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INTRODUCTION

The costs of pharmaceuticals have been steadily increasing in many countries, including those in the Organization for Economic Cooperation and Development ("OECD"), a cohort of nations with similarly developed economies as the United States.[1] Since 1998, OECD countries have collectively increased their spending on pharmaceuticals by an average of thirty-two percent, after adjusting for inflation.[2] In 2013, pharmaceutical spending across OECD countries reached approximately $800 billion, which accounted for nearly twenty percent of total health spending on average.[3] This trend is even more pronounced in the United States, where retail prescription drug spending has increased from $90 per person in 1960 to $1,025 per person in 2017.[4] While a significant portion of this increase in spending represents the cost of buying new and innovative products, part of the increase is the result of the incentives on pharmaceutical companies and a balancing act in which individual countries engage.[5]

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[1] Neeraj Sood et al., *The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries*, HEALTH AFF.: WEB EXCLUSIVE (2008), www.healthaffairs.org/doi/pdf/10.1377/hlthaff.28.1.w125; *Our Global Reach*, OECD, https://www.oecd.org/about/members-and-partners/ (last visited on Dec. 31, 2020).

[2] Sood et al., *supra* note 1, at w125.

[3] Ed Silverman, *Soaring Prescription Drug Prices Take Big Bite Out of National Budgets*, STAT NEWS (Nov. 4, 2015), https://www.statnews.com/2015/11/04/soaring-prescription-drug-prices-take-big-bite-out-of-national-budgets/.

[4] Rabah Kamal et al., *What are the Recent and Forecasted Trends in Prescription Drug Spending?*, HEALTH SYS. TRACKER (Apr. 14, 2020), www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-nominal-and-inflation-adjusted-increase-in-rx-spending_2017.

[5] Toon van der Gronde et al., *Addressing the Challenge of High-Priced Prescription Drugs in the Era of Precision Medicine*, 12 PLOS ONE 1, 22–23 (2017).

Pharmaceutical companies are incentivized to differentiate prices on a country-to-country basis in order to achieve the highest possible profits in each country.[6] This leaves governments with conflicting internal incentives. On the one hand, governments have good reason to expedite their price negotiations by accepting pharmaceutical companies' sticker prices to avoid delaying the introduction of innovative new drugs; however, they also want to reduce healthcare spending by negotiating prices that consumers can afford to pay.[7] The idea is that when governments agree to pay premium prices, drug companies are incentivized to develop and launch new drugs faster, but consumers are left with higher costs as a result.[8] Unlike almost every other OECD country, the U.S. government does not control reimbursement prices for pharmaceuticals and drug companies are therefore free to set their own prices based on market calculations aimed at maximizing profits.[9] As a result, U.S. prescription drug prices are among the highest in the world,[10] which results in clinical as well as economic consequences for U.S. patients who pay an increasing share of drug expenses in the form of co-payments.[11]

While patients face these high costs, the pharmaceutical industry enjoys higher profit margins than many other industries.[12] For example, in 2002, the median profit margin of the top ten drug companies in the United States was seventeen percent, compared to a margin of 3.1% for all the other industries on the Fortune 500 list.[13] Even more striking, those ten companies generated more in profits that year than the remainder of the Fortune 500 list combined.[14] Some researchers contend that these abnormally high profit margins justify regulatory interventions that improve access and affordability by reducing the costs of pharmaceuticals.[15] On the other hand, some analysts point to research that suggests that the high cost and low output nature of drug development causes investments in new pharmaceuticals to be more of

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[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] So-Yeon Kang et al., *Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries*, 38 HEALTH AFF. 804, 804–11 (2019).
[11] Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 864 (2016).
[12] Marcia Angell, *Excess in the Pharmaceutical Industry*, 171 CAN. MED. ASS'N J. 1451, 1451–53 (2004).
[13] *Id.*
[14] *Id.*
[15] Sood et al., *supra* note 1, at w131.

a gamble than other investments.[16] These analysts argue that such high profits are necessary to incentivize drug companies to engage in the high risk process of pharmaceutical research and development ("R&D") which facilitates the creation of new medications.[17]

This paper seeks to add to the debate regarding regulatory intervention in the pharmaceutical industry by focusing on a recently proposed policy called the International Price Index ("IPI"). Part I will explain the structure of the IPI, the issues it seeks to address, and criticisms from those who claim that it will have devastating effects on revenue in the pharmaceutical industry. Part II analyzes these criticisms through an economic analysis of market power in the pharmaceutical industry and the capacity of consumers to negotiate. Part III compares the IPI to another regulatory intervention with a similar policy mechanism. Part IV predicts the effect that the IPI will have on prices and revenue based on an analysis of the elasticity of demand for pharmaceuticals. Part V then offers a brief conclusion.

I. THE INTERNATIONAL PRICE INDEX

A. Background of Medicare Part B and Structure of the IPI

The IPI was proposed by U.S. Health and Human Services Secretary, Alex Azar, in 2018 as a way to reduce the costs of Medicare Part B drugs.[18] Medicare Part B covers physician-administered therapies such as biologics, injectables, IVIG, immunoglobulins, and other products.[19] Medicare Part B plays an important role in the market for cancer, ophthalmic, and rheumatology therapies because manufacturers' pricing strategies are influenced by Medicare Part B's reimbursement.[20] In other words, the Part B program affects pricing patterns in private markets.[21] The drugs covered

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[16] WAYNE WINEGARDEN, THE ECONOMICS OF PHARMACEUTICAL PRICING 6 (Pac. Res. Inst., June 2014), https://www.pacificresearch.org/wp-content/uploads/2017/06/Phama PricingF.pdf (explaining that the cost of capital for investments into research and development for new pharmaceuticals must compensate investors for the risks and cost associated with bringing new pharmaceuticals to market).

[17] Sood et al., *supra* note 1, at w126.

[18] Susan Peschin & Duane Schulthess, *International Pricing Index 'Accomplishes Nothing it Sets Out to Do,'* STAT NEWS (Oct. 21, 2019), https://www.statnews.com/2019/10/21/international-pricing-index-research-development/.

[19] Adam J. Fein, *Follow the Vial: The Buy-and-Bill System for Distribution and Reimbursement of Provider-Administered Outpatient Drugs*, DRUG CHANNELS (Oct. 14, 2016), https://www.drugchannels.net/2016/10/follow-vial-buy-and-bill-system-for.html.

[20] Cole Werble, *Health Policy Brief: Medicare Part B*, HEALTH AFF., 1, 1 (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000171/full/healthpolicybrief_171.pdf.

[21] *Id.*

under Medicare Part B are often some of the most innovative and expensive, and thus expenditures on Part B drugs have increased faster than other Medicare expenditures over the last twenty years.[22] As a result, Medicare Part B is both a controversial, as well as a potentially fruitful, area for policy reform.

As calculated under the IPI model, Medicare currently pays 180% of the average international price for the drugs covered under the Part B program.[23] This disparity has led industry and U.S. government officials to argue that, because of foreign governments' regulations on drug prices, they are not paying for their fair share of R&D costs and thus unfairly benefit from the innovation for which the United States pays.[24] While such claims may not be entirely accurate,[25] it is clear that these arguments were a motivating force behind the IPI.[26] The IPI's central purpose, then, is to pressure other countries to be more flexible in their current price regulations of pharmaceuticals.[27] The IPI would create this pressure on other countries to increase prices by setting a price ceiling on Medicare's reimbursement for various drugs.[28]

Currently, Medicare Part B reimbursement is a "buy-and-bill" process.[29] Under this process, a doctor or other provider purchases the drugs they require using their own source of funds.[30] Then, after administering the drugs

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[22] *Id.*

[23] Duane Schulthess et al., *Tying Medicare Part B Drug Prices to International Reference Pricing Will Devastate R&D*, 53 THERAPEUTIC INNOVATION & REG. SCI. 746, 746–748 (2019).

[24] Salomeh Keyhani et al., *US Pharmaceutical Innovation in an International Context*, 100 AM. J. PUB. HEALTH 1075, 1075–81 (2010).

[25] Donald W. Light & Joel Lexchin, *Foreign Free Riders and the High Price of US Medicines*, 331 BMJ PUB. GROUP 958, 958–60 (2005) (A "free rider" is a term economists use in the context of an accounting method that assigns the fixed costs of a product to different groups based on the prices that each group pays. To illustrate, "if Group A (call it Europe) pays $1 per pill and Group B (call it the U.S.) pays $2 a pill and each buys a million pills, then this accounting method would assign half as much of the fixed cost to Group A as to Group B." The term can be misleading, though depending on various circumstances. For example, "[i]f, however, the fixed costs are only $300,000 (a tenth of the total revenue) for the two million pills, the fixed costs could be allocated by volume rather than by price ($150,000 for each group) and [one could] conclude that Group A more than pays the fixed costs and Group B pays much more than it has to.").

[26] Keyhani, *supra* note 24, at 1.

[27] *What You Need to Know about President Trump Cutting Down on Foreign Freeloading,* DEP'T. HEALTH & HUM. SERVS. (Oct. 25, 2018), https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html.

[28] Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54,546, 54,556 (Oct. 30, 2018) [hereinafter Pricing Index Model, 83 Fed. Reg.].

[29] Fein, *supra* note 19.

[30] *Id.*

to a patient, the provider files a reimbursement claim to Medicare.[31] Medicare pays the provider the portion of the cost for which it is responsible and the provider is responsible for collecting the patient's share of the drug reimbursement.[32]Under the IPI model, the amount of reimbursement that Medicare could provide for Part B drugs would be limited based on the average prices in the Indexed Countries,[33] which include Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy,[34] CMS would determine the average international price for each drug included in the model based on a standard equivalent units of drugs in the Indexed Countries.[35] The ceiling for the reimbursement of each unit of the particular drugs would be set by multiplying the average international price by 126%.[36]

The IPI is proposed to be implemented over a five-year period, during which its ramifications will be examined.[37] CMS stated that it would examine whether the model affects the quality of care that U.S. patients receive, the availability of drugs, and the IPI's overall costs.[38] Reimbursement prices during the rollout of the model would be calculated based on a mixture of average sales prices ("ASP") in the United States and the indexed price, adjusted to not exceed a thirty percent decrease from current prices, using the following compositions:

Year 1: eighty percent of ASP + twenty percent of target price
Year 2: sixty percent of ASP + forty percent of target price
Year 3: forty percent of ASP + sixty percent of target price
Year 4: twenty percent of ASP + eighty percent of target price
Year 5: 100% of target price.[39]

For each phase-in year, CMS plans to set the limits on the prices that Medicare can pay by using the ASP prices for the included drugs and

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[31] *Id.*
[32] *Id.*
[33] Pricing Index Model, 83 Fed. Reg. at 54,547.
[34] Emily Cook et al., The International Pricing Index Model: Breaking Down CMS's Proposed Drug Pricing Model, MCDERMOTT WILL & EMERY 16 (Nov. 19, 2018) https://www.mcdermottplus.com/wp-content/uploads/2018/11/IPI-Webinar-Slides.pdf (mentioning vendors will have the responsibility to negotiate drug prices with manufacturers).
[35] Pricing Index Model, 83 Fed. Reg. at 54,556.
[36] U.S. DEP'T. HEALTH & HUM. SERVS., *supra* note 27.
[37] Cook et al., *supra* note 34, at 11.
[38] *Fact Sheet, ANPRM International Pricing Index Model for Medicare Part B Drugs,* CMS (Oct. 2018), https://www.cms.gov/ newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs.
[39] Cook et al, *supra* note 34, at 14.

estimated international prices for comparable drugs.[40] CMS would then arrive at the final values by multiplying the amount of Part B drugs purchased by the ASP price portion, and then by the international price portion.[41] By the fifth year, U.S. prices would be phased down to reflect 126% of the prices calculated in the IPI.[42]

The model would also phase in the drugs that are included.[43] Examples of the types of drugs that the model would include are drugs for cancer and cancer related conditions, drugs for macular degeneration, and biologicals used to treat rheumatoid arthritis and other immune mediated conditions.[44] By the end of the phase-in period, CMS intends for the IPI to include drugs that make up seventy-five percent of all the charges under Medicare Part B.[45]

The IPI model also addresses a problem within the current buy-and-bill payment process by eliminating inefficient incentives that have led to physicians prescribing higher priced drugs.[46] As discussed above, under the current structure, Medicare calculates the reimbursement payment after a physician files a claim by calculating the ASP of the administered drug plus an "add-on" fee.[47] This "add-on" fee has resulted in incentives for physicians to prescribe more expensive drugs because it is calculated as a percentage of the ASP of the particular drug that the physician prescribes.[48] Research shows that when doctors are given the option of two drugs and one is financially beneficial to the doctor, doctors are more likely to prescribe the drug with the financial benefit.[49] Because Medicare accepts Part B drug prices without negotiation,[50] physicians are incentivized to prescribe the most expensive of the already high priced drugs to take advantage of the add-on fee calculation.[51] This ultimately means higher out-of-pocket drug expenses for U.S. patients, especially seniors.[52]

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[40] Pricing Index Model, 83 Fed. Reg. at 54,556.
[41] *Id.*
[42] Cook et al., *supra* note 34, at 14 (noting that the reimbursement price in year five would be 100 percent of the target price); U.S. DEP'T. HEALTH & HUM. SERVS., *supra* note 27 (explaining that the final target price is 126% of the average international price).
[43] *See* Cook et al., *supra* note 34, at 11.
[44] Pricing Index Model, 83 Fed. Reg. at 54,554.
[45] *Id.* at 54,555.
[46] *Id.* at 54,547.
[47] Werble, *supra* note 20, at 1.
[48] *Id.*
[49] Gronde et al., *supra* note 5, at 11.
[50] *See HHS Advances Payment Model to Lower Drug Costs for Patients*, U.S. DEP'T. HEALTH & HUM. SERVS. (Oct. 25, 2018), https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html (stating Medicare accepts sales prices for Part B drugs with no negotiation).
[51] Pricing Index Model, 83 Fed. Reg. at 54,547.
[52] U.S. DEP'T. HEALTH & HUM. SERVS., *supra* note 50.

The IPI would eliminate the incentive to prescribe higher priced drugs by changing the calculation method for the physician add-on payments.[53] Providers and hospitals would still receive an add-on payment for administering, storing and handling drugs, but payment would not be tied to the prices of individual drugs.[54] Instead, the payment would be based on (1) the class of drugs administered; (2) the physician's specialty; or (3) the physician's practice.[55] The add-on payment change is intended to be budget-neutral, as CMS stated that the purpose of the model is to remove the incentive for physicians to prescribe higher priced drugs, not to reduce costs through decreasing add-on payments.[56] Even so, the reality is that providers who currently administer the most expensive products will likely see a decrease in revenue, while providers who administer the least expensive alternatives will likely see an increase in revenue.[57]

B. Concerns about the Impact on R&D and Stifling Innovation

Some commentators fear that pursuing these goals through the IPI will have substantial unintended consequences on pharmaceutical innovation.[58] In a widely cited study, the authors argue that implementing the IPI would result in a decrease in pharmaceutical innovation because of the decrease in revenue caused by the IPI.[59] In making their argument, the authors begin by making three assertions. First, the Indexed Countries would not accede to demands from pharmaceutical companies to accept higher prices.[60] Second, pharmaceutical companies' total revenue is directly tied to aggregate investments into R&D.[61] And third, the current price levels of

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[53] Pricing Index Model, 83 Fed. Reg. at 54,547.
[54] *Id.*
[55] *Id.*
[56] Jacqueline LaPointe, *Would the IPI Model Reduce Medicare Reimbursement for Providers?*, RECYCLE INTELLIGENCE (Nov. 5, 2018), https://revcycleintelligence.com/news/would-the-ipi-model-reduce-medicare-reimbursement-for-providers (reporting that the Department of Health & Hum. Services addressed concerned physicians by explaining that its goal is not to reduce costs through reducing the add-on payment and that the purpose of the change is to make compensation independent of pricing).
[57] Joseph R. Antos & James C. Capretta, *A Market-Oriented Framework for Reforming Medicare Part B Drug Payment*, HEALTH AFF.: BLOG (July 9, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190708.831097/ full/ ("In general, practices using the highest-priced products today, with the highest ASPs, would stand to lose under the administration's proposal, while those using lower-priced products would stand to gain.").
[58] Duane Schulthess et al., *Tying Medicare Part B Drug Prices to International Reference Pricing Will Devastate R&D*, 53 THERAPEUTIC INNOVATION & REG. SCI. 746, 746–748 (2019).
[59] *Id.*
[60] *Id.*
[61] *Id.*

pharmaceuticals are necessary to maintain R&D within the industry.[62] Based on these three assertions the study concludes that pharmaceutical R&D budgets would decrease by millions of dollars under the IPI.[63] The authors come to this conclusion by calculating the decrease in revenue that pharmaceutical companies would experience under an implementation of the IPI, given the assumption that prices in the Indexed Countries would not change.[64] They then conclude that the IPI would put R&D at risk by calculating the decrease in companies' R&D budgets under the assumption that such budgets would be decreased by one-fifth of their total loss in revenue.[65] While this study is widely referenced by IPI critics, its foreboding conclusion that a reduction in drug prices necessarily comes with a loss in innovation is unlikely to actualize.

The argument that the high prices of pharmaceuticals are justified by the costs and labor involved in developing them is not new, as pharmaceutical companies and their lobbyists in Washington, D.C. have long argued that revenue from high prices today is necessary to facilitate future R&D.[66] They argue that restricting the price of drugs will have the unintended consequence of negatively impacting the rate at which new medications are developed.[67] Some in the pharmaceutical industry have posited that $2.6 billion is required to develop a successful new drug.[68] However, "the rigor of this widely cited number has been disputed" and there are several reasons to question the idea that current prices are a result of the need for future R&D investments.[69]

First, this argument incorrectly assumes that pharmaceutical companies spur innovation. The fact is that academic institutions and financial support from public sources, such as the National Institutes of Health ("NIH"), are the sources of much of the innovation that leads to new drug products.[70] A

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[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] Kesselheim et al., *supra* note 11, at 863; *see also* Angell, *supra* note 12 ("The pharmaceutical industry has the largest lobby in Washington, DC — there are more pharmaceutical lobbyists there than members of Congress — and it gives copiously to political campaigns.").
[67] *See* BOB YOUNG ET AL., RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" 7–8 (Public Citizen, July 2001), https://www.citizen.org/wp-content/uploads/rdmyths.pdf (explaining that drug companies stress how difficult it is to develop new drugs because of research costs).
[68] Kesselheim et al., *supra* note 11, at 863.
[69] *Id.*
[70] *See generally* Bhaven N. Sampat & Frank R. Lichtenberg, *What are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFF. 332, 339 (2011) (arguing that direct government funding is crucially important in the development of innovative new drugs).

study on public spending in pharmaceutical development found that, in the 2001 fiscal year, the NIH had a $20.3 billion dollar budget and that a substantial portion of this was money to be spent on research for the purposes of discovering and developing new drugs.[71] The NIH study also found that researchers who were funded by U.S. tax dollars produced fifty-five percent of the published research that was responsible for the development of the top five selling drugs in 1995.[72] Further, large pharmaceutical companies frequently acquire startups and other small companies whose early-stage drug development research originated in academic laboratories.[73]

Second, the assertion that drug companies would cut R&D budgets by one-fifth of their total loss in revenue is contradicted by spending trends in the industry that show a disconnect between R&D investment and final price. In recent years, large pharmaceutical companies have invested an average of twenty percent of revenue in R&D,[74] a percentage which is markedly lower if one considers only innovative product development.[75] A much larger share of revenue goes instead to marketing expenditures aimed at doctors and pharmacists.[76] Pharmaceutical companies' marketing expenditures dwarf their R&D efforts since the 1990s when thirty-five percent of the top ten drug companies' expenditures was on marketing and administration, while just eleven to fourteen percent was spent on R&D.[77]

Third, the argument that drug companies price their products based on the cost of R&D is inaccurate because sunk costs do not determine price.[78] In other words, by the time a drug becomes available on the market, the cost of its R&D has already been largely paid for, therefore R&D expenditures are often considered sunk costs by the time a company is ready to sell its product.[79] Based on economic principles, these sunk costs should not impact how a profit-maximizing company prices its drugs.[80] Economists generally

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[71] YOUNG ET AL., *supra* note 67.
[72] *Id.*
[73] University of Cambridge, *Study: Acquisitions Threaten Access to Breakthrough Drugs*, PHARMACEUTICAL PROCESSING WORLD (Jul. 29, 2016), https://www.pharmaceutical processingworld.com/study-acquisitions-threaten-access-to-breakthrough-drugs/.
[74] *Spending of U.S. Pharmaceutical Industry for Research and Development as a Percentage of Total Revenues from 1990 to 2018*, STATISTA (2019), https://www.statista.com/statistics/ 265100/us-pharmaceutical-industry-spending-on-research-and-development-since-1990/.
[75] Kesselheim et al., *supra* note 11, at 863.
[76] Gronde et al., *supra* note 5, at 10.
[77] Angell, *supra* note 12, at 1452.
[78] Rena M. Conti & Darius N. Lakdawalla, *Putting More Value into Biopharmaceutical Value Assessments*, HEALTH AFF.: BLOG (Jan. 3, 2018), https://www.healthaffairs.org/ do/10.1377/hblog20171227.196339/full/.
[79] *Id.*
[80] *Id.*

believe that firms with market power price their products based on what the market is willing to pay – the demand – not cost of development and production.[81] In the pharmaceuticals market, this means that companies price their products based primarily on how much consumers value a drug and the availability of alternative therapies.[82] Companies consider both of these factors early on in the development process.[83] Companies will predict the cost of bringing a drug to market and then make estimates about its value based on the drug's ability to improve or extend people's lives, the existence of competitors, the target market's ability to pay, and the likely insurance coverage for the drug.[84] The demand for some drugs might enable a firm to generate revenue well above a particular drug's R&D costs, while other drugs may never recover their overhead costs.[85] A pharmaceutical company's long term business depends on its average profits, which provide an ordinary return over its costs, including the sunk costs of R&D.[86] It is likely an oversimplification to assume that investment in R&D will stay at a fixed portion of total revenue considering the extraordinary profits these companies currently generate.[87]

Critics do identify one legitimate drawback to the IPI, which is the possibility that some of the Indexed Countries could be deprived of essential medicines.[88] This is based on the idea that if a country traditionally has maintained drug prices far below the United States, pharmaceutical companies might not seek market access in that country after IPI implementation because of the downward pressure the low price would have on the international average price.[89] While the possibility of a pharmaceutical company refusing to sell to a country that rejects proposals for higher prices

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[81] *See* RUSSELL COOPER & ANDREW JOHN, ECONOMICS: THEORY THROUGH APPLICATIONS 244–48, 268 (Saylor Foundation, 2012) (explaining how price is calculated based on the intersection of a demand curve and supply curve).
[82] Jessica Wapner, *How Prescription Drugs Get Their Prices, Explained*, NEWSWEEK (Mar. 17, 2017, 8:00 AM), www.newsweek.com/2017/04/14/prescription-drug-pricing-569444.html.
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *See id.* (explaining the various costs of developing a drug and stating that companies analyze how much they could charge for a drug to determine whether it is capable of recuperating these costs).
[87] MARC-ANDRE GAGNON & SIDNEY WOLFE, MIRROR, MIRROR ON THE WALL 13 (Carleton Univ., Sch. Pol'y & Admin., 2015), https://www.citizen.org/wp-content/uploads/2269a.pdf.
[88] Schulthess et al., *supra* note 58, at 750.
[89] *Id.*

is a concern, it also illustrates the pressure that the IPI would place on pharmaceutical companies to change their current practices.[90]

Whether this pressure would result in increased drug prices in the Indexed Countries is a central question in the debate over the IPI. If the IPI completely fails in pressuring the Indexed Countries to adjust the prices they pay for pharmaceuticals, as some critics claim it will, concerns over stifling future R&D might become more legitimate.[91] Given the disconnect between total revenue and investments into R&D discussed above, though, even a moderately successful price increase by the IPI would likely avert the significant consequences that its critics fear. To understand why the IPI is likely to succeed in its goal of pressuring other countries to modify their drug prices, it is helpful to understand the economic background in which pharmaceutical companies operate.

II. MARKET POWER, PRICING, AND CONSTRAINED NEGOTIATION

A. The Market Power of Pharmaceutical Companies

For pharmaceutical companies, "market power" refers to a company's ability to sell its products at prices above the marginal costs of those products.[92] In other words, in a competitive market where two companies are competing against each other, each will have an incentive to lower its prices until the price of each unit equals the cost of producing that unit, that cost being the marginal cost.[93] A company with market power has the ability to charge more than marginal cost and may earn additional revenue by doing so.[94] The primary reason pharmaceutical companies have enough market power to command such high prices is the market exclusivity granted by the U.S. Patent and Trademark Office and the Food & Drug Administration ("FDA").[95] A recent study found that brand-name drugs encompass ten percent of prescription in the United States and seventy-two percent of drug spending.[96] Further, from 2008 and 2015, prices increased 164% for the most

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[90] *See* discussion *infra* Section III(a) (explaining how the pressure the IPI would create could result in certain drugs being inaccessible in some countries).
[91] Schulthess et al., *supra* note 58, at 750 (noting the total decrease in revenue caused by Medicare paying 126% of the current price as calculated under the IPI).
[92] GLOSSARY OF INDUS. ORG. ECON. & COMPETITION LAW, ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT 57, (ebook).
[93] *See id.* at 31 (stating that profit maximizing firms will produce an output such that marginal cost equals marginal revenue).
[94] *Id.* at 34, 57.
[95] Kesselheim et al., *supra* note 11, at 860–61 (this "market exclusivity" means that no other manufacturer, generic or otherwise, may legally offer the approved drug for sale).
[96] *Id.* at 860.

common brand-name drugs, a shocking figure in comparison to the consumer price index, which recorded a twelve percent increase in prices.[97] In the past, such disproportionately high prices were limited to brand-name drugs used to treat rare conditions, but in recent years, even drugs treating common conditions have a high price tag.[98] Examples include new cancer drugs, which can cost more than $100,000 per course of therapy, as well as insulin, which increased 300% in price between 2002 and 2013.[99]

A brand name drug's market exclusivity arises from two forms of legal protection.[100] First, the regulatory exclusivity awarded by FDA approval protects new small-molecule drugs from competition for a guaranteed period of five to seven years and new biologic drugs for twelve years.[101] Second, patent law generates market protection that is often longer in duration than the FDA's protection.[102] Today, a new drug that is successfully patented will receive twenty years of protection starting from the date on which the application for the patent was filed.[103] However, the filing date often occurs years before a company can actually introduce the drug on the market because of the amount of time necessary to complete the development process and receive regulatory approvals.[104] Consequently, companies are therefore allowed to apply for extensions to make up for this lost time when the drug was not able to be sold, and may receive up to fifteen additional years of patent protection.[105]

When a brand-name drug loses its market exclusivity, generic drugs often become available and at a price that is, on average, eighty-five percent lower than their brand-name counterparts.[106] Interestingly, numerous studies have found that the availability of generic drugs does not lead to a price reduction in the branded alternative.[107] Rather, the brand-name drug retains a price similar to what it garnered during the period of market exclusivity and loses

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[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.* at 861.
[101] *Id.*
[102] *Id.*
[103] Michael Dunn, *Timing of Patent Filing and Market Exclusivity*, 10 NATURE REV. DRUG DISCOVERY 487, 487–88 (July 2011).
[104] *Id.*
[105] *Id.*
[106] *Generic Drug Facts*, U.S. FOOD & DRUG ADMIN. (Apr. 15, 2020, 9:00 AM), https://www.fda.gov/drugs/ generic-drugs/generic-drug-facts.
[107] Joel Lexchin, *The Effect of Generic Competition on the Price of Brand-Name Drugs*, 68 HEALTH POL'Y 47, 52 (2004) (finding that entry of generic drugs into the Canadian market did not result in a statistically significant change in brand name drug prices and noting that several studies have found similar results regarding the entry of generic drugs in U.S. markets).

the majority of its share of the market.[108] The end of a brand-name drug's market exclusivity period thus marks a steep decline in cost for consumers and revenue for the manufacturer.

Pharmaceutical manufacturers often address this eventual decline in revenue by engaging in "pay for delay" activities and "product life-cycle management."[109] "Pay for delay" refers to the large cash transfers that brand-name pharmaceutical companies pay to the manufacturers of generics to settle litigation challenging the validity of the brand-name's drug patent.[110] The fact that brand-name companies are willing to pay such large sums of cash to quell generic manufacturers is telling of how valuable it can be to maintain their market exclusivity. Brand-name manufacturers can also delay a generic drug's introduction into the market through life cycle management, which involves extending a drug's market exclusivity period through what are often referred to as "me-too" drugs.[111]

"Me-too" drugs are drugs that allow companies to prolong market exclusivity by filing for patents on specific features of a drug, including a pill's coating, the drug's salt moiety, its formulation, or the administration method. [112] This is often a successful strategy because the permissive standards for "novelty or usefulness" under the U.S. Patent and Trademark Office allow for nontherapeutic aspects to be patented after the drug's initial patent expires.[113] Me-too drugs do not require the large investments in R&D needed to develop innovative drugs, nor do they carry the same risks as innovative drugs in the clinical trial and development processes.[114] Thus, me-too drugs are cheaper to develop and have become staples in the industry.[115] From 1998 through 2003, the FDA approved a total of 487 drugs.[116] Of these drugs, 379 had similar therapeutic qualities as drugs already available on the market, while only sixty-seven of them offered benefits over previous medications.[117] The pharmaceutical industry has attempted to justify me-too drugs by arguing that they help lower prices by creating competition.[118] The prices for these drugs, however, are often substantially the same as the original brand name drug, and manufacturers often promote them to

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[108] *Id.*
[109] Kesselheim et al., *supra* note 11, at 860–61.
[110] *Id.*
[111] Angell, *supra* note 12, at 1451.
[112] Kesselheim et al., *supra* note 11, at 860–61.
[113] *Id.*
[114] Angell, *supra* note 12, at 1451.
[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.* at 1452.

consumers as improved products instead of cheaper alternatives.[119] This raises a central question; how do pharmaceutical companies decide the price of a drug?

B. The Price Determinants of Pharmaceuticals

Many pharmaceutical companies that sell brand-name drugs have enough market power for economists to consider them monopolies.[120] A monopolist benefits from its market power by having a large amount of control over the price of the products it sells.[121] In the pharmaceutical industry, this market power results from the fact that medications are not suitable substitutes for each other, and there is often only one company in the market that produces a particular medication[122] In fact, as explained above,[123] the U.S. government guarantees pharmaceutical companies that it will protect them from potential competitors that seek to sell similar products through granting patents.[124]

One way to measure the monopoly power of pharmaceutical companies is by using the Learner Index.[125] The Lerner Index is a tool that economists use to quantify monopoly power and is calculated by subtracting the marginal cost that a company incurs for producing a product from the price the company charges for that product.[126] The Lerner Index is expressed as $L = (P - MC) / P$, where P represents price and MC represents marginal cost.[127] When there is a large difference between marginal cost and price, L will be close to one, signifying a large amount of monopoly power.[128] The Lerner index for drug companies is typically 0.72 at a minimum because the marginal cost of producing a drug is much lower than its price.[129]

A monopolist may utilize its market power to maximize profit and may engage in price discrimination to do so.[130] Price discrimination describes the

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[119] *Id.*
[120] Gail Rattinger et al., *Principles of Economics Crucial to Pharmacy Students' Understanding of the Prescription Drug Market*, 72 AM. J. PHARMACEUTICAL EDU. 1, 1–3 (2008) (discussing the principles of economics within the pharmaceutical industry).
[121] MARK ARMSTRONG, RECENT DEVELOPMENTS IN THE ECONOMICS OF PRICE DISCRIMINATION 2 (Univ. C. London, 2006).
[122] Rattinger, *supra* note 120.
[123] *See* discussion *infra* Section II(a).
[124] Rattinger, *supra* note 120.
[125] STUART O. SCHWEITZER & JOHN Z. LU, PHARMACEUTICAL ECONOMICS AND POLICY: PERSPECTIVES, PROMISES, AND PROBLEMS 213–214 (Oxford Univ. Press 3rd ed., 2018).
[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] ARMSTRONG, *supra* note 121.

situation wherein a company sells multiple products, each with equal marginal cost, at different prices.[131]

> There are many forms of price discrimination, including: charging different consumers different prices for the same good (third-degree price discrimination); making the marginal price depend on the number of units purchased (nonlinear pricing); making the marginal price depend on whether other products are also purchased from the same firm (bundling); making the price depend on whether this is the first time a consumer has purchased from the firm (introductory offers; customer "poaching").[132]

Price discrimination thus accurately describes the current state of the pharmaceuticals market in which drug companies maximize their profits by charging U.S. consumers more than their counterparts in other OECD countries. A perfect price discriminator requires complete information about both its customers and the world so that it knows what the perfect price would be for each person in each situation; however, not many, if any, companies are able to achieve such precise discrimination.[133] Although drug companies do not have a perfect price schedule — one that would account for a multitude of customer categories — they are able to identify customers who have substantial negotiating power and those who do not, as explained below.[134]

Compared to competitive pricing, monopoly pricing and price discrimination each have the effect of leaving sellers better off and buyers worse off. [135] The differences between competitive pricing, nondiscriminatory monopoly pricing, and perfect price discrimination can be seen in Figure 1.[136]

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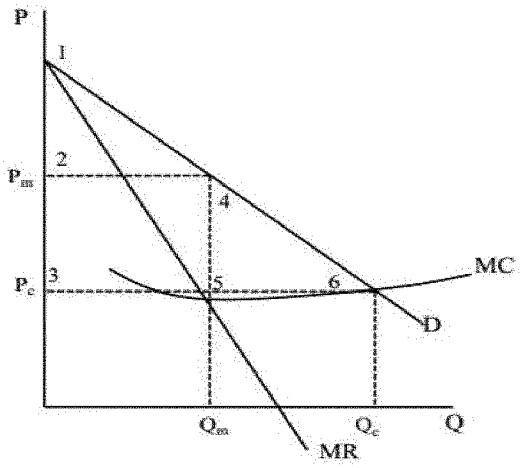
[131] *Id.*
[132] *Id.*
[133] Hayne E. Leland & Robert A. Meyer, *Monopoly Pricing Structures with Imperfect Discrimination*, 7 BELL J. ECON. 449, 450 (1976).
[134] *See* discussion *infra* Section II(c) (describing the price negotiation process and negotiation power).
[135] E. Thomas Sullivan et al., *Chapter 8: Secondary-Line Differential Pricing and the Robinson-Patman Act*, *in* 7 PENN LAW: LEGAL SCHOLARSHIP REPOSITORY 1, at 3 (ebook, 2013).
[136] *Id.* at 3–4.

Figure 1: Pricing Comparisons[137]



The demand curve "D" represents total consumer demand for an entire market.[138] The line "MC" represents marginal cost, and the line "MR" represents marginal revenue.[139] In a competitive industry, prices would be pressured downward towards marginal cost and "the price of each unit of output would be determined by the point where marginal cost is equal to demand."[140] The intersection of MC and D thus represents the competitive price, noted as "P_c," on the vertical axis.[141] When price is at this level, demand will be high.[142] Some consumers, though, "would have been willing to pay more than the competitive price, and triangle 1-3-6 represents [this] 'consumers' surplus' — the amount of wealth created by the fact that many consumers can purchase the product for less than the value they place on it."[143]

Any company that desires to achieve the highest possible profit would want to convert as much consumer surplus into producer surplus as possible.[144] This is where the monopolist's ability to decide on price provides

[137] *Id.* at 4 ("Figure 1 illustrates the differences between competitive pricing, nondiscriminatory monopolistic pricing, and perfect price discrimination").
[138] *Id.* at 3.
[139] *Id.*
[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] *Id.* at 4.

an advantage.[145] "If the seller sells at its nondiscriminatory profit-maximizing price, P_m . . . , then the seller has created for itself a producers' surplus equal to rectangle 2-3-5-4, which represents revenues in excess of marginal cost."[146] As a result, consumers' surplus is "reduced to triangle 1-2-4," and "triangle 4-5-6 represents deadweight loss[,]" the value that neither consumers nor producers receive.[147] This value is lost because customers are unwilling to pay price P_m and instead chose to buy what would have been a less appealing substitute in a competitive market.[148] If the seller had the ability to perfectly determine the price that each buyer was willing to accept, the seller could eliminate the deadweight loss by making every sale at the determined price, and the seller would effectively translate the 1-3-6 triangle into producer surplus.[149]

The result under perfect price discrimination is therefore an allocation with similar efficiency as that under perfect competition.[150] Compared to their outcomes in the discriminatory market, however, some consumers would be better off in the monopoly-priced market.[151] In the monopoly-priced market, all consumers would pay price P_m but some of them value the product more than that price, and thus would have paid more under perfect price discrimination.[152] In the international pharmaceuticals market, this group is representative of U.S. consumers. U.S. consumers "value" life-saving drugs higher than P_m because, as a result of government-granted market exclusivity, there are often no comparable substitutes for those drugs.[153] The IPI, then, is essentially a policy mechanism meant to curtail the pharmaceutical industry's exercise of price discrimination; the IPI is meant to drive the U.S. price closer to the monopoly price.

C. Constrained Negotiating Power of the United States

A buyer's capacity to effectively negotiate is the primary countervailing force against the market power of pharmaceutical firms.[154] There is a unique landscape of negotiating power in the United States because, unlike most

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[145] *See id.* (describing how a single firm with substantial market power may influence the demand, cost, and revenues curves).
[146] *Id.* at 5.
[147] *Id.*
[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] *Id.*
[153] SCHWEITZER & LU, *supra* note 125, at 13 (explaining that the U.S. government provides market protections for brand name drugs which prevent access to substitutes).
[154] Kesselheim et al., *supra* note 11, at 862.

other OECD countries, the United States does not regulate pharmaceutical prices.[155] In the United Kingdom ("U.K."), the National Institute for Health and Care Excellence ("NICE") performs careful appraisals of new pharmaceutical products before they can be introduced into the U.K. market. [156] The National Health Service, the U.K.'s publicly-funded healthcare system, will only cover drugs that are recommended by NICE, and since 2000, NICE has only recommended twenty percent of drugs considered. [157] In Germany, drug manufacturers must prove that the additional benefits of new therapies justify higher prices when negotiating with the government, and it is unlikely for a newly approved drug that offers little to no clinical improvement over existing treatments to receive a higher coverage price from public insurance plans.[158] In Australia, drug companies undergo similar scrutiny, as they must submit an application to the Pharmaceutical Benefit Advisory Committee, and produce evidence showing that their drug offers better clinical value than what is already on the market.[159]

In contrast, when companies seek to introduce new drugs into the U.S. market, they have the freedom to set their own prices.[160] Further, public as well as private buyers each suffer from limited negotiating power. While Medicare makes up twenty-nine percent of U.S. prescription drug spending, it is not only prevented by federal law from negotiating drug pricing and leveraging its massive purchasing power, but also required to cover a large number of drugs, including every available product in some categories, like oncology.[161] Congress established this restrictive framework after hearing input from representatives in the pharmaceutical industry who argued that, if the U.S. government was able to negotiate, revenues in the industry would suffer. [162] Further, state Medicaid organizations must provide insurance coverage for all drugs approved by the FDA and have no authority to exercise discretion based on the clinical value or cost-effectiveness of a particular drug.[163] The Veterans Health Administration, on the other hand, is permitted to exercise discretion in selecting which drugs it will cover. [164] Research

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[155] *Id.*
[156] Schweitzer & Lu, *supra* note 125, at 125.
[157] *Id.*
[158] Victoria D. Lauenroth & Tom Stargardt, *Pharmaceutical Pricing in Germany: How is Value Determined Within the Scope of AMNOG?*, 20 VALUE HEALTH 927, 933 (2017).
[159] Andrew Wilson & Joshua Cohen, *Patient Access to New Cancer Drugs in the United States and Australia*, 14 VALUE HEALTH 944, 945 (2011).
[160] Gronde et al., *supra* note 5, at 9.
[161] Kesselheim et al., *supra* note 11, at 862.
[162] *Id.*
[163] *Id.*
[164] *Id.*

shows that because of this discretion, the Veterans Health Administration is able to attain lower drug costs in comparison to the Medicare drug program and state Medicaid organizations.[165]

Private buyers, although not as directly hindered by law, face unique negotiating difficulties. Private buyers, such as insurance companies, are often able to effectively negotiate with pharmaceutical companies by leveraging the list of drugs included in their insurance plans.[166] Medicare, however, often requires private buyers to include certain drugs in their insurance policies and, because drug companies have the ability to negotiate with each private insurance company individually, these private buyers suffer from unequal bargaining power at the negotiating table.[167] Studies have shown that the enrollment of 100,000 additional members came with a 2.5% decrease in pharmaceutical prices and five percent decrease in drug profits earned on prescriptions filled because when insurers experienced an enrollment increase after the Medicare Part D implementation, they were able to negotiate lower drug prices.[168] This suggests that the scattering of buying power in the United States has resulted in a multitude of insurance companies that are unable to effectively negotiate with pharmaceutical companies.

III) REGULATING AGAINST PRICE DISCRIMINATION

A. The Robinson-Patman Act

The IPI would not be the first instance in which the United States has engaged in regulatory intervention against price discrimination.[169] Examining the results of these previous interventions can provide insight when predicting the potential results of the IPI. The Robinson-Patman Act, though it does not operate within the pharmaceuticals market, is a perfect example of a regulatory intervention against price discrimination. The most relevant section of the Act is section 2(a), 15 U.S.C. § 13(a), which makes it unlawful:

> [T]o discriminate in price between different purchasers of commodities of like grade and quality . . . where the effect of such

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[165] *Id.*
[166] John B. Kirkwood, *Buyer Power and Healthcare Prices*, 91 WASH. L. REV. 253, 263–64 (2015).
[167] *Id.*
[168] Nat'l. Bureau of Econ. Res., *How Insurers' Bargaining Power Affects Drug Prices in Medicare Part D*, NAT'L BUREAU ECON. RES. BULL. AGING & HEALTH, Dec. 2009, at 1.
[169] Thomas W. Ross, *Winners and Losers Under the Robinson-Patman Act*, 27 J.L. ECON. 243, 244 (1984).

> discrimination may be substantially to lessen competition or tend to create a monopoly in any line of commerce, or to injure, destroy, or prevent competition with any person who either grants or knowingly receives the benefit of such discrimination, or with customers of either of them.[170]

This section came about as a result of a revolution in distribution during the late nineteenth and early twentieth centuries.[171] The rise of large chain stores disrupted the typical supply chain from manufacturer to wholesaler to retailer.[172] The chain stores represented a new group of buyers — one that could bypass the wholesaler and demand lower prices for goods than the typical small independent store.[173] Manufacturers started promoting bulk discounts and eventually the chain stores, especially grocery stores, were able to undercut their smaller competitors by offering lower prices to consumers.[174]

There are several parallels that one can draw between the Robinson-Patman Act and the IPI. First, the Robinson-Patman Act is an intervention against price discrimination, promulgated for the purpose of raising prices for a certain group of buyers.[175] Its purpose, then, is similar to the purpose of the IPI, which, as explained in Part II(b), is intended to pressure the Indexed Countries to raise the prices they pay for pharmaceuticals.[176] The Robinson-Patman Act accomplished its purpose by forcing manufacturers to justify the asymmetrical prices they offered and limiting the difference between prices to the difference between marginal costs.[177] Figure 2 illustrates the effect of the Robinson-Patman Act in a situation in which a seller is selling the same product to two different groups of buyers.[178]

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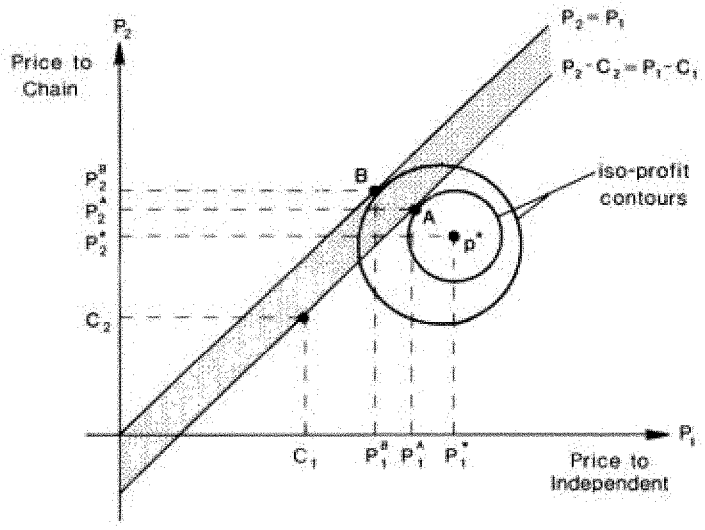
[170] The Robinson-Patman Act § 2, 15 U.S.C. § 13 (2020).
[171] Ross, *supra* note 169.
[172] *Id.* at 244–245.
[173] *Id.* at 245.
[174] *See id.* (stating that the chain stores were large organizations that threatened smaller, higher-cost independent retailers because the chain stores gained economic advantages by integrating the wholesale and retail functions).
[175] Wesley J. Liebeler, *Let's Repeal It*, 45 ANTITRUST L.J. 18, 27 (1976).
[176] *See* discussion *infra* Section II(b).
[177] *See* Liebeler, *supra* note 175, at 27-28 (noting that the Act contributes to higher prices by inhibiting the competitive price setting process and encouraging behavior that tends to stabilize prices).
[178] Ross, *supra* note 169, at 250–52.

Figure 2: Robinson-Patman Constraint[179]



The seller's goal is to maximize profits by selecting prices (P1, P2).[180] Independent retailers represent the first group of buyers, and chain stores represent the second.[181] Each group of buyers experiences constant but different marginal costs.[182] When the seller sells a unit to a chain store, "C2", the seller incurs a lower marginal cost than that incurred when selling a unit to an independent retailer, "C1."[183] This seller would have the freedom to choose any price, or any point in space, without the Robinson-Patman Act, and would presumably select p* to maximize profits.[184] The iso-profit contours around p* denote the decreasing levels of profit resulting from price moving further from p*.[185] The Robinson-Patman Act mandates that the difference between two prices for the same product may not exceed the difference between the cost of selling to one consumer and the cost of selling to the other consumer; that is, P1 - P2 must be less than or equal to C1 - C2.[186] The legal price vectors are characterized by the shaded area between lines

[179] *Id.* at 251, Figure, Profit Maximizing Prices Under the Robinson-Patman Act.
[180] *Id.* at 249.
[181] *Id.* at 249.
[182] *Id.*
[183] *Id.* at 250.
[184] *Id.*
[185] *Id.*
[186] *Id.*

P1= P2 and P1 - P2 = C1 - C2.[187] To maximize profits while complying with the Act, the seller will move to point A where P1 = P^A1 and P2 = P^A2.[188]

The seller thereby reduces prices for the independent retailers and raises them for the chain stores.[189] This redistribution of prices is exactly what the Robinson-Patman Act intended to accomplish, and it is almost exactly what policy makers today hope to accomplish through implementing the IPI.[190] In Figure 2, the shaded area could be formulated to represent legal price vectors under the IPI by changing it to a single line where the price to the independent stores equals 126% of the price to the chain stores. It is reasonable to expect that sellers would still experience the same pressure to conform to the new vector.[191]

The empirical evidence of the results of the Robinson-Patman Act confirm the predictions of this model. The act had a negative effect on grocery store chain profits because the prices they paid for inventory increased.[192] This result was found through analyzing the changes in a stock portfolio of chain stores before and after the Robinson-Patman Act.[193] From June 1935 to December 1937, the chain store portfolio lost to the market, having a negative abnormal return between ten and twenty percent.[194] It is clear, then, that the Robinson-Patman Act takes from both the seller and the chains and gives to the independent retailers; the fact that the negative abnormal returns were only ten to twenty percent suggests that both the manufacturers and the chain stores shouldered the burden of the act.[195] In other words, when the manufacturer was forced to curtail its use of price discrimination, it did not simply lower prices for the independent stores, but raised prices for the chain stores as well.[196] This is exactly the result that the IPI is designed to

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[187] *Id.*
[188] *Id.*
[189] *Id.* at 250–51.
[190] Liebeler, *supra* note 175, at 28; Pricing Index Model, 83 Fed. Reg. at 54,547.
[191] *See generally*, Thomas Ross, *The Costs of Regulating Price Differences*, 59 J. BUS. 143 (1986) (stating that price setting equations and derivatives show that the Robinson-Patman Act results in a lower price to small business and a higher price to chains and is likely to be representative of many real-world cases where firms attempt to maximize profits while staying within constraints of the law).
[192] Ross, *supra* note 169, at 253–59.
[193] *Id.*
[194] *Id.* at 258.
[195] *Id.* at 258–59.
[196] *Id.* at 258 ("In the first years after Robinson-Patman was passed, chains continued to lose ground to independents. As revealed in Table 3, the share of total retail sales going to chains of four or more stores fell from 1933 to 1935 and continued to decline through to 1939. Leading this decline were the grocery chains, which accounted for about 30 percent of total chain retail sales. The losses of the drug, shoe, and variety chains were much smaller.").

achieve—making the results of the Robinson-Patman Act a pertinent parallel to consider when predicting the effects of the IPI.

Another potential parallel between the IPI and the Robinson-Patman Act is their unintended consequences. The Robinson-Patman Act was somewhat controversial due in part to the incentives it created for manufacturers to simply refuse to deal with smaller retailers or specialized outlets that did not handle a large volume of a particular product.[197] For example, there was a case brought against a furniture manufacturer because the manufacturer was offering substantial discounts to bulk buyers and charging small designers more.[198] The Robinson-Patman Act forced the manufacturer to decide between equalizing prices or selling exclusively to bulk buyers.[199] The manufacturer chose the latter, forcing the small designer firms to pay more elsewhere.[200] The IPI could cause a similar result; if a pharmaceutical company is offering lower prices to one of the Indexed Countries, the IPI would pressure the company to choose between either raising the price in that country or refusing to sell to that country.[201] The company would face this pressure because the price the company offers the Indexed Country would affect the price the United States pays.[202] If the company agrees to a low price for a particular Indexed Country, it will also lose revenue from a corresponding decrease in the price in the United States. If that Indexed Country is unable or unwilling to accept a higher price, the company might generate more revenue by simply refusing to sell to that country and maintaining the higher U.S. price.[203] This consequence was even alluded to by the CEO of Allergan when he said, "companies could raise prices or stop selling entirely in those countries, or not launch new products in those countries . . . I don't think we'd really be impacted by the IPI [pricing model]."[204]

When considering the interests of the United States, though, the potential benefits from implementing the IPI still likely outweigh the costs. If the IPI achieves a similar redistribution of costs as the Robinson-Patman Act, the United States is likely to see a net benefit in the form of lower drug prices. Whereas the Robinson-Patman Act was controversial, in large part, because

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[197] Liebeler, *supra* note 175, at 32.
[198] *Id.* at 33.
[199] *Id.*
[200] *Id.*
[201] *See* discussion *supra* Section I(b).
[202] Liebeler, *supra* note 175, at 32.
[203] *Id.*
[204] Ed Silverman & Mathew Herper, *Allergan CEO: We Stuck to the Spirit of our Social Contract with Recent Price Hikes*, STAT (Jan. 8, 2019), https://www.statnews.com/pharmalot/2019/01/08/allergan-drug-prices-social-contract/.

of competing ideas about what constitutes an ideal welfare function,[205] the common interests that U.S. policy makers have should cause an *effective* redistribution under the IPI to be more palatable. Whether such a redistribution is effective, though, depends on the willingness of the Indexed Countries to accept increased prices.[206] The price change caused by the Robinson-Patman Act modeled in Figure 2 relies on the assumption that the buyer's demand function does not change.[207] There is reason to believe, however, that these functions actually changed significantly because the Robinson-Patman Act applied to every firm in the market; thus, just as the seller in the model could not continue to provide the chain stores with discounts, the other sellers in the market were also unable to do so.[208] The chain stores therefore sacrifice some bargaining power in transactions with suppliers, essentially decreasing their elasticity of demand.[209] Similarly, the IPI would apply to every pharmaceutical firm that participates in the Medicare Part B market. Because so many pharmaceutical companies participate in the U.S. market, European buyers may likewise experience a shift in their demand functions.

IV) PREDICTING PRICE CHANGES UNDER THE IPI

A. Elasticity of Demand

Whether the demand curves of the Indexed Countries would shift is determinative of whether the Indexed Countries would accept higher prices for pharmaceuticals. As explained below, static demand curves would mean that the Indexed Countries would not accept higher prices, causing greater revenue loss for pharmaceutical companies, whereas responsive demand curves would mean less or no loss in revenue. Therefore, any prediction about the IPI's effect on revenue must include an analysis on the elasticity of demand of the Indexed Countries.

Demand for a good or service is defined as inelastic if price changes do not affect the demand for that good or service.[210] In other words, inelastic demand means that the amount of goods demanded changes by less than one

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[205] Ross, *supra* note 169, at 251–53.
[206] *Id.* at 252 (noting that that the price redistribution under the Robinson Patman Act depended on changing demand functions).
[207] *Id.*
[208] *Id.*
[209] *Id.*
[210] *Elasticity of Demand*, LIBR. ECON. & LIBERTY (Apr. 16, 2020, 12:00 PM), https://www.econlib.org/library/ Topics/College/elasticityofdemand.html.

percent even when there is a one percent change in the price of those goods.[211] A perfectly inelastic demand curve appears as a vertical line which represents that a change in price has no impact on quantity demanded.[212] There are likely no real-life examples of goods with perfect inelasticity, but there are some products that come close because of a lack of suitable substitutes.[213] Prescription drugs are among the most common products with inelastic demand, along with food and tobacco.[214]

The inelasticity of the demand for pharmaceuticals is well-documented and researched.[215] Several studies found that the elasticity of demand for prescription drugs in various European countries ranged from -0.09 to -0.64, with the most frequent findings falling in the middle of this range.[216] An elasticity of -0.09 means that for every percentage point that prescription drug prices increased, the quantity of prescription drugs purchased decreased by 0.09%.[217] These values thus represent a highly inelastic demand. Further, demand for the newest, most innovative drugs is often especially inelastic because the alternative therapies for those products are not adequate substitutes.[218]

Countries that have high rates of insurance coverage also tend to have less elastic demand for pharmaceutical drugs because insured patients are less price sensitive, or less affected by the price of drugs covered by their insurance.[219] Consumers in many of the Indexed Countries have higher rates of insurance coverage than consumers in the United States.[220] Therefore, the consumers in many of the Indexed Countries are likely to have less elastic

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[211] *Id.*

[212] RICE UNIV., PRINCIPLES OF ECONOMICS, POLAR CASES OF ELASTICITY AND CONSTANT ELASTICITY 3, loc. 5.2 (2014) (ebook).

[213] *Id.*

[214] Mary Hall, *Elasticity Vs. Inelasticity of Demand*, INVESTOPEDIA (Aug. 9, 2020), https://www.investopedia.com/ ask/answers/012915/what-difference-between-inelasticity-and-elasticity-demand.asp.

[215] Marin Gemmil, The Price Elasticity of Demand for Prescription Drugs: An Exploration of Demand in Different Settings 58–61 (Jan. 2008) (unpublished Ph.D thesis, London Sch. Econ. & Pol. Sci.), https://etheses.lse.ac.uk/2944/ 1/U615895.pdf.

[216] *Id.* at 60 (several of these studies were based on relatively small sample sizes though).

[217] *Id.* at vii. ("Price elasticity of demand - the percentage change in the quantity demanded brought about by a one percentage change in the price of the good or service.").

[218] *Id.* at 49.

[219] Patricia Danzon & Eric Keuffel, *Regulation of the Pharmaceutical-Biotechnology Industry*, *in* ECONOMIC REGULATION AND ITS REFORM: WHAT HAVE WE LEARNED? 407, 407 (Nancy L. Rose ed., U. Chi. Press 2014) (noting that produces can charger higher prices on those who are insured).

[220] Eric Schneider et al., *International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care*, COMMONWEALTH FUND (Apr. 16, 2020, 12:20 PM), https://interactives.commonwealthfund.org/2017/july/mirror-mirror/.

demand than their U.S. counterparts. Although co-payments can make insured consumers more price sensitive, demand for prescription drugs remains highly inelastic.[221]

B. Pharmaceutical Review Agencies

The highly inelastic demand for prescription drugs is one of the reasons that so many European countries have pharmaceutical review agencies that act as a negotiating agent for their respective countries.[222] These agencies are meant to mitigate the inelasticity of demand for consumers who might otherwise accept higher prices. [223] Their role in negotiating with pharmaceutical companies will therefore cause some variation in the general measurements of elasticity.[224] Accordingly, an accurate prediction of price changes under the IPI must account for this and analyze the parameters of these countries' negotiating capacities. The largest foreign markets referenced in the IPI, such as Japan, Germany, and France, all have governmental agencies with the specific tasks of determining the value and cost-effectiveness of new drugs before they enter their respective markets.[225] These agencies often allow for price premiums for drugs that are "more cost-effective or support a small market or pediatric indication" and will calculate "price adjustments if the proposed prices vary significantly from the average sales price in comparable foreign markets."[226]

Similar to the U.S. health care system, the German health care system arrives at pharmaceutical prices primarily through negotiation, instead of regulation, and is financially supported through multiple private payers.[227]

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[221] Danzon & Keuffel, *supra* note 219, at 442 (noting that copayments can mitigate the insurance effect, but because copayments also reduce financial protection, in practice most public insurance plans include only very modest copayments).

[222] *See generally* Jacob Morey & Daniel Charytonowicz, *International Pricing Index: Outsourcing Negotiations will Continue the US Drug Cost Crisis*, HEALTH AFF. (Apr. 16, 2020, 12:00 PM), https://www.healthaffairs.org/do/ 10.1377/hbl-og20190307.887201/full/ ("These countries all have governmental agencies with the specific tasks of developing cost-effectiveness analyses and calculating price adjustments if the proposed prices vary significantly from the average sales price in comparable foreign markets.").

[223] *Id.*

[224] *See id.* (describing how these agencies act as a mediator between the pharmaceutical companies and consumers, and their cost-effectiveness analyses and price calculations represent more than merely the quantity demanded by the consumers within their respective countries).

[225] *Id.*

[226] *Id.*

[227] James C. Robinson et al., *Reference Pricing in Germany: Implications for U.S. Pharmaceutical Purchasing*, COMMONWEALTH FUND (Apr. 16, 2020, 1:10 PM), https://www.commonwealthfund.org/publications/issue-briefs/2019/jan/reference-pricing-germany-implications.

Where the German system differs is in its two-tiered pricing system; the prices for drugs that offer benefits over currently available medications are determined by negotiating with pharmaceutical companies, but reference pricing is used when a drug offers little or no benefit over these other medications.[228] This two-tiered pricing system allows German consumers to access drugs at considerable lower prices than U.S. consumers.[229] Germany enforces this system by limiting the amount that insurance companies can pay for drugs with therapeutically equivalent alternatives.[230] This allows pharmaceutical companies to set their own prices, but limits insurance payments for new drugs based on the amount that insurance companies provide for similar drugs unless a new drug offers a clinical benefit that its competition does not.[231]

Unlike many frameworks used by European countries, Germany and the United States do not directly evaluate the relative clinical benefit of new pharmaceuticals or negotiate prices,[232] but the German system has several features which are distinct from the U.S. system.[233] In Germany, all pharmaceuticals authorized by the European equivalent to the FDA, the European Medicines Agency ("EMA"), may be prescribed by physicians immediately after approval.[234] In this initial period, pharmaceutical companies are free to set the price of the new drug as they see fit and receive full reimbursement.[235] But over the course of the initial one year period, Germany analyzes the new drug's clinical safety and effectiveness as compared to other available alternatives.[236] If the German government determines the new drug has incremental benefits, it may increase the price it pays in comparison to a specified comparator drug within the same class of medication.[237] And conversely, if no such finding is made, the price will fall to the lowest price bracket within the class.[238]

Despite Germany's evaluation system, many new drugs gain access to the German market, including less innovative drugs.[239] Research shows that

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[228] *Id.*
[229] *Id.*
[230] *Id.*
[231] *Id.*
[232] *Id.*
[233] *Id.*
[234] *Id.*
[235] *Id.*
[236] *Id.*
[237] *Id.*
[238] *Id.*
[239] *No Evidence of Added Benefit for Most New Drugs, Say Researchers*, BMJ (Apr. 16, 2020, 1:20 PM), https://www.bmj.com/company/newsroom/no-evidence-of-added-benefit-for-most-new-drugs-say-researchers/.

over half of the drugs that Germany approves have no added benefit over their alternatives.[240] In Germany, from 2011 to 2017, their pharmaceutical review agency approved 216 drugs, the vast majority of which had already received EMA approval.[241] Fifty-four of the drugs were found to have a "considerable or major added benefit."[242] For thirty-five of the drugs, "the added benefit was either minor or could not be quantified," and 125 of them showed no added benefit compared to the alternative products that were already available.[243] Further, an assessment of oncology pharmaceuticals authorized by the EMA between 2009 and 2013 showed that a majority had been approved with zero evidence of "clinically meaningful benefit on patient relevant outcomes (survival and quality of life)," an outcome which did not change over time.[244]

In France, the Comité Economique des Produits de Santé ("CEPS") is the primary economic decision maker in the realm of pharmaceuticals and it negotiates the final reimbursement rate for all new pharmaceuticals based on an assessment from a medical evaluation commission.[245] The technical assessment that the commission provides includes three findings.[246] First, the commission estimates the Medical Benefit ("SMR") by determining a drug's reimbursement eligibility and the recommended parameters of the potential reimbursement rate.[247] The SMR assessment includes investigations into a variety of factors, including: (a) a drug's efficacy and safety, (b) the position of the medicine in the therapeutic strategy and whether there are any close alternatives available, (c) the severity of the relevant disease, (d) whether the treatment is preventive, curative or symptomatic, and (e) the public health impact.[248] Using those elements, the commission determines the drug's medical benefit, the levels of which range from major, important, moderate, weak, and insufficient to reimburse.[249] Second, it provides an Improvement of Medical Benefit assessment ("ASMR"), which establishes a target price

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[240] *Id.*
[241] *Id.*
[242] *Id.*
[243] *Id.*
[244] *Id.*
[245] Alexander Natz & Marie-Geneviève Campion, *Pricing and Reimbursement of Innovative Pharmaceuticals in France and the New Healthcare Reform*, 13 FARMECONOMIA HEALTH ECON. & THERAPEUTIC PATHWAYS 49, 50–51 (2012). "The Comité Economique des Produits de Santé" translates to "The Healthcare Products Pricing." Committee."
[246] Annie Chicoye et al., *France – Pharmaceuticals*, ISPOR (Apr. 16, 2020), https://tools.ispor.org/htaroadmaps/ France.asp.
[247] *Id.*
[248] *Id.*
[249] *Id.*

by comparing the new drug to currently available alternatives.[250] Except for cases involving drugs that use unique mechanisms to treat a condition, the agency performs this comparison by looking at alternatives within the same therapeutic class.[251] The agency then provides one of five ASMR levels ranging from major innovation, important improvement, significant improvement, minor improvement, and no improvement.[252]

CEPS then uses these findings as a basis for its negotiations with pharmaceutical companies.[253] The drugs recognized as major or irreplaceable, like HIV drugs, and drugs that treat chronic and severe diseases are reimbursable at 100% — that is, the consumer or other buyer is reimbursed for 100% of the cost of the drug.[254] In 2007, the average reimbursement rate for retail pharmacist drugs was 76.77%.[255] This broad insurance coverage means that demand for pharmaceuticals in France is particularly inelastic. Thus, even in this complex framework, spending on pharmaceuticals in France is rapidly increasing.[256]

The French regulatory scheme for hospital drugs provides drug companies more flexibility in setting prices.[257] This fact is especially relevant because these drugs would likely include those drugs covered under Medicare Part B.[258] In France, hospitals have authority to agree to drug prices with pharmaceutical companies independent from the government, however, for the more expensive drugs that will be charged to health insurance, the company must thereafter disclose to the government the price they intend to charge, as well as the prices they offer in other European countries.[259] If CEPS does not approve the declared price, it will intervene and negotiate with the drug company.[260] These negotiations are based on similar considerations as the SMR and ASMR ratings.[261]

In Italy, the Italian Medical Agency ("AIFA") negotiates with pharmaceutical companies using similar parameters as Germany and France,

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[250] *Id.*
[251] *Id.*
[252] *Id.*
[253] *Id.*
[254] *Id.*
[255] *Id.*
[256] Nathalie Grandfils, *Drug Price Setting and Regulation in France* 2 (IRDES Working Paper N. DT16, Sept. 2008), https://www.irdes.fr/EspaceAnglais/Publications/WorkingPapers/DT16DrugPriceSettingRegulationFrance.pdf.
[257] *Chicove* et al., *supra* note 246.
[258] *See* Fein, *supra* note 19 (explaining that Medicare Part B includes physician-administered drugs).
[259] *Chicove* et al., *supra* note 246.
[260] *Id.*
[261] *Id.*

but provides greater flexibility for highly innovative drugs.[262] During their negotiation with AIFA, companies may request approval for status as an innovative drug.[263] Italy has established separate funds to cover expenditures for innovative drugs which are not subject to the same reimbursement constraints of other drugs.[264] AIFA may grant full "innovative status," which provides access to these separate funds, or "conditional status," which means the drug will be included in Italy's Regional Therapeutic Handbooks.[265] AIFA determines how innovative a drug is for a particular indication by considering three evaluation criteria: unmet therapeutic need, added therapeutic value, and quality of evidence.[266] In 2017, Italy introduced a new algorithm to assess whether a drug should receive this status and increased its innovative drug fund to $1.2 billion.[267] The new algorithm is expected to provide more flexibility and room for reviewer discretion.[268] The new algorithm and increased funding will likely cause demand for innovative pharmaceuticals to become more inelastic.

C. The IPI's Effect on Revenue

It is clear that the pharmaceutical review agencies in Indexed Countries mitigate the inelastic demand of consumers; however, it is also clear that the negotiating processes described above consider a wide variety of factors and allow pharmaceutical companies opportunities to justify prices for new drugs. Critics of the IPI are not alone in their fears that decreased revenue will lead to a decrease in innovation as the policies of Germany, France, and Italy demonstrate that these countries understand the high costs involved in pharmaceutical development and that they are willing to pay more for more innovative drugs.[269] For example, the French system is sometimes praised as an exemplary method of controlling spending on pharmaceuticals compared

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[262] Mauro Putignano & Sonia Selletti, *Pricing & Reimbursement 2019: Italy*, GLOBAL LEGAL INSIGHTS (Apr. 16, 2020, 2:20 PM), https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/Italy.
[263] *Id.*
[264] *Id.*
[265] *Id.*
[266] Yulia Privolnev, *What is Pharmaceutical Innovation, Anyway? Italy's New Algorithm & the Global Trend*, PHARMACEUTICAL ONLINE (April 16, 2020, 2:30 PM), https://www.pharmaceuticalonline.com/doc/what-is-pharmaceutical-innovation-anyway-italy-s-new-algorithm-the-global-trend-0001.
[267] *Id.*
[268] *Id.*
[269] *See generally* discussion *supra* Section IV(b).

to other countries,[270] yet drug companies have been consistently successful in negotiating prices in France.[271]Further, when drug companies are pushed to charge higher prices in these countries as a result of the IPI, they will likely benefit from some of the reference pricing mechanisms described above.[272] This is because companies will likely put pressure on multiple countries that reference each other's prices, thus pushing the reference points higher.

The result of pharmaceutical review agencies, then, is not transforming demand for pharmaceuticals from highly inelastic to highly elastic. Rather, the result is a change from highly inelastic demand to a moderately inelastic demand. Therefore, when considering the potential effects of the IPI, the relevant inquiry is not whether prices in the Indexed Countries will change but how much prices will change.

The fact that the IPI would cause prices in the Indexed Countries to increase provides a basis to estimate net revenue changes. In other words, by modeling various potential price changes in the Indexed Countries, it is possible to more clearly understand the extent to which total revenue would change under the IPI. The charts below provide several models of how revenue may change by using fictional sales data from a hypothetical drug ("Hypothimta").[273] Assume that, for each of the Indexed Countries, 0.03% of their populations suffer from a condition and that Hypothimta is the only treatment or has no close substitutes. Each person who is afflicted by the condition needs a total of ten grams of Hypothimta to recover from the disease.

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[270] *See* David Andelman, *The French Solution to US Drug Prices*, CNN (Apr. 16, 2020, 2:00 PM), https://www.cnn.com/2019/04/30/opinions/healthcare-drug-prices-compared-france-intl/index.html (explaining that France has enormous bargaining power with drug manufacturers because the government runs the country's universal healthcare program, which make it's by the far the largest purchaser for most drugs, and thus successfully sets price ceilings for drug makers).

[271] *Grandfils*, *supra* note 256, at 17.

[272] *See generally supra* Section IV(b) (explaining that reference pricing ties the price of a drug in one country to its price in other countries).

[273] *See World Population Clock*, WORLDOMETER, https://www.worldometers.info/world-population/ (last visited Oct. 31, 2020) (explaining data on populations of each country); *Medicare Fast Facts*, NAT'L COMMITTEE TO PRESERVE SOC. SEC. & MEDICARE (June 2, 2020), https://www.ncpssm.org/our-issues/medicare/medicare-fast-facts/ (explaining data on Medicare Part B population).

Figure 3: Pre-IPI Revenue[274]

COUNTRY	PRICE PER GRAM	RATE	POPULATION	TOTAL GRAMS BOUGHT	REVENUE
Austria	$2,642	0.03%	8,955,102	26,865	$70,978,138
Belgium	$2,736	0.03%	11,539,328	34,618	$94,714,804
Canada	$2,840	0.03%	37,411,047	112,233	$318,742,120
Czech Republic	$3,030	0.03%	10,689,209	32,068	$97,164,910
Denmark	$2,710	0.03%	5,786,561	17,360	$47,044,741
Finland	$2,793	0.03%	5,532,156	16,596	$46,353,935
France	$2,755	0.03%	65,129,728	195,389	$538,297,202
Germany	$2,783	0.03%	83,517,045	250,551	$697,283,809
Greece	$2,693	0.03%	10,473,455	31,420	$84,615,043
Ireland	$2,400	0.03%	4,882,495	14,647	$35,153,964
Italy	$2,800	0.03%	60,550,075	181,650	$508,620,630
Japan	$2,725	0.03%	126,860,301	380,581	$1,037,082,961
Netherlands	$2,810	0.03%	17,124,402	51,373	$144,358,709
United Kingdom	$3,173	0.03%	67,530,172	202,591	$642,819,707
AVERAGE	$2,778				
US (Medicare)	$5,000	0.05%	52,100,000	260,500	$1,302,500,000
TOTAL					$5,665,730,673

The price that each country pays per gram of Hypothimta differs between these countries up to a margin of fifteen percent above or below the index average, which is consistent with real world data for many of the top Medicare Part B drugs.[275] The Medicare price per gram is 180% of the index average, and, because the Medicare population includes a higher percentage of sick people than the general population of the United States, the incidence of the disease is higher in the Medicare population.[276] Figure 3 models the revenue generated from the Indexed Countries for Hypothimta before the IPI is implemented. Here, Hypothimta generates a total of $5,665,730,673 in revenue.

[274] Figure 3 illustrates the likely kinds of *percentage changes* in revenue that the IPI would cause, the exact dollar amounts are arbitrary; any index average would result in informative results given that the price that each Indexed Country pays are not wildly different from each other, and the price that Medicare pays is 180% of the index average.

[275] U.S. DEPT. HEALTH & HUM. SERVS., COMPARISON OF U.S. AND INTERNATIONAL PRICES FOR TOP MEDICARE PART B DRUGS BY TOTAL EXPENDITURES at13Table 2 (2018), https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf.

[276] MELISSA ALDRIDGE & AMY KELLEY, DYING IN AMERICA: IMPROVING QUALITY & HONORING INDIVIDUAL PREFERENCES NEAR THE END OF LIFE, Appendix E: Epidemiology of Serious Illness and High Utilization of Health Care 310, 517 (2015) (ebook).

Figure 4: No-Price-Change Revenue[277]

COUNTRY	PRICE PER GRAM	RATE	POPULATION	TOTAL GRAMS BOUGHT	REVENUE
Austria	$2,642	0.03%	8,955,102	26,865	$70,978,138
Belgium	$2,736	0.03%	11,539,328	34,618	$94,714,804
Canada	$2,840	0.03%	37,411,047	112,233	$318,742,120
Czech Republic	$3,030	0.03%	10,689,209	32,068	$97,164,910
Denmark	$2,710	0.03%	5,786,561	17,360	$47,044,741
Finland	$2,793	0.03%	5,532,156	16,596	$46,353,935
France	$2,755	0.03%	65,129,728	195,389	$538,297,202
Germany	$2,783	0.03%	83,517,045	250,551	$697,283,809
Greece	$2,693	0.03%	10,473,455	31,420	$84,615,043
Ireland	$2,400	0.03%	4,882,495	14,647	$35,153,964
Italy	$2,800	0.03%	60,550,075	181,650	$508,620,630
Japan	$2,725	0.03%	126,860,301	380,581	$1,037,082,961
Netherlands	$2,810	0.03%	17,124,402	51,373	$144,358,709
United Kingdom	$3,173	0.03%	67,530,172	202,591	$642,819,707
AVERAGE	$2,778				
US (Medicare)	$3,500	0.05%	52,100,000	260,500	$911,776,050
TOTAL					$5,275,006,723

Figure 4 illustrates the change in revenue if prices do not change in the Indexed Countries and the U.S. price becomes 126% of the current average. This result is unlikely. Based on the market power that pharmaceutical companies have, the inelastic demand for pharmaceuticals, and the results of similar regulations against price discrimination, it is unreasonable to think that the IPI would create results comparable to those in Figure 4. Revenue in Figure 4 is decreased to $5,275,006,723, a decrease of almost seven percent. However, this decrease in revenue likely overstates the percentage of revenue that most companies would actually lose because if the revenue from sales to countries other than the Indexed Countries was included, total revenue would be higher, making the change a smaller percentage of total revenue.

[277] Figure 4, data consistent with U.S. DEPT. HEALTH & HUM. SERVS., *supra* note 275.

Figure 5: Price-Changes Revenue[278]

COUNTRY	PRICE PER GRAM	RATE	POPULATION	TOTAL GRAMS BOUGHT	REVENUE
Austria	$2,774	0.03%	8,955,102	26,865	$74,527,045
Belgium	$2,873	0.03%	11,539,328	34,618	$99,450,544
Canada	$2,982	0.03%	37,411,047	112,233	$334,679,226
Czech Republic	$3,182	0.03%	10,689,209	32,068	$102,023,155
Denmark	$2,846	0.03%	5,786,561	17,360	$49,396,978
Finland	$2,933	0.03%	5,532,156	16,596	$48,671,632
France	$2,893	0.03%	65,129,728	195,389	$565,212,062
Germany	$2,922	0.03%	83,517,045	250,551	$732,147,999
Greece	$2,828	0.03%	10,473,455	31,420	$88,845,795
Ireland	$2,520	0.03%	4,882,495	14,647	$36,911,662
Italy	$2,940	0.03%	60,550,075	181,650	$534,051,662
Japan	$2,861	0.03%	126,860,301	380,581	$1,088,937,109
Netherlands	$2,951	0.03%	17,124,402	51,373	$151,576,644
United Kingdom	$3,332	0.03%	67,530,172	202,591	$674,960,693
AVERAGE	$2,917				
US (Medicare)	$3,675	0.05%	52,100,000	260,500	$957,364,853
TOTAL					$5,538,757,060

Figure 5 illustrates revenue when prices in each Indexed Country increase by five percent. The actual result of the IPI would not be so uniform; prices in some countries would likely increase substantially while other countries would experience moderate or small increases. The model, however, still makes several important points. First, the five percent increase in price is a modest increase in expenditure for each of the Indexed Countries. For example, Italy would need to pay approximately twenty-five million dollars more in total for Hypothimta, an increase slightly more than two percent of its yearly funds for innovative pharmaceuticals alone. Second, a five percent price increase in the Indexed Countries pushes the Medicare price up. This result is an anticipated part of the IPI.[279] The goal of implementing the IPI is not to decrease Medicare prices to 126% of current prices but to 126% of higher future prices.[280] Medicare still benefits though, as Figure 5 indicates that Medicare would save approximately $345 million on the total cost of Hypothimta under the IPI. The Hypothimta manufacturer loses $126,973,613.8 in Hypothimta revenue, representing a decrease in revenue of approximately 2.24%.

[278] Figure 5, data consistent with U.S. DEPT. HEALTH & HUM. SERVS., *supra* note 275.
[279] Pricing Index Model, 83 Fed. Reg. 54,556.
[280] Cook et al., *supra* note 34, at 1.

Figure 6: Excluding Small Buyers[281]

COUNTRY	PRICE PER GRAM	RATE	POPULATION	TOTAL GRAMS BOUGHT	REVENUE
Austria	$2,774	0.03%	8,955,102	26,865	$74,527,045
Belgium	$2,873	0.03%	11,539,328	34,618	$99,450,544
Canada	$2,982	0.03%	37,411,047	112,233	$334,679,226
Czech Republic	$3,182	0.03%	10,689,209	32,068	$102,023,155
Denmark	$2,846	0.03%	5,786,561	17,360	$49,396,978
Finland	$2,933	0.03%	5,532,156	16,596	$48,671,632
France	$2,893	0.03%	65,129,728	195,389	$565,212,062
Germany	$2,922	0.03%	83,517,045	250,551	$732,147,999
Greece	$2,828	0.03%	10,473,455	31,420	$88,845,795
Ireland	$2,400	0.010%	4,882,495	4,882	$11,717,988
Italy	$2,940	0.03%	60,550,075	181,650	$534,051,662
Japan	$2,861	0.03%	126,860,301	380,581	$1,088,937,109
Netherlands	$2,951	0.03%	17,124,402	51,373	$151,576,644
United Kingdom	$3,332	0.03%	67,530,172	202,591	$674,960,693
AVERAGE	$2,908				
US (Medicare)	$3,664	0.05%	52,100,000	260,500	$954,551,453
TOTAL					$5,510,749,985

Figure 6 illustrates a potential unintended consequence of the IPI. Here, assume that Ireland refuses to accept a higher price, and that Ireland does not want to buy as much of Hypothimta as other countries, either because it happens to have a lower incidence of the underlying disease or because it has access to some alternative therapy. Hypothimta's manufacturer would be better off refusing to sell to Ireland because of the downward pressure Ireland's price would have on the Medicare price limit. Figure 6 shows that total revenue for Hypothimta when the manufacturer sells to Ireland is $5,510,749,985; conversely, if the manufacturer excluded Ireland, total revenue would be $5,511,862,724.

The above models illustrate the pressure that the IPI will put on prices in the Indexed Countries and the resulting decreases in revenue. This framework and analysis should assist in providing some context to claims that the IPI will devastate R&D investments. Given that revenue decreases in a similar way as is illustrated in Figure 6, it is unclear whether the IPI would significantly affect R&D budgets or merely decrease profit margins. One study, which analyzed ten of the world's largest pharmaceutical companies' annual accounting reports from 1996 to 2005, found that the reports disclosed net operating profits of $413 billion after tax, and a 29% net return on shareholders' investments.[282] This is not a normal return on

[281] Figure 6, data consistent with U.S. DEPT. HEALTH & HUM. SERVS., *supra* note 275.
[282] GAGNON & Wolfe, *supra* note 87.

investment in any other industry.[283] Further, of their net earnings, the ten companies allocated 77%, or $317 billion, to shareholders, and 16%, or $65 billion, to future mergers and acquisitions.[284]

V. CONCLUSION

Arguments claiming that the IPI will reduce the pace of innovation likely overstate its potential impact on revenue and understate, both, the amount of revenue generated from un-innovative pharmaceuticals, such as "me-too" drugs, and the amount of revenue that is distributed as profits rather than invested in R&D. Pharmaceutical companies' market power provides substantial leverage in their negotiations with consumers who attach a high value to innovative drugs, and thus it is reasonable to conclude that the IPI's upwards pressure on prices in the Indexed Countries will be at least moderately successful. In support of this conclusion, the Robinson Patman Act illustrates that policy mechanisms that create this kind of upwards price pressure are effective. The IPI is thus likely to be a successful mechanism in addressing the high cost of pharmaceuticals under Medicare Part B without causing substantial decreases in investments into R&D.

[283] *Id.*
[284] *Id.*