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I. THE UNITED STATES' INTERNATIONAL PATENT EXHAUSTION REGIME WILL NOT ALLOW FOR PARALLEL IMPORTS OF PHARMACEUTICALS AND WILL NOT PREVENT UNFAIR PRICE DISCRIMINATION

The patent exhaustion doctrine generally provides that when a patent holder sells or authorizes the sale of a patented product, the patent rights in that item are exhausted. The patent holder cannot chase the item down the stream of commerce to impose restrictions on its use or resale.[1] One issue that arises is whether a domestic sale is required to trigger patent exhaustion, or if sales overseas can also trigger patent exhaustion. The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") is agnostic on this question, providing that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual

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1. *See generally* Samuel F. Ernst, *Total Patent Exhaustion!*, 59 IDEA 41, 43–44 (2018).

property rights."[2] As a result, some countries have adopted a "national exhaustion" regime, where only a domestic sale triggers exhaustion, but other countries have adopted an "international exhaustion" regime, where sales in foreign countries trigger exhaustion.[3] The European Union ("E.U.") opted for a regime of "regional exhaustion," whereby the authorized sale of a patented product in any E.U. country exhausts patent rights throughout the E.U., but patent rights in the item survive to prevent resale outside of the E.U.[4]

In 2001, the U.S. Court of Appeals for the Federal Circuit decided that U.S. patent law provides for national exhaustion, holding exhaustion only occurs "when a patented device has been lawfully sold in the United States."[5] But, in 2016, the Supreme Court granted certiorari to consider that issue in the case of *Impression Products v. Lexmark*.[6] The Pharmaceutical Research and Manufacturers of America ("PhRMA") filed an amicus brief in the case urging the Court to affirm the Federal Circuit's adoption of a national exhaustion regime. Among PhRMA's arguments was that national exhaustion was good policy because it allowed for geographic price discrimination for patented pharmaceuticals:

> The current rule that foreign sales do not exhaust U.S. patent rights allows pharmaceutical manufacturers to independently price and distribute medicines in a socially optimal way. Differences in pricing can provide patients in lower-income countries access to important drugs, while also providing the opportunity for pharmaceutical companies to recoup their costs and continue further research and development.[7]

PhRMA warned that adopting an international exhaustion regime would allow for parallel imports of patented pharmaceuticals into the United States, which would force pharmaceutical companies to suspend useful price discrimination for lower-income countries or to withdraw from those markets:

> Faced with the prospect of automatic foreign exhaustion—and the inability to assert its patent rights against entities importing drugs first sold in other countries for lower prices—a U.S. patent holder

2. The Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 108 Stat. 4809, 1869 U.N.T.S. 299, Art. VI. [hereinafter "Trips Agreement"].

3. *See* SHUBHA GHOSH & IRENE CALBOLI, EXHAUSTING INTELLECTUAL PROPERTY RIGHTS 88–113 (2018).

4. *Id.* at 103.

5. Jazz Photo Corp. v. Int'l Trade Comm'n, 264 F.3d 1094, 1105 (Fed. Cir. 2001), *abrogated by* Impression Prod., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 198 L.Ed.2d 1 (2017).

6. Impression Prods. v. Lexmark Int'l, Inc., 137 S. Ct. 546 (Dec. 2, 2016) (order granting certiorari).

7. Brief for Pharmaceutical Res. & Manufacturers of America ("PhRMA") as Amici Curiae Supporting Respondent, Impression Prods. Inc., v. Lexmark Int'l, Inc., 137 S. Ct 1523 (2017) (No. 15-1189), 2017 WL 894890.

> might decide not to sell in a foreign market at all. As one academic has noted, citing an example of a drug product in France, patentholders 'may rationally choose to abandon small markets that contribute minimally to global revenues rather than accept prices that would pull down the revenues that can be achieved in other, larger markets.' A rule of automatic foreign exhaustion that would permit the importation and resale of U.S.-patented goods from overseas, free and clear of U.S. patent rights, would only compound pharmaceutical manufacturers' concerns about entering foreign markets with stringent price controls or weak patent regimes that result in lower drug revenues.[8]

Despite these warnings, the Supreme Court rejected PhRMA's position in *Impression Products*, ruling that "a patentee's decision to sell a product exhausts all of its patent rights in that item, regardless of. . . the location of the sale."[9]

And, PhRMA's warnings proved false. Branded pharmaceutical companies continue to engage in geographic price discrimination, although as discussed below, they do not do so in a way that is "socially optimal."[10] Their ability to price discriminate is facilitated by the fact that even under an international exhaustion regime, parallel imports of pharmaceuticals without the authorization of the manufacturer are prohibited in the U.S.

Pursuant to the Prescription Drug Marketing Act of 1987 ("PDMA"), only the original manufacturer of a prescription drug is permitted to import or re-import it into the United States.[11] Regarding re-importation, the statute provides, "no drug subject to section 353(b) of this title or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug."[12] PhRMA's amicus brief in *Impression Products* argued that this statute did not provide pharmaceutical companies with adequate protection because "the text of the statute makes clear that it applies only to drugs manufactured in the United States, not those produced abroad."[13] However, the very next section of the statute prohibits the importation of pharmaceuticals produced abroad into the U.S. unless the original manufacturer has labeled the drug to be marketed in the United States (something the manufacturer can easily avoid doing). The statute provides:

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8. *Id.*

9. Impression Prods., 137 S. Ct. at 1529.

10. *Infra* Section II.

11. *See* Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 623, 643–48 (2005) (on file with *The University of the Pacific Law Review*).

12. 21 U.S.C.A. § 381(d)(1)(A) (West, Westlaw through Pub. L. 116–91).

13. Brief for PhRMA as Amici Curiae Supporting Respondent, Impression Prods. Inc., v. Lexmark Int'l, Inc., 137 S. Ct 1523 (2017) (No. 15-1189), 2017 WL 894890.

> [N]o drug that is subject to section 353(b)(1) of this title may be imported into the United States for commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States.[14]

PhRMA argued it needed a private right of action to sue for patent infringement to prevent importation despite these laws—suggesting the government inadequately enforced them.[15] To the contrary, federal enforcement of these laws has been vigorous. As Kevin Outterson has observed:

> Federal and state officials are currently attacking Internet pharmaceutical arbitrage on multiple fronts. The FDA is aggressively enforcing against U.S. companies involved in the trade. The Customs Department has posted clarifications of the personal use exception to discourage importation. Facilitators such as the Discount Prescription Center in West Virginia have been challenged by state Boards of Pharmacy as engaged in the unlicensed practice of pharmacy. The FDA has sued regional facilitators such as Rx Depot for assisting in the importation of prescription drugs. The FDA and state pharmacy investigators have also purchased prescription drugs in undercover operations.[16]

PhRMA contended "[t]o PhRMA's knowledge, the federal government has never brought an action under § 381(d) against a parallel importer that legitimately purchased a drug abroad and then sought to resell it in the United States."[17] This statement appears false, or at the very least, disingenuous. For example, the government sued and successfully enjoined Rx Depot from illegally importing pharmaceuticals from Canada.[18] Indeed, in the late 1980s the FDA promulgated regulations automatically requiring detention and exportation of pharmaceuticals re-imported into the United States from foreign countries unless the importers

14. 21 U.S.C.A. § 381(d)(1)(B) (West, Westlaw through Pub.L. 116–91b).

15. Brief for PhRMA, *Impression Prods. Inc.*, 137 S. Ct 1523 (2017) (No. 15-1189).

16. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 193, 285 (2005) (citing, *inter alia*, Lolita C. Baldor, FDA: Too Costly To Legalize Drug Imports, Law Vegas Sun (Dec. 24, 2003); Gardiner Harris & Monica Davey, *U.S. Steps Up Effort Against Drug Imports*, N.Y. TIMES (Jan. 24, 2004), at C1; *Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments*, FDA NEWS (Jan. 27, 2004); Becker v. W. Va. Board of Pharm., No. 03-C-1237, slip op. at 11–12 (W. Va. Cir. Ct. Nov. 3, 2003); United States v. Rx Depot, Inc., 290 F. Supp. 2d 1238 (N.D. Okla. 2003) (granting preliminary injunction against Rx Depot)).

17. Brief for PhRMA, *Impression Prods. Inc.*, 137 S. Ct 1523 (2017) (No. 15-1189).

18. United States v. Rx Depot, Inc., 290 F. Supp.2d 1238, 1239–40, 1244, 1250–51 (N.D. Okla. 2003).

could provide documentation establishing authorization from the original manufacturer.[19] The district court for the Eastern District of New York invalidated the regulations for failure to comply with notice and commenting rulemaking requirements.[20] But, PhRMA's suggestion that U.S. laws prohibiting parallel imports are not enforced is incorrect.

There is no doubt that despite these prohibitions, pharmaceuticals are illegally imported into the U.S. and that this can raise valid health and safety concerns.[21] However, as discussed below, unlawful importation has not resulted in the inability of the pharmaceutical industry to engage in price discrimination, even in the context of an international patent exhaustion regime.

II. THE PRICE DISCRIMINATION CURRENTLY ENGAGED IN BY THE BRANDED PHARMACEUTICAL INDUSTRY IS NOT SOCIALLY OPTIMAL BECAUSE IT IS NOT BASED ON ABILITY TO PAY

In the abstract, geographic price discrimination has support in economic theory.[22] The ability to charge different prices in different countries according to relative price elasticity in each region increases output while maximizing profit.[23] In the pharmaceuticals context, price discrimination could increase the utilization of medicines, particularly in the least-developed nations, thereby improving health outcomes.[24] The increased profits for pharmaceutical companies could encourage more research and development and result in the development of more drugs.[25]

But, like most abstract economic theories, this one is based on the false premise of rational, frictionless markets and people who are more akin to dispassionate Vulcans than short-sighted, grasping, flawed human beings. Once the premise is exposed as a fiction, the entire edifice crumbles.[26] Sarah Rajec points

19. *See* Bellano Int'l Ltd. v. FDA, 678 F. Supp. 410, 411 (E.D.N.Y. 1988).

20. *Id.* at 416.

21. *See Imported Drugs Raise Safety Concerns*, U.S. FOOD & DRUG ADMIN. (Mar. 1, 2018), https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143561.htm (on file with *The University of the Pacific Law Review*).

22. *See* Patricia M. Danzon, *Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues*, PHARMACOECONOMICS 2 (July 30, 2018), *available at* https://faculty.wharton.upenn.edu/wp-content/uploads/2018/07/Danzon-2018-PharmacoEconomics-1.pdf (on file with *The University of the Pacific Law Review*).

23. Danzon, *supra* note 22 at 2 ("Under normal conditions, such price discrimination increases utilisation by price-sensitive consumers and, in aggregate, increases consumer welfare and producer profits, relative to charging all customers the same price."); Frank R. Lichtenberg, *Pharmaceutical Price Discrimination and Social Welfare*, 5 CAPITALISM AND SOCIETY 1, Article 2 at 24 ("[P]rice discrimination can increase output and raise social welfare."); Christine Ongchin, Note, *Price Discrimination in the Textbook Market: An Analysis of the Post-Quality King Proposals to Prevent and Disincentivize Reimportation and Arbitrage*, 15 CARDOZO J. INT'L & COMP. L. 223, 234 (2007) ("Third-degree price discrimination is economically favorable because it allows textbook publishers to sell textbooks in foreign markets. . .. Because of the increase in total output, average costs are lowered, allowing for a reduction of prices in the United States.").

24. Lichtenberg, *supra* note 23, at 25–26.

25. *Id.* at 23.

26. *See e.g.,* Samuel F. Ernst, *Patent Exhaustion for the Exhausted Defendant: Should Parties Be Able to*

out that geographic price discrimination "may not be the most desirable form of price discrimination for consumers, however, because it is imprecise in identifying differing demand curves."[27] For example, geographic price discrimination might not be sensitive to wealth disparities within countries, resulting in less drug access and utilization by lower income individuals. Indeed, this is the pharmaceutical industry's current situation: targeting the highest income individuals in the least-developed countries for their branded pharmaceuticals. Peter Yu writes:

> [B]ecause wealth is usually distributed very unevenly in many less developed countries—South Africa being the most cited example—some pharmaceutical companies choose to sell their products at high prices that are affordable by the more affluent minority, even if it means that the product will become unaffordable to the larger and poorer majority.[28]

But even geographic price discrimination adherents agree it is a socially optimal practice only to the extent that prices are set in relation to some measure of willingness to pay.[29] Prices should differ in various countries based on average per capita GDP or income, for example.[30] To the extent price discrimination is not tied to price sensitivity in each country, it results in output losses and inequities between nations with respect to the availability of medicines at all levels of society.

The problem with the pharmaceutical industry is that its price discrimination practices do not adhere to these principles. Pharmaceutical companies engage in geographic price discrimination and continue to do so even after the *Impression Products* ruling, but the prices set are not tied to willingness to pay.

The most striking example of this is the high price of pharmaceuticals in the United States as compared to countries with comparable average per capita GDP and incomes. Studies measuring drug prices in different countries differ to some degree in their results due to methodological differences and problems with obtaining accurate drug prices.[31] Studies vary with respect to the sample of drugs researchers select for study and variables, such as whether to weigh the drugs in the sample by the quantity dispensed.[32] The accurate determination of drug prices is hindered by companies varying from their list prices, offering discounts to

Contract Around Exhaustion in Settling Patent Litigation?, 2014 U. ILL. J. L. TECH. & POL'Y 445, 469–71 & notes 173–78 (2014).

27. Sarah R. Wasserman Rajec, *Free Trade in Patented Goods: International Exhaustion for Patents*, 29 BERKELEY TECH. L.J. 317, 321 (2014).

28. Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 844–45 (2007) (citing, *inter alia*, Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT'L L.J. 563, 566 (2002)).

29. Danzon, *supra* note 22 at 2–4.

30. *Id.* at 2–3.

31. *See generally* Judith Wagner & Elizabeth McCarthy, *International Differences in Drug Prices*, 25 ANN. REV. PUB. HEALTH 475, 478 (2004).

32. *Id.* at 480–81.

various distributors, and keeping these price variances as trade secrets.[33] Moreover, private insurers do not make public the effective prices paid by ultimate purchasers of drugs, and Medicaid does not make public the rebates it obtains from manufacturers.[34]

As a result of these difficulties and methodological differences, the studies vary in their exact determinations of the relative price of pharmaceuticals in the U.S. compared to other countries. Nonetheless, all the studies agree pharmaceutical prices are far higher in the U.S. than in Europe or Canada. The studies show drug prices in United States are approximately 32-41% higher than in Canada.[35] Drug prices are between 51%–60% higher in the U.S. than they are in the United Kingdom.[36] By comparable magnitudes, drugs prices in the U.S. are also far higher than drug prices in Switzerland, Germany, France, Australia, the Netherlands, Norway, and Sweden.[37] By any measure, drug prices in the U.S. are astronomically high and rising like a rocket ship.[38] Robin Feldman reports that between 2006 and 2014 drug prices in Medicare D rose by an average of 57% cumulatively; that a 2016 industry report projected that drug prices would rise 11.6% in 2017 for young Americans and 9.9% for adults over 65 with wages only rising by 2.5%; and that between 2000 and 2008, the prices of 416 branded drugs increased by a range of 100%–499%.[39]

This price discrimination against the U.S. is not the type of price discrimination that economists applaud as a social good because it is in no way tied to the relative wealth or ability to pay of these various countries. In 2017, the estimated gross domestic product ("GDP") per capita of the U.S. was $59,500.[40] Norway and Switzerland had far higher per capita GDP than the U.S.: $71,800 and $61,400, respectively.[41] The other countries had per capita GDP comparable with the U.S.: The Netherlands, $53,600; Sweden, $51,500; Germany, $50,400; Australia, $50,300; Canada, $48,300; U.K., $44,100; and France, $43,800.[42] The story is the same with respect to gross national income ("GNI") per capita. The

33. *Id.* at 478-80.

34. *Id.* at 480.

35. *Id.* at 483; Dana O. Sarnak et al., *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, ISSUE BRIEF, Oct. 2017, Ex. 2, *available at* https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier (on file with *The University of the Pacific Law Review*); Danzon, *supra* note 22 at Fig. 2.

36. Wagner & McCarthy, *supra* note 31, at 483; Sarnak et al., *supra* note 35.

37. Sarnak et al., *supra* note 35.

38. *See* FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES 7–8 (Cambridge Univ. Press 2019).

39. *Id.* at 7–8.

40. *The World Factbook: Country Comparison: GDP Per Capita*, CENT. INTELL. AGENCY, https://www.cia.gov/library/publications/the-world-factbook/rankorder/2004rank.html (on file with *The University of the Pacific Law Review*).

41. *Id.*

42. *Id.*

U.S. GNI per capita at the time of this writing was $60,200.[43] Switzerland and Norway were higher, with $69,920 and $66,390, respectively.[44] The other nations on the list are slightly lower but comparable to the U.S.: The Netherlands, $57,380; Germany, $55,800; Sweden, $53,990; Australia, $49,930; Canada, $47,280; France, $46,900; and the U.K., $45,660.[45]

Hence, the price discrimination that the pharmaceutical industry engages in with respect to the United States is not socially useful under the theories of the most committed price discrimination adherents because it is not based on willingness to pay. The setting of prices in the U.S versus these other countries is not due to price sensitivity or price elasticity. The true reason for unreasonably high drugs prices in the U.S. is a corrupt system of kickbacks, middlemen, perverse incentives, and anticompetitive collusion discussed immediately below.

III. THE PHARMACEUTICAL INDUSTRY'S CORRUPT PRICING SYSTEM

Robin Feldman's groundbreaking new book, *Drugs, Money, and Secret Handshakes*, provides an elegant and accessible analysis of why drug prices in the U.S. are so high.[46] Feldman describes "the highly secretive and highly concentrated industry known as 'pharmacy benefit managers' (PBMs)" who collaborate with the branded drug companies to raise prices and create economic pressure and perverse incentives for other health care system actors to also facilitate price increases.[47] Only a brief summary of Feldman's observations is possible here. I urge readers to refer directly to Feldman's book for the complete analysis, sources, and details. That said, following is a brief summary, with any mistakes my own:

PBMs ostensibly work for their clients, insurance companies and other payers, to negotiate lower drug prices with the pharmaceutical companies.[48]

Accordingly, insurers pay PBMs based on the discounts from list prices they extract from the drug companies.[49]

Then, the PBMs write the formularies for insurance companies containing the pharmaceuticals that will be covered by the insurance plans.[50]

In practice, however, the PBMs agree to secret deals with the drug companies to artificially raise drug prices and then grant rebates. On the surface, it appears the PBM has extracted a large rebate paid for by the insurance company. In fact,

43. *GNI Per Capita, PPP (Current International $)*, THE WORLD BANK (2019), https://data.worldbank.org/indicator/NY.GNP.PCAP.PP.CD?year_high_desc=true (on file with *The University of the Pacific Law Review*).

44. *Id.*

45. *Id.*

46. *See generally* FELDMAN, *supra* note 38, at 7–8.

47. *Id.* at 2.

48. *Id.* at 12.

49. *Id.* at 19.

50. *Id.* at 13.

however, because of this gimmick, the rebated price of the drug remains high.[51]

Moreover, the deals between the PBMs and the drug makers are kept as trade secrets, even from the insurance companies. Hence, the insurance companies do not know the actual level of a particular rebate. The PBMs can thereby often keep part, or all, of the rebates they extract.[52]

In exchange, the PBMs agree they will list their particular branded drugs in the formularies to exclude competition that would otherwise potentially lower prices.[53]

Moreover, drug companies induce PBMs with other kickback payments they disguise with euphemisms such as "administrative fees or data managing fees."[54]

Moreover, the PBM industry is concentrated, with only three PBMs— Express Scripts, CVS Health, and OptumRX—having 85% of the market share.[55] This means the insurance companies have little choice but to deal through these large corporate middlemen if they want to negotiate with the drug companies. The PBMs discourage the insurance companies from demanding transparency or that more of the rebate be passed through to the insurance company by charging more to insurance companies that demand such concessions.[56] Any insurance company bravely insisting on a better deal with the PBMs and lower drug prices would experience high short-term losses, resulting in insurance company shareholders revolting and demanding new management.[57]

U.S. pharmacists are practically prevented from addressing this problem as well. Although the FDA allows pharmacists to substitute a generic drug for a branded drug in a prescription, pharmacists may only do so if it is the precise FDA-approved generic for the branded drug; but drug companies circumvent this problem by patenting obvious variations of their products once the patents expire.[58] Moreover, some PBMs, such as CVS Health, have acquired massive corporate pharmacies, and can therefore instruct their pharmacist employees not to substitute the generic.[59] And then, the PBM writes a formulary that "give[s] preference to its own retail pharmacy, restricting patients' access to drugs and preventing independent drugstores from competing for new customers."[60] The PBMs pay kickbacks to large, independent pharmacies in exchange for dispensing the branded drugs they prefer—motivated by the kickbacks they themselves receive from the branded drug companies.[61]

The PBMs then offer kickbacks, artificial rebates, and other incentives to

51. *Id.* at 19.
52. FELDMAN, *supra* note 38, at 13–14, 19.
53. *Id.* at 20.
54. *Id.* at 19.
55. *Id.* at 14.
56. *Id.* at 35.
57. *Id.*
58. FELDMAN, *supra* note 38, at 44–45, 61–62.
59. *Id.* at 46–47.
60. *Id.* at 47.
61. *Id.* at 45.

doctors and hospitals to induce them to prescribe particular branded drugs.[62] These are layered on top of pressure from sales representatives, who wine and dine doctors, and marketing campaigns directed at doctors and patients.[63]

Next, drug companies provide coupons to patients to induce them to prefer their drugs. The drug companies then fund "patient advocacy groups" to lobby for policies that favor branded drug companies.[64]

Finally, all of this is compounded by the drug companies' gaming the patent system to extend their monopolies well beyond the 20-year term of a patent. Through the practice of "evergreening," when a patent is about to expire, the drug company patents a new drug that is very often nothing more than a reformulation, combination of known medicines, alternative delivery system, or other modification that should be invalid for obviousness under the law but is granted a patent anyway.[65] If generic companies challenge such patents in court, the branded drug companies often attempt a reverse settlement, paying the generic company money to stay off the market and drop the challenge to the patent.[66]

Again, this is merely a high-level summary of the major examples comprising the web of collusion and perverse incentives allowing drug prices in the U.S. to soar unchecked.

IV. A SINGLE SOLUTION TO THE PHARMACEUTICAL INDUSTRY'S CORRUPT PRICE DISCRIMINATION SYSTEM?

What can be done to lower the prices of pharmaceuticals in the U.S. relative to Europe and Canada? Unfortunately, many of the proposals that are currently being floated would do little to make a dent in the labyrinth of corruption described above.

For example, one solution Democrats in Congress proposed would be allowing the federal government to negotiate directly with drug companies for lower prices of drugs in Medicare, the government healthcare plan for senior citizens.[67] This would be a desirable reform to reverse a bizarre policy whereby the government is statutorily prohibited from interfering with price negotiations between drug manufacturers and the private healthcare plans that administer the Medicare prescription drug benefit.[68] Also, the reform would ideally also eliminate the law providing that the government "may not require a particular formulary or institute a price structure for the reimbursement of covered [Medicare] part D drugs."[69]

62. *Id.* at 50–51.
63. *Id.*
64. *Id.* at 55.
65. FELDMAN, *supra* note 3, at 60–85.
66. *Id.*
67. *See* Katie Thomas, *Assessing Plans to Trim Drug Prices*, N.Y. TIMES, June 16, 2019, at B1.
68. 42 U.S.C.A. § 1395w-111(i) (West, Westlaw through Pub. L. No. 116–91).
69. *Id.*

However, only about 43 million people receive drug coverage through Medicare,[70] and presumably the drug companies would jack up prices for the remaining 284 million Americans to make up for any lost profits resulting from this plan. Moreover, the current plans in Congress would only allow negotiations for 250 drugs.[71] Other initiatives that only target Medicare recipients, such as lowering or capping out-of-pocket expenses for beneficiaries,[72] while desirable, also fail to provide a comprehensive solution, and drug companies could offset these benefits by raising prices for other payers.

Another option would be to outlaw the reverse payment settlements branded drug companies pay to generic companies to settle lawsuits and delay the entry of generic drugs onto the market. Additionally, Congress could strengthen the validity requirements for follow-on drug patents to more easily deny such patents for obviousness because they introduce no true innovation other than extending the drug maker's monopoly. While this, too, would be desirable to address the "evergreening" issue, it would only address one aspect of the myriad of corrupt practices discussed above.[73] Specifically, branded drug companies would still have twenty years of patent monopoly for the original drug and would still have recourse to the non-patent related devices for raising prices; they would just be constrained in extending their patent monopolies beyond those twenty years.

Another option would be to reform PBM practices or make them unlawful altogether, something Feldman refers to as "slaying the dragon."[74] Certainly, this would be highly desirable. But Feldman is skeptical of this as a silver bullet solution because if the insurance companies were to negotiate directly with the drug makers rather than through a corporate middleman, the drug companies could simply use many of the same tactics directly with the insurance companies to block low-priced competition that they currently use with PBMs.[75] Consider the following:

> A company with a drug coming off patent would still have the volume position that would allow it to offer attractive inducements to insurance plans—inducements that the new, lower-priced entrant could not beat. Companies with a stable of drugs—some with stronger protection, some with weaker protection—could

70. Juliette Cubanski, Anthony Damico, &and Tricia Neuman, *Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing*, HENRY J. KAISER FAM. FOUND. (May 17, 2018), https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/ (on file with *The University of the Pacific Law Review*).

71. Thomas, *supra* note 67; *see also* FELDMAN, *supra* note 38, at 60–85 (demonstrating skepticism of this as an overall solution on the basis that "Medicare is an enormously complex program, which breeds numerous opportunities for manipulation" and "the pharmaceutical industry has proven quite adept at outflanking the federal government in the face of complex legislative and regulatory scheme).

72. Thomas, *supra* note 67.

73. *See supra* Section III.

74. FELDMAN, *supra* note 38, at 93–95.

75. *Id.* at 93.

> bargain across all of those drugs, once again sharing some of the monopoly rents from one drug to strangle nascent competition. . . . The fact that health insurance executives need to meet financial expectations could enhance a drug company's ability to offer enticements. The short-term allure of persuasion payments could tempt insurers far more than the uncertain long-term benefits of competition.[76]

Increasing transparency is another potential solution. The current presidential administration enacted a regulation requiring drug companies to post the list prices of drugs in their commercials.[77] However, on July 8, 2019, after Merck, Eli Lilly, and Amgen sued on the basis that the Department of Health and Human Services ("HHS") purportedly lacks statutory authority to enact the rule, a federal district judge invalidated the rule.[78] Given how little attention the public pays to the voluminous small print appearing in the margins of pharmaceutical commercials, such a modest and symbolic proposal would have done little to reduce the price of drugs or even provide meaningful transparency. That the drug companies filed a federal lawsuit to block such an inconsequential rule indicates how embarrassed they are by their own price gouging.

One hopes that more ambitious transparency measures than this could be effectively pursued. Feldman proposes various direct and indirect measures the states or federal government could take to force PBMs and drug companies to reveal the details of their secret agreements to raise drug prices and establish anticompetitive formularies.[79] Shedding light on the shameful details of these contracts is undeniably a crucial reform. However, would it really solve the overall problem? Elsewhere in her book, Feldman opines that providing insurance companies the data files on all claims and rebate checks might be an empty gesture because of the vast and complicated nature of the data:

> [O]ne cannot overestimate the data analysis challenges and the enormous time and resources necessary for health insurers to fully interpret what is happening—even on their own side of the equation. A full, claims, data transfer can be akin to giving people the alphabet and assuring them that they can write Shakespeare. Yes, in theory, in time, they could—but it's not an appealing approach.[80]

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76. *Id.* at 94.

77. Regulation to Require Drug Pricing Transparency in Medicare and Medicaid Programs, 47 C.F.R. § 403.1202 (2019).

78. Merck & Co., Inc. v. US Dept of Health & Human Servs., 385 F. Supp. 3d 81 (D.C. Cir. 2019).

79. FELDMAN, *supra* note 38, at 95–102.

80. *Id.* at 33.

If sophisticated insurance companies could not process this information, what are the hapless U.S. Congress and the public to do with a dump of information on the drug companies' secret rebates and kickbacks to the PBMs? Even if the details of this corruption would spur Congress into action, it would only raise a further question: What action could be taken to control drug prices that would be effective?

To answer that question requires probing into the roots of the problem. The most likely explanation for the fact that the U.S. pays astronomically higher prices for drugs than European countries and Canada is that these countries employ health care systems whereby there is only a single payer for health care, the government; or a two-tiered system, with the government paying for basic health care and premium care available for those who pay for it.[81] Because the government is at least purchasing basic healthcare, these countries enjoy the power of a monopsony to demand lower prices.[82] In effect, the single payer can tell the drug companies, "lower your price or don't sell your drug in this country." U.S. purchasers of health care, however, have no such monopsony power, which allows for all the corrupt monkey hijinks described above whereby drug companies can raise prices to no perceivable limit. As a result, the U.S. bears a far heavier per capita load in subsidizing the research and development of pharmaceuticals than any other country.

Should the U.S. adopt a single payer or two-tiered health care system? Although this may be the ideal solution, one must immediately acknowledge that it is currently unlikely to happen in this country. Even in 2010, when the Democratic Party held supermajorities in both houses of Congress as well as the presidency, there was insufficient political will to adopt even a public insurance option in the insurance exchanges established by the Affordable Care Act.[83] Hence, even in the best of political circumstances, we have not yet reached the point where the U.S. would likely adopt a wholly government-funded health care system.

Accordingly, before considering that option, it is worth considering one final alternative approach: an approach more in line with this country's free market philosophy. The answer to lowering pharmaceutical prices in the U.S. may lie in allowing parallel imports from Canada and/or Europe.[84] A recent report from the

81. *See* Kelly Montgomery, *Differences Between Universal Coverage and Single-Payer*, VERYWELL HEALTH (Nov. 22, 2019), https://www.verywellhealth.com/difference-between-universal-coverage-and-single-payer-system-1738546 (on file with *The University of the Pacific Law Review*) (discussing that countries with a single payer system include Norway, the United Kingdom, Sweden, Canada, Finland, Slovenia, Italy, Portugal, Cyprus, Spain, and Iceland and countries with a two-tiered system include Denmark and France).

82. *See* Wagner & McCarthy, *supra* note 31, at 486–88.

83. Helen A. Halpin & Peter Harbage, *The Origins and Demise of the Public Option*, HEALTH AFF. (June 2010), *available at* https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2010.0363 (on file with *The University of the Pacific Law Review*).

84. Brief for PhRMA, Impression Prods. Inc.,137 S. Ct 1523 (2017) (No. 15-1189). I would not propose allowing for parallel imports from the least developed nations because PhRMA has threatened that it would react to such importation by "choos[ing] to abandon small markets that contribute minimally to global revenues rather than accept[ing] prices that would pull down the revenues that can be achieved in other, larger markets," Brief

Congressional Budget Office estimated that allowing for the importation of prescription drugs from Canada would save between $1 billion and $1.5 billion per year in government spending on pharmaceuticals.[85] Theoretically, the pharmaceutical companies would not be able to offset these losses by raising prices in Canada or Europe because of the price control mechanisms and monopsony conditions in those countries.

The E.U. provides one example of the parallel importation of pharmaceuticals. The E.U. employs a system of regional patent exhaustion, that allows companies and individuals to export products, including pharmaceuticals, from one country to another within the E.U. without permission of the patent holder.[86] Some studies have found that this has led to a substantial decrease in prices of pharmaceuticals in the importing countries.[87] Pavel Kanavos and his colleagues analyzed four studies on the effects of parallel importation on pharmaceutical prices in importing countries in Europe. Two of the studies found substantial decreases in prices, including decreased prices of 12%–19% in Sweden.[88] Two other studies attributed lower prices to other factors, such as the entry into the market of generic competition.[89] This would suggest it would be useful to combine parallel importation with heightened validity requirements for follow-on pharmaceutical patents and the outlawing of reverse settlement payments. Patricia M. Danzon has observed that "[i]n the European Union (EU), traditional price differentials between countries are being undermined by parallel trade and regulation based on foreign prices. This break down of market segmentation leads manufacturers to adopt uniform prices EU-wide."[90]

Presumably, a similar effect would occur to at least some degree if the U.S. allowed for parallel imports of pharmaceuticals from Canada and/or Europe. The passage of legislation allowing for such importation would not be as politically difficult as one might assume. In fact, the U.S. already passed such legislation in 2000, although it was never implemented and has since expired. Pursuant to the Medicine Equity and Drug Safety Act of 2000, the HHS could have promulgated

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for PhRMA, Impression Prods. Inc.,137 S. Ct 1523 (2017) (No. 15-1189); s*ee* Rajec, *supra* note 27, at 373 ("[A] patent holder could respond to the introduction of international exhaustion by not selling drugs in low-income markets at all . . . ."); *see also* Daniel J. Hemel & Lisa Larrimore Ouellette, *Trade and Tradeoffs: The Case of International Patent Exhaustion*, 116 COLUM. L. REV. SIDEBAR 17, 26–27 (2016) (observing that international exhaustion could be detrimental to access to medicine in developing countries).

85. *CBO: Drug Importation Saves $1 Billion Per Year*, COMM. COMMITTEE FOR A RESPONSIBLE FED. BUDGET (Aug. 1, 2017), https://www.crfb.org/blogs/cbo-drug-importation-saves-1-billion-year (on file with *The University of the Pacific Law Review*).

86. GHOSH & CALBOLI, *supra* note 3, at 88–113.

87. *See* Panos Kanavos et al., *Parallel Trading in Medicines: Europe's Experience and Its Implications for Commercial Drug Importation in the United States*, AARP PUB. POL'Y INST. 22–24 (June 2005), *available at* https://assets.aarp.org/rgcenter/health/2005_07_trade.pdf (on file with *The University of the Pacific Law Review*) (analyzing four studies).

88. *Id.* at 24.

89. *Id.*

90. Patricia M. Danzon, *Price Discrimination for Pharmaceuticals: Welfare Effects in the US and the EU*, 4 INT'L J. ECON. OF BUS. 301, 301 (2011) (on file with *The University of the Pacific Law Review*).

regulations for the importation of pharmaceuticals from Canada if the Secretary simply made the certification that doing so would "(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer."[91] No Secretary ever opted to take that measure, and in 2001, Tommy Thompson—the HHS Secretary under President George W. Bush—made the contrary certification, stating to Congress that "[a]fter a thorough review of the law, FDA has concluded that it would be impossible to ensure that the MEDS Act would result in no loss of protection for the drugs supplied to the American people."[92] Secretary Thompson continued, "[T]he MEDS Act will pose a greater public health risk than we face today and a loss of confidence by Americans in the safety of our drug supply."[93]

Secretary Thompson's statements are manifestly false. With respect to the parallel importation of drugs within the European Union, Kanavos concludes:

> [w]hile there have been problems that have emerged associated with packaging, labeling, product inserts and potential violation of trademark rules, there is no evidence as to whether these problems have had an adverse impact on health care. Nor is there any evidence that these problems have raised substantial concerns among consumers, health care providers, or government officials.[94]

And far from it being "impossible" to ensure that drugs imported from Canada or Europe are safe for the American people, Kanavos writes:

> [s]uch issues are not beyond the scope of legislation. For example, safety provisions could include requirements that importers and exporters be registered with the federal government and that the government have the right to inspect facilities and places of business, verify chains of custody of the products, and determine compliance with regulations.[95]

A cynical observer might be tempted to believe that Secretary Thompson's conclusion was founded, not in a concern for the safety of pharmaceuticals in this country, but by a concern for the profits of the powerful U.S. pharmaceutical industry. In any event, the certification to allow for importation was never made

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91. 21 U.S.C.A. § 384(l)(1) (West, Westlaw through Pub. L. No. 116–91).

92. Cahoy, *supra* note 11, at 646 (quoting Letter from HHS Secretary Tommy G. Thompson to Sen. James Jeffords (July 9, 2001)).

93. *See* Daniel L. Pollock, *Blame Canada (and the Rest of the World): The Twenty-Year War on Imported Prescription Drugs*, 30 SETON HALL LEGIS. J. 331, 363, n. 214 (2006) (on file with *The University of the Pacific Law Review*) (quoting Letter from HHS Secretary Tommy G. Thompson to Sen. James Jeffords (July 9, 2001)).

94. Kanavos et al., *supra* note 87, at 28.

95. *Id.*

and it appears that Secretary Thompson's contrary certification has rendered the legislation null and void, because it provides:

If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.[96]

Subsequent bills allowing for the large-scale importation of pharmaceuticals died in Congress.[97]

Due to the current public outrage at the crippling cost of pharmaceuticals, importation provisions may now be politically feasible. Even the current Republican administration has floated the idea of allowing for the importation of drugs from Canada, although it appears to be a weak, token proposal.[98] Rather than authorizing and implementing a national system of drug importation for all medicines, the proposal would merely allow the states to implement "demonstration projects" that are "time limited and require reporting and renewal" around the importation of some of the less expensive drugs.[99] In particular, the plan would exclude importation of almost all drugs that are not taken in pill form and most high-priced drugs. This is because the proposal would exclude the importation of "biological products [any drug manufactured in or extracted from a biological source], infused drugs [drugs administered into the veins through infusion], intravenously injected drugs [drugs administered into the veins through injection], drugs inhaled during surgery, and certain parenteral drugs [drugs administered into the body other than via the mouth or the alimentary canal]."[100] Moreover, "the Secretary [of Health and Human Services] would have broad discretion to terminate a demonstration project if the continuation could pose additional risk to public health and safety."[101] In other words, another conclusory letter like the one Secretary Thompson sent to Congress in 2001 stating that a particular "demonstration project" posed a risk to health and safety would end that program. Indeed, not twelve months before introducing the proposal, Alex M. Azar II, the current HHS Secretary, called the notion of allowing for importation of

96. 21 U.S.C.A. § 384(l)(2) (West, Westlaw through Pub. L. No. 116–91).

97. Daniel L. Pollock, *Blame Canada (and the Rest of the World): The Twenty-Year War on Imported Prescription Drugs*, 30 SETON HALL LEGIS. J. 331, 364–67, n.100 (2006) (on file with *The University of the Pacific Law Review*).

98. Katie Thomas, *Rules Would Allow Import of Some Cheaper Prescription Drugs, but with Limits*, N.Y. TIMES, July 31, 2019, at A19.

99. Safe Importation Action Plan, U.S. Food & Drug Admin. 1 (July 31, 2019), *available at* https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf (on file with *The University of the Pacific Law Review*).

100. *Id.* at 2.

101. *Id.* at 3.

drugs a "gimmick."[102] To the contrary, his current proposal is a gimmick. As Elizabeth Rowley, the director of the diabetes advocacy group T1International concluded, "[t]his is kind of a distraction from the real issue, and the real problem . . . which is pharmaceutical companies are setting costs at exorbitant rates and patients are suffering and dying."[103]

What about a true program for the importation of pharmaceuticals from Canada and Europe, implemented nationally, applying to all FDA-approved drugs, and enshrined in a statute that cannot be terminated by a letter from the HHS Secretary? Would flooding the market with fair-priced competition lower the cost of drugs in the U.S.? When I presented this paper at the McGeorge School of Law, various experts in attendance expressed doubt. This is because the branded pharmaceutical companies would react to such a reform by limiting the supply of drugs to the countries of exportation, such that there would be insufficient drugs to import into the United States. Countries in Europe and Canada would then rationally bar the export of pharmaceuticals from their countries, in order to safeguard a sufficient supply for their own citizens. Indeed, Canadian citizens and the Canadian government reacted with hostility even in response to the current U.S. administration's toothless proposal for allowing limited "demonstration projects" around the importation of the least-expensive pills from Canada. One recent article reported the following response from a Canadian professor: "'You are coming as Americans to poach our drug supply, and I don't have any polite words for that,' said Amir Attaran, a professor at the University of Ottowa, who calls the plan 'deplorable' and 'atrociously unethical.' 'Our drugs are not for you, period.'"[104] The president of a Canadian patient advocacy organization said, "[i]t's time for [the importation proposal] to crash and burn. . . . Canadians may die."[105] In response, Canada's health minister "pledged to 'ensure there are no adverse effects to the supply or cost of prescription drugs in Canada.'"[106] Options on the table for Canada would include placing pharmaceuticals on Canada's export control list, passing a law banning the export of pharmaceuticals, or imposing high exportation taxes on pharmaceuticals.[107]

Would the pharmaceutical companies really cut off their nose to spite their face in this manner? Would they really drastically reduce their output of pharmaceuticals to Canada and the entire E.U. if the U.S. approved importation

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102. Thomas, *supra* note 98, at A19.

103. *Id.* ("[T]his is a plan to make a plan on importation. . . . This is not happening in the next week, in the next month or likely even in the next year because the administration will need to carry out the rule-making process.").

104. Nicholas Florko & Lev Facher, *Canadians Are Hopping Mad About Trump's Drug Importation Plan. Some of Them Are Trying to Stop It*, STAT NEWS (Aug. 12, 2019), *available at* https://www.statnews.com/2019/08/12/canadians-are-hopping-mad-about-trumps-drug-importation-plan-some-of-them-are-trying-to-stop-it/ (on file with *The University of the Pacific Law Review*).

105. *Id.*

106. *Id.*

107. *Id.*

from all of those countries? They were not able to do so in response to the allowance of parallel imports within the E.U. because the E.U. has restrictions "that manufacturers may not explicitly ban exports to other E.U. member states; monitor the final destination of products; or make written agreements with wholesalers or other direct purchasers to restrict supply."[108] But reducing output of pharmaceuticals to all of Europe and to Canada to the extent that it triggers an international pharmaceutical trade war would surely not be in the pharmaceutical industry's long-term interest. Indeed, allowing for fair trade of pharmaceuticals may increase drug sales overall. While fair trade would reduce the individual price of drugs, more drugs would be sold overall because sick Americans could actually afford to fill their prescriptions.[109]

V. CONCLUSION

If the U.S. cannot rely on this free market importation solution of riding on the coattails of low drug prices single payer and two-tiered countries negotiated, then the only solution is to join those countries. The surest way to end the pharmaceutical industry's corrupt price discrimination system is for the U.S. to adopt a single-payer system, at least with respect to pharmaceuticals. Although this was not politically feasible when Congress passed the Affordable Care Act in 2010, times change. Members of "Generation Z," now in their teens, are more liberal and believe in government more than preceding generations.[110] Should our civilization survive the Climate Crisis, perhaps this new generation will implement a single payer system. In this way, the U.S. government, under the threat of not buying a particular drug at all and wielding the power of a monopsony, could demand prices at the level of Europe and Canada for each drug. Such a system would remove from the equation the profit-seeking PBMs and other factors that create perverse incentives, kill competition, and exert economic pressure to send the prices of medicines ever higher.

108. Kanavos et al., *supra* note 87, at 10.

109. *Id.* (analyzing four studies).

110. Colby Itkowitz, *The Next Generation of Voters is More Liberal, More Liberal, More Inclusive and Believes in Government*, WASH. POST (Jan. 17, 2019, 9:32 AM), https://www.washingtonpost.com/politics/2019/01/17/next-generation-voters-are-more-liberal-more-inclusive-believe-government/ (on file with *The University of the Pacific Law Review*).