info.evaluategroup.com/rs/evaluatepharmaltd/images/EP240614.pdf (showing the high concentration of the pharmaceutical industry amongst a relatively small number of companies).

[10] *See generally* PHRMA, BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES (2016), http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf (speaking generally about failure risk and the high cost of drug development).

[11] *Id.*

[12] *Id*.

[13] *Pharmaceuticals / Health Products*, OPENSECRETS.ORG http://www.opensecrets.org/industries/indus.php?ind=h04 (last visited Jan. 18, 2016) (internal citations omitted) (summarizing the lobbying contributions of the pharmaceutical industry over recent years).

desires for safety, effectiveness, and cost effectiveness helps a drug company capture higher market shares from their competitors.[14] In practice, however, any effects from desires to satisfy consumers are limited by consumers' lack of knowledge and choice.[15] For instance, it can be assumed that a pharmaceutical consumer will naturally choose the safer of two equally effective drugs, but a consumer may often have limited knowledge about the actual probability of harm of a particular medicine.[16] Thus, in a market free of regulation, large investments for extensive safety research would not likely be justified by increased sales to consumers.[17] Moreover, a drug manufacturer's motivation to provide price-competitive medicine is also limited due to patent protections giving manufacturers short term monopolies for the sales of their drugs.[18] Consider the following hypothetical example:

> Drug X is a newly patented drug, the only drug available which can effectively treat Disease X. The drug costs $10,000,000 to produce and the disease affects 10,000 people. Market studies conducted by the manufacturer, showed that all 10,000 potential consumers would be willing to pay $1,100, netting 10% profit for the manufacturer. However, the same study also showed that 8,000 of the 10,000 suffering Disease X would be willing to pay $2,000 for the drug, netting the company 60% profit for the manufacturer.

Any profit driven company with knowledge of this study would certainly set the price for a drug at $2,000 rather than $1,100, even though this would leave 20% of those suffering from Disease X untreated. Because of this disconnect

---

[14] ANNETINE C. GELIJNS & ETHAN A. HALM, INST. MED., THE CHANGING ECONOMICS OF MEDICAL TECHNOLOGY COMMITTEE ON TECHNOLOGICAL INNOVATION IN MEDICINE 3 (1991) (ebook) (noting the importance of consumer feedbacks in production and research for future profitable projects).

[15] *Id.* The article cited comments generally on the limited knowledge available to patients when making treatment decisions. Safety information and statistics can be included in the broad range of information referenced by the article's authors that patient's do not have complete access to when making treatment decisions.

[16] *Id.*

[17] Enrique Fefer, *Pharmaceutical Regulation and Legislation*, *in* MDS-3: MANAGING ACCESS TO MEDICINES AND OTHER HEALTH TECHNOLOGIES § 6.2 (Mgmt. Scis. for Health ed., 2012) (noting the insufficiency of consumer knowledge to drive safety decisions).

[18] *See generally Patents and Exclusivity*, FDA/CDER SBIA CHRONICLES (CDER Small Bus. & Indus. Assistance, Silver Spring, M.D.) (May 19, 2015), http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307.pdf (outlining the different lengths of patent protections for different classes of medicines); *see also* Alfred Engelberg, *How Government Policy Promotes High Drug Prices,* HEALTH AFF. (Oct. 15, 2015), http://healthaffairs.org/blog/2015/10/29/how-government-policy-promotes-high-drug-prices/.

between the interests of drug manufacturers and the public welfare, and because of the large impact that pharmaceutical technology has on both the economy and public health, governments around the world must develop and implement legislation in order to regulate the industry and protect the interests of their citizens.[19]

As with any legislation, however, the interests of the public are often sharply divided. For instance, governments must balance the interest of public safety with the interest of affordable access to medicines, as more stringent testing regulations lead to higher development costs and consumer prices.[20] Decreasing consumer costs for pharmaceuticals can also lead to increased competitive pressure in the pharmaceutical industry, which often causes high paying jobs to be transferred overseas.[21] In any case, all of these interests must be accounted for when considering any new legislation, and the interests of both consumers and the pharmaceutical industry must be balanced for the greater common good. The following section will examine how the United States, United Kingdom, and Australia have developed polices to balance these interests.

II. LEGAL POLICIES OF THE PHARMACEUTICAL PROGRAMS OF AUSTRALIA, THE UNITED KINGDOM, AND THE UNITED STATES

A. American Pharmaceutical Policies—Medicare and Medicare Part D

In the United States, the buying and selling of pharmaceutical drugs has generally been a private market, with consumers buying the drugs on their own or in conjunction with privately purchased health insurance.[22] However, high levels of uninsured elderly Americans, extremely high insurance costs for the elderly, and poor access to treatment for low income individuals pushed the nation to pass the Social Security Amendments Act of 1965, establishing both Medicare and Medicaid as the nation's federally subsidized health program for disabled, elderly, and low income individuals.[23] In 2003, provisions in the Medicare Modernization

---

[19] *See generally* Fefer, *supra* note 17, at 6.1 (concerning the necessity of effective and comprehensive regulation of the pharmaceutical industry in order to protect public health).

[20] *Id.*

[21] *See* Jordan Weissman, *Once Again, Pfizer Is Trying to Move Overseas to Avoid U.S. Taxes*, SLATE: MONEY BOX (Apr. 26, 2016 6:14 PM), http://www.slate.com/blogs/moneybox/2015/11/23/pfizer_announces_merger_with_allergan_that_will_let_it_avoid_u_s_taxes.html (providing a case example of how competitive pressures can negatively impact jobs in the United States, causing them to be taken overseas).

[22] *See generally* Timothy Noah, *A Short History of Healthcare*, SLATE: CHATTERBOX (Apr. 26, 2016 6:45 PM), http://www.slate.com/articles/news_and_politics/chatterbox/2007/03/a_short_history_of_health_care.html (explaining the rise of private healthcare in the United States).

[23] Steve Anderson, *A Brief History of Medicare in America,* MEDICARERESOURCES.ORG (Oct. 26, 2016), https://www.medicareresources.org/basic-

Act expanded Medicare to include coverage of subsidized pharmaceuticals under Medicare Part D.[24] Today, more than 39 million Americans receive pharmaceutical drug benefits under Medicare Part D, which accounts for approximately 23% of pharmaceutical drug purchases within the United States.[25]

Individuals eligible for Medicare may elect to enroll in a prescription drug plan (PDP) under Medicare Part-D in order to receive coverage for the costs of prescription medications. These PDPs are regulated under and sponsored by Medicare Part-D but are administered by private health insurance companies who have fairly wide discretion in determining plan benefits.[26] The drugs covered by these PDPs vary depending on what drugs are included in that particular provider's formulary.[27] In many cases, these formularies may have a tiered system where a covered individual will pay differing amounts depending on the drug being purchased.[28] While the law under the Medicare Modernization Act does have some authority over what drugs must be covered by these PDPs, the task of negotiating the prices of these drugs was left specifically to the private insurance company administering the plan.[29] In fact, the language of the Medicare Modernization Act specifically prohibits the Government from being involved in the negotiations for the prices of drugs included in the PDPs' formularies.[30] This prohibition on governmental price negotiation is found in 42 USCS § 1395w-111(i), which reads as follows:

> In order to promote competition under this part [42 USCS §§ 1395w-101 et seq.] and in carrying out this part [42 USCS §§ 1395w-101 et seq.], the Secretary—
> (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and
> (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.[31]

---

medicare-information/brief-history-of-medicare/ (explaining the political motivations leading to the creation of the Medicare program); *see generally Social Security Act Amendments (1965)*, OURDOCUMENTS.GOV (Mar. 24, 2017), https://ourdocuments.gov/doc.php?flash=false&doc=99.

[24] *Id*.

[25] *Healthcare Reform Hits U.S. Drug Spending in 2010*, DRUG CHANNELS (Jan. 12, 2012), http://www.drugchannels.net/2012/01/healthcare-reform-hits-us-drug-spending.html [hereinafter *Healthcare Reform Hits*] (see chart under subtitle: Who Paid for Prescription Drugs in 2010?).

[26] *The Medicare Part D Prescription Drug Benefit,* HENRY J. KAISER FAMILY FOUND (Apr. 26, 2016 6:50 PM), http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/ (outlining the basics on how the Medicare Part D system works).

[27] *Id.*

[28] *Id.*

[29] *See generally* 42 U.S.C. § 1395w-104 b(3)G.

[30] *See generally* 42 U.S.C. § 1395w-111(i).

[31] *Id.*

This prohibition of governmental price negotiation in effect breaks down the ability of the government to leverage its buying power as a purchaser of a large percentage of the drugs in the American market.[32] It leaves the PDP sponsor companies to individually negotiate the prices for the drugs included in their formularies, with each PDP sponsor holding the purchasing power of only a small percentage of the Medicare Part-D enrollees.[33] This break up in the negotiating power of drug purchasers gives pharmaceutical companies a greater ability to charge higher prices to the PDP sponsors without running the risk of losing large quantities of sales, particularly when selling a high demand drug that consumers want included in the PDP's formulary.[34]

Two justifications are often given for this negotiating restriction. First, the restriction allegedly protects the quality of the formularies available to Medicare Part-D enrollees.[35] This argument is based upon the belief that the government would try to save costs by dropping important drugs from coverage if it were allowed to influence price negotiations or manage the specific drugs included in a PDP's formulary.[36] By allowing each of the PDPs to develop their own formularies and negotiate prices independently, the PDP sponsors are encouraged by competition to maintain coverage in their formularies for the best drugs available, and those in high demand with consumers.[37]

This argument is supported by a comparison between the formularies currently covered by Medicare PDPs and the Department of Veteran's Affairs (VA), which is allowed to control its formulary and negotiate prices with drug manufacturers. One study found that the formulary covered by the VA included only 59% of the top 200 drugs (by national sales volume), while formularies provided by Medicare Part-D PDPs included 85% of the top 200 drugs (on average, with the lowest inclusion percentage being 68%).[38] However, the ability of the VA to both control its formulary and negotiate prices had both a dramatic and negative impact on the prices it paid for its drugs, with this same study reporting that the VA paid on average only 60% of the prices paid by Medicare

---

[32] *See generally* Walid F. Gellad et al., *What if the Federal Government Negotiated Pharmaceutical Prices for Seniors? An Estimate of National Savings*, 23 J. GEN. INTERNAL MED. 1435–40 (Sept. 23, 2008) (on the anticompetitive effects of not being able to leverage buying power on pharmaceuticals, and potential cost savings if the policy were reversed).

[33] *Id.*

[34] *Id.*

[35] *See generally* Austin Frakt et al., *Should Medicare Adopt the Veterans Health Administration Formulary?* (Health Care Fin. & Econ., Working Paper No. 11-04, 2012), http://www.hcfe.research.va.gov/docs/wp_2011_04.pdf (regarding the necessity of formulary restrictions in order to maximize cost savings realized through price negotiations).

[36] *Id.* at 3.

[37] *Id.* at 7.

[38] *Id.* at 13 (regarding the comparative inclusion of the 200 most common drugs of the VA and PPD formularies).

Part-D PDPs for the same drugs.[39] If allowing Medicare Part-D to control its formulary and negotiate prices were to result in price efficiency similar to that of the VA benefits system, the government would stand to save almost $14 billion annually.[40] A second justification given for barring the government from involvement in Medicare Part-D price negotiations is that allowing negotiations would cause a sharp decrease in the profitability of the pharmaceutical industry, which would in turn result in the stagnation of the industry's research and development investment.[41] While this argument is worth analysis, it is also important to remember that while Medicare is one of the largest drug purchasers in the United States, it still only makes 23% of prescription drug purchases.[42] This means that any impact on research investment caused by allowing Medicare to negotiate prices would be significantly less severe in the United States than in a different country where the government held an even greater percentage of the market.[43] Likewise, however, the cost savings that could be expected by allowing Medicare price negotiations would similarly be somewhat less than if Medicare had negotiating leverage over a higher market share.[44] This relationship between research spending and profitability will be analyzed in depth in the following sections of this article.

B. Australian Pharmaceutical Policy and the Single Payer System

When compared with the United States, Australia has taken a significantly different path in developing its pharmaceutical policy. In 1948, the country established a government subsidized pharmaceutical plan known as the Pharmaceutical Benefits Scheme (PBS).[45] The scheme is currently operated under Australia's National Health Act of 1953; it provides all Australian citizens—and

---

[39] *Id.* at 6 (showing the average prices paid for medicines by the VA as only 60% of what is currently paid by the Medicare Part D program).

[40] Frakt et al*., supra* note 35*,* at 16 (comparing a 40% potential cost savings with the total cost of pharmaceutical purchases made by Medicare in 2014, as outlined by the 2014 Medicare Annual Report).

[41] Richard Frank & Joseph Newhouse, *Should Drug Prices Be Negotiated Under Part D Of Medicare? And If So, How?*, 27 HEALTH AFF. 33, 34 (2008), http://content.healthaffairs.org/content/27/1/33.full.pdf+html (commenting on the risk of slowing pharmaceutical innovation if Medicare price negotiations were to push prices too low).

[42] *Healthcare Reform Hits*, *supra* note 25.

[43] *Id.* (noting that a 23% percent market share has significantly less price leverage than would be achieved if Medicare were expanded to be a single payer system, and thus the both the cost savings and research impact would be dampened by the rest of the privatized market).

[44] *Id.*

[45] *See generally* Amanda Biggs, E-Brief, *The Pharmaceutical Benefits Scheme—An Overview,* PARLIAMENT AUSTL. (Jan. 2, 2003), http://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/Publications_Archive/archive/pbs (explaining the legislative history of the Australian Pharmaceutical Benefit Scheme).

citizens of some reciprocal nations—access to government subsidized medicines.[46] Under the law, once the Australian Drug Evaluation Committee (ADEC) approves a new drug for safety and efficacy, the manufacturer may apply to have it added and subsidized under the PBS.[47] The Pharmaceutical Benefits Advisory Committee (PBAC) evaluates applications for inclusion by evaluating the drug for effectiveness and cost effectiveness.[48] If the PBAC finds the drug both effective and cost efficient means for treating a condition, it recommends it for subsidization to the Parliament.[49] Not all pharmaceuticals become subsidized under this scheme, but the vast majority of drugs prescribed in Australia are subsidized under the PBS.[50] In 2014, it was estimated that 214.9 million for subsidized medicines, with only 74.2 million prescriptions being written for drugs not subsidized under the program.[51] Consumer costs under this system are quite limited, as out of pocket costs in 2014 were only $36.90 per prescription for general consumers and $6.00 per prescription for pensioner and concession patients.[52] Annual patient out-of-pocket payments are also capped under the PBS, with the 2014 general patient cap set at $1,421.20 and the concession patient cap set at $360 for the same year.[53]

It is important to note that prescriptions for concession patients have accounted for more than 60% of prescriptions written in Australia for the last several years because these purchases rely more heavily on government subsidization than general purchases or purchases made under copayment.[54] Copayment prescriptions and general prescriptions made up the second and third largest shares of prescriptions written, with private purchases making up only a very small percentage of all prescriptions.[55]

Beyond the base copays set by the PBS, a consumer may also have to pay brand premiums or a therapeutic group premium.[56] Brand premiums were

---

[46] *Id.*; *see generally* National Health Act 1953, AUSTRALIAN GOV., https://www.legislation.gov.au/Series/C1953A00095 (providing an additional overview of Australia's current National Health Act).

[47] AUSTRALIAN PHARM. BENEFITS DIV., AUSTRALIAN STATISTICS ON MEDICINES 2014 6 (2015), http://www.pbs.gov.au/statistics/asm/2014/australian-statistics-on-medicines-2014.pdf [hereinafter AUSTL. STATISTICS 2014] (explaining the path from approval to subsidization for pharmaceutical drugs covered under the Pharmaceutical Benefits Scheme).

[48] *Id.*

[49] *Id.*

[50] *Id.* at 32.

[51] *Id.* at 30–31.

[52] AUSTL. STATISTICS 2014, *supra* note 47, at 7.

[53] *Id.*

[54] *Id.* at 32.

[55] *Id.* at fig.B (outlining the number of prescriptions by payment classification).

[56] *See* Hans Lofgren, *Generic Drugs: International Trends and Policy Developments in Australia*, 27 AUSTRALIAN HEALTH REV. 39, 44–45 (2004) (regarding the additional co-payments required of pharmaceutical beneficiaries electing branded medicines and other brand and generic policies).

introduced in 1990 though policy changes to the PBS, and legislation regarding brand substitutions was passed in 1994 to amend the National Health Act of 1953 to specifically allow pharmacists to substitute bioequivalent drugs for brand name drugs without seeking authorization from the prescribing doctor.[57] Consumers are charged brand premiums when they purchase drugs that have an equivalent generic drug available at a lower cost.[58] In these instances, the Australian government will only subsidize the drug up to the cost of the lowest price generic, with the remaining difference being charged to the consumer as a brand premium.[59] If no generic drug is available, then the government will likely subsidize the whole price of the drug, unless the drug is assigned a therapeutic group premium.[60]

Therapeutic group premiums are groups of drugs that are non-equivalent but can interchangeably treat a given condition with similar safety and efficacy.[61] If a drug is being prescribed to treat a condition for which there are other cheaper drugs in the same therapeutic group, then the cost of the drug will only be subsidized up to the price of the cheapest drug in that therapeutic group, with the remaining cost passing on to the consumer as a therapeutic group premium.[62] This ensures that the Australian government does not end up paying prices disproportionate to the efficacy of a medicine; it also encourages pharmaceutical companies to price their branded medicines proportionally to the medicine's therapeutic advantage.[63] Furthermore, the provisions allowing pharmacists to exchange equivalent drugs to non-branded generics without a doctor's consent allows consumers greater control over choosing with which medicine they want to be treated.[64] These premiums also act to discourage excessive pharmaceutical marketing toward doctors, because even if doctors were convinced to prescribe more expensive branded medicines, a sale would still not be guaranteed if the consumer felt the price for the branded medicine was not justified.[65]

C. The Pharmaceutical Policy of the United Kingdom—Profit Capping and Value Based Pricing

In the United Kingdom, the government has adopted a hybrid pharmaceutical policy system, containing elements similar to both the Medicare system found in the United States and the PBS used in Australia. The UK government has provided its citizens with public healthcare since 1948 through

---

57 *Id.*
58 *Id.*
59 Lofgren, *supra* note 56.
60 *Id.*
61 *Id.*
62 *Id.*
63 *Id.*
64 Lofgren, *supra* note 56.
65 *Id.*

the establishment of national healthcare services in England, Wales, Northern Ireland, and Scotland.[66] Collectively, these publicly funded healthcare systems are referred to as the National Health Service.[67] Though each of the four systems are implemented and regulated by each country's parliament, many of the policies and rules governing the National Health Service are jointly enacted by all four systems.[68] This makes the individual National Health Service programs found in the four nations similar to the state-level Medicare systems found in the United States. Pharmaceutical benefits are provided to the citizens under all of the National Health Service programs, however, these services may be provided for differently in each of the countries within the United Kingdom.[69] However, unlike the Medicare system in the United States, prices paid to manufacturers for the medicines provided by the National Health Service are set at the national level.[70]

This pricing of National Health Service medicines is done through two systems: the voluntary scheme and the statutory scheme. These systems are applied throughout the National Health Service in the United Kingdom.[71] Both systems operate to control prices that the government pays for branded pharmaceutical medicines, though pharmaceutical sellers electing to take part in the voluntary scheme are not covered under the laws of the statutory scheme.[72] Unbranded or generic drug prices are also negotiated, but through a different process.[73]

The voluntary scheme was enacted by law through § 261(1) of the National Health Services Act of 2006, which reads:

> The powers under this section may be exercised where there is in existence a scheme (referred to in this section and sections 262 and 263 as a "voluntary scheme") made by the Secretary of State and the industry body for the purpose of—

---

[66] *See generally* Konstantina Grosios et al., *Overview of Healthcare in the UK*, 1 EPMA J. 529, 529 (2010) (concerning the history and organizational makeup of the healthcare system of the United Kingdom).

[67] *Id.*

[68] *Id.* at 530.

[69] *Id*.

[70] *See* ASS'N BRITISH PHARM. INDUS., UNDERSTANDING THE 2014 PHARMACEUTICAL PRICE REGULATION SCHEME 1 (2016), http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding_pprs2014.pdf [hereinafter 2014 PHARM. PRICE REGULATION] (explaining the overall payment system established between the government of the United Kingdom and the British pharmaceutical industry).

[71] *Id.* at 1, 7 (commenting that the PPRS voluntary system is used in all four countries within the United Kingdom, and noting, on page 7, that any company not falling under the PPRS will fall under the statutory scheme).

[72] *Id.* at 4.

[73] *Id*. While important, the negotiation of unbranded drug prices will not be discussed in depth in this article, in part because the prices of unbranded drugs are not normally inflated to the same degree as branded drugs.

> (a) limiting the prices which may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines, or
> (b) limiting the profits which may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any health service medicines.[74]

Under the voluntary scheme, drug manufacturers may elect to accept the prices offered by the UK's Department of Health, which negotiates the prices with the Association of the British Pharmaceutical Industry (ABPI) for the following five years.[75] The ABPI also negotiates with the Department of Health to set a reasonable maximum profit margin for members of the pharmaceutical industry.[76] These members of the pharmaceutical industry may elect to set their own prices for their medicines as long as their overall profit margin is below the negotiated maximum.[77] If a pharmaceutical company electing to participate in this profit-capping plan exceeds the negotiated maximum profit level, the company must pay the excess profits back to the government the following year.[78]

As noted in the name of the voluntary scheme, participation in the plan is optional for a drug manufacturer. The voluntary scheme does offer drug manufacturers certain advantages, however, because the prices and price increase rates set under the scheme are negotiated for several years at a time.[79] This allows a drug manufacturer to better forecast its future sales and profits compared to a company covered by the UK's statutory pricing scheme.[80] Participation in the profit-capping portion of the voluntary scheme also allows more flexibility in the pricing of individual medicines when compared with the statutory scheme, which could make it more likely for a company to actually achieve the target profitability level when compared to a company covered under the statutory scheme.[81]

The UK's statutory scheme is established by law in § 263(1) of the National Health Services Act of 2006, which reads as follows:

> The Secretary of State may, after consultation with the industry body, make a scheme (referred to in this section and section 264 as a statutory scheme) for the purpose of—

---

74 National Health Services Act 2006, c. 41, § 261(1) (U.K.).

75 2014 PHARM. PRICE REGULATION, *supra* note 70, at 1 (outlining the negotiating process between the United Kingdom's Department of Health and the Association of the British Pharmaceutical Industry).

76 *Id.* at 6–8 (explaining the profit payback system of the PPRS).

77 *Id.*

78 *Id.*

79 *Id.* at 1 (noting the stability of a multi-year agreement against the uncertainty of the statutory scheme).

80 2014 PHARM. PRICE REGULATION, *supra* note 70, at 1.

81 *Id*. (The overall flexibility of the voluntary scheme allows a company to better adapt to changing market conditions by giving it some control over its own drug pricing.)

> (a) limiting the prices which may be charged by any manufacturer or supplier for the supply of any health service medicines, or
> (b) limiting the profits which may accrue to any manufacturer or supplier in connection with the manufacture or supply of any health service medicines.[82]

Under the United Kingdom's statutory pricing scheme, drug prices for medicines offered by the National Health Services are similarly negotiated between the United Kingdom's Department of Health and the ABPI, but the agreed upon prices apply to all drug manufacturers not covered under the voluntary scheme.[83] Only the price of medicine is controlled, allowing a drug producer to earn profits in excess of those allowable under the voluntary scheme's profit caps.[84] However, the prices set under the statutory scheme are presumably set at low enough limits to assure this is uncommon, as evidenced by the scheme's low levels of participation.[85] The statutory scheme also varies from the voluntary scheme in that it does not create long-term price and price growth plans, making unpredictable changes in the prices offered by the National Health Service a possibility each year.[86] Because of these disadvantages—and the government's motivation in increasing enrollment in the voluntary scheme when setting statutory scheme price caps—the vast majority of pharmaceutical companies doing business in the United Kingdom currently elect to be covered under the voluntary scheme.[87] This trend is shown in an ABPI report, which calculated that only 7% of branded pharmaceutical sales were made under the statutory scheme, compared to 93% of branded sales made under the voluntary scheme.[88]

In both of the United Kingdom's schemes, the ability of the government to set medicine prices has also given the government the ability to use prices to

---

[82] National Health Services Act 2006, c. 41, § 263(1) (U.K.).

[83] *See* DEPARTMENT OF HEALTH, CONSULTATION ON CHANGES TO THE STATUTORY SCHEME TO CONTROL THE PRICES OF BRANDED HEALTH SERVICE MEDICINES, 2015, at 5–6 (U.K.), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/459219/stat_scheme_consultation_2015.pdf (explaining the purpose and process of implementation of statutory scheme price regulations).

[84] 2014 PHARM. PRICE REGULATION, *supra* note 70, at 7-8 (noting that the statutory scheme only controls price not profit).

[85] David Watson, *ABPI Statement on the Department of Health Consultation on Changes to the Statutory Scheme*, ABPI (Apr. 26, 2016), http://www.abpi.org.uk/mediacentre/newsreleases/2015/Pages/100915.aspx (showing that the statutory scheme currently only covers approximately seven percent of drug sales in the United Kingdom, presumably because the prices being set have made the voluntary scheme a generally more profitable option).

[86] *Id.* (noting the benefit of price certainty offered to pharmaceutical companies through the voluntary scheme but not included in the statutory scheme).

[87] *Id*. (noting the vast majority of companies who have joined the voluntary scheme).

[88] *Id.*

encourage pharmaceutical development and innovation in specific areas; the government has done this through the National Health Service's value-based pricing system, for example.[89] Under this system, new drugs which vary only slightly in efficacy from previously existing generic drugs are offered small price premiums, while drugs offering substantial increases in efficacy are given high price premiums.[90] While it may seem quite simple, the policy serves to prohibit the common practice whereby pharmaceutical companies continually make slight modifications to medicines and re-patent them to keep an edge over generic medicines.[91] This ensures that research and development dollars are spent in meaningful ways, likely to provide the maximum benefit to the public.

III. ANALYSIS—HOW DOES POLICY IMPACT INDUSTRY?

A. The Research Argument

One of the most common arguments made against allowing the American government to negotiate pharmaceutical prices at a national level is that the government would inevitably use its leverage to squeeze pharmaceutical companies to such an extent that they would need to significantly reduce their research spending in order to remain profitable.[92] The belief behind this argument is if government negotiations leveraged down the profitability of individual drugs, then pharmaceutical companies would be forced to concentrate their research into developing only highly profitable drugs, while neglecting to perform research on drugs for which the negotiated prices would no longer justify the expected research costs.[93]

In many cases, this type of profit-limited research investment already takes place as a result of the extensive FDA drug approval process.[94] Often times, promising drugs do not have a large enough market to justify going through the expensive process of FDA approval.[95] One particular study even showed that

---

[89] *See* DEPARTMENT OF HEALTH, THE PHARMACEUTICAL PRICE REGULATION SCHEME 2014, 2013, at 22–26 (U.K.), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf (outlining how pricing decisions are made through the practice of value based pricing).

[90] *Id.*

[91] *Id*.

[92] *See generally* Frank & Newhouse, *supra* note 41 (regarding the risk of slowed innovation associated with decreased profitability in the pharmaceutical market).

[93] *Id.*

[94] AVIK ROY, MANHATTAN INST., PROJECT FDA REPORT, NO. 5, STIFLING NEW CURES: THE TRUE COST OF LENGTHY CLINICAL DRUG TRIALS 7 (2012), http://www.manhattan-institute.org/pdf/fda_05.pdf (noting how the high cost of bringing new medicines through the FDA approval process is directing research and development funds away from many promising medicines where the expected return from sales does not outweigh the cost of getting the drug approved).

[95] *Id.*

leading pharmaceutical companies spent an average of almost 5.8 billion dollars to develop and gain FDA approval for the new drugs approved between 1997 and 2011.[96] In the analysis of these astronomical research and development costs, it was found that Phase III research costs, which normally occur after a drug is shown to be generally effective, represented almost 40% of total research expenditures and 90% of expenditures on any individual drug.[97] It stands to reason that, in the face of such high developmental costs, drugs that could treat conditions experienced by only a few thousand individuals would never even be considered for development because the prices required to make such a drug profitable would be beyond what almost any consumer would be able to pay. Similarly, if the government were able to leverage its bargaining power to lower selling prices of medicines, it is possible that fringe drugs with a low margin of profitability would be less likely to see development.

While this argument follows logically, in practice, this effect may be much less likely to occur than pharmaceutical manufacturers would suggest. This is because current profit margins within the pharmaceutical industry remain high enough that even if governmental negotiations did reduce profit margins significantly, pharmaceutical manufacturing would still remain a good investment.[98] Furthermore, programs such as the United States' Orphan Drug Program already help to offset the drug development costs of pharmaceuticals intended to treat diseases where less than 200,000 people suffer from the disease or where the expected revenue from the drug is not expected to pay for the cost of drug development.[99]

B. Pharmaceutical Profits Compared to Other Industry Profits

Comparing the pharmaceutical industry's profit margins to those of other industries—especially industries with similar economic considerations—reveals that pharmaceutical companies in the United States still enjoy significantly advantageous profit margins.[100] Consider technology companies producing computers or phones. Like pharmaceutical companies, technology companies

---

[96] *Id.* at 1.

[97] *Id.* at 2.

[98] *See* Aswath Damodaran, *Margins by Sector (U.S.)*, DAMODARAN ONLINE, http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/margin.html (last updated Jan. 31. 2017). The data collected by NYU shows that the biotechnology drug sector enjoyed an after-tax lease & R&D adjusted profit margin of 30.75% and that the pharmaceutical drug sector enjoyed a similarly high after-tax lease & R&D adjusted profit margin of 23.87%. *Id.* This shows that both sectors could see a significant decrease in their profit margins and still be well above the average 9.32% after-tax lease & R&D adjusted profit margin measured across all industries. *Id.*

[99] *See generally Developing Products for Rare Diseases & Conditions*, FDA, http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm20055 25.htm (last updated Jan. 5, 2017) (explaining the FDA's Orphan Drug Program).

[100] Damodaran, *supra* note 98.

have high start-up research costs and remain competitive in the industry only by continually innovating and patenting technology. Risks are also high because both industries run the risk of investing large sums of money only to have a competitor develop and patent a similar product first.[101]

One study, performed by New York University's Stern School of Business, performed such a comparison by calculating the after tax, lease, and research and development adjusted profit margins of different industry sectors within the United States.[102] This study found the drug industry's margins to be 23.87% for pharmaceutical drugs and 30.8% for bio-technologic drugs, compared to only 3.30% in consumer and office electronics, 9.98% for aerospace and defense, and 9.32% as the average across all industries.[103] In fact, the after tax lease and research and development adjusted profit margin of the biotechnology drug sector was the second highest out of the 94 industries analyzed.[104] This shows that even if federal Medicare Part-D price negotiations were to cut the profit margins of pharmaceutical companies in half, down to 11.90%, the industry would still be achieving a margin higher than the current average of all industries.[105] The individual analysis of the profit margins of several larger American pharmaceutical companies shows the disproportion of profit margins in this industry to an even greater extent. In 2013, for instance, Pfizer Inc. netted profits exceeding 42% of total revenue.[106]

C. The American Subsidization of the Pharmaceutical Industry

Governments also must now take into account how local and national laws will interact in an increasingly globalized market when drafting and passing legislation.[107] As players within the pharmaceutical industry are increasingly

---

[101] Andrew Lo, *How Does Increased Competition Affect Research-Intensive Industries?*, WORLD ECON. FORUM (Mar. 24, 2015), https://www.weforum.org/agenda /2015/03/how-does-increased-competition-affect-research-intensive-industries (speaking generally about the risks in research intensive industries, especially the biopharma).

[102] Damodaran, *supra* note 98 (comparing profit margins between selected American industry sectors).

[103] *Id.* (noting the relative average profit margins of the major industry sectors in the United States).

[104] Damodaran, *supra* note 98.

[105] *Id.*

[106] PFIZER INC., 2014 FINANCIAL REPORT 16 (2014), http://www.pfizer.com/system/ files/presentation/2014_Pfizer_Financial_Report.pdf (noting net income to Pfizer as a percentage of total revenue).

[107] *See generally* Frank Lichtenberg, *Pharmaceutical Companies' Variation Of Drug Prices Within and Among Countries Can Improve Long-Term Social Well-Being*, 30 HEALTH AFFAIRS 1539 (2011), http://content.healthaffairs.org/content/30/8/1539.full.pdf +html (concerning the increasingly globalized nature of the pharmaceutical market, and possible advantages having nationally differentiated prices could have on research investment).

global, drug companies selling medicines in the United States now market their medicines in several other countries as well.[108] Though the expenses and research costs of these companies are often centered in the country in which they are headquartered, the revenues of these companies are brought in from all over the world.[109]

This national diversity within the pharmaceutical consumer market creates inherent differences in the prices consumers experience. As a result of the differences in each nation's pharmaceutical legislation, price reflexivity within the market varies significantly around the globe.[110] Many countries that allow their national governments to negotiate prices on medicines currently experience significantly lower costs for medicines than those seen in the United States.[111] Consider again the comparison between the United States, the United Kingdom, and Australia. In 2008, Australia spent $509 per capita on pharmaceutical expenditures, the United Kingdom spent $367, and the United States, $960.[112] To explain this vast disparity in expenditures, some point out that America is generally less healthy, which causes more drugs to be purchased and a higher per capita expenditure.[113] With some studies showing that over 48% of the American population may be taking a prescription drug in a given month, this theory certainly sounds appealing.[114] However, even if the prices of individual drugs are considered, Americans still pay much more than consumers in other countries.[115]

Studies have consistently shown that the United States pays significantly more than almost all other countries for the most popular drugs.[116] One such study even found that for the twenty most popular prescription drugs, the United States spends an average of three times the amount spent in the United Kingdom.[117] The price difference for individual medicines was even greater between the United States and developing nations such as Brazil, where the same

---

[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] *Pharmaceutical Expenditure Per Capita,* OECD iLIBRARY (June 30, 2014), http://www.oecd-ilibrary.org/social-issues-migration-health/pharmaceutical-expenditure-per-capita-2014-1_pharmexpcap-table-2014-1-en (showing per capita pharmaceutical drug expenditures among OECD countries).

[112] *Id.*

[113] Jim Purcell, Opinion, *Unhealthy Lifestyles Fuel Health Care Cost Increases*, PROVIDENCE BUS. NEWS (Dec. 14, 2013, 12:05 AM), http://pbn.com/Unhealthy-lifestyles-fuel-health-care-cost-increases,93727.

[114] Qiuping Gu et. al*., supra* note 7.

[115] *See generally* Ben Hirschler, *Exclusive—Transatlantic Divide: How U.S. Pays Three Times More for Drugs,* REUTERS (Oct. 12, 2015), http://www.reuters.com/article/us-pharmaceuticals-usa-comparison-idUSKCN0S61KU20151012 (noting how the average costs of many of the most common drugs are up to three times high in the United States than they are in the United Kingdom, and many times higher than in other developing countries).

[116] Hirschler, *supra* note 115.

[117] *Id.*

medicines were sold on average for only one sixth of what was paid in the United States.[118] Though some note that the costs of medicines recorded in the United States often do not take into consideration undisclosed price discounts offered to insurance companies, the vast difference in prices remains striking.[119]

This price inequality implies that the United States is largely subsidizing the global pharmaceutical industry, in part due to our government not maximizing its negotiating power to reduce the prices of these drugs.[120] If the United States allowed the national government to negotiate drug prices, pharmaceutical companies would have to adjust their pricing strategies to cover their expenses with a greater percentage of foreign revenues. In theory, this would help reduce the highly inflated prices Americans currently pay for their medicines to prices more comparable with those being paid in other countries.

1. Does Increased Profitability Motivate Increased American Research?

The argument that a highly profitable drug pricing system motivates greater research investment might justify America's over expenditure on pharmaceuticals to some extent, as many would find motivating innovation in the medical field worthwhile despite an increased cost. A look at the differentiation of investment in research and development across international lines supports this theory to some degree. One study analyzing these research and development investment levels found in 2014 the United States pharmaceutical industry spent the equivalent of 21% of pharmaceutical sales on research and development investments, marginally higher than the 17% of sales invested in research and development by the European Union.[121] Furthermore, the United States spent the highest amount of any country on research and development, totaling over 49 billion in 2014, or 35% of the global investment.[122]

On the surface, this seems to indicate that the high profitability in the United States drug market may have encouraged higher R&D investment levels. However, when one considers that the United States pharmaceutical sales makes up 35% of the total market, a 35% share in global R&D investment is only what would be expected if the United States' share of research expenditures were to

---

[118] *Id.*

[119] *Id.*

[120] *See generally* Frank & Newhouse, *supra* note 41 (noting how the lack of negotiating power can lead to higher prices).

[121] INT'L FED'N PHARM. MFRS. & ASS'NS, THE PHARMACEUTICAL INDUSTRY AND GLOBAL HEALTH FACTS AND FIGURES 2014 13 (2015), http://www.ifpma.org/wp-content/uploads/2016/02/IFPMA-Facts-And-Figures-2014.pdf [hereinafter FACTS AND FIGURES 2014].

[122] *Id.* at 41 (showing global R&D investments of 137 billion USD and an American R&D expenditure of 49 billion USD).

match its share in global sales.[123] Also, if the $340 billion total global sales of American-made pharmaceuticals are also included, then United States $49 billion investment in research and development accounts for only 14.4% of sales.[124] This shows that increased market profitability in the United States did not increase research-spending rates significantly.

This diminishing return relationship between profits and research investment can be highlighted by comparing the profitability and research spending of pharmaceutical companies in nations, which allow their governments to negotiate for much lower drug prices. For instance, the pharmaceutical industry in the United Kingdom has consistently seen research and development spending levels above 30% of sales, reaching 34.8%, 34.1%, and 33.8% in 2011, 2012, and 2013 respectively, despite having a marginally lower industry profitability than the United States.[125]

Research spending in Australia came out at a much lower percentage—only 7% of industry revenue in 2011—but during the same year, the Australian pharmaceutical industry only saw 2.5% profits.[126] While this does support the finding that drastically lowering profitability will have a negative impact on research spending, one must also note that only a very small percentage of the company's manufacturing and selling in Australia were actually headquartered there.[127] In fact, one study found only 3% of the drugs used in Australia were manufactured by Australian companies, which could indicate that many of the pharmaceutical companies involved in the Australian market are spending their research and development dollars in their home nation and simply manufacturing in Australia.[128] By these comparisons it becomes clear while profitability does

---

[123] GLOBAL OUTLOOK, *supra* note 4, at 34 (concerning the US market share in global pharmaceutical sales).

[124] *Compare id.*, *with* FACTS AND FIGURES 2014, *supra* note 121, at 41 (concerning the drop in the percentage of sales used for R&D investment by the United States if global sale of the American Pharmaceutical industry are considered in total sales.).

[125] *Research and Development*, ASS'N BRITISH PHARMACEUTICAL INDUSTRY fig.6 (Jan. 18, 2016), http://www.abpi.org.uk/industry-info/archive/knowledge-hub/randd/Pages/expenditure.aspx#5 (showing year to year R&D investments as a percentage of sales).

[126] *See* MEDICINES AUSTL., THE AUSTRALIAN PHARMACEUTICALS INDUSTRY WINDS OF CHANGE 7 (2010), https://medicinesaustralia.com.au/files/2011/03/20100603-pub-MedicinesAustralia-winds-of-Change.pdf [hereinafter WINDS OF CHANGE] (relating to the size of the Australian Pharmaceutical Market and amount invested in research and development—$20 .7 billion in industry turnover and $929 million in research investment); *see also* Arna Richardson, *Healthy and Wealthy: The Industry Maintains Mature Growth as Competition Intensifies*, *in* IBIS WORLD INDUSTRY REPORT, PHARMACIES IN AUSTRALIA (IBIS World, Report No. G525a, 3, 2012) (The report shows an annual industry revenue of $12.4 billion with only $310 million in profits. This equates to a net profit margin of only 2.5%).

[127] WINDS OF CHANGE, *supra* note 126, at 8 (displaying a chart that shows only 3% of Australian pharmaceutical sales were made by companies with corporate headquarters inside Australia).

[128] *Id.*

seem to have some impact on research spending, large scale governmental price negotiations do not necessarily lead to drastically lower profit margins or drastically reduced research spending.

2. Increased Profitability in Wealthy Nations Allows for Greater Access to Pharmaceuticals in Poor Nations

A second argument often made to justify unequal international drug pricing is if prices were held equal around the world, many poor people in developing areas would lose access to medications because they would not be able to afford prices similar to those charged in richer nations.[129] The fact that pharmaceutical companies most often sell their medications in these countries at deeply discounted rates helps to protect the local population's access to these medicines. This type of unequal pricing can be differentiated from the unequal pricing experienced between higher income nations by recognizing the differences in price elasticity of consumers from different income levels. Generally, consumers in wealthier nations pay prices below the maximum price they would be willing to pay to have access to an effective medicine to treat their diseases.[130] Thus, there tends to be lower levels of upward price elasticity in these markets compared to lower income markets where consumers could not afford increased prices and even a relatively small increase in price might result in non-sales.[131] However, even when comparing the United States against nations with similar economic and market characteristics, Americans still pay prices above those paid by virtually all of our economic peers.[132] This means that the previously mentioned drug accessibility argument, while a valid moral argument generally, still cannot account for the levels of price inequality between the United States and other developed nations with similar financial circumstances.

Thus, while there is ethical merit in accepting that higher income nations should pay higher prices, the Unites States is doing more than its fair share in this regard by paying significantly more for its medicines than other nations of similar economic prosperity. Ideally, countries with equal economic advantage would pay equally to cover the costs of developing and manufacturing medicines. This

---

[129] *See generally* Lichtenberg, *supra* note 107.

[130] *See id.*

[131] *See* David Henry & Andrew Searles, *Pharmaceutical Pricing Policy*, *in* MDS-3: MANAGING ACCESS TO MEDICINES AND OTHER HEALTH TECHNOLOGIES, *supra* note 17, § 9.2 (noting the difference in price elasticity in low income countries).

[132] ORG. ECON. CO-OPERATION & DEV., PHARMACEUTICAL PRICING POLICIES IN A GLOBAL MARKET 28 (2008), http://apps.who.int/medicinedocs/documents/s19834en/s19834en.pdf [hereinafter OECD, GLOBAL MARKET] (showing a chart with US per capita expenditures as the highest amongst the OECD, including nations with higher GDPs per capita).

is a reality when comparing many developed nations, but not for the United States, which remains a high paying nation in the developed world.[133]

V. IMPLICATIONS FOR THE FUTURE

A. How Could the United States Implement Price Negotiation for Medicare Part-D?

Since the passage of the Medicare Modernization Act in 2003, many calls to lift the prohibition on governmental drug price negotiation have been made.[134] Several bills were even introduced into congress for this purpose, with the Medicare Prescription Drug Price Negotiation Act of 2007 even being passed in the House of Representatives.[135] This bill would have required Medicare to negotiate the prices it was paying for covered drugs, but it was later blocked in the Senate.[136] More recently, a similar bill was introduced in the United States Senate called the Medicare Prescription Drug Price Negotiation Act of 2015.[137] This bill would amend 42 USCS § 1395w-111(i), replacing the text barring governmental price negotiations with the following:

> (i) Negotiation Of Lower Drug Prices.—
> (1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under an MA–PD plan.
> (2) NO CHANGE IN RULES FOR FORMULARIES.—
> (A) IN GENERAL.—Nothing in paragraph (1) shall be construed to authorize the Secretary to establish or require a particular formulary.
> (B) CONSTRUCTION.—Subparagraph (A) shall not be construed as affecting the Secretary's authority to ensure

---

[133] *Id.* (noting the clustering of per capita pharmaceutical expenditures of most OECD nation, with the United States as an outlier).

[134] David Morgan, *Obama Administration Seeks to Negotiate Medicare Drug Prices*, REUTERS (Feb. 2, 2015), http://www.reuters.com/article/us-usa-budget-medicare-idUSKBN0L61OW20150202 (regarding calls made by the Obama administration for Congress to pass legislation allowing Medicare Part D price negotiation).

[135] Medicare Prescription Drug Price Negotiation Act of 2007, H.R. 4, 110th Cong. (2007).

[136] *Id*.

[137] Medicare Prescription Drug Price Negotiation Act of 2015, S. 31, 114th Cong. (2015).

> appropriate and adequate access to covered part D drugs under prescription drug plans and under MA–PD plans, including compliance of such plans with formulary requirements under section 1860D–4(b)(3).
> (3) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan, or an organization offering an MA–PD plan, from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated under paragraph (1).[138]

If a bill like this were to be enacted, it would change the question from whether the government should be negotiating Medicare Part-D drug prices to how the government should be negotiating Medicare Part-D drug prices. As shown by the differences in the systems of the United Kingdom and Australia, there is certainly more than one way for a government to negotiate prices, with each offering distinct advantages. Any new system implemented for negotiating the prices of Medicare Part-D could be modeled after the systems of both the United Kingdom and Australia, combining the most effective strategies from them to create a plan that would match with the United States' policy goals for the Medicare program.

Implementing a system of value-based pricing, like that used in the United Kingdom, could help to direct research expenditures toward developing new medicines that offer significant benefits over those currently available instead of toward developing new patentable versions of existing medicines that only offer minor improvements in effectiveness. Similarly, implementing a system of brand premiums or therapeutic group premiums, similar to those used in Australia, could serve to motivate consumers to purchase generic drugs whenever possible, in turn leveraging premium brand producers to reduce their prices to be closer to those of generics. Implementing this would require the creation of some governmental body that could evaluate the relative efficacy and therapeutic value of medicines, similar in function to the PBAC of Australia.

Unfortunately, the United States has yet to adopt a comparative body like those mentioned above. The FDA currently evaluates the efficacy of each drug individually, but does not do comparative analysis of the efficacy of one drug versus another.[139] Though such an organization would not come without costs, these costs could be offset by the tax dollars saved by lowering prices of Medicare medicines. With a potential savings of up to $28 billion annually, significant tax dollar savings could be reasonably applied for this purpose.[140] Additionally, having such an independent review on the comparative efficacy of medicines might also reduce the amount of money spent by drug companies on marketing

---

[138] *Id.*

[139] Nadia Kounang, *Why Pharmaceuticals Are Cheaper Abroad*, CNN (Sept. 28, 2015), http://www.cnn.com/2015/09/28/health/us-pays-more-for-drugs/ (noting the United States lack of an independent agency that performs comparative studies of drug efficacy).

[140] *See supra* Part III(A); Frakt et al., *supra* note 35.

and divert some of that money back into meaningful research. With the ability and duty to investigate the efficacy and value of each medicine considered for purchase by the Medicare program, this body would also be in a better position to ensure that Medicare did not restrict efficacious and beneficial medicines from its formulary, something which is a common criticism of the VA and Medicaid pharmaceutical benefit plans.[141] In a situation where more than one medicine was found to be effective, but to varying degrees, a system of therapeutic group premiums like those of Australia could again prove advantageous. Such a system could allow the government to keep all of the medicines included under the Medicare formulary, but would pass the difference in cost on to the consumer. This could help prevent formulary restriction, and would also encourage consumer drug purchasers to make mindful cost decisions.

The government should also consider that extremely low profitability levels did correspond with significantly decreased research and development spending in Australia, while in the United Kingdom, research expenditure levels remained higher than in the United States, despite a marginally lower profit level.[142] This might encourage any entity in charge of setting negotiated prices to aim for only a moderate reduction in prices, in order to ensure that any reduction in research spending was optimally balanced to the amount being saved in price reductions.

Research spending could also be incentivized despite price reductions through increased tax incentives similar to those used both the United Kingdom and Australia.[143] This could encourage pharmaceutical companies to spend a higher percentage of revenues toward research versus other expenditures such as the advertising and marketing of marginally superior medicines.

Allowing the Medicare program to negotiate the prices it pays for its medicines could inadvertently cause pharmaceutical companies to shift their costs to private insurance purchasers in order to compensate for lower prices being paid by Medicare. This effect could lead to somewhat higher costs in the private market, but the effect would most likely be marginal due to the private insurance companies' ability to negotiate prices on their own behalf. Furthermore, this cost shifting would not be limited to America alone, as decreased profitability from negotiated Medicare purchases might also lead to increased prices in public pharmaceutical benefits programs of other countries which already negotiate the prices of drug purchases. This could greatly decrease the extent that Medicare has been effectively subsidizing the pharmaceutical industry and would encourage pharmaceutical companies to charge other countries' health plans prices more comparable to those being charged to Medicare.

---

[141] *See* Frakt et al., *supra* note 35.

[142] *Supra* Part IV(C)(1).

[143] *See generally* 2014 PHARM. PRICE REGULATION, *supra* note 70 (regarding the research and development tax incentives in the United Kingdom); *see also* AUSTL. STATISTICS 2014, *supra* note 47 (regarding tax incentives as part of Australian pharmaceutical policy).

VI. CONCLUSION

When the effectiveness of the Medicare Part-D pharmaceutical benefits scheme is compared with benefits schemes allowing governmental price negotiation, it becomes clear that the Medicare program could experience considerable cost savings if the ban on price negotiation was repealed. These other benefits schemes, such as the United Kingdom's NATIONAL HEALTH SERVICE, Australia's PBS, or the United States' VA Pharmaceutical Benefits Program, are able to consistently negotiate prices lower than those paid for by the Medicare Program, and these savings contribute significantly to lower per capita pharmaceutical expenditures in the United Kingdom and Australia.[144]

Legislation has been introduced several times in the United States Congress to repeal the Medicare Part-D price negotiation ban, but thus far these changes have not been enacted due to fears that allowing price negotiation might negatively impact research spending and drug availability within Medicare's formulary. The validity of these concerns is supported in some ways by comparisons with other benefits schemes. One such comparison, discussed above, showed that the Australian pharmaceutical industry currently invests in research at a much lower rate than the United States, arguably because it experiences only 2.5% profit margins.[145] Another comparison between the formularies of Medicare Part D and the VA Pharmaceutical Benefits Program also revealed that the current Medicare formulary covers a significantly higher percentage of commonly used drugs than the VA formulary, which is permitted to negotiate prices with pharmaceutical manufacturers.[146]

However, other comparisons discussed above painted a different picture. The comparison between the United States and the United Kingdom's National Health Service pharmaceutical benefits plan showed that despite negotiating for much lower prices on medicines, the United Kingdom was able to maintain research and investment rates higher than those in the United States.[147] This shows that with when implemented carefully and thoughtfully, legislation allowing price negotiations could achieve a reduction in the price of Medicare Part D, while simultaneously incentivizing research and protecting formulary access to beneficial medicines. Tried and effective practices used in United Kingdom—such as value based pricing and reasonable and moderate profit targets could be incorporated into the Medicare system—encouraging research investment into developing medicines that offer significant increases in efficacy compared to medications that only slightly modify existing drugs in order to extend patent protections. Incorporating a government body into the price negotiations, similar to Australia's Pharmaceutical Benefits Advisory Committee, could also help independently evaluate the effectiveness and value of individual medicines, helping to ensure that formulary restrictions like those experienced with the VA

144 OECD, GLOBAL MARKET, *supra* note 132.
145 *Supra* note 126 and accompanying text.
146 Frakt et al., *supra* note 35, at 13.
147 *Research and Development, supra* note 125, fig.6.

formulary would not exclude medicines with significant benefits over cheaper available options.

In conjunction with allowing the Medicare program to negotiate its drug prices, other related measures could be taken to help drive down costs and maintain research investment. Increasing tax incentives was one method used in the United Kingdom to help maintain research investment in a lower profit market, a method that could also be used in the United States. Also, incorporating reforms to the burdensome FDA approval process to might stimulate research investing to an even greater degree. With a decreased cost associated gaining FDA approval for new drugs, many promising medicines previously viewed as unprofitable might be put back on the track towards development.

Put most simply, a comparison between America's current Medicare system and the pharmaceutical benefits systems of the United Kingdom and Australia shows two things. First, that significant cost savings have been realized in other nations, and might also be realized within the United States by allowing governmental price negotiations for pharmaceutical medicines. Second, although these price negotiations would decrease profitability in the pharmaceutical industry, the risk of such a decrease negatively impacting research investment could be effectively mitigated if successful practices from abroad were thoughtfully incorporated into the Medicare system. Such a change carries risk, but also a great opportunity for making Medicare Part D much more affordable.