THE NEXT STEP IN THE BATTLE AGAINST HIGH PHARMACEUTICAL PRICES: *LEXMARK* & THE DSCSA HAVE PAVED THE WAY FOR PARALLEL IMPORTATION

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I. INTRODUCTION

Drug prices in the United States are too high, and Americans are suffering as a result. President Obama made attempts to combat this issue,[2] and currently, President Trump has vowed to bring prices

1. I am grateful to my family and friends for all their love, support, and encouragement throughout law school and the drafting of this Article. I am also thankful for Professor Frederick M. Abbott's insight, expertise, and advice, without which this Article would not have been written. Lastly, I would like to thank Hannah Rodgers, Lauren Pettine, and the rest of the Florida State University Law Review editors for their hard work in editing this Article.

2. Noam N. Levey, *Obama Administration Proposes New Effort to Combat High Drug*

down.[3] A recent poll indicated that over 70 percent of Americans are in favor of allowing importation of drugs to lower these prices.[4] This Article argues that the Supreme Court's decision in *Impression Products v. Lexmark* along with new drug safety regulations present the Trump Administration with the ideal opportunity to keep its promise by introducing competition into the patented drug market.

In short, this Article proposes a statutory change and cooperation between U.S. and EU authorities that will sanction parallel importation of patented pharmaceuticals in limited circumstances, which will bring much needed competition into the monopolized patented drug market. The suggestions will allow these pharmaceuticals to be traded under the current drug safety regulations, ensuring that Americans will be able to purchase the same safe medicines they take now, but at lower prices.

Part II of this Article explores the issue of high drug prices in the United States, which presents the need for parallel importation. Part III gives general background information necessary to understand the patent issues confronted in *Lexmark* and discusses the impact the Court's holding could have. In Part IV, the Article delves into the potential influence parallel importation could have on the pharmaceutical industry and the U.S. market.

Part IV analyzes the current regulatory scheme for the sale of pharmaceuticals in the United States, detailing new drug safety and tracing requirements that the Food and Drug Administration has implemented. Additionally, Part V discusses U.S. consumer's abuse of the current system that further demonstrates the need for change. In Part VI, the Article suggests a slight statutory change to the existing law and an agreement between U.S. and EU agencies, which would carve out a meaningful exception for parallel traders. The exception's main purpose would be to curtail the abuses of the current system and lower drug prices for struggling Americans. Lastly, in Part VII, the Article examines the road blocks to successfully implementing a parallel pharmaceutical trade (PPT) system in the United States.

Prices, L.A. TIMES (Mar. 8, 2016), http://www.latimes.com/business/la-fi-drug-prices-20160308-story.html [https://perma.cc/D3UD-B3YA].

3. Paul R. La Monica, *Trump Vows to Bring Drug Prices 'Way Down'*, CCN MONEY (Mar. 7, 2017, 12:49 PM), http://money.cnn.com/2017/03/07/investing/president-trump-drug-prices-healthcare/index.html [https://perma.cc/E7Y7-B22X].

4. Bianca DiJulio, Jamie Firth & Mollyann Brodie, *Kaiser Health Tracking Poll: August 2015*, KKF (Aug. 20, 2015), https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/ [https://perma.cc/G6CM-QWAL].

II. THE ISSUE OF HIGH DRUG PRICES IN THE UNITED STATES

Pharmaceutical prices in the United States are astronomical and are steadily rising. Since 1993, drug costs have increased 303 percent.[5] To put this number into perspective, let us briefly explore the prices of drugs meant to treat a particular disease: cancer. After adjusting for inflation and expected survival benefits, the initial prices of novel, patented cancer drugs in the United States steadily rose ten percent a year from 1995 to 2013.[6] The market entry price for patented cancer drugs in the United States is consistently in excess of $100,000 per patient/treatment and that price can skyrocket to $400,000 for certain orphan drugs.[7] Often times patients will require multiple treatments, too.

These alarming numbers have not gone unnoticed. Several expert oncologists coauthored an editorial protesting the outrageous prices.[8] In particular, the piece argues that the prices consumers have to pay for cancer treatments do not reflect a fair price for the benefits they receive from the drugs.[9]

High prices are not solely a national problem—the issue persists in every country and is worsening with the development of new drugs. In a study comparing the prices of a new Hepatitis C medicine in thirty countries of varying wealth, researchers found that "the total cost of treating all patients with hepatitis C [within the countries] would be equal to at least a tenth of the current annual cost for *all* medicines in

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5. INST. FOR HEALTH & SOCIO-ECON., MARCHING TOWARD MONOPOLY – MERGERS AND ACQUISITIONS IN THE PHARMACEUTICAL INDUSTRY 1 (2016) [hereinafter IHSP: MONOPOLY], https://www.nationalnursesunited.org/sites/default/files/nnu/files/pdf/research/MarchingTowardMonopoly-PharmaMA10-17-16.pdf.

6. Patricia M. Danzon, *Affordability and Accessibility to Medicines in EMs: Differential Pricing is the Solution*, ISB INSIGHT (June 1, 2016), http://isbinsight.isb.edu/affordability-and-accessibility-to-medicines-in-ems-differential-pricing-is-the-solution/ [https://perma.cc/ND4H-L8CH].

7. *Id.* For background on what constitutes an "orphan" drug, see *Designating an Orphan Product: Drugs and Biological Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm [https://perma.cc/ATP9-MG78] ("The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product ('drug') to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes 'orphan status'). For a drug to qualify for orphan designation both the drug and the disease or condition must meet certain criteria specified in the ODA and FDA's implementing regulations . . . . Orphan designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits for qualified clinical testing.").

8. Experts in Chronic Myeloid Leukemia, *The Price of Drugs for Chronic Myeloid Leukemia (CML) is a Reflection of the Unsustainable Prices of Cancer Drugs: from the Perspective of a Large Group of CML Experts*, 121 BLOOD J. 4439 (2013).

9. *Id.* at 4439.

all of the countries studied."[10] Despite this issue's global reach, the United States has far and away the highest pharmaceuticals prices in the world.[11] This was evident in the Hepatitis C study, which found that U.S. prices for both products evaluated were considerably higher than in countries with equivalent GDP per capita than the United States, such as the United Kingdom.[12]

Breaking the issue down reveals that newly patented pharmaceuticals are priced far higher than generic or off-patent drugs.[13] The patent rights on these "brand name" drugs are almost always held by the company that "originates" the drug. An "originator" is a company that develops a drug and is first to receive approval from health authorities—the Food and Drug Administration (FDA) in the United States—to market the drug to the public.[14] Upon receiving approval from the FDA and the U.S. Patent and Trademark Office, originators receive a period of market exclusivity and patent rights.[15] Patent rights usually last for twenty years from the date of filing. During this period the FDA cannot approve generic equivalents to the patented drug, unless the patent is invalidated or the generic drug does not infringe the patent.[16] Thus, the originator is granted a monopoly over the pricing of the new drug, because nobody else can produce or sell the product.

While there have been outstanding price increases in both generic and patented drugs,[17] the pricing of patented drugs has leveled the

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10. Swathi Iyengar et al., *Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis*, 13 PLOS MED. 1, 3 (2016) (emphasis added), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002032 [https://perma.cc/FRU3-VSLH].

11. FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW'S WORLD 22 (2009); *see also* Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform*, 316 JAMA 858, 860 (2016).

12. Iyengar et al., *supra* note 10, at 10.

13. For an explanation of the differences between a patented and a generic pharmaceutical, see Erik Mogalian, *What's the Difference Between Brand-Name and Generic Prescription Drugs?*, SCI. AM. (Dec. 13, 2014), https://www.scientificamerican.com/article/whats-the-difference-betw-2004-12-13/ [https://perma.cc/9P85-GFBZ] ("The major difference between a [patented] pharmaceutical and its generic counterpart is neither chemistry nor quality, but whether the drug is still under patent protection by the company that initially developed it. When a company develops a new drug, it typically receives a patent that lasts 20 years. This means that other pharmaceutical companies may not sell this substance without permission from the developing company during that time.").

14. ABBOTT & DUKES, *supra* note 11, at 19.

15. *See* Kesselheim et al., *supra* note 11, at 860. For more discussion on market exclusivity, see U.S. GOV'T ACCOUNTABILITY OFF., GAO-10-201, BRAND-NAME PRESCRIPTION DRUG PRICING: LACK OF THERAPEUTICALLY EQUIVALENT DRUGS AND LIMITED COMPETITION MAY CONTRIBUTE TO EXTRAORDINARY PRICE INCREASES 5-6 (Dec. 2009) [hereinafter GAO: BRAND-NAME PRICING], https://www.gao.gov/assets/300/299848.pdf [https://perma.cc/HP9V-2DKL].

16. GAO: BRAND-NAME PRICING, *supra* note 15, at 5 n.10.

17. IHSP: MONOPOLY, *supra* note 5.

biggest impact. Generic producers often have a higher volume of sales, but patent holding originators make much higher revenues.[18] To illustrate, in 2007, worldwide pharmaceutical sales reached approximately US$650 billion, where roughly US$550 billion of these sales came from patented products.[19] The brunt of this has been felt in United States, which "has the highest originator pharmaceutical prices in the world and contributes the largest share of originator industry revenues."[20]

Contrary to almost all other advanced nations, the United States permits manufacturers to set their own prices for pharmaceuticals.[21] Without direct regulatory oversight of pricing and protection from competition via patent rights, U.S. originators have been free to set the prices of patented pharmaceuticals as high as they please.

Another aspect that adds fuel to the originators' pricing power is the relatively inelastic demand for drugs.[22] For most nonessential products, if the price increases greatly, consumers will likely stop buying them. As convenient and entertaining as Netflix is, most people would not subscribe to it if its price rose from $10 a month to $100 a month. On the other hand, pharmaceuticals are necessities, rendering them inelastic as their prices increase. Even when pharmaceuticals make tenfold price jumps,[23] people must continue to buy them.

The evidence establishes that patent holders have taken advantage of the lack of competition, minimal price controls, and unwavering demand. U.S. originators have charged high prices in the United States,

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18. ABBOTT & DUKES, *supra* note 11, at 22.

19. *Id.*; *see also* Frederick M. Abbott, *Parallel Trade in Pharmaceuticals: Trade Therapy for Market Distortions*, *in* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY EXHAUSTION AND PARALLEL IMPORTS 145, 151 (2016) [hereinafter Abbott, *Parallel Trade in Pharmaceuticals*] ("As of 2015, aggregate global revenues from sales of pharmaceutical products should exceed U.S.$1 trillion. Generic drugs will account for about U.S.$300–350 billion of that total. Yet, the volume of generic drugs in international trade far exceeds the volume of patented drugs.").

20. Frederick M. Abbott, *Inside Views: US Supreme Court Adopts International Exhaustion For Patents: Paving the Way for Parallel Imports to Exert Downward Pressure on Domestic Pharmaceutical (and Other) Prices*, INTELL. PROP. WATCH (May 31, 2017) [hereinafter Abbott, *Inside Views I*], https://www.ip-watch.org/2017/05/31/us-supreme-court-adopts-international-exhaustion-patents-paving-way-parallel-imports-exert-downward-pressure-domestic-pharmaceutical-prices/ [https://perma.cc/4CJE-UM64]; PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES, IMPLICATIONS FOR AM. CONSUMERS, PRICING, RES. AND DEV., AND INNOVATION BEFORE THE COMM. ON HEALTH, EDUC., LABOR AND PENSIONS 4 (2005) [hereinafter PHARMACEUTICAL PRICE CONTROLS], https://www.help.senate.gov/imo/media/doc/Aldonas-SenHELP-Rx-2-17-05.pdf [https://perma.cc/AEK7-RX66] (testimony of Grant D. Aldonas) ("We found that patented drugs that were best sellers in the United States sold for less in other OECD countries.").

21. Kesselheim et al., *supra* note 11, at 860.

22. *See Pharmaceutical Pricing and Reimbursement and the Broader Pharmaceutical Policy Environment*, *in* OECD HEALTH POLICY STUDIES: PHARMACEUTICAL PRICING POLICIES IN A GLOBAL MARKET 97 (2008).

23. GAO: BRAND-NAME PRICING, *supra* note 15, at 10-15.

while blatantly charging foreign nations much less for the same product.[24] This price discrimination is evident in various studies. A study conducted by the U.S. Department of Commerce found that among Organization for Economic Cooperation and Development (OECD) member countries, the aggregate pharmaceutical prices were anywhere from 18 percent to 67 percent less than prices charged in the United States.[25] What these numbers fail to demonstrate is the real-life impact that this greed has on U.S. citizens. Politicians and news outlets have tried to bring this to light.[26]

Clearly, action must be taken to drive down the prices of patented pharmaceuticals. One solution would be to increase competition in the market. You might be wondering—and for good reason—how competition can be increased when originators have patent rights over the sale of the product. The U.S. Supreme Court's decision in *Impression Products v. Lexmark* may provide relief in this area.

Prior to the *Lexmark* decision, there was uncertainty about whether the sale of a patented product in a foreign country exhausted the U.S. patent owner's rights in the patented product. The Court in *Lexmark* unequivocally adopted a rule of international exhaustion of patent rights.[27] In doing so, it has presented legislators and rule-makers with the opportunity to crack open the door for parallel importers to add competition to the market.[28] This Article argues that in limited circumstances, importers should be able to purchase FDA approved drugs on

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24. *See* Panos Kanavos et al., *Higher U.S. Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs*, 32 HEALTH AFFAIRS 753 (2013); James Paton & Naomi Kresge, *Why the $600 EpiPen Costs $69 in Britain*, BLOOMBERG (Sept. 29, 2016), https://www.bloomberg.com/news/articles/2016-09-29/epipen-s-69-cost-in-britain-shows-other-extreme-of-drug-pricing-itnvgvam; Robert Langreth et al., *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, BLOOMBERG (Dec. 18, 2015), https://www.bloomberg.com/graphics/2015-drug-prices/ [https://perma.cc/Y78M-HG3P].

25. PHARMACEUTICAL PRICE CONTROLS, *supra* note 20, at 4.

26. *See* Ali Velshi et al., *Prescription Price Crisis? 28 Million Americans See Spike in Drug Prices*, NBC NEWS (June 11, 2017, 9:45 AM), https://www.nbcnews.com/business/consumer/prescription-price-crisis-28-million-americans-see-spike-drug-prices-n770291 [https://perma.cc/FEF6-PLRH]; Bernie Sanders, *High Drug Prices Are Killing Americans*, HUFF. POST (Aug. 31, 2016), https://www.huffingtonpost.com/bernie-sanders/high-drug-prices-are-kill_b_8059526.html [https://perma.cc/9GYB-MA6L]; Liz Szaboa, *Drug Costs Soar, People Delay or Skip Cancer Treatments*, NPR (March 15, 2017, 5:00 AM), https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments [https://perma.cc/8E66-J2YL]; Joseph Walker, *Patients Struggle With High Drug Prices*, WALL ST. J. (Dec. 31, 2015), https://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981 [https://perma.cc/Y556-UTUZ].

27. Under a rule of national (rather than international) exhaustion, a U.S. originator who sold its drug in a foreign market would preserve the right to sue for infringement if a company attempted to buy the foreign drug and resell it in the United State. Inhibiting this trade allows the patent holder to sustain a competition-free market. *See infra* Part V.

28. For a definition of parallel importation, see Gene M. Grossman & Edwin L.C. Lai, *Parallel Imports and Price Controls*, 39 RAND J. OF ECON. 378, 378 (2008) ("Parallel trade

the foreign market at low prices and resell them in the United States. Sanctioning the sale of parallel imported drugs at cheaper prices would undercut the high prices originators charge. Allowing PPT in United States will not be a complete solution to the drug price crisis; however, it will start to push prices in the right direction—down.

III. PATENT EXHAUSTION & THE *LEXMARK* DECISION

A. Background

This brief section provides general background information necessary to understanding the patent issues confronted in *Lexmark* and its potential impact on pharmaceutical prices. The chief purpose of the patent system is to function as an incentive for individuals to do something they would not have done otherwise, such as "invent, disclose, commercialize, or design around."[29] To create this incentive, the Patent Act grants patentees the "right to exclude others from making, using, offering for sale, or selling the[ir] invention[s]."[30] A patentee can defend and enforce these rights in an infringement action. Such actions provide patentees with the ability to secure injunctions and/or recover monetary damages for violations of the rights.[31]

A patentee's exclusionary rights over a patented product is not boundless. Significantly, the rights are limited by a valid sale of the patented item.[32] When a patentee chooses to sell an item, the purchaser becomes the owner of that product and gains the rights and benefits of ownership. Consequently, the sale terminates or exhausts the patentee's right to exclude others, including the purchaser, from using or selling that item.[33] This exhaustion of rights is often referred

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occurs when a good protected by a patent, copyright, or trademark, having been legally purchased in one country, is exported to another without the authorization of the local owner of the intellectual property rights in the importing market.").

29. Kieff F. Scott, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules* 8-9 (Harvard Law and Economics, Discussion Paper No. 415, 2003), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=392202 [https://perma.cc/4HNU-7D64].

30. 35 U.S.C. § 154(a) (2012). Note that this exclusion right is restricted to "whatever product or process is covered by the patent's claim or claims. Thus, for example, patents do not interfere with other governmental efforts to restrict use, such as to mitigate environmental impact." Scott, *supra* note 29, at 9.

31. *See* Mark A. Lemley, *Should Patent Infringement Require Proof of Copying*, 105 MICH. L. REV. 1525 (2007).

32. *See* United States v. Univis Lens Co., 316 U.S. 241, 250 (1942) (discussing the termination of rights upon a sale of a patented product).

33. Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1531 (2017); *see also* Quanta Computer, Inc. v. LG Electrs., Inc., 553 U.S. 617, 625 (2008). A sale will not result in a patent owner losing all rights associated with their patent. Notwithstanding an authorized sale, a patentee will "retain[] his right to exclude purchasers of the articles from making

as the "first sale" doctrine; its main purpose is to limit the patentee's monopoly over a patented article in an effort to facilitate the free movement of patented goods in the market.[34]

The first sale doctrine was well-established in U.S. case law prior to the *Lexmark* decision. As such, it is well-known that when a U.S. patentee sells his or her product within the United States, the patentee no longer has patent rights to exclude activities such as resale, ordinary use, or repair of the article.[35] Despite the rule's long history, there was much uncertainty about whether the first sale of a patented product in a foreign country exhausted the patentee's rights in the United States; and, whether post-sale contractual restrictions entered into by the patentee and a purchaser of the product preserved the rights that would otherwise be exhausted by such a sale.[36] In *Impression Products v. Lexmark*, the Supreme Court set out to answer these pressing questions.

B. Lexmark

The respondent in this seminal decision was Lexmark International, Inc. (Lexmark), a company that designed, manufactured, and sold toner cartridges globally.[37] The company held various patents covering cartridge mechanisms and how they are used.[38] When these cartridges ran out of toner it was easy for competitors to refill and sell them again.[39] Fully aware of this issue, Lexmark developed a business model attempting to stifle resale competition.[40] It gave buyers two options: 1) purchase a "Regular" cartridge at full price that was not subject to any restrictions; or 2) purchase a "Return Program" cartridge at a discount, subject to the contractual restriction that the buyer

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the patented invention anew." Amelia Smith Rinehart, *Contracting Patents: A Modern Patent Exhaustion Doctrine*, 23 HARV. J.L. & TECH. 484, 484 n.4 (2010). Thus, when this Article refers to the exhaustion of patent rights, it refers only to the rights of restricting sales or uses of products that have been sold by the patentee, not the right to restrict others from creating the patented product.

34. Rinehart, *supra* note 33, at 484; *see also Lexmark Int'l, Inc.*, 137 S. Ct. at 1531 ("For over 160 years, the doctrine of patent exhaustion has imposed a limit on that right to exclude.").

35. Rinehart, *supra* note 33, at 484-85; *Lexmark Int'l, Inc.*, 137 S. Ct. at 1529-31 (noting that the rule is "well-established" after discussing and citing cases which solidified the rule).

36. *Compare* Jazz Photo Corp. v. Int'l Trade Comm'n, 264 F.3d 1094 (Fed. Cir. 2001) (holding that sales made outside the United States were outside the reach of exhausting U.S. patent rights), *with* Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992) (finding that post-sale restrictions preserved some patent holders' rights despite an authorized sale).

37. *Lexmark Int'l, Inc.*, 137 S. Ct. at 1529.

38. *Id.*

39. *Id.*

40. *Id.*

would not reuse the cartridge and would not transfer the cartridge to anyone other than Lexmark after the toner ran out.[41]

Despite Lexmark's efforts, remanufacturers continued to successfully buy, refill, and resell both types of cartridges.[42] In reaction, Lexmark brought patent infringement claims against several remanufacturers, including the petitioner, Impression Products, Inc. (Impression), regarding two groups of cartridges. The first group were Return Program cartridges that Lexmark sold within the United States.[43] Lexmark argued that the remanufacturers infringed the patents regarding this group because of its express prohibition against reuse and resale.[44] Lexmark based its infringement argument for the second group—consisting of cartridges Lexmark sold abroad that were subsequently imported into the United States by remanufacturers—on the fact that it never gave anyone the authority to import the cartridges.[45] In response, Impression maintained that both infringement claims were invalid, because Lexmark's sale of the cartridges, both abroad and in the United States, exhausted Lexmark's patent rights.[46]

The Court held that Impression was not liable for patent infringement, finding that the post-sale restrictions Lexmark placed on the "Return Program" cartridges did not give rise to patent rights, and that the lawful sale of the cartridges aboard exhausted Lexmark's patent rights within the United States.[47] In reaching this decision, the Court was faced with two major issues: 1) whether a patent holder that sells an item with express resale and reuse prohibitions may enforce the restrictions through an infringement action; and 2) whether a patentee exhausts its patent rights by selling its product outside the United States.[48]

In addressing the first issue, the Court concluded that post-sale contractual provisions had no effect on the exhaustion of Lexmark's

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41. *Id.* at 1529-30. Patent owners are often well aware of the limitations of patent rights after an authorized sale. Consequently, patentees will place post-sale restrictions in their sales contracts with purchasers, just as Impression did with the Return Program cartridges. This is done in the hopes of recovering damages in a legal action based on contract law if the first sale doctrine restricts them from recovering based on a patent infringement claim; *see* Rinehart, *supra* note 33, at 495-97; *see also infra* Part VII.C.2.

42. *Lexmark Int'l, Inc.*, 137 S. Ct. at 1530.

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. Sarah R. Wasserman Rajec, Impression Products, Inc. v. Lexmark Inc.*: Will International Patent Exhaustion Bring Free Trade in Patented Goods*, PATENTLY0 (June 1, 2017), https://patentlyo.com/patent/2017/06/impression-international-exhaustion.html [https://perma.cc/M55C-9AKY].

48. *Lexmark Int'l, Inc.*, 137 S. Ct. at 1529.

patent rights.[49] The Court noted that the single-use/no-resale restrictions in the customers' contracts may have given Lexmark enforceable rights against the customers under contract law; however, the provisions in no way enabled Lexmark to preserve patent rights in the items.[50]

In resolving the second issue, the Court firmly embraced a rule of international exhaustion. Making it clear that "[a]n authorized sale outside the United States, just as one within the United States, exhausts all rights under the Patent Act."[51] The Court reasoned that adopting the rule of international exhaustion was "straightforward," considering that international exhaustion is applied to copyright protections.[52]

Notwithstanding the Court's ease in reaching its conclusion on international exhaustion, the ruling has enormous implications. The opinion applies to all patents, and its impact will not be limited to the pharmaceutical industry; it will have far reaching implications for all U.S. consumers and affect virtually every industry.[53] The opinion, as commentators have noted, certainly leaves questions unanswered.[54] The remainder of this Article will focus on the effects the opinion could have on the pharmaceutical sector. Specifically, it will explore the opportunities that the decision presents for arbitrage of patent pharmaceuticals.

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49. *Id.* at 1531.

50. *Id.*

51. *Id.* at 1535.

52. *Id.* at 1536.

53. *See* Abbott, *Inside Views I*, *supra* note 20; *see also* Frederick M. Abbott, *Inside Views: US Supreme Court Adopts International Exhaustion Of Patents (Part II): Addressing the New Competitive Landscape*, INTELL. PROP. WATCH (Aug. 06, 2017) [hereinafter *Abbott, Inside Views II*], http://www.ip-watch.org/2017/06/08/us-supreme-court-adopts-international-exhaustion-patents-part-ii-addressing-new-competitive-landscape/ [https://perma.cc/M9TU-XADM] ("The decision has wide-ranging effect. Importers of computers and cellphones that are produced with components lawfully sourced outside the United States no longer must be concerned about attempts to block resales through patent-owner infringement actions.").

54. *See* Rajec, *supra* note 47, at 2 ("[T]he opinion leaves open some questions about international trade in patented goods. Some are legal and will likely spur further litigation (e.g., whose authorization is required for an 'authorized sale abroad' to occur?) while others are empirical and still speculative (e.g., with geographic price discrimination off the table, what other methods will businesses pursue for price discrimination and control of downstream sales?"); *see also* Gene Quinn, *Patent Exhaustion at the Supreme Court: Industry Reaction to* Impression Products v. Lexmark, IPWATCHDOG (May 30, 2017), http://www.ipwatchdog.com/2017/05/30/patent-exhaustion-supreme-court-industry-reaction-impression-products-v-lexmark/id=83822/ [https://perma.cc/6JVA-XW7F].

IV. EFFECTS OF PARALLEL IMPORTATION ON THE U.S. PHARMACEUTICAL MARKET

The pharmaceutical industry is, by any measure, highly regulated, and justifiably so.[55] Unlike industries with minimal regulatory barriers, parallel importation of pharmaceuticals cannot take place in the United States without an analysis of, and changes to, the current regulatory scheme. Before moving on to this legal analysis, it is critical to further understand the need for such importation—in short, how will it drive prices down.

The establishment of international exhaustion aligns U.S. patent law with free trade principles and will likely spark competition by reducing barriers to trade.[56] When a patentee completes a valid sale of its product abroad, international exhaustion nullifies the patentee's ability to claim infringement when a competitor resells that product in the United States.[57] This will stifle a patent holder's ability to participate in geographic price discrimination between the United States and foreign markets. If the *Lexmark* decision triggers a move toward parallel importation of pharmaceuticals, it will result in the originator industry losing some control over setting prices for patented pharmaceuticals.[58]

A pharmaceutical patent holder will no longer have the ultimate right to determine the selling price of its product other than upon its initial sale.[59] Thus, if the patent holder chooses to sell its drug at a low price point in a foreign country, that drug may be resold at a low price within the United States.[60] As noted, price discrimination is rampant, and U.S. consumers are often the ones most affected by it.[61]

Patent rights create an atmosphere of minimal to no competition.[62] The U.S. Government Accountability Office views this lack of competition as a contributing factor to the "extraordinary" prices of patented drugs.[63] Parallel importation is a tool that would introduce competition into the market and may lead to a decrease in prices that the United States so desperately needs.

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55. *See generally* ABBOTT & DUKES, *supra* note 11.

56. Rajec, *supra* note 47, at 1.

57. See *supra* note 52 and accompanying text.

58. Abbott, *Parallel Trade in Pharmaceuticals*, *supra* note 19, at 151.

59. *Id.*

60. *Id.*

61. Abbott, *Inside Views I*, *supra* note 20 ("The US public stands to gain from the downward pricing pressure that may come from parallel imports of patented pharmaceuticals.").

62. *See Lemley*, *supra* note 31.

63. GAO: BRAND-NAME PRICING, *supra* note 15, at 16.

Economic models concur that parallel importation will result in originators lowering prices of the product for the importing country and increasing prices in the country which they are exported from (assuming that the exporting country had lower prices prior to the parallel importation).[64] As result, U.S. originators may need to raise prices in foreign markets and lower prices in the United States in order keep up with new competition from parallel imports; this should bring the market towards more uniform global prices for patented pharmaceuticals.[65] If the price of the drug is higher in the U.S market than in a foreign country, U.S. consumers will benefit by receiving new, lowered prices.[66]

Some have vehemently argued that sanctioning parallel trade will cripple the originator industry's ability to fund research and development (R&D), which will decrease the number of new drugs being invented.[67] There is evidence that suggests otherwise. First, large originator companies have shown that—even without the pressure of parallel imports—R&D is not one their top priorities.[68] "There is a considerable lack of transparency in pharmaceutical R&D investment, but the available data indicate that *only about 10%* of drug sales go towards R&D on new products."[69] Indeed, many large originator companies have shifted their focus away from R&D, instead relying on mergers and acquisitions (M&A) to acquire the rights to newly invented drugs.[70] Rather than spend revenue on R&D to invent new drugs or treatments, these companies have opted

64. Daniel J. Hemel & Lisa Larrimore Oullette, Trade and Tradeoffs: *The Case of International Patent Exhaustion*, 116 COLUM. L. REV. ONLINE 17, 24-26 (2016) (discussing in the introduction how the United States almost always has higher prices than foreign countries); Catalina Bordoy & Izabela Jelovac, *Pricing and Welfare Implications of Parallel Imports in the Pharmaceutical Industry*, 5 INT'L J. HEALTH CARE FIN. & ECON. 5, 7 (2005).

65. *See* Martin Richardson, *An Elementary Proposition Concerning Parallel Imports*, 56 J. OF INT'L ECON. 223 (2002); David Malueg & Marius Schwartz, *Parallel Imports, Demand Dispersion, and International Price Discrimination*, 37 J. INT'L ECON. 167 (1994); Brief for Professor Frederick M. Abbott as Amicus Curiae Supporting Petitioners at 20, Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189) [hereinafter Brief for Professor Abbott].

66. Brief for Professor Abbott, *supra* note 65, at 20; *see also* Bordoy & Jelovac, *supra* note 64, at 6 ("We first confirm a result already reported in the literature: Parallel trade makes the prices [of pharmaceuticals] converge.").

67. JACOB ARFWEDSON, INST. FOR POLICY INNOVATION, RE-IMPORTATION (PARALLEL TRADE) IN PHARMACEUTICALS: POLICY REPORT 182, at 6 (2004), https://www.ipi.org/docLib/PR182-ParallelTrade.pdf=OpenElement.pdf.

68. *See* INST. FOR HEALTH & SOCIO-ECON. POLICY, THE R&D SMOKE SCREEN: THE PRIORITIZATION OF MARKETING & SALES IN THE PHARMACEUTICAL INDUSTRY (2016) [hereinafter IHSP: SMOKE SCREEN], https://nurses.3cdn.net/e74ab9a3e937fe5646_afm6bh0u9.pdf [https://perma.cc/5FBR-DFHV].

69. Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLOS BIOLOGY 147, 148 (2004) (emphasis added).

70. *See* IHSP: MONOPOLY, *supra* note 5.

to purchase smaller firms that have invented a new drug through their own R&D departments. Once the transaction is complete, the combined or remaining company's R&D funding is cut substantially.[71]

Second, almost all of the top pharmaceutical companies spend more on marketing and sales (M&S) than on R&D by a large margin—a majority spend over twice as much on M&S.[72] Notwithstanding the debates of the ethics of advertising prescription drugs directly to consumers,[73] it seems that U.S. citizens cannot watch ten minutes of cable television without seeing a commercial for a prescription drug. The numbers show that this advertising certainly is not cheap.[74] In the event that parallel imports result in a decrease of originator revenue, the amount spent on M&S demonstrates that there are plenty of funds that companies could reallocate to ensure the same level of investment in R&D.[75]

Moreover, even if the originator industry decides to apportion less funds to R&D, it may not result in a decrease of newly invented drugs. A substantial source of pharmaceutical R&D funding comes from the National Institutes of Health (NIH).[76] It provides about $37.3 billion dollars for medical research annually, much of which is allocated to pharmaceutical R&D funding.[77] This considerable and steady source of funding is unlikely to be affected by parallel imports, because the funds do not depend on profitability of patented drugs. Lastly, if the originator industry increases prices abroad, as the economic models predict, the increased revenue from foreign sales could undoubtedly help the companies maintain the current level of R&D funding.[78]

Another argument launched against PPT is that it will not result in meaningful benefits to U.S. consumers. A 2004 report by the U.S. Department of Health and Human Services (HHS) estimated that the savings to the U.S. consumer would be modest in comparison to the

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71. *Id.* at 9.

72. IHSP: SMOKE SCREEN, *supra* note 68, at 2-3.

73. *See* ABBOTT & DUKES, *supra* note 11, at 183-89 (discussing how there are only *two countries* in the world who allow direct-to-consumer advertising and noting the ethical issues that accompany such advertising); *see also* R. Stephen Parker & Charles E. Pettijohn, *Ethical Considerations in the Use of Direct-To-Consumer Advertising and Pharmaceutical Promotions: The Impact on Pharmaceutical Sales and Physicians*, 48 J. BUS. ETHICS 279 (2003).

74. IHSP: SMOKE SCREEN, *supra* note 68, at 4. From 2011-2015, a *single* originator (Novartis) spent over $60,000,000,000 on Marketing and Sales. *Id.*

75. Brief for Professor Abbott, *supra* note 65, at 24.

76. *Id.* at 24-25.

77. *What We Do: Budget*, U.S. DEP'T HEALTH AND HUM. SERVS., NAT'L INSTS. HEALTH (APRIL 11, 2018), https://www.nih.gov/about-nih/what-we-do/budget [https://perma.cc/9KP3-9QX6].

78. Brief for Professor Abbott, *supra* note 65, at 20.

overall pharmaceutical industry.[79] The HSS report found that if PPT remedies the price discrepancy between the United States and foreign jurisdictions, the benefit may not be fully felt at the consumer level, because third parties—such as insurance companies and importers/exporters—will take a large portion of the savings.[80] Since the report was published, however, the gap between pharmaceutical prices in the United States and foreign countries has increased.[81]

Additionally, globalization has made the cost of shipping goods less expensive.[82] It is likely that companies in the best position to step in as parallel traders—companies such as Walmart, Costco, and Amazon, which have specialized in this kind of trade for years—will have found ways to reduce their costs since 2004. This could translate into parallel importers taking a smaller percentage of the difference in prices than the HHS Report estimated, and result in more savings trickling to the consumer. Furthermore, as the Report notes, even if the savings to consumers overall will be modest, the individuals most in need of relief from high drug prices—the uninsured—are those most likely to significantly benefit from parallel imports.[83]

To be clear, the discussion above does not go into great detail regarding the economic theory involved in determining the influence of PPT. There is significant debate on the impact PPT will have on overall global welfare and on the full influence it will have on prices at the consumer level.[84] Despite the importance of economics to this debate, an empirical study analyzing the exact financial impact is beyond the scope of this paper. However, even assuming that parallel imports will

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79. *See* U.S. DEP'T OF HEALTH AND HUM. SERVS., HHS TASKFORCE ON DRUG IMPORTATION, REPORT ON PRESCRIPTION DRUG IMPORTATION 65-70 (2004) [hereinafter HHS TASKFORCE REPORT], https://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf [https://perma.cc/6SQW-3YZD].

80. *See id.* at 65.

81. *See* Kanavos et al., *supra* note 24, at 756-58.

82. *See* Deborah Abrams Kaplan, *The Real Cost of E-Commerce Logistics*, SUPPLY CHAIN DIVE (June 6, 2017), https://www.supplychaindive.com/news/amazon-effect-logistics-cost-delivery/444138/ [https://perma.cc/DM6Y-SF4V] ("While shipping is costly for Amazon, the company is reducing its transportation expenses on a per package and per order basis every quarter of every year . . . .").

83. HHS TASKFORCE REPORT, *supra* note 79, at 67. ("[S]ome individuals may enjoy significant savings. Uninsured people who buy chronic use patented name-brand drugs on a regular basis may enjoy meaningful savings if they are able to buy safe and effective foreign versions of U.S. drugs . . . .").

84. For a more in depth economic analysis, see Grossman & Lai, *supra* note 28; *see also* Jelovac & Bordoy, *supra* note 64, at 7 (finding that PPT's effect on welfare will depend on the drug needs and health insurance policies of the countries involved as well as originators reactions to the introduction of parallel trade); Patricia Danzon, *The Economics of Parallel Trade*, 13 PHARMACOECONOMICS 293 (1998); Hemel & Oullette, *supra* note 64, at 27 ("[N]et winners and losers from a U.S. international exhaustion rule are somewhat ambiguous . . . .").

only have a limited impact on lowering U.S. pharmaceutical prices, it would still be important progress.

The United States has the highest originator pharmaceutical prices in the world.[85] Frankly, any developments that alleviate prices are a step in the right direction. Parallel trade will, at a minimum, loosen the grip the originator industry has on patented pharmaceutical prices. The importance of breaking up the pricing monopoly is clear. The remainder of this Article will focus on the feasibility of implementing a successful scheme to do so.

V. REGULATORY SCHEME AND CONSUMER ACTIONS UNDER THE SCHEME

A. Current International Legal Scheme

The United States is not a party to an international agreement that directly restricts parallel importation.[86] The international legal scheme and trade rules largely leave the legality of parallel importation in the hands of the importing country.[87] The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to which the United States is a party, demonstrates the deferential nature of international law regarding exhaustion and parallel importation.[88] Article 6 of TRIPS, specifies that nothing in the Agreement "shall be used to address the issue of the exhaustion of intellectual property rights."[89]

Despite this language, some challenged the legality of the parallel importation under TRIPS.[90] In the late 1990s, the originator pharmaceutical industry launched a challenge to the South African government's authorization of PPT, arguing that TRIPS prohibited such activity.[91] Stated simply, the issue in the case boiled down to whether

85. Abbott, *Inside Views I*, *supra* note 20.

86. Susy Frankel & Daniel J. Gervais, *International intellectual property rules and parallel imports*, *in* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY EXHAUSTION AND PARALLEL IMPORTS 85, 92 (Calboli & E. Lee, Edward Elgar eds., 2016); Brief for Professor Abbott, *supra* note 65, at 9.

87. Grossman & Lai, *supra* note 28, at 399.

88. Frankel & Gervais, *supra* note 86, at 92.

89. *General Agreement on Tariffs and Trade - Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods*, 33 I.L.M. 81, 86 (1994); *see also* Frankel & Gervais, *supra* note 86, at 92.

90. *See* Frederick M. Abbott, *First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, 1 J. INT'L ECON L. 607, 609 (1998).

91. Abbott, *Parallel Trade in Pharmaceuticals*, *supra* note 19, at 146.

South Africa's authorization of parallel importation violated TRIPS.[92] The case was ultimately abandoned by the originator industry, who chose to pay South Africa's legal expenses, but the answer to the issue was clearly "no."[93] South Africa has since implemented the regulations sanctioning PPT, and they are still in place today.[94]

A lack of consensus on the issue of exhaustion at the international level has led to a policy of deference to individual nations. International challenges to national laws accepting parallel importation have not been successful, as evidenced by the South African example. Moreover, PPT has been successfully implemented for many years in the European Union.[95] Thus, there are no real international roadblocks to the United States initiating legislation that fosters PPT. However, it is not so clear cut at the domestic level.

B. Federal Legal Landscape

1. Compliance with Drug Applications and the Ban on Reimports

All aspects of pharmaceuticals in the United States—from manufacture to sale—are regulated by the FDA. The origins of this authority stem from the Food, Drug, and Cosmetic Act of 1938 (FDCA), which allows the FDA to regulate the import and export of pharmaceuticals.[96] For starters, section 510 of the FDCA requires firms that manufacture, prepare, propagate, compound, process, or import drugs in the United States to register with the FDA.[97] This requirement extends to companies even if they are solely repacking or relabeling drugs, which, as discussed below, is fairly important in the context of PPT.[98]

The FDA enforces restrictions against the importation of any drug that it has not approved through a new drug application (NDA).[99] Specifically, the FDCA prohibits the introduction into interstate commerce

92. *Id.*

93. *Id.*

94. *Id.* at 147.

95. PANOS KANAVOS ET AL., PARALLEL TRADING IN MEDICINES: EUROPE'S EXPERIENCE AND ITS IMPLICATIONS FOR COMMERCIAL DRUG IMPORTATION IN THE UNITED STATES i (2005), https://assets.aarp.org/rgcenter/health/2005_07_trade.pdf [https://perma.cc/C4DQ-DGSX].

96. 21 C.F.R. § 314.410 (2017); Elliott A. Foote, *Prescription Drug Importation: An Expanded FDA Personal Use Exemption and Qualified Regulators for Foreign-Produced Pharmaceuticals*, 27 LOY. CONSUMER L. REV. 369, 377 (2015).

97. *See* 21 U.S.C. § 360 (2012).

98. *Id.*

99. Marvin A. Blumberg, *Information on Importation of Drugs*, U.S. FOOD & DRUG ADMIN. (Apr. 3, 1998), https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm [https://perma.cc/2DCX-HZL3].

of any "new drug" that has not been approved via an NDA.[100] This justifiable prohibition of unapproved drugs has little negative impact on PPT, because drugs that have not been approved cannot be sold in the United States, regardless of whether they are imported. The following restrictions have more of an influence on the potential for PPT.

If a drug does gain approval, the FDA prohibits versions of the drug that do not meet the specifications of the NDA.[101] Most drugs sold at lower prices abroad are labeled for sale in that foreign country or region (such as the European Union); therefore, under the FDCA, anybody who buys the drug in a foreign market will need to relabel it with the appropriate U.S. labels in order to sell it here. Moreover, "if a product is manufactured in a different facility from the facilities listed in the NDA, or if it is manufactured according to different specifications, it is considered an unapproved new drug—even if it is made by the same company."[102] Essentially, imported drugs must fully comply with U.S. labeling requirements and comport to any specifications (manufacturing facility or otherwise) within the NDA.[103]

Thus, the foreign version of an originator's pharmaceutical product cannot be legally imported, even if the same originator retails an identical FDA-approved version to U.S. patients.[104] However, this would not prohibit the importation of a drug manufactured in a foreign country if the labeling, manufacturing facility, and product complied with the originator's NDA.[105]

Lastly, the FDCA places a ban on re-importation of pharmaceuticals.[106] For example, when a prescription drug is manufactured within the United States and exported to another country, it cannot be imported back into the United States (unless it is being returned to the

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100. 21 U.S.C. § 355(a) (2012); Erika Lietzan, *Demystifying Drug Importation after Impression v. Lexmark*, PATENTLY0 (JUNE 6, 2017), https://patentlyo.com/patent/2017/06/demystifying-importation-impression.html [https://perma.cc/KRX4-A54N].

101. *See* Blumberg, *supra* note 99.

102. Lietzan, *supra* note 100.

103. *Id.*

104. Professor Lietzan provides a great example of this restriction in action. *See id.* ("Pfizer sells Viagra in the United States under an NDA that [the] FDA has approved. Pfizer also sells Viagra in Europe. That drug is marketed pursuant to authorization by the European Commission on the basis of a separate marketing application that complied with European law. If the European product is made at a facility that is not listed in the U.S. application, or if it is manufactured according to different specifications, or if it is composed differently (different inactive ingredients for instance), then it cannot be imported into the United States. Certainly it is labeled in accordance with European labeling rules, and the European labeling is not the same as the FDA-approved labeling, so again it cannot be imported into the United States.").

105. *See infra* Part VI.

106. 21 U.S.C. § 381(d)(1) (2012).

original manufacturer).[107] Thus, if a drug is originally made in the United States, re-importing it for sale on the U.S. market is prohibited.

2. The Drug Supply Chain Security Act

More recently in 2013, the Drug Supply Chain Security Act (DSCSA)[108] was added to the FDCA under which the FDA has implemented more rules that affect the potential for PPT.[109] This Act and its rules are meant to ensure the safety and quality of drugs as they change hands before reaching U.S. patients.[110] Specifically, the regulations are meant to certify that a drug sold to a U.S. consumer can easily be traced back to when it was created, and that there is a record of who handled the product prior to the consumer's purchase. The DSCSA defines each of the actors involved in the drug supply chain, including manufacturers, repackagers, wholesale distributors, and dispensers.[111] Discussed below, parallel traders will likely fall under the definition of repackagers and will have to be registered as such.

Each actor in the supply chain must be appropriately registered for the activity it engages in and must only sell products to certain "authorized trading partners."[112] For manufacturers, repackagers, wholesale distributors, or dispensers to sell or buy a drug from another trader, the buyer must meet the requirements to be an *authorized* trading partner.[113] Manufacturers and repackagers seeking recognition as authorized trading partners "must have a valid registration in

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107. *Import Alert 66–14*, U.S. FOOD & DRUG ADMIN. (2014), www.accessdata.fda.gov/cms_ia/importalert_177.html [https://perma.cc/FF3Z-NNL8].

108. 21 U.S.C § 360eee (Supp. I 2013-2014); *see Drug Supply Chain Security Act*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ [https://perma.cc/4Q6V-XCAH].

109. *See infra* Part VI.

110. U.S. FOOD & DRUG ADMIN. ET AL., DSCSA STANDARDS FOR THE INTEROPERABLE EXCHANGE OF INFORMATION FOR TRACING OF CERTAIN HUM., FINISHED, PRESCRIPTION DRUGS: HOW TO EXCHANGE PRODUCT TRACING INFORMATION: GUIDANCE FOR INDUSTRY 1 (Nov. 2014), https://www.fda.gov/downloads/drugs/guidances/ucm424895.pdf [https://perma.cc/E8LL-AJW6] ("Section 582 was added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) and facilitates the tracing of products through the pharmaceutical distribution supply chain by requiring certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and a transaction statement (product tracing information) when engaging in transactions involving certain prescription drugs." (footnotes omitted)).

111. 21 U.S.C § 360eee (Supp. I 2013-2014); *see also* U.S. FOOD & DRUG ADMIN. ET AL., IDENTIFYING TRADING PARTNERS UNDER THE DRUG SUPPLY CHAIN SECURITY ACT (2017) [hereinafter FDA, IDENTIFYING TRADING PARTNERS], https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572252.pdf [https://perma.cc/89EG-ECDJ] (listing the code provisions which define each actor).

112. *See* IDENTIFYING TRADING PARTNERS, *supra* note 111, at 3-5 (emphasis omitted).

113. *Id.* at 2.

accordance with section 510 of the [FDCA] and accept or transfer direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser."[114] Moreover, the regulations require each trading partner to have a system in place for identifying suspect or illegitimate products and notifying the FDA and their trading partners when such a product is detected.[115]

Most significantly, the DSCSA requires each trader to comply with product tracing and identification regulations. Pursuant to the DSCSA, the FDA has set in motion a multi-phase regulation plan that obligates each trader to implement product tracing, product recognition, and information storing systems.[116]

The regulations increase incrementally over a period of about 10 years; the plan is currently in the middle stages of implementation, with the finalized regulations and guidance documents set to be completed by 2024.[117] Each phase creates more stringent and sophisticated tracking procedures for the traders. The requirements seriously increase the complexity of the regulatory system; in fact, the added burden has caused some to fear that traders will fall out of compliance, at least temporarily.[118]

To better understand these requirements, it is easiest to start from the beginning of the supply chain—manufacturers. In January 2015, the FDA began requiring product identifiers to be placed on each lot or batch of products introduced into commerce by a transaction (that is, any batch that exchanges ownership).[119] The identifiers are contained on a bar code,

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114. *Id.* at 3.

115. *See* U.S. FOOD & DRUG ADMIN. ET AL., DRUG SUPPLY CHAIN SECURITY ACT IMPLEMENTATION: IDENTIFICATION OF SUSPECT PRODUCTS AND NOTIFICATION: GUIDANCE FOR INDUSTRY (2016) [hereinafter FDA, DSCSA: IDENTIFICATION], https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf [https://perma.cc/D2HW-NEXC].

116. U.S. FOOD & DRUG ADMIN., DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) IMPLEMENTATION PLAN [hereinafter FDA, DSCSA: IMPLEMENTATION], https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm382022.htm [https://perma.cc/9Wff-7V6L].

117. *Id.*

118. Meg Snyder, *Understanding Serialization Challenges*: *Tracelink Reveals Webinar Survey Findings About How Companies Have Adapted to Lot-Level Requirements and DSCSA Sterilization Deadlines*, R&D (Dec. 15, 2016, 8:30 AM), https://www.pharmpro.com/article/2016/12/understanding-serialization-challenges [https://perma.cc/BLG9-RJVE] ("[M]ore than half of the companies are sending documentation to some (but not all) trading partners and some were not able to address the requirements at all.").

119. Chris Souza, *DSCSA: What Phase II Implementation Means For You*, TRACKTRACERX (Apr. 3, 2016), http://blog.tracktracerx.com/dscsa-phase-ii-implementation-means/ [https://perma.cc/8MFM-S6R3]; *Personal Importation*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm432661.htm [https://perma.cc/SQF7-VYUT].

but they must also be legible to humans.[120] Beginning in November 2018, manufacturers will be required to place an individual product identifier on every "package and homogenous case."[121] To those who are unfamiliar with this industry it may seem very similar to the 2015 requirement, but the November 2018 requirement is a much taller order.

For context, there may be a hundred thousand individual packages in a lot, and the November 2018 requirement mandates that a distinct serial number be placed on each one so that the package can be tracked individually.[122] In addition to the product identifier, the National Drug Code (NDC), expiration date, serial number, and lot number must also be legible on the package.[123] This serialization at the package level was originally set to be enforced for products manufactured after November 2017, but the deadline was pushed back a year to allow industry members time to fully comply.[124] This illustrates the added burden that package and homogenous case serialization places on traders.[125]

Once the product is sold, the product identifiers must be utilized. In January 2015, the regulations began requiring each trading partner to utilize the lot-level product identifiers to capture, maintain, and provide subsequent buyers with product tracing information when engaging in sales.[126] First, "trading partners are required to provide the subsequent

120. *See* 21 U.S.C. § 360eee(14) (Supp. I. 2013-2014) (stating that a product identifier contains "a standardized graphic . . . in both human-readable form and on a machine-readable data carrier").

121. *See* U.S. FOOD & DRUG ADMIN. ET AL., PRODUCT IDENTIFIER REQUIREMENTS UNDER THE DRUG SUPPLY CHAIN SECURITY ACT – COMPLIANCE POLICY: GUIDANCE FOR INDUSTRY (2017) [hereinafter FDA, PRODUCT IDENTIFIER REQUIREMENTS], https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf [https://perma.cc/SE2P-9NUG].

122. Souza, *supra* note 119.

123. Karla L. Palmer, *Any Drug Manufacturer (or Repackager, Dispenser, and Distributor) Affected by the Looming Serialization Deadline in the Drug Supply Chain Security Act Really Should Read This One*, FDA L. BLOG (July 2, 2017), http://www.fdalawblog.net/2017/07/any-drug-manufacturer-or-repackager-dispenser-and-distributor-affected-by-the-looming-serialization/ [https://perma.cc/A9FW-CCEX].

124. *Id.*

125. The regulations provide exceptions to the tracing requirements for products that do not have tracing information because they were manufactured before the product identifier requirements kicked in (before November 2018). This is referred to as the Grandfathering policy. *See* U.S. FOOD & DRUG ADMIN. ET AL., GRANDFATHERING POLICY FOR PACKAGES AND HOMOGENOUS CASES OF PRODUCT WITHOUT A PRODUCT IDENTIFIER; GUIDANCE FOR INDUSTRY (2017) [hereinafter FDA, GRANDFATHERING POLICY], https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586509.pdf [https://perma.cc/GN43-D4VZ].

126. *See* U.S. FOOD & DRUG ADMIN., DSCSA IMPLEMENTATION: PRODUCT TRACING REQUIREMENTS—COMPLIANCE POLICY (2014) [hereinafter FDA, DSCSA IMPLEMENTATION], https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM427867.pdf [https://perma.cc/2S9S-CVEK].

purchaser with product tracing information."[127] Second, traders "are required to capture and maintain the applicable product tracing information" for at least six years after the transaction.[128] The product tracing information must be delivered electronically (bar code format),[129] and it is comprised of the transaction information (TI), transaction history (TH), and a transaction statement (TS).

The TI that trading partners must provide consists of ten distinct elements: 1) Proprietary or established name of the drug; 2) strength and dosage form of the product; 3) National Drug Code number of the drug; 4) container size; 5) number of containers; 6) lot number of the product; 7) date of the transaction; 8) date of the shipment (if shipment occurs more than 24 hours after the date of the transaction; 9) business name and address of the person from whom ownership is being transferred; and 10) business name and address of the person to whom ownership is being transferred.[130] In March 2018, the FDA released a draft guidance document to help ensure that traders are providing TI in a consistent manner.[131] The document gives some information on how each of the ten elements should be displayed in an effort to standardize the way traders deliver the TI.

Transaction history is separate from TI, but the March 2018 guidance provides direction to the industry on how to standardize TH as well.[132] TH should include the TI "for each prior transaction going back to the manufacturer of the product. In general, the [TH] for a product should be a compilation of the transaction information for each prior transaction involving that product."[133] Traders can generate a single document for the TH based on the information it collected from the product's previous owner, with the product information for the current transaction placed at the top of the document.[134]

Lastly, the trading partner has to provide a transaction statement (TS) to the purchaser before or at the time of the transaction.[135] The TS must state that the entity transferring ownership is: 1) Authorized

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127. U.S. FOOD & DRUG ADMIN. ET AL., STANDARDIZATION OF DATA AND DOCUMENTATION PRACTICES FOR PRODUCT TRACING GUIDANCE FOR INDUSTRY 2 (2018) [hereinafter FDA, STANDARDIZATION OF DATA], https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM598734.pdf [https://perma.cc/PW9C-LZYY] (citation omitted).

128. *Id.*

129. 21 U.S.C. § 360eee (1)(b)(1)(C) (Supp. I. 2013).

130. *See* FDA, STANDARDIZATION OF DATA, *supra* note 127, at 6-9.

131. *Id.* at 6.

132. *Id.* at 11.

133. *Id.*

134. *Id.*

135. *Id.* at 12.

to do so under the DSCSA; 2) has received the product from an authorized trading partner; 3) has received the TI and a TS from the prior owner; 4) has not knowingly shipped a "suspect or illegitimate product"; 5) "had systems and processes in place to comply with verification requirements under section 582"; 6) did not knowingly deliver false TI; and 7) did not knowingly modify the TH.[136] As of now, traders have to provide the TI, TH, and TS for the batch or lot level, but the requirement, as discussed above, will graduate to the package level in the near future.[137]

3. Emergency and Personal Use Exemptions

There are exceptions to the FDA's current regulations. The first is more of a discretionary choice, but its result is similar to that of an exception. Section 384(j) of the FDCA gives the FDA "discretion to permit individuals to make . . . importations [if] . . . the importation is clearly for personal use[] and the prescription drug or device imported does not appear to present an unreasonable risk to the individual."[138] A drug is a personal importation if it is brought into the United States and is not meant to be sold or distributed by the purchaser.[139] This is a discretionary provision, thus there is no absolute right to import drugs for personnel use—and the FDA's stance on this could potentially change at any time.[140]

The FDA has released a set of criteria regarding situations for which personal importation of a prescription drug might be allowed.[141] It notes that the product must be for a serious condition with no effective treatment available domestically, and the quantity should not exceed a three months' supply.[142] Some "Americans view the personal use

136. *Id.*

137. *See* Palmer, *supra* note123.

138. 21 U.S.C. § 384(j)(1)(B).

139. *Personal Importation*, *supra* note 119.

140. AARP, PRESCRIPTION DRUG RE-IMPORTATION QUESTION AND ANSWER SHEET, https://assets.aarp.org/www.aarp.org_/articles/international/ReimportationQA.pdf [https://perma.cc/JA3Q-C9G4].

141. FDA, STANDARDIZATION OF DATA, *supra* note 127, at 1.

142. *Id.* at 2. The full set of criteria are as follows:

> The product is for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means. There is no known commercialization or promotion of the product to persons residing in the U.S. The product does not represent an unreasonable risk. The consumer affirms in writing that the product is for personal use. The quantity is generally not more than a three month supply[,] and either: [p]rovide the name and address of the doctor licensed in the U.S. responsible for your treatment with the product, or [p]rovide evidence that the product is for the continuation of a treatment begun in a foreign country.

exception policy as a way to access lower prices for medicines already approved in the U.S."[143] However, the FDA makes clear that "the [personal use exemption] is not intended to permit personal importation of cheaper versions of FDA approved drugs from . . . foreign countries."[144]

Secondly, section 801(d)(2) of the FDCA provides an exception for importing a drug when authorized by the Secretary in the case of a medical emergency.[145] This medical emergency exception is construed very narrowly, but it allows individuals to bring in medicines from aboard into the United States for personal use in cases of serious medical emergencies.[146]

4. Abuse of the Current Systems and Failed Attempts

Over the years, abuse of these exceptions has become rampant. In fact, "[by] one estimate, parallel imports of prescription drugs from Canada amounted to $1.1 billion in 2004, or about 0.5% of the U.S. market."[147] The FDA has certainly taken notice of the abuse. "[I]n the face of organized trips [of] seniors planning to buy drugs abroad and the increase in Internet-based pharmacies, the [FDA] . . . indicated that it will increase its prosecutions of" individuals exploiting these provisions.[148]

Clearly, these provisions do not provide the relief that people need from high drug prices, despite consumer attempts to use them as such. Lawmakers have tried to address this issue with legislation sanctioning parallel trade, but these attempts have failed in the face of lobbying opposition and poor drafting.[149] One such bill—the Medicine Equity

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Id.

143. AARP, *supra* note 140.

144. PERSONAL IMPORTATION POLICY, FDA GUIDANCE DOCUMENT, https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/importsandexportscompliance/ucm297909.pdf [https://perma.cc/V8AN-K9Z8].

145. Abbott, *Parallel Trade in Pharmaceuticals*, *supra* note 19, at 151 n.28.

146. ATARA NOLADE, REGULATORY FOCUS, DRUG REIMPORTATION: IS IT THE SOLUTION TO THE HIGH COST OF PRESCRIPTION DRUGS IN THE US? 3 (2013), https://advanced.jhu.edu/wp-content/uploads/2013/04/Drug_Reimportation-Noiade-Atara.pdf [https://perma.cc/RVK2-V5NM].

147. Grossman & Lai, *supra* note 28, at 379.

148. NOLADE, *supra* note 146, at 3.

149. Rachel Bluth, *Trump's Promise to Rein in Drug Prices Could Open Floodgate to Importation Laws*, KAISER HEALTH NEWS (March 22, 2017), https://khn.org/news/trumps-promise-to-rein-in-drug-prices-could-open-dam-to-importation-laws/ [https://perma.cc/8RPY-NGNW] ("Many previous bills to allow importation or to allow Medicare to negotiate prices for its beneficiaries have failed in the face of $1.9 billion in congressional lobbying by the pharmaceutical industry since 2003 . . . ."); Rene J. Theriault III, *Drug Reimportation: Prescription, Placebo, or Poison?*, LEDA AT HARV. L. SCH. (Apr. 2002), https://dash.harvard.edu/bitstream/handle/1/8846805/theriault.html?sequence=2 [https://perma.cc/TB62-ZDAC] ("The L.A. Times reported that the bill 'was so riddled with potential loopholes that even

and Drug Safety Act—was introduced in the early 2000s. To be implemented, the bill had to gain approval of the Secretary of HHS, who at that time was Donna Shalala.[150] Her approval was contingent upon a finding that the Act would result in substantial taxpayer savings and would not pose a greater threat to public safety than the previous rule. She ultimately decided that it did not meet these qualifications, indicating that safety was a major concern.[151]

One of the most recent attempts—the Affordable and Safe Prescription Drug Importation Act—was introduced by Senators Bernie Sanders (I-Vt.), Cory Booker (D-N.J.), and Bob Casey (D-Penn.).[152] But the bill was met with strong opposition for its focus on importing only Canadian drugs for a trial period and for its failure to address safety concerns.[153] The bill never passed the committee stage.[154]

While attempts have failed, abuse continues. One estimate indicated that "[i]n 2016, about 19 million Americans purchased pharmaceuticals illegally from foreign sources through online pharmacies or while traveling."[155] U.S. consumers need access to less expensive medicines, and the FDA should provide this access in a more structured and monitored way—rather than through narrow exceptions or discretionary rules that have been blatantly abused. This is achievable through a well-crafted exception for parallel traders and coordination with the European Union.

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some of its most ardent opponents acknowledge privately they could no longer tell what, if anything, it would do.' " (footnote omitted)).

150. Abraham N. Saiger, *In Search of a Government That Will Govern: Senate Bill 812 and Reimporting Prescription Medication from Canada*, 12 ELDER L.J. 177, 197 (2004).

151. Laurie McGinley, *Shalala Declines to Implement Law on Importing Prescription Drugs*, WALL ST. J. (Dec. 27, 2000, 12:01 AM), https://www.wsj.com/articles/SB977872635716464949 [https://perma.cc/K3QM-LAKX].

152. *Affordable and Safe Prescription Drug Importation Act Introduced to Help Lower Skyrocketing Cost of Medicine*, BERNIE SANDERS (Feb. 28, 2017), https://www.sanders.senate.gov/newsroom/press-releases/affordable-and-safe-prescription-drug-importation-act-introduced-to-help-lower-skyrocketing-cost-of-medicine [https://perma.cc/ED6U-BHWW].

153. Leona Aglukkaq, *Dear Bernie Sanders: Canada is Not the United States' Drugstore*, WASH. POST (May 12, 2017), https://www.washingtonpost.com/news/global-opinions/wp/2017/05/12/dear-bernie-sanders-canada-is-not-americas-drug-store/?noredirect=on&utm_term=.7b9e89bef012 [https://perma.cc/VKM3-T6MT]; Zaid Jilani & David Dayen, Cory *Booker Joins Senate Republicans To Kill Measure To Import Cheaper Medicine From Canada*, INTERCEPT (Jan. 12, 2017), https://theintercept.com/2017/01/12/cory-booker-joins-senate-republicans-to-kill-measure-to-import-cheaper-medicine-from-canada/ [https://perma.cc/4V6J-6HPW].

154. S. 469, 115th Cong. (2017).

155. Emily Kopp & Rachel Bluth, *Nonprofit Working to Block Drug Imports Has Ties to Pharma Lobby*, NPR (Apr. 18, 2017, 5:00 AM), https://www.npr.org/sections/health-shots/2017/04/18/524363014/nonprofit-working-to-block-drug-imports-has-ties-to-pharma-lobby [https://perma.cc/9JRW-7MC9].

VI. MAKING PARALLEL IMPORTATION ACHIEVABLE UNDER THE CURRENT SYSTEM

A. Carving Out an Exception for Parallel Trade

As Part V indicates, the FDA has fairly strict regulations on the importation of drugs. The current regulations foreclose PPT in the United States. However, changes in the current scheme could lead to scenarios in which parallel importation would be legal. The following is an example which will help illustrate and guide the discussion:

> Originator (a drug manufacture) produces[156] X (its newly patented drug) at a facility in Ireland. It has acquired approval from the FDA to sell X in the United States, as well as approval from EU health authorities to sell X within the European Union. The European Union and the United States have different labeling requirements for X, as is the case with every drug. The NDA for X lists the Irish facility as the manufacturing facility for X (meaning the facility was FDA approved after an inspection). Originator authorizes the sale of X for five dollars a pill in the United States, while selling it for one dollar a pill in Ireland. Company A, a parallel trader, buys substantial amounts of X in Ireland at the one-dollar price, with the intention of selling it in the United States. However, this version of X does not have the proper labeling to be sold in the United States because it was originally labeled for sale in the European Union. Then, Company A relabels X with proper FDA approved U.S. labels. In this situation, can Company A legally sell the relabeled X in the United States for three dollars? In other words, can they participate in parallel trade?

After *Lexmark*, this would not run afoul of Originator's patent rights because the authorized sale in Ireland exhausts those rights. Thus, Company A is not in jeopardy of being sued by X's patent holder, Originator in this example, for infringement. Moreover, Company A's sale of X would not violate the ban on re-importation because X was never manufactured in the United States.

Company A would need to comply with the FDA requirements regarding registration, because removing the EU label and placing the U.S. label on X qualifies Company A as a repackager.[157] Specifically,

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156. Originators, like Pfizer, often license the rights to make their drugs to other manufacturing companies or to subsidiary corporations. *See* Tom Bergin & Kevin Drawbaugh, *How Pfizer has Shifted U.S. Profits Overseas for Years*, REUTERS (Nov. 16, 2015, 11:49 AM), https://www.reuters.com/article/us-pfizer-tax-insight/how-pfizer-has-shifted-u-s-profits-overseas-for-years-idUSKCN0T51ZS20151116 [https://perma.cc/35J8-QEAT]. If these facilities and companies are listed on the NDA, the fact that another company manufactures the drug is unlikely to result in a different outcome.

157. FDA, IDENTIFYING TRADING PARTNERS, *supra* note 111, at 7 ("DSCSA defines re-

Company A would have to apply and receive authorization from the FDA to relabel the product with new labels and ensure that it was placing the proper U.S. label on X.[158] Furthermore, the relabeling would need to occur at an FDA approved facility.[159] If these requirements are not met, Company A would fail to meet the authorized trading partner requirements, negating its ability to sell to any traders in the United States. Company A would also need to ensure that the buyer it sells X to is an authorized trading partner under the DSCSA.

While burdensome, Company A could comply with the requirements above. The real issue for Company A would undoubtedly be ensuring that it was receiving and storing proper tracing information for X. This is the major obstacle blocking PPT in the United States.

Under the March 2018 guidance document, Company A cannot accept ownership of X unless *the previous owner* provides Company A with TI, TH, and a TS prior to, or at the time of, the sale.[160] Company A would fail to comply with these requirements in this scenario because X was originally labeled for sale in the European Union. In other words, Company A will not be able to accept ownership of X, because the manufacturer will not be able to provide Company A with tracing information for drugs originally labeled for European sale.

To further explain this problem, breaking down the U.S. tracking requirements is helpful. Recall that the United States requires that a drug's NDC number and lot number be included as two of the ten elements of TI.[161] The National Drug Code number is a ten-digit code that is used strictly in the U.S. tracking system.[162] It is broken down into three segments: "The first set of numbers in the NDC identifies the labeler (manufacturer, repackager, or distributer). The second set of numbers is the product code, which identifies the specific strength,

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packager in section 581(16) of the FD&C Act as 'a person who owns or operates an establishment that repacks and relabels a product or package for – (A) further sale; or (B) distribution without a further transaction.' Under section 510 of the FD&C Act . . . any person who owns or operates any establishment that manufactures, prepares, propagates, compounds, or processes drugs . . . that are offered for import into the United States must be registered with the FDA. This includes repackagers of drugs. Thus, such repackager establishments must be registered in accordance with section 510 to be considered authorized trading partners." (citations omitted)).

158. *See* 21 U.S.C. § 360 (a)-(d), (i) (2012); 21 C.F.R. § 1.95 (2017); *see also* FDA, *supra* note 115, at 7.

159. FDA, IDENTIFYING TRADING PARTNERS, *supra* note 111, at 7.

160. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 113-54, § 582(e)(1)(A)(i), 127 Stat. 605 (2013); *see also supra* notes 126-129 and accompanying text.

161. For a review of the ten elements of information that TI must have, see *supra* text accompanying note 130.

162. IDAHO MMIS, NATIONAL DRUG CODES (Feb. 9, 2018), https://www.idmedicaid.com/Reference/NDC%20Format%20for%20Billing%20PAD.pdf [https://perma.cc/4JEU-3M77].

dosage . . . and formulation of a drug for a specific manufacturer. Finally, the third set . . . identifies package sizes and types."[163] The first set is specific to the trading partner (similar to a name), while the product and package code are assigned based on the product.[164]

The European Union mandates a different kind of serialization for its products. Thus, a drug purchased for sale in European Union will not be labeled with an NDC number or a U.S. lot number. For instance, if a U.S. company is going to export drugs for sale to the European Union, it needs to use a different identification system in order to comply with the European Union's tracing requirements.[165]

1. Parallel Trade Certification Number

Regulatory changes could be implemented to solve this roadblock. To begin, new legislation should mandate any trader that plans to engage in parallel trade within the United States to have an extra approval from the FDA, in addition to gaining approval to be a repackager, wholesaler, or other trading partner. It would require each company to be registered specifically as a parallel trader.

Most importantly, the legislation must allow the parallel trader—Company A—to purchase X *without* the manufacturer having to provide the tracing information. Instead, an exception should be carved out to allow Company A to accept ownership of a drug from a manufacturer who does not supply it with TI, TH, and a TS prior to the sale, *if* Company A creates a "PT Certification Number" for the transaction and provides it to subsequent buyers along with the other tracing requirements.

The PT Certification Number would alleviate Company A's need to buy from a manufacturer that provides it with tracing information. The PT Certification Number would be in bar-code format and would indicate what facility the drug was purchased from, what the product is, how much was purchased, the strength and dosage of the product, and the date of the transaction. Company A would need to record and store this information for six years.

While this PT Certification Number would essentially take the place of Company A having to record tracing information in the original transaction with the foreign manufacturer, Company A would still need to provide tracing information to subsequent buyers in order to comply with the remaining DSCSA requirements. It is at this juncture that United States coordination with the European Union becomes critical.

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163. *Id.*

164. *Id.*

165. Souza, *supra* note 119.

2. Mutual Facilities List

Company A will need to provide subsequent purchasers with TI (including an NDC and lot number), TH, and a TS, but in the transaction with the manufacturer Company A created a PT Certification Number. Thus, it would not have a NDC or lot number. Therefore, the legislation would have to allow parallel traders to create their own NDC numbers and lot numbers for products they buy with PT Certification Numbers. Once created, Company A would have proper tracing information necessary to make subsequent sales in the United States.

When selling the relabeled product, Company A will provide the purchasers with the PT Certification Number and newly created TI, TH, and a TS. The TI, TH and TS that Company A will pass along in subsequent transactions will look slightly different from the typical transaction, because Company A never received tracing information from the manufacturer.

To meet this standard, Company A requires all the information necessary to create TI, TH, and a TS for subsequent transactions. In the past, attempts to authorize parallel trade have been unsuccessful, in part, because of a failure to acknowledge or plan for the difficulties parallel traders would face in trying to acquire the information necessary to create U.S. labels or tracing information.[166] Coordination with European authorities could alleviate this issue.

The legislative change shall require the FDA and the European Medicines Agency (EMA)[167] to create a "Mutual Facilities List." The list would be compiled jointly by the organizations and posted on a designated internet site.[168] Any manufacturing facility that is authorized under both an FDA NDA and a centralized EMA marketing-authorization application[169] will be placed on the list. In other words, only

166. Theriault III, *supra* note 149, at nn.72-74.

167. The EMA is a centralized agency that helps to facilitate and coordinate the evaluation and approval of medicinal products in the European Union. *See About Us: What We Do*, EUROPEAN MEDS. AGENCY, http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42 [https://perma.cc/G857-PDB2].

168. Senator Sanders's most recent attempt at sanctioning parallel trade, Bill S. 469, had a similar website provision. *See supra* note 154 ("The Secretary shall publish on a dedicated Internet Web site a list of certified foreign sellers, including the Internet Web site address, physical address, and telephone number of each such certified foreign seller.").

169. In the European Union, there are several different paths that companies can take in getting a drug approved. The centralized EMA approval process is one such path. "The centralized process is controlled through the EMA. Every member state of the EU is represented on the EMA Committee for Medicinal Products, which issues a single license [allowing the holder to sell] in all EU member states." Gail A. Van Norman, *Drugs and Devices Comparison of European and U.S. Approval Processes*, 1 JACC: BASIC TO TRANSACTIONAL SCI. 399, 400 (2016), https://www.sciencedirect.com/science/article/pii/S2452302X16300638 [https://perma.cc/6CPD-N39Q]; *see also* U. Nitin Kashyap et al., *Comparison of Drug Ap-*

facilities that manufacture drugs for sale in both the United States and the European Union will be on the list. Moreover, the list will indicate which drugs (by proprietary and established name) are approved for sale in the European Union and United States and are produced at the facilities. This information is crucial to allowing parallel traders to create tracing information for future transactions, including NDC and lot numbers.

The list would be an exhaustive list of the facilities that parallel traders could purchase from, ensuring that parallel traders are buying from safe and secure manufacturers. Since all of the facilities on the list would be FDA approved, the manufacturers selling drugs made in a facility on the list would be authorized trading partner under the FDCA.

With the "Mutual Facilities List," parallel traders would have the information necessary to create tracing information for later sales. The list would have the European and U.S. names of the drugs that are made at each facility. With these names, parallel traders will be able to make an NDC number for future transactions. The FDA publishes a National Drug Code Directory, which list NDC numbers for every drug and the Directory is "updated daily."[170] Once a parallel trader has the EU name of the product and the name of the United States equivalent, looking up the right NDC will just be a matter of searching the Excel spreadsheet that the FDA provides.[171]

With the proper NDC and lot number, parallel traders will be able to provide subsequent buyers in the United States with proper tracing information. The tracing information that the parallel trader provides will follow the product through the supply chain. At any point in the supply chain, traders or the FDA will be able to track the drug back to the parallel trader using the tracing information. Although the tracing information will not be traceable back to the manufacturer, the PT Certification Number—which will be transferred to subsequent buyers along with standard tracing information—will allow regulators and traders to track the product's origins.

3. Liability

Parallel traders would be liable for falsifying a PT Certification Number or if a PT Certification Number was not accurate. The provision could place both civil liability and criminal liability on the parallel

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proval Process in United States & Europe, 5 J. PHARM. SCI. & RES. 131, 133-34 (2013) (describing the "regulatory steps to go through before a drug is approved to be marketed in the European Union").

170. *See National Drug Code Directory*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm [https://perma.cc/QK6E-H7HF].

171. *See id.*

traders for failure to meet the requirements. This is in line with the DSCSA provision making it both a crime and a violation of the DSCSA to falsify tracing information.[172]

B. Feasibility of the Changes

1. Creation of PT Certification Number, NDC Number, and Lot Number

Requiring that parallel traders create a PT Certification Number, NDC numbers, and lot numbers is not a stretch from what is currently required of them under the existing system. Notably, the FDA notes that there are currently "situations where trading partners are permitted by law to provide other trading partners with product tracing information that *omits* certain elements that would otherwise be required."[173] Parallel trade would simply be another one of those situations, but the omitted tracing information would be replaced with a PT Certification Number. Moreover, under the current system, repackagers are already required to use their own NDC numbers for initial transactions when buying from foreign or U.S. manufacturers that have labeled the product for sale in the United States.[174] For example, the FDA states that, "repackagers that are creating the first transaction information for the product they are introducing into commerce should use their [own] NDC number."[175]

Lot numbers function the same way as NDC numbers. When a repackager receives a product from a manufacturer, it often changes the entire package—breaking it down into smaller packages for further sale.[176] These new packages require new lot numbers. In these situations, the FDA mandates that the repackager "use the new lot number [they created] in the transaction information that it provides to subsequent purchasers."[177]

In other words, repackagers are often providing subsequent buyers and manufacturers with NDC and lot numbers that are unique to the repackager; these numbers do not match the NDC and lot numbers that the manufacturers supplied to repackager. Thus, an exception allowing repackagers to make their own NDC and lot numbers when buying a product originally labeled for sale in the European Union

172. *See* FDA, DSCSA IMPLEMENTATION, *supra* note 126, at 18.

173. FDA, STANDARDIZATION OF DATA, *supra* note 127, at 2 (emphasis added).

174. *Id.* at 8.

175. *Id.*

176. INSIDE EU FMD AND THE DELEGATED ACTS: A COMPLIANCE PRIMER 15 (2016), https://www.tracelink.com/uk/_assets/pdf/inside-eu-fmd-and-the-delegated-acts-uk.pdf [https://perma.cc/MW8F-GHRC].

177. *See* FDA, DSCSA IMPLEMENTATION, *supra* note 126, at 9.

doesn't stray far from the current system—repackagers make their own lot and NDC numbers already.

The responsibility would be on the repackager to demonstrate that the label and packaging is the only difference between the drug they are relabeling for sale in the United States and its equivalent that was originally labeled for sale in the United States. This statutory crave out will only allow for the parallel importation of FDA approved drugs manufactured in FDA approved facilities on the "Mutual Facilities List"—the PT Certification Number will ensure that repackagers can demonstrate this in further sales.

2. Foreign Manufacturing

Given the complexity of the regulations and the required alterations to the current scheme, it is valid to question whether the scenario described in the example above occurs frequently enough to warrant the changes.

While U.S. drugs are often made domestically, the United States is the largest importer of pharmaceuticals in the world.[178] "In fact, 136,400 foreign facilities from more than 150 countries export FDA-regulated products to the United States."[179] The United States imported about $86 billion dollars in pharmaceuticals in 2015—roughly 40 percent by volume of the finished drugs sold in the United States are imported.[180]

U.S. drugs are manufactured in many countries, but the United States imports mostly from Ireland, Germany, the United Kingdom, Switzerland and India.[181] There are a lot of FDA approved facilities in Ireland.[182] Factoring in the growth rate of imports in recent years and

178. Ari Altstedter, *Where the U.S. Actually Gets Its Drug Supply: QuickTake Q&A*, BLOOMBERG (Jan. 17, 2017), https://www.bloomberg.com/news/articles/2017-01-17/where-the-u-s-actually-gets-its-drug-supply-quicktake-q-a [https://perma.cc/89RS-TP95] ("[T]he $86 billion of medicine brought in from the rest of the world in 2015 still makes the U.S. the biggest drug importer on the planet.").

179. *FDA Globalization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/ [https://perma.cc/9QQX-UL4X].

180. Thomas J. Bollyky & Aaron S. Kesselheim, *Can Importation Address High Generic Drug Prices?* 12 (Hutchins Center, Working Paper No. 29, 2017), https://www.brookings.edu/wp-content/uploads/2017/05/wp29_bollykykesselheim_drugimportation.pdf [https://perma.cc/8GXK-K2XG]; *see also* Howard Sklamberg & Michael Taylor, *In India, With Our Sleeves Rolled Up*, FDA VOICE (March 18, 2015), https://blogs.fda.gov/fdavoice/index.php/tag/globalization/ [https://perma.cc/6KRA-ZCKC].

181. Altstedter, *supra* note 178.

182. *See* Elaine Burke, *Ireland is a Home for 24 of the World's Top Biotech and Pharma Companies*, SILICON REPUBLIC (May 29, 2017), https://www.siliconrepublic.com/careers/biotech-pharma-companies-ireland [https://perma.cc/PV7K-86RF]; Altstedter, *supra* note 178.

the FDA's stance on lowering the barriers for approving foreign facilities,[183] the number of FDA-approved foreign facilities and the number of drugs being manufactured outside of the United States is likely to continue growing.[184]

Thus, it is probable that FDA approved facilities are, and will continue to be, manufacturing drugs for sale in foreign countries, which could be sold within the United States with implementation of the changes laid out above. In a boarder sense, it seems logical considering that the United States is already importing the same drugs from the FDA-approved facilities that would be on the "Mutual Facilities List"—the only difference between the parallel traded drug is that it was labeled or packaged differently.

3. Coordination between the FDA and EMA

No nationally-implemented legislation could require the European Union to cooperate in creating a "Mutual Facilities List." The European Union would have to agree to it willingly. If the United States proposed such an initiative, there is reason to believe the European Union would join in the effort. A coordination between the FDA and EMA in creating the "Mutual Facilities List" is in line with the United States and European Union's collaboration in the Mutual Recognition Agreement.[185]

In 2017, the EMA and the FDA agreed to enter into a Mutual Recognition Agreement, which allows U.S. and EU regulators to "utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities."[186] Both the FDA and EMA must inspect manufacturing facilities to ensure that they are in compliance with regulatory requirements, and for drug approval. The Agreement "allows for recognition of each other's inspection outcomes and hence for better use of inspection expertise and resources."[187] FDA Commissioner Scott Gottlieb, commented on the agreement:

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183. *See* Press Release, FDA, Mutual Recognition Promises New Framework for Pharmaceutical Inspections for United States and European Union (Mar. 2, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm544357.htm [https://perma.cc/Q6W7-TJ33].

184. *See* David C. Gibbons & Dara Katcher Levy, *FDA is Driving the Manufacture of Drug Products Outside the United States*, FDA L. BLOG (Mar. 1, 2018), http://www.fdalawblog.net/2018/03/fda-is-driving-the-manufacture-of-drug-products-outside-the-united-states/ [https://perma.cc/2PLV-7LFU].

185. *See* Press Release, FDA, *supra* note 183; *see also* Press Release, EMA, EU-US mutual recognition of Inspections of Medicines Manufacturers Enters Operational Phase (Oct. 31, 2017), http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/10/news_detail_002842.jsp&mid=WC0b01ac058004d5c1 [https://perma.cc/39G6-XXUV].

186. Press Release, FDA, *supra* note 183.

187. Press Release, EMA, *supra* note 185.

> At a time in which medical product manufacturing is truly a global enterprise, there is much to be gained by partnering with regulatory counterparts to reduce duplicative efforts and maximize global resources while realizing the greatest bang for our collective inspectional buck. . . . By partnering with these countries we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues . . . .[188]

The Agreement demonstrates that the European Union and United States are dedicated to providing safe drugs and promoting public health through cooperation. A "Mutual Facilities List" would be another step in this direction. Countries and regions where parallel products are exported may not be interested in facilitating that parallel trade, because it often correlates with an increase in the price of the product for their citizens.[189] However, the European Union may be incentivized to help with the coordination and implementation of the "Mutual Facilities List," being that it will promote transparency and information sharing that consumers and traders in the industry deserve.

The FDA and the EMA already have a great relationship, and a "Mutual Facilities List" would further solidify this relationship. The Mutual Recognition Agreement has fostered safety of drug trading and improved efficiency—a move to a "Mutual Facilities List" would be in line with that. Moreover, manufacturers could be incentivized to agree to the creation of a "List" if there was a provision allowing any manufacturer who is on the "List" to have expedite inspections.

4. Willingness to Enter Heavily Regulated Market

Lastly, it is quite evident that a change allowing for PPT will have no effect on U.S. pharmaceuticals prices if importers are unwilling to enter the market. Fortunately, importers stand to make profits from this process.[190] This attractive monetary incentive should make it unlikely for companies with the proper resources to shy away from participating in PPT (if they could legally do so). As Professor Fredrick Abbott, the Edward Ball Eminent Scholar, notes, filling this role will be especially enticing to large corporations with a foothold in global markets and access to global supply chains, such as Amazon, Costco,

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188. Press Release, FDA, FDA takes unprecedented step toward more efficient global pharmaceutical manufacturing inspections (Oct. 31, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm [https://perma.cc/CY7V-W9L6].

189. *See* Bordoy & Jelovac, *supra* note 64, at 7.

190. *See* HHS TASKFORCE REPORT, *supra* note 79, at 67-69 (claiming benefits to consumers from parallel importation would be modest, because "intermediaries (exporters/importers) will take a large portion of the price differences").

and Walmart.[191] Not only would U.S. consumers benefit for these companies in engaging in PPT, but the companies are likely to as well.

These companies are known for taking advantage of price discrimination and profiting from imports.[192] Amazon has moved into the healthcare industry and speculation has been swirling as to whether it will take a role as a distributor.[193] Moreover, Walmart and Costco are already retail sellers of pharmaceutical goods.[194] A transition into this market would be easy for these companies considering that they all "operate vast global supply chain[s] with sophisticated controls";[195] "[e]ach understands the complexity of regulatory compliance and the up-front expense that may be entailed in disrupting an existing market structure."[196]

There have been complaints by traders who are already in the pharmaceutical industry regarding fears of updating their procedures to meet the evolving DSCSA regulations.[197] But having to comply with these regulations should not deter big corporations from entering into PPT. To be fair, the regulatory hurdles to becoming a trader in the industry are high, but compliance is not impossible. If slight regulatory changes are made allowing PPT in limited situations, companies could certainly comply with tracking requirements.

By way of example, the state of California and even some localities place very similar product-tracking requirements on marijuana manufacturers, processors, wholesalers, and dispensaries who apply for permits to conduct business.[198] The regulations require tracking marijuana from "seed-to-sale," similar to the way pharmaceuticals are

191. *See* Abbott, *Inside Views II*, *supra* note 53.

192. *See* Hiroko Tabuchi, *Walmart's Imports from China Displaced 400,000 Jobs, a Study Says*, N.Y. TIMES (Dec. 9, 2015), https://www.nytimes.com/2015/12/09/business/economy/walmart-china-imports-job-losses.html [https://perma.cc/45H6-9BFS].

193. Eric Sagonowsky, *Amazon Finally Moved Into Healthcare. What's Next for Pharma?*, FIERCEPHARMA (Jan 31, 2018. 11:42 AM), https://www.fiercepharma.com/pharma/amazon-finally-moved-into-healthcare-but-its-pharma-ambitions-are-still-far-from-clear [https://perma.cc/4BXC-9SGW].

194. Abbott, *Inside Views II*, *supra* note 53.

195. *Id.*

196. *Id.*

197. Snyder, *supra* note 118.

198. *See Commercial Medical Cannabis Track and Trace Program*, HUMBOLDT COUNTY, https://humboldtgov.org/2225/Track-and-Trace [https://perma.cc/S9Y6-UYET] (discussing the tracing program that Humboldt County, CA requires as a condition for receiving a permit to cultivate, distribute, or dispense marijuana within county limits); *see also* Matt Leonard, *California Tracks Marijuana From Seed to Sale*, GCN (Jan. 12, 2018), https://gcn.com/articles/2018/01/12/california-cannabis-tracking-system.aspx [https://perma.cc/BK7K-4HFA] (discussing the tracking regulations implemented at the state level).

tracked under the DSCSA.[199] New businesses trying to comply with these regulations will usually purchase systems—such as BioTrack-THC—to help them comply with the product tracking requirements.[200] Services like BioTrackTHC are not necessarily cheap, but they provide the infrastructure to easily implement product tracking and labeling procedures.

If these small local businesses are able to comply with operating procedures and tracking requirements that the state of California and other localities have implemented, it should not be difficult for companies with significant resources and experience in heavily regulated industries to comply with the DSCSA. In fact, potential parallel traders can rely on companies like GS1 US, who freely posts lists of companies, products, and services similar to BioTrackTHC, which specializes in helping companies comply with the DSCSA.[201]

Significantly, if companies like Costco, Amazon, or Walmart enter into PPT, they may be able to bypass these aids—cutting out the extra cost—because they already use sophisticated storage, tracking, and information sharing systems in their current business models.[202] Moreover, the incremental implementation of the tracking regulations has created a prime opportunity for parallel traders to step in. Over the next couple of years, all of the traders in the pharmaceutical industry will have to divert resources to adapt their systems to meet the new regulations.

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199. Catherine Goldberg, *Everything You Need to Know About Seed to Sale Technology*, GREEN MARKET REP. (Sept. 15, 2017), https://www.greenmarketreport.com/everything-you-need-to-know-about-seed-to-sale-technology/ [https://perma.cc/VTJ3-XH5A]; *see also* Jake Methow, *How California's New Medical Marijuana Rules Track Seed-to-Sale Laws*, POT VALET (May 5, 2017), https://www.potvalet.com/blog/how-californias-new-medical-marijuana-rules-track-seed-to-sale-laws/ [https://perma.cc/9923-K6ND].

200. *Processing and Manufacturing Business Solution*, BIOTRACKTHC, https://www.biotrack.com/cannabis-processing/ [https://perma.cc/EGC9-QZES] ("Record the necessary data for compliance, save time and increase transparency to your licensed cannabis operation."); *see also* Goldberg, *supra* note 199 (noting that "the cannabis industry has adopted the latest systems management technology offered by a variety of specialized vendors to implement . . . 'seed-to-sale' system[s] that track[] products").

201. *Drug Supply Chain Security Act (DSCSA) - for Pharmaceutical Wholesalers: Who Can Help?* GS1 (Oct. 28, 2015), at 3-7, https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=623&language=en-US&PortalId=0&TabId=134 [https://perma.cc/N7F7-NMLU].

202. *See* Syed Ali Ameer, *Inventory Management: How Costco Aggressively Manages Inventory to Thrive in Tough Times*, LINKEDIN (Apr. 16, 2016), https://www.linkedin.com/pulse/inventory-management-how-costco-aggressively-manages-thrive-ameer [https://perma.cc/S2DP-KGLV] ("Costco . . . employs a just-in-time inventory management system, which includes sharing data directly with many of its largest suppliers. Companies like Kimberly-Clark calculate re-order points in real time and send new inventory, as needed, to replenish store shelves.").

PPT will only be allowed in limited circumstances, even with the implementation of the change. But the discussion above demonstrates that PPT in the United States is feasible, and hopefully it will lead politicians, companies, advocacy groups, and concerned citizens to fight for the changes that will make PPT possible. Indeed, this presents large companies—ones that are often labeled negatively as "big business"[203]—with the opportunity to lobby and fight for changes that will help U.S. consumers struggling with high drug prices. Moreover, this presents the Trump Administration with the opportunity to take action to follow through with its campaign promise of lowering drug prices.[204] As an incentive, these efforts could lead to increased profits for the companies and an enhanced public image for both the companies and the Trump Administration.

VII. ADDITIONAL BARRIERS

Unfortunately, the present regulatory scheme is not the only road block to successful implementation of PPT in the United States. If the suggested changes are made, strong political opposition and other hurdles may present problems to the implementation of a successful PPT system. This Part analyzes the legitimacy of some of these barriers and discusses the threat each poses to PPT in the United States. The list below is not meant to be exhaustive, but addresses some of the most pressing issues.

A. Domestic Price Controls

Currently in the United States, price controls are not a threat to the implementation of PPT. Moreover, if changes are made to allow PPT, then price controls are unlikely to pose a threat to companies looking to enter in to the parallel trade business. An overwhelming majority of advanced nations have some direct regulatory oversight of the prices set for pharmaceuticals within their borders.[205] These countries sacrifice a

203. *See, e.g.*, Kate Taylor, *Amazon is the New Walmart: The E-Commerce Giant Is Increasingly Becoming a Symbol for Everything Wrong with Big Business*, BUS. INSIDER (Aug. 6, 2017, 9:40 AM), http://www.businessinsider.com/amazon-is-the-new-walmart-2017-8 [https://perma.cc/N6V8-HHS3] ("Walmart was once considered the symbol of everything that was wrong with the retail industry. Now, Amazon is taking on that undesirable role."). Many individuals, including this author, do not share these views; in fact, Walmart has made important strides in the environmental context. *See* Michael P. Vandenbergh, *The Implications of Private Environmental Governance*, 99 CORNELL L. REV. ONLINE 117, 118, 132-33 (2014). However, the fact remains that a segment of the public has a negative view of big businesses, and positive publicity could sway, or at least affect, these opinions.

204. La Monica, *supra* note 3.

205. Kesselheim et al., *supra* note 11, at 860; ABBOTT & DUKES, *supra* note 11, at 22.

free market by setting price limitations on drugs in order to secure affordable prices for consumers.[206]

The United States is the outlier. Compared to the rest of the world, U.S. prices are fairly unregulated.[207] Here, drug prices in the private sector are not subjected to regulation at the federal level.[208] Moreover, pharmaceuticals sold through parallel trade would be priced lower than the drugs sold by originators.[209] Thus, if the United States were to enact price controls, the only controls that would have a prohibitive effect on PPT would be those that set a minimum price at which a product could be sold.

This lack of price regulation may change in the future. The U.S. government certainly has the authority to set price controls. Obviously, regulation of prices by the federal government would not violate the international agreements that the United States has obligations under, nor would it violate domestic law.[210] However, given the government's reluctance to regulate prices in the past and the enormous political obstacles standing in the way, it seems unlikely that the United States will set controls in response to efforts that are aimed at lowering prices. In fact, if the implementation of adequate price controls were practical, discussion of parallel trade would likely be unnecessary.

B. Safety Concerns

There are some who argue that the sanctioning of parallel trade will lead to the importation of counterfeit or poor-quality drugs.[211] While drug quality and safety is one of the most—if not the most—important aspects of the pharmaceutical trade, PPT sanctioned under the changes suggested above is unlikely to reduce drug quality or cause increased safety concerns.

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206. Lana Kraus, *Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry*, 37 VAND. J. TRANSNAT'L L. 527, 532-33 (2004).

207. Abbott, *Parallel Trade in Pharmaceuticals*, *supra* note 19, at 160-62; *see also* William Davis, *The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals*, 9 TUL. J. INT'L & COMP. L. 483, 507 (2001).

208. GAO: BRAND-NAME PRICING, *supra* note 15, at 8. Pharmaceutical originators are subject to federal enforcement if their prices or actions violate antitrust laws. For discussion on this topic, see Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 289-95 (2016).

209. *See supra* Part V.

210. Abbott, *Parallel Trade in Pharmaceuticals*, *supra* note 19, at 161.

211. *See* Bryan A. Liang, *Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into the Public Health*, 31 N.C. J. INT'L L. & COM. REG. 847 (2005); Davis, *supra* note 208, at 502; *see also* Kopp & Bluth, *supra* note 155.

Past legislation aimed at sanctioning PPT has failed because health authorities could not guarantee the quality of the imported drugs.[212] The proposal suggested above alleviates these increased safety concerns. Under these changes, parallel traders would still have to comply with safety requirements that the FDA already has in place for regularly imported drugs. The beauty of these complicated regulations is that they are designed specifically to ensure quality and safety.[213]

First, drugs brought in through PPT will be manufactured in the same facilities and consist of the same ingredients as drugs that U.S. consumers are currently taking; the imported drugs will need to be manufactured and handled in FDA-approved facilities—ones which are inspected for quality purposes.[214] Second, the imported drugs will be tracked throughout the supply chain, assuring knowledge of where, how, and who manufactured or came into contact with the drugs.[215] Lastly, the regulations require each trading partner to have a system in place for identifying suspect or illegitimate products and notifying FDA and trading partners when such a product is detected.[216]

Considering the requirements that the FDA has in place, it is doubtful that PPT will introduce safety concerns that are not already present for all drugs imported into the United States. The FDA's requirements will ensure the quality of parallel imported drugs, just as they do now for drugs imported with the patent holder's permission.

C. Defensive Measures by Patent Holders

The biggest risk to PPT in the United States comes from those who will face increased competition from its implementation. No company would stand idly by in the face of lost profits. It would be naïve to think that the originator industry will be an exception. The suggestions above would strip the originators of their pricing monopoly—and they have the funds and savvy to put up a fight.

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212. Laurie McGinley, *Shalala Declines to Implement Law on Importing Drugs*, WALL ST. J. (Dec. 27, 2000), https://www.wsj.com/articles/SB977872635716464949 [https://perma.cc/L5WV-BR83].

213. *See* FDA, *supra* note 108 ("[The DSCSA] will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.").

214. *See supra* Section V.B.

215. *See supra* note Section V.B.2.

216. *See supra* note 115 and accompanying text.

1. Lobbying

First and foremost, any suggested change to authorize PPT will face opposition right out of the gate. The industry will certainly lobby against any legislative change. There has been strong lobbying against foreign drug imports in the past,[217] and this proposal would be met with lobbying as well. While this proposal would face the same opposition as past attempts, it does not have to meet the same fate.

This proposal mandates that drugs sold through PPT will comply with the tracing and safety regulations currently in place. This will lessen the potency of the safety concern argument, which lobbyists relied on heavily to inhibit past attempts.[218] Moreover, if the large companies that could profit in the role of parallel traders back the proposed legislation, it would greatly increase the bill's chances.[219] Parallel importation legislation has come close in the past;[220] with enhanced support and emphasis on safety, this proposal may be able to withstand opposition lobbying.

2. Limitations on Supply

If these changes are implemented, the originator industry could employ supply-limiting techniques to squeeze out parallel trade in a more indirect fashion. Originators will likely utilize contractual provisions and general limitations on production in hopes of cutting parallel traders off from lower-priced drugs, or to retain a right to sue the parallel traders for selling the drugs in the United States.

In addressing contractual restrictions, the example provided in Part VII.A is useful. Originators often license out the patent rights allowing others to produce the drug for a fee.[221] If an originator or one of its subsidiaries owns and operates a manufacturing facility, they could place post sale contractual restrictions on all drugs labeled for sale in Europe (or any country other than the United States). The restrictions would likely aim to limit the purchaser's right to relabel the drugs for sale in the United States. Back to the example, if Company A purchased the drug with these contractual restrictions, selling the drug in

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217. Bluth, *supra* note 149; *see also* Jilani & Dayen, *supra* note 153 ("Booker and some of his Democratic colleagues who opposed the Sanders amendment are longtime friends of the drug industry. As MapLight data shows, Booker has received more pharmaceutical manufacturing cash over the past six years than any other Democratic senator: $267,338.").

218. Bluth, *supra* note 149; *see also* Jilani & Dayen, *supra* note 153.

219. *See supra* notes 203-204 and accompanying text.

220. *See* Jilani & Dayen, *supra* note 153.

221. Bergin & Drawbaugh, *supra* note 156; *see also* Abbott, *Parallel Trade in Pharmaceuticals*, *supra* note 19, at 155.

the United States may constitute a breach of the sales contract—subjecting them to a lawsuit.

These post sale contractual restrictions are not uncommon. Recall that similar defensive measures were employed by Lexmark in *Impression Products v Lexmark*.[222] Lexmark placed post-sale/single-use restrictions in the sales contracts for their toner cartridges, prohibiting the original purchaser from reselling to a remanufacturer.[223] However, Lexmark could not rely on the contractual protections to sue the remanufacturers (such as Impression Products) for breach of contract because Lexmark never entered into a contractual agreement with remanufacturers; Lexmark was only in privity with the individual consumers who were reselling the cartridges to the remanufacturers.[224] Lexmark could have sued the individual consumers who they had sales agreements with for breach of contract,[225] but this would have been economically unwise—which is likely what led Lexmark to make the patent infringement claims.

By contrast, if a parallel trader purchases a drug from an originator manufacturer and the agreement contains post-sale contractual restrictions against selling the drug in the United States, the restrictions would be enforceable; the parties would be in privity. Thus, if the parallel trader resold the drug within the United States, the manufacturer could sue the trader for breach of contract.[226]

Moreover, if the originators license out the patent rights, allowing others to produce the drug, they could place contractual restrictions in the licensee agreements. These restrictions would likely condition the license to manufacture the drug on the licensee not selling to traders who intend to resell the drug in the United States.[227] The effectiveness of these provisions remains to be seen.

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222. *See supra* note 41 and accompanying text.

223. *See* text accompanying notes 41 & 49.

224. Impression Prod., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1530 (2017) ("Lexmark's contractual single-use/no-resale agreements were with the initial customers, not with downstream purchasers like the remanufacturers."); *see also supra* notes 40-42 and accompanying text.

225. *See id.* at 1531 ("The single-use/no-resale restrictions in Lexmark's contracts with customers may have been clear and enforceable under contract law.").

226. *See id.*

227. These kinds of contractual provisions have been recommended as a way to guarantee that low-income countries that receive drugs under discount programs continue to receive the low prices even when parallel trade is authorized. To be clear, if PPT is authorized in the United States, efforts should be made to ensure that such trade does not interfere with low-income countries' access to discounted medicine. For Professor Abbott's discussion on how to combat this issue, see Brief for Professor Abbott, *supra* note 65, at 33-36; Abbott, *Parallel Trade in Pharmaceuticals*, *supra* note 19, at 154-56, but the discussion should be continued in further literature.

Lastly, the originators could place general limitations on production.[228] The pharmaceutical producers manufacturing in foreign facilities approved by the FDA are capable of much more substantial production.[229] However, if PPT is authorized, manufacturers may try to keep production low precisely to limit the pharmaceuticals that would be available for parallel trade. In other words, originators would sell only so much of their product as is necessary to meet "local demand," and "resulting shortages based on parallel exports would be a subject for the national government to address."[230] In fact, originator companies have used this technique in Europe before.[231] This issue is, in part, a competition law question. When challenges were brought against this type of activity in Europe, "the [Court of Justice of the European Union] . . . refused to prohibit th[e] practice as per se unlawful as a matter of competition law."[232] However, the way that U.S. courts will react to the activity remains to be seen.

These barriers are pressing issues, and this Article certainly does not set out to solve them. They should, and likely will, be the topic of future literature. However, one thing is for certain: these roadblocks should not cause lawmakers, corporations, or citizens to abandon the campaign to legalize PPT in the United States.

VIII. CONCLUSION

U.S. drug prices must be lowered. A majority of Americans, regardless of their political party, support importation as a way to lower these prices.[233] This Article suggests a way in which parallel importation of patented pharmaceuticals can be safely implemented. But the road will not be easy—past attempts with similarly good intentions have faltered.

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228. Michel, *Consequences of SCOTUS Lexmark Decision on Parallel Drug Imports: Exclusive Interview with Professor Abbott*, FUDIABETES (June 4, 2017), https://forum.fudiabetes.org/t/consequences-of-scotus-lexmark-decision-on-parallel-drug-imports-exclusive-interview-with-professor-abbott/1116 [https://perma.cc/EQ24-BHR7] ("Pharmaceutical originators will not expand overseas supplies to fill new demand for parallel imports in the United States. Some of the bills introduced in Congress try to address potential efforts to restrict the quantity of goods available for parallel trade, but this is a difficult business, and in any case remains to be seen.").

229. Comment from Professor Abbott, on file with author.

230. Abbott, *Parallel Trade in Pharmaceuticals*, *supra* note 19, at 160.

231. *Id.*

232. *Id.* (emphasis omitted).

233. Dylan Scott, *Trump's Abandoned Promise to Bring Down Drug Prices, Explained*, VOX (Feb 2, 2018), https://www.vox.com/policy-and-politics/2018/1/30/16896434/trump-drug-prices-year-one [https://perma.cc/LTT6-UMJZ]; *see also* David Nather, *Trump's Health Care Plan Takes (Another) Page from the Democrats*, STAT NEWS (March 2, 2016), https://www.statnews.com/2016/03/02/trump-health-care-plan/ [https://perma.cc/TAJ4-CERA] ("In a STAT-Harvard poll last year, 39 percent of Republican voters said drug reimportation would be their top choice for dealing with expensive prescription drugs.").

Legislation to facilitate PPT in the United States will introduce competition into the patented pharmaceutical market and should lead to a decrease in prices. PPT will not be the single antidote to this country's drug-pricing epidemic, but it will get the ball rolling. For the millions of Americans struggling with high prices, progress has to be made, and safe, efficient PPT is a great place to start.