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ENOUGH EXCUSES ON DRUG IMPORTATION: A NEW TRANSNATIONAL PARADIGM FOR FDA REGULATION AND LOWER US DRUG PRICES

> If FDA is leaning forward in areas of new technology, if it's investing in good tools for doing its own work, and better science for evaluating regulatory questions – in other words, if we're doing our jobs and leveraging the authorities [Congress has] given us…we can have better efficiency, and better safety, and also remain faithful to FDA's *gold standard* for regulatory conduct. – Scott Gottlieb, MD, former FDA Commissioner, and current member of Pfizer's Board of Directors.[1]

> In the past, the United States taught the Europeans how to authorize drugs safely. Now the Europeans can give something back to the U.S. by sharing their knowledge of the harmonization of drug authorization systems.[2]

INTRODUCTION

The Food, Drug and Cosmetic Act (FDCA), and the agency created to enforce it, the US Food and Drug Administration (FDA or the "Agency"), are supposed to protect Americans from unsafe drugs,[3] not protect the pharmaceutical industry's profits.[4] The FDA does the latter by conflating the importation of lower-cost drugs with counterfeit drugs and rogue

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1. *Nomination of Scott Gottlieb, M.D. to Serve as Commissioner of Food and Drugs, Hearing on Examining the Nomination of Scott Gottlieb, M.D., to Serve as Commissioner of Food and Drugs Before the S. Comm. on Health, Education, Labor, and Pensions,* 115th Cong. 9 (2018) (Statement of Scott Gottlieb, MD) (emphasis added).

2. Kai P. Purnhagen, *The Challenge of Globalization in Pharmaceutical Law–Is an International Drug Approval System Modeled After the European System Worth Considering?*, 63 FOOD & DRUG L.J. 623, 634 (2008).

3. *FDA's Mission Statement,* US FOOD & DRUG ADMIN (Mar. 28, 2018), https://www.fda.gov/about-fda/what-we-do#mission. The word "drug" will mean "prescription drug" throughout this Note.

4. *See* Gabriel Levitt, *Scare Tactics Over Foreign Drugs*, N.Y. TIMES (Mar. 23, 2014) (describing how the FDA conflates safe, imported medicine for personal use with counterfeit or otherwise dangerous pharmaceuticals).

online pharmacies,[5] and by perpetuating the notion that it remains the world's regulatory "gold standard" in drug safety.[6] These are the FDA's excuses to prevent drug importation, also referred to as "parallel importation."[7] If commercial parallel importation was permitted, then the resulting competition would force down drug prices in the United States (US).[8]

According to a RAND Corporation study, the prices of the top sixty drugs and all innovator, brand-name drugs, based on sales revenue, are 395% and 344% higher in the US than in other countries of the Organization of Economic Cooperation and Development (OECD), respectively.[9] A large majority of pharmaceuticals sold in the US are foreign-made, and a plurality of brand-name drugs are made in Europe,[10] but the

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5. *See* Kevin Outterson & Ryan Smith, *Counterfeit Drugs: The Good, the Bad and the Ugly*, 16 ALB. L.J. SCI. & TECH. 525, 529, (2006) (asserting that "after consumer focus groups identified safety as a primary concern with internet drug purchases…the industry and the FDA began to publicly discuss the [counterfeit drug] problem as an important tool to enforce the industry's price discrimination structures across borders, enhancing overall industry profits.").

6. *See* Thomas J. Bollyky & Aaron S. Kesselheim, *Reputation and Authority: The FDA and the Fight over U.S. Prescription Drug Importation*, 73 VAND. L. REV. 1331, 1332 (2020) ("Furthermore, FDA officials describe themselves as 'the gold standard' for drug review—more thorough and rigorous about regulation than their counterparts—and, until recently, as able to fulfill their core institutional mandates without the cooperation of foreign counterparts.").

7. *See generally* Outterson & Smith, *supra* note 5, at 529, 536–37 (arguing that "Mindlessly conflating criminal placebos with importation [under a bill being considered at the time] only serves the interest of drug company profits rather than a serious discussion of public health."); *see* Bollyky & Kesselheim, *supra* note 6, at 1332.

8. *See* Stephen Salant, *Arbitrage Deterrence: A Theory of International Drug Pricing*, 8 HEALTH MGMT., POL'Y AND INNOVATION 1, 21 (2023); *see* Muhammad Zaheer Abbas, *Parallel importation as a policy option to reduce price of patented health technologies*, 17 J. OF GENERIC MEDICINES 1, 214–19 (2021) [Hereinafter Parallel Importation Economic Analyses].

9. *See* Andrew W. Mulcahy et al, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies* 49 (Rand Corporation, 2021) [Hereinafter Rand Report].

10. *See* Gabriel Levitt & Lucia Mueller, *Not Made in the USA: The Global Pharmaceutical Supply Chain and Prospects for Safe Drug Importation* 18, PHARMACYCHECKER.COM (2021), https://policycommons.net/artifacts/2182087/not-made-in-the-usa-pharmacycheckercom/2938064/; *see generally* Mary Van Beusekom, *Report*

FDCA bans commercial drug importation except by drug manufacturers.[11] This has led to a "monopoly on importation" that helps drug companies protect "exorbitant prices" in the US.[12] A public health crisis exists due to these high drug prices in which tens of millions of Americans forgo taking prescribed drugs each year, causing sickness and death.[13]

Importation, as one policy to end this drug price crisis, has received increasing attention and bipartisan action.[14] But the prevailing importation policy recommendations and programs are inadequate because they (1) are limited to Canada, which has too small of a pharmaceutical market for a large increase in exports to the US;[15] (2) rely on Section 804 of the FDCA, a cumbersome statutory framework for importation, which also prohibits the importation of a class of expensive drugs called biologics, among other medical products,[16] and, relatedly, (3) adhere to a dated regulatory paradigm that drugs are only safe

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Details Where Top100 Brand-name Rx Drugs Are Made, CTR. FOR INFECTIOUS DISEASE RSCH. AND POL'Y, UNIV. OF MINN. (Jan. 26, 2022), https://www.cidrap.umn.edu/news-perspective/2022/01/report-details-where-top-100-brand-name-rx-drugs-are-made (providing commentary on Levitt & Mueller research).

11. 21 U.S.C. § 381(d).

12. Levitt & Mueller, *supra* note 10, at 2 (quoting parts of Stephen Salant's Foreword for Levitt & Mueller research).

13. *See* discussion *infra* Section I.A.

14. *See* Bollyky & Kesselheim, *supra* note 6, at 1393-94; *see also* Victoria Knight, *A Proposal to Import Drugs from Other Countries Creates an Unusual Alliance in the Senate*, KAISER HEALTH NEWS (June 17, 2022), https://khn.org/news/article/drug-imports-canada-senate-sanders-paul-unusual-alliance; Brad Dress, *DeSantis sues FDA in Push to Import Prescription Drugs from Canada*, THE HILL (Aug. 31, 2022, 5:02 PM). https://thehill.com/regulation/court-battles/3622833-desantis-sues-fda-in-push-to-import-prescription-drug-from-canada/.

15. *See Readout of Acting Ambassador Kristen Hillman's Meeting With Joe Grogan Assistant to the President for Domestic Policy*, CONNECT2CANADA (Nov. 1, 2019), https://connect2canada.com/2019/11/readout-of-acting-ambassador-kirsten-hillmans-meeting-with-joe-grogan-assistant-to-the-president-for-domestic-policy (Canada's acting ambassador to the US said, "…it is important to recognise that Canada's market for pharmaceuticals is too small to have any real impact on U.S. drug prices. Canada represents only 2% of global pharmaceutical consumption vs America's 44%.").

16. 21 U.S.C. §§ 384(a)(3)(B); *see also* Bollyky & Kesselheim, *supra* note 6, at 1345.

and effective if they are evaluated by the FDA, opposed to other drug regulators.[17]

In *Reputation and Authority: The FDA and the Fight over U.S. Prescription Drug Importation*, Thomas J. Bollyky and Aaron S. Kesselheim have identified the central obstacle to making importation work. That obstacle is the FDA's historical and institutional hostility to drug equivalence determinations, which, if permitted, would allow the marketing and sale of drugs in the US based on the safety and efficacy evaluations of other drug regulatory authorities (DRAs).[18] The Agency's opposition to importation is so strong and its influence so entrenched that "the statutory requirements for the FDA maintaining direct oversight over prescription drug imports from Canada are onerous and unlikely ever to be fulfilled."[19]

Bollyky and Kesselheim recommend a limited form of importation, one potentially more acceptable to the FDA, to alleviate problems related to generic drug shortages and "extreme price hikes among off-patent drugs that function like product shortages,"[20] instead of legal reforms to remove or amend those "onerous" requirements. Their proposal would thus not address the biggest drug price problem in the US: patented, brand-name drugs.[21]

In contrast, this Note proposes legislation to amend the FDCA that would mandate regulatory reforms to broadly facilitate the parallel importation of drugs for commercial use from the European Union (EU) to make drugs more affordable for US patients.[22] This Note names the proposed legislation the Parallel Drug Import Competition Act (PDICA).

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17. *See* Bollyky & Kesselheim, *supra* note 6, at 1361.

18. *See id*. at 1336.

19. *Id.* at 1331.

20. *See id*. at 1400 (the author's "proposed U.S. prescription drug importation strategy… accommodates the institutional and reputational preferences of the FDA"), and at 1373 ("Extreme drug price hikes function like shortages" because generic drug shortages can be caused by market consolidation or FDA-granted market exclusivities where only one or two companies manufacture a given generic drug, thus granting market power like patented drugs where there is no competition.).

21. *See* Rand Report*, supra* note 9, at vi (patented brand name drug prices in the US are on average 344 percent higher than countries of the OECD).

22. *See* Salant, *supra* note 8, at 21.

The FDCA's provisions on drug importation, legislation to amend it, and Bollyky and Kesselheim's importation proposal, all accede to the prevailing regulatory paradigm of drug safety that the FDA's traditional role must be protected.[23] The novelty of this Note's proposed legislation rests in its demonstration that the FDA's raison d'etre—ensuring safe and effective drugs for Americans based on scientifically rigorous evaluations of drugs before they can be sold[24]—is better served by a new regulatory paradigm that relies on the international harmonization of drug standards,[25] and recognition that the EU and European Medicines Agency (EMA) may have eclipsed the FDA's "gold standard" as a new "platinum standard."[26]

Part I of this Note briefly describes the public health crisis in the US caused by high drug prices and explains the price discrepancies between the US and other countries. Part II will show that high drug prices have already forced patients in the US to personally import drugs, and how opposition to personal importation by drug companies and the FDA rests on the gold standard narrative, and their use of scare tactics about counterfeit drugs. Part III will discuss how the FDCA prevents the safe importation of lower-cost drugs from Europe for commercial use, and why current proposals on importation are insufficient. Part IV shows how the EU, led by the EMA, has emerged as a platinum standard in drug regulation. Part V employs the theoretical framework of reputation-based power in suggesting a new transnational paradigm for FDA's drug regulatory role. Part VI proposes specific legal reforms to amend the FDCA to make parallel trade in pharmaceuticals from the EU lawful and safe. Part VII shows how the proposed reforms are grounded in and symbiotically supported by the theory of transnational legal harmonization, and US law.

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23. *See* discussion *infra* Section IV.
24. *See* US FOOD & DRUG ADMIN., *supra* note 3.
25. *See* discussion *infra* Section IV.
26. *See id.*

I. THE UNIQUE AMERICAN HEALTH CRISIS OF HIGH DRUG PRICES

A. High US Drug Prices Cause Sickness and Death

In the US, high drug prices create life-or-death purchasing decisions, and many are dying because they cannot afford prescription drugs.[27] About three in ten Americans do not fill prescriptions as directed, and twenty-one percent do not fill prescriptions at all because of cost.[28] In contrast with all OECD countries, the US does not guarantee healthcare for its citizens.[29] Thus, a far higher percentage of Americans go without medical treatments than citizens of other countries.[30] Lower drug prices would lead to greater patient adherence to prescriptions and better health in the US.[31]

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27. *See* S. Willner et al., *Life or death: Experiences of Insulin Insecurity Among Adults with Type 1 Diabetes in the United States*, 11 SSM POPUL. HEALTH 3, 8 (2020); Press Release, West Health, New Study Predicts More Than 1.1 Million Deaths Among Medicare Recipients Due to the Inability to Afford Their Medications (Nov. 19, 2020), https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs.

28. Liza Hamel et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices.

29. *See* D.L. Davis, *The United States is the Only Industrialized Country Without Universal Healthcare,* POLITIFACT: THE POYNTER INST. (June 21, 2019), https://www.politifact.com/factchecks/2019/jun/21/mark-pocan/universal-health-care-diagnosis-mark/.

30. *See* Robin Osborn et al., *In New Survey of Eleven Countries, US Adults Still Struggle With Access To And Affordability Of Health Care*, 35 HEALTH AFFAIRS 2327, 2327 (2016); *see also* S. Dickson, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report* 19 (West Health Pol'y Ctr, 2021), https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf.

31. *See generally* SC Van Alsten et al., *Cost-Related Nonadherence and Mortality in Patients With Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000–2014*, 17 PREVENTING CHRONIC DISEASE 2, 14 (2020) (concluding that lower out-of-pocket costs for patients leads to greater adherence to prescriptions and better health).

B. Why Are Prices in Other High-Income Countries Much Lower?

Drug prices are much lower in other high-income countries due to their myriad laws and regulations.[32] They include, inter alia, mandating drug price negotiations between governments and drug companies, government-set reimbursement schedules, and external reference pricing rules that set prices based on the average in other countries.[33]

Under the newly passed Inflation Reduction Act, the federal government is authorized to negotiate drug prices in Medicare with manufacturers, mandate a maximum price on a small number of the most expensive drug products, and curtail price increases above the inflation rate on a larger number of drugs.[34] These reforms in Medicare represent a notable step in allowing public policies to control drug pricing, but they do not extend to the private market,[35] and they face legal challenges brought by the pharmaceutical industry.[36] Thus, the degree to which the new law will alleviate the crisis of high drug prices for most Americans remains uncertain. In contrast, permitting broad-based parallel importation would lead to greater drug-price parity, including in the private market, between the US and the EU.[37]

II. THE BOGEYMAN OF PERSONAL PRESCRIPTION DRUG IMPORTATION

The illegal commercial importation of prescription drugs, meaning drug imports for re-sale, often results in jail

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32. *See generally,* MA Rodwin, *Common Pharmaceutical Price and Cost Controls in the United Kingdom, France, and Germany: Lessons for the United States*, 51 INT'L J. OF HEALTH SERVICES 379, 379 (2021).

33. *See id.*

34. *See* Amy Kapczynski, *The Political Economy of Market Power in Pharmaceuticals*, 48 J. HEALTH POL., POL'Y & LAW 224, 239 (2023).

35. See *Id.*

36. Sheryl Gay Stolberg & Rebecca Robbins, *Drugmakers Are 'Throwing the Kitchen Sink' to Halt Medicare Price Negotiations*, N.Y. TIMES (Jul. 25, 2023), https://www.nytimes.com/2023/07/23/us/politics/medicare-drug-price-negotiations-lawsuits.html.

37. *See* Parallel Importation Economic Analyses, *supra* note 8.

sentences.[38] In stark contrast, the law technically allows, and is even supportive of otherwise unlawful, personal prescription drug importation ("personal importation").[39] Tens of millions of Americans have crossed borders into Canada and Mexico, traveled to other countries, or used international online pharmacies, to buy and import prescription drugs at lower prices.[40] Annually, about 2.3 million people with a prescription personally import drugs; many of them are uninsured, underinsured, or immigrants.[41]

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38. 21 U.S.C. §§ 333(a)(1)-(2), (b)(1), 381(d)(1), 332. Convictions for illegal drug importation can lead to sentences of up to ten years. *See* Press Release, Dept. of Justice, Eastern District of Virginia, US Attorney's Office, Illegal Drug Company Gallant Pharma and Co-Founder Sentenced (Mar. 18, 2015), https://www.justice.gov/usao-edva/pr/illegal-drug-company-gallant-pharma-and-co-founder-sentenced.

39. Several provisions of federal law reflect Congress' position that individuals, but not businesses other than drug manufacturers, under some circumstances can lawfully import FDA-approved drugs, or should be able to import foreign versions of FDA-approved drugs for their personal use if it is not an unreasonable risk. *See* the Prescription Drug Import Fairness Act of 2000, Pub. L. 106-387, § 746, 114 Stat. 1549A–40 (stating "Patients and their families sometimes have reason to import into the United States drugs that have been approved by the Food and Drug Administration ('FDA')"); *see* 21 U.S.C. § 384(j)(1), (stating "Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs… the Secretary should exercise discretion to permit individuals to make such importations in circumstances in which (i) the importation is clearly for personal use; and (ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual"; *see* 21 U.S.C. 335a(b)(5) (which protects individuals who import a misbranded prescription drug for their personal use from debarment by reserving such liability to only persons that import "in an amount, frequency, or dosage that is *inconsistent with personal or household use by the importer*.") (Emphasis added.)). [hereinafter Personal Importation Statutory Framework.].

40. Rachel Bluth, *Faced with Unaffordable Drug Prices, Tens of Millions Buy Medicines Outside U.S.,* KAISER HEALTH NEWS (Dec. 16, 2016), https://khn.org/news/faced-with-unaffordable-drug-prices-tens-of-millions-buy-medicine-outside-u-s.

41. Young-Rock Hong, et al, *Socioeconomic and Demographic Characteristics of US adults Who Purchase Prescription Drugs from Other Countries*, 3 JAMA NETWORK OPEN, 1, 12 (2020) (analyzing data from the US National Health Interview Survey, estimating that annually 2.3 million people in the US import medicines for personal use and for which they have a prescription).

While there is no specific law banning the personal importation of prescription drugs, according to the FDA, personal importation usually violates federal law,[42] and some case law supports the FDA's position.[43] Since the practice is somewhat prevalent, and patients are never charged or prosecuted for illegal personal importation,[44] experts in government frequently refer to it as only "technically" illegal.[45] Further, because of statutory support for personal importation,[46]

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42. *See Personal Importation*, US FOOD & DRUG ADMIN. (Nov. 2, 2023), https://www.fda.gov/industry/import-basics/personal-importation.

43. *See In re* Canadian Imp. Antitrust Litig., 470 F.3d 785, 790–91 (8th Cir. 2006) ("By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. § 384."). The author of this Note disagrees with the holding as it applies to personal importation, *see e.g.,* Personal Importation Statutory Framework, *supra* note 39; *see also* United States v. Vepuri, 74 F.4th 141, 146 (3d Cir. 2023) (the court in *In re* Canadian Imp. Antitrust Litig did "not discuss the text of the FDCA, and we…decline to adopt the apparent assumption" that drugs from Canada are "unapproved" because their labels are different from the labels used in the U.S., "which in turn violates § 355(a).").

44. Michael McAuliff, *Trump Administration Seizing Cheaper Medications From Canada And Other Countries*, HEALTH NEWS FLA. (June 18, 2018, 9:34 AM), https://health.wusf.usf.edu/health-news-florida/2018-06-18/trump-administration-seizing-cheaper-medications-from-canada-and-other-countries (quoting an FDA spokesperson referring to personal drug imports: "The FDA does not and would not prosecute an individual for buying medicines online for their personal use….The product would be refused and no additional action would be taken against the individual.")

45. CONG. RSCH. SERV., RL32191, PRESCRIPTION DRUG IMPORTATION: A LEGAL OVERVIEW, (2008) ("Currently, the [FDCA] prohibits anyone other than the manufacturer of a prescription drug from importing that drug into the United States. Thus, [personal importation] is *technically* a violation of the statute…" (emphasis added)); *see also* Meredith Freed, et al., *10 FAQs on Prescription Drug Importation*, KAISER FAM. FOUND. (Oct. 8, 2020), https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation ("Even if the personal importation of a drug is *technically* illegal, current law directs the FDA to exercise discretion in permitting personal importation of drugs when the product is "clearly for personal use, and does not appear to present an unreasonable risk to the user.") (emphasis added).

46. Personal Importation Statutory Framework, *supra* note 39.

the FDA's personal importation policy,[47] resource constraints,[48] and politics,[49] over ninety-nine percent of most personal imports reach the patients who ordered them.[50] Some scholars, consumer advocates, and medical practitioners advocate expressly permitting personal importation, not just tolerating it.[51]

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47. US FOOD & DRUG ADMIN., *supra* note 42.

48. *Report of the HHS Task Force on Drug Importation*: *Hearing* before the S. Special Comm. on Aging, 109th Cong. 3 (2005) (statement of Richard H. Carmona, M.D., Surgeon General).

49. Members of Congress periodically complain to the FDA when it appears that the Agency is increasing the number of prescription orders it detains and destroys. *See, e.g.*, Letter from Senator Bill Nelson to FDA Commissioner Dr. Scott Gottlieb (Dec. 20, 2017), (on file with author); *see also* Letter from Senators Chuck Grassley (R-IA) and Amy Klobuchar (D-MN) to FDA Commissioner Dr. Scott Gottlieb (Dec.18, 2017) (on file with author); Additionally, in letters to the FDA, members of Congress have reinforced their position that under current law, regulation, and public policy, patients in the US should be allowed to import prescription drugs for personal use. *See* Letter from Sens. Debbie Stabenow and Scott Peters (Nov. 17, 2020) (on file with author) ("We strongly urge that any importation regulations, guidance, or requests for proposals allow continued, and expanded, access to safe and affordable medicines for the millions of Americans that are currently importing medicines for personal use.").

50. *See The Fight to Keep Illegal, Unapproved, Counterfeit and Potentially Dangerous Drugs from Entering the United States*, *U.S. Food and Drug Administration and the International Mail Facilities* 7, US FOOD & DRUG ADMIN. (Apr. 2019) ("Estimat[ing] that the FDA is able to inspect less than *0.18%* of the packages assumed to contain drug products that are shipped through the international mail facilities…" (emphasis added)).

51. *See* Outterson & Smith, *supra* note 5, at 536 (asserting that instead of stopping personal drug importation, "an alternative is to legalize and regulate it, bringing this trade out of the grey market"); 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, 371–72 (2015); *see also* Roger Bate, *Personal medicine importation: What are the risks, and how can they be mitigated?1,* AM. ENTER. INST. (2019), https://www.aei.org/research-products/report/personal-medicine-importation-what-are-the-risks-and-how-can-they-be-mitigated (arguing that "it is both equitable and efficient for underinsured (usually low-income) Americans to pay less [for prescription drugs] than they currently do and, further, that personal importation achieves this aim without overhauling America's existing drug framework or compromising patient safety"); *see also*
Caleb J. Scheckel & S. Vincent Rajkumar, *Drug Importation: Limitations of Current Proposals and Opportunities for Improvement*, 11 BLOOD CANCER J., 3, 4 (2021) ("However, the importation of a broader definition of pharmaceuticals from a broader array of industrial nations while codifying personal importation

Indeed, personal importation already helps people with drug affordability.[52] This Note's arguments can be used in support of legislative reforms and public policies seeking to expand personal importation.[53] Opponents of importation, namely the FDA and the pharmaceutical industry, invoke public health threats from counterfeit drugs attributed to personal importation to make their cases against it.[54] Further, the pharmaceutical industry funds several non-profit organizations and programs that focus on deterring consumers from purchasing and importing lower-cost prescription drugs.[55] To

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exemptions may offer U.S. consumers a degree of price relief for a moderate period of time while more sustainable strategies to reduce cost are pursued."); *see generally* PRESCRIPTION JUST., *How the Trump Administration Can Rapidly Lower Drug Costs for Americans* (2017), https://prescriptionjustice.org/policy-recommendations-personal-importation-trump-executive-authorities.pdf (advocating use of executive authorities under current law to expressly permit and encourage safe personal drug importation).

52. *See* Bluth, *supra* note 40; *see also* Bram Sable-Smith, *American Travelers Seek Cheaper Prescription Drugs In Mexico And Beyond*, SHOTS: HEALTH NEWS FROM NPR (Feb. 11, 2019, 5:01 AM), https://www.npr.org/sections/health-shots/2019/02/11/691467587/americans-seek-cheaper-meds-in-mexico; *see also* Bernard J. Wolfson, *Shopping Abroad For Cheaper Medication? Here's What You Need To Know*, CAL. HEALTHLINE: ASKING NEVER HURTS (Aug. 21, 2019), https://californiahealthline.org/news/shopping-abroad-for-cheaper-medication-heres-what-you-need-to-know.

53. *See* sources cited in *supra* note 51.

54. *See* Outterson & Smith, *supra* note 5, at 529; *see also* Levitt, *supra* note 4 (describing how the FDA conflates safe imported medicine for personal use with counterfeit or otherwise dangerous pharmaceuticals); *see also* Rep. Rosa DeLauro (D-CT), *Imported Drugs: FDA Suddenly Gets 'Concerned'*, LA TIMES: WORLD & NATION, (Nov. 5, 2003), https://www.latimes.com/archives/la-xpm-2003-nov-05-oe-delauro5-story.html (writing "[i]t is curious that at exactly the time that the pharmaceutical industry is spending heavily to defeat legislation [in favor of importation] that overwhelmingly passed in the House, the FDA has suddenly become concerned about the "dangers" of imported drugs…").

55. *See* Michael McAuliff, *Keeping International Pharmacies Under a Cloud*, TARBELL (May 2, 2018), https://web.archive.org/web/20180704025609/http://www.tarbell.org/2018/05/keeping-international-pharmacies-under-a-cloud/ (reporting on the positions and efforts of the Alliance for Safe Online Pharmacies, Center for Safe Internet Pharmacies, LegitScript, National Association of Boards of Pharmacies, and the Partnership for Safe Medicines, McAuliff writes that "Millions of Americans pinched by high drug prices turn to overseas Internet pharmacies each year. An array of groups funded by the pharmaceutical industry seeks to

bypass fearmongering about personal importation, this Note focuses on a potentially more defensible and efficient system of highly regulated commercial parallel importation (also called wholesale importation).

Explaining the FDA's periodic enforcement against personal importation can help the reader understand the Agency's use of the gold standard narrative—that the FDA is superior to all other DRAs— to oppose importation.

The FDA sometimes refuses and destroys personal drug imports coming in through international mail facilities, causing access issues for patients and political headaches.[56] In 2017, Senator Bill Nelson (D-FL), hearing from constituents that the FDA was "seizing" their drugs, sent a letter to FDA Commissioner Scott Gottlieb expressing concern that the FDA was "cracking down on seniors who are buying their medications from other countries because they cannot afford" them domestically.[57] The FDA responded: "We take very seriously our responsibility to help ensure that the drugs Americans take are safe and effective, and that our actions live up to our *reputation* as the world's *gold standard*."[58] Generally, to defend the agency's administrative destruction of personal prescription drug orders, the FDA asserts, "Any version of a drug that has not been approved by the FDA is considered an "unapproved

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steer people away from the money-saving option, citing safety concerns that advocates say are largely unfounded."); *see also* Emily Kopp & Rachel Bluth, *Nonprofit Working To Block Drug Imports Has Ties To Pharma Lobby*, SHOTS: HEALTH NEWS FROM NPR (Apr. 18, 2017, 5:00 AM ET), https://www.npr.org/sections/health-shots/2017/04/18/524363014/nonprofit-working-to-block-drug-imports-has-ties-to-pharma-lobby (referring to the Partnership for Safe Medicines, reports that "A nonprofit organization that has orchestrated a wide-reaching campaign against foreign drug imports has deep ties to the Pharmaceutical Research and Manufacturers of America, or PhRMA…"; *see also* Nicole Longo, *Look at the facts. Drug importation is dangerous*, PHARM. RESEARCHERS AND MFRS. OF AM. (Feb. 22, 2019), https://web.archive.org/web/20230702160325/https://catalyst.phrma.org/look-at-the-facts.-drug-importation-is-dangerous ("Today, 1 in 10 medicines worldwide and up to 50 percent of drugs consumed in developing nations are counterfeit. Importation proposals would open the U.S. borders to these dangerous and potentially deadly substances.").

56. *See* McAuliff, *supra* note 44.

57. Letter from Senator Ben Nelson, *supra* note 49.

58. *See* Letter from the FDA to Senator Ben Nelson (emphasis added) (June 18, 2018) (on file with author).

drug.…Drugs from foreign sources that are not FDA-approved do not have the same assurance of safety, effectiveness, and quality as drugs subject to FDA oversight."[59]

The FDA's opposition to importation includes misleading testimony before Congress that "foreign unapproved drugs"[60]—a phrase that can encompass safe foreign versions of FDA-approved drugs—are as dangerous as counterfeit drugs.[61] The FDA has also misused the opioid crisis as a pretext to obtain more funding to refuse and destroy non-opioid, prescription drugs ordered for personal import.[62] Such import refusals still represent less than one percent of international prescription drug orders.[63]

Despite the rhetoric, personal importation has proven to be safe when patients buy prescription drugs from Canadian pharmacies or order from properly credentialed international online pharmacies, which facilitate personal imports sourced from several countries, including European countries.[64]

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59. *See FDA's Administrative Destruction Authority*, US FOOD AND DRUG ADMIN. (Nov. 23, 2020), https://www.fda.gov/industry/import-basics/fdas-administrative-destruction-authority.

60. *Counterfeit Drugs: Fighting Illegal Supply Chains: Hearing Before the Subcomm. on Oversight and Investigations, of the H. Comm. on Energy and Com.*, 113th Cong. 162 (2014) (answers to questions by Howard Sklamberg, JD, Deputy Comm'r. for Global Regul. Operations and Policy, FDA ("Foreign unapproved drugs which pose the same public health risk as a counterfeit drug.").

61. *See* Gabriel Levitt, *supra* note 4; *see also* Outterson & Smith, *supra* note 5, at 531–32.

62. Phil Galewitz, *Asthma, Cancer, Erectile Drugs Sent From Abroad Make Up Most Confiscations, Despite Opioid Claims*, CNN (Mar. 7, 2023, 7:55 AM), https://www.cnn.com/2023/03/07/health/fda-drug-shipments-khn-partner/index.html.

63. *See* US FOOD & DRUG ADMIN., *supra* note 50, at 7.

64. *See* Outterson & Smith, *supra* note 5, at 532; *see also* Roger Bate et. al., *In Whom We Trust: The Role of Certification Agencies in Online Drug Markets*, 14 B.E. J. OF ECON. ANALYSIS & POL'Y 132, 136, 150 (2013) (categorizing credentialed U.S. online pharmacies as Tier 1, credentialed foreign online pharmacies as Tier 2, and foreign online pharmacies with no credentialing as Tier 3, and finding "[no] significant quality difference between tier 1 and tier 2, but drugs ordered from tier-2 websites are on average 49.2% cheaper than the same drug from tier-1 websites." Further, drug products ordered from Tier 2 online pharmacies were sourced from Australia, Canada, India, Israel, Italy, Germany, Turkey, and the UK); *see also* Bate, *supra* note 51, at 9; *see also Drug Importation: Would The Price Be Right? Examining The Price Of Drug*

Critically, for the purposes of this Note, the fact that Americans already import prescription drugs because of high US prices demonstrates a public demand for a new parallel importation regulatory framework.

III. HOW US LAW PREVENTS THE IMPORTATION OF SAFE AND LOWER-COST DRUGS

A. Lexicon for Understanding Legal and Illegal Drug Importation

1. FDA-Approved Drug

Only an FDA-approved drug can be sold in the US.[65] Thus, only FDA-approved drugs can be imported for commercial use,[66] and only by or under the authorization of the drug manufacturer.[67] To market new, patented drug products in the US, drug companies must first obtain FDA approvals by submitting new drug applications (NDAs) to the Agency.[68] There are other categories of drugs with different application requirements, including generic versions of brand-name drugs,[69] biologic drugs, which are medical products made with living matter,[70] and

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Reimportation, Focusing On Implications For United States Consumers, Pricing, Research and Development, and Innovation: Hearing before the S. Comm. on Health, Ed., Labor, and Pensions, 109th Cong. 68–69 (2005) (answers to questions by Professor Kevin Outterson, JD, Assoc. Professor, W. Va. Univ., College of Law) (encouraging importation from countries with "equivalent drug regulatory systems" to the U.S., and specifically referring to Europe, stating "If we allowed importation on a safe basis, I think we would, in a sense, create a revolution for markets in the European Union on drug pricing.").

65. *See New Drug Application (NDA)*, US FOOD AND DRUG ADMIN. (Jan. 21, 2022), https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

66. *See* Amanda K. Sarata, CONG. RSCH. SERV., IF11056, PRESCRIPTION DRUG IMPORTATION 1 (2022).

67. 21 U.S.C. § 381(d).

68. *See* US FOOD AND DRUG ADMIN., *supra* note 65.

69. *Abbreviated New Drug Application (ANDA),* US FOOD AND DRUG ADMIN. (Dec. 16, 2022), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda.

70. See *Biologics License Applications (BLA) Process (CBER)*, U.S. FOOD & DRUG ADMIN. (Jan. 27, 2021), https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber.

biosimilars, which are off-patent products equivalent to biologics.[71] This Note will use the word "drug" to refer to all categories.

To receive FDA approval, an NDA must contain, inter alia: (1) the results of an investigational new drug (IND) study, which includes three phases of clinical trials to demonstrate the safety and efficacy of the drug; (2) the formulation, dosage, strength, and route of administration of the drug (e.g., capsule, twice-daily, 20 mg, orally); (3) all drug ingredients, both active pharmaceutical ingredients (APIs) and inactive ingredients (such as pill binders and coloring); (4) the "name and address of each manufacturer of the drug product; a description of the manufacturing and packaging procedures and in-process controls for the drug product;" (5) "the specifications necessary to ensure the identity, strength, quality, purity, potency, and bioavailability of the drug product;" and (6) the recommended label content to properly communicate the indication of the drug, its potential risks, and how it should be used.[72] Under NDAs, the FDA's Center for Drug Evaluation and Research evaluates drugs and decides—based on whether the drugs are safe and effective and the benefits outweigh the risks—if they should be FDA-approved.[73]

2. Unapproved and Misbranded Drugs

Any drug that is not FDA-approved, including a foreign version of an FDA-approved drug, is considered an "unapproved drug."[74] Such unapproved drugs could include EMA-approved versions of FDA-approved drugs that contain the same (1) APIs,[75] (2) strength, and (3) clinical effects as the FDA-approved

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71. *Biosimilar Development, Review, and Approval*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2022), https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval.

72. *See* 21 C.F.R. § 314.50; *see also* 21 U.S.C. § 355.

73. *Development & Approval Process*, US FOOD & DRUG ADMIN, https://www.fda.gov/drugs/development-approval-process-drugs (last visited August 24, 2023).

74. *See* Sarata, *supra* note 66, at 1 ("Foreign-made versions of FDA-approved drugs that have not been evaluated through the FDA process are typically considered unapproved new drugs and are illegal").

75. *Active Pharmaceutical Ingredients and Intermediates for the Pharmaceutical Industry*, PHARM. TECH., https://www.pharmaceutical-technology.com/buyers-guide/active-pharmaceutical-ingredients/ (last visited

version, but with different formulations or manufacturers. For example, AstraZeneca sells the drug Nexium in the US in a capsule formulation;[76] whereas GlaxoSmithKline sells Nexium in the EU in a tablet formulation.[77] The EU Nexium is considered a new unapproved drug by the FDA because, inter alia, the version of Nexium approved for sale in the US is a capsule, not a tablet, or it has different manufacturers.[78]

Any drug that is not labeled in accordance with the FDA's requirements is deemed misbranded.[79] Some drugs sold in other countries are FDA-approved drugs, but labeled for non-US markets, which the FDA recognizes as multimarket authorization (MMA) drugs.[80] For example, the drug Januvia sold in the US is licensed to Merck Sharp & Dohme Corp., and is made in and exported from the UK to the US.[81] Januvia is licensed in the EU to Merck Sharp & Dohme BV in the

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Jan. 4, 2023) ("Active pharmaceutical ingredients (APIs) are the active components in a pharmaceutical drug that produce the required effect on the body to treat a condition.").

76. *Drug Label Information* (DailyMed - Nexium), NAT'L INST. OF HEALTH, NAT'L LIBR. OF MED., https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f4853677-1622-4037-688b-fdf533a11d96 (last visited Nov. 3, 2023).

77. *Summary of Product Characteristics* (Nexium), EUR. MED. AGENCY 2 (last visited Jan. 4, 2023), https://www.ema.europa.eu/en/documents/product-information/nexium-control-epar-product-information_en.pdf.

78. *See CDER Small Business and Industry Assistance: Import and Export of Human Drugs and Biologics*, US FOOD & DRUG ADMIN. (Apr. 25, 2016), https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/cder-small-business-and-industry-assistance-import-and-export-human-drugs-and-biologics ("Unapproved new drugs include any drugs—including foreign-made versions of U.S. approved drugs—that have not been manufactured in accordance with FDA approval.").

79. *See* 21 U.S.C. § 352.

80. Importation of Certain Food and Drug Administration-Approved Human Prescription Drugs, Including Biological Products, and Combination Products Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; 85 Fed. Reg 61,955, 61,956 (Oct. 1, 2020).

81. *Drug Label Information* (DailyMed - Januvia), NAT'L INST. OF HEALTH, NAT'L LIBR. OF MED. (July 31, 2023), https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f85a48d0-0407-4c50-b0fa-7673a160bf01.

Netherlands.[82] Januvia's API, sitagliptin, is the same in both countries.[83] The inactive ingredients appear to be the exact same as well.[84] Additionally, they have the same numbers imprinted on the tablets.[85] Except by its manufacturer, importing FDA-approved Januvia for commercial use that is labeled for sale in the EU is illegal because the drug is considered misbranded.[86]

Therefore, illegal imports of drugs could include (1) foreign versions of FDA-approved drugs, because they are deemed "unapproved drugs,"[87] or (2) FDA-approved drugs but labeled for a foreign market, because they are deemed "misbranded drugs."[88]

B. FDCA Importation Laws

1. Section 801: Imports

Under Section 801(a) of the FDCA, the Secretary of the Department of Health and Human Services (hereinafter "HHS Secretary") provides the Secretary of the Treasury with a list of foreign drug manufacturing establishments that are registered with the FDA as producing FDA-approved drugs for the US market.[89] FDA-approved drugs made in those facilities can be imported for commercial use by their manufacturers.[90] Imported drugs that are not manufactured in such establishments are subject to FDA's review and refusal if the drugs were not made

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82. *Summary of Product Characteristics* (Januvia), EUR. MED. AGENCY 17 (Oct. 27, 2022), https://www.ema.europa.eu/en/documents/product-information/januvia-epar-product-information_en.pdf.

83. *See id.; see also supra* note 82.

84. *Drug Information on Januvia, supra* note 81; *Summary of Product Characteristics for Januvia*, *supra* note 82.

85. *Id.*

86. *See* 21 U.S.C. §§ 352, 355 (A drug that is sold in the US is misbranded if its packaging or labeling does not conform to the label requirements pursuant to the drug's FDA application and approval).

87. *See* US FOOD & DRUG ADMIN., *supra* note 78.

88. *See* Sarata, *supra* note 74, at 1 (noting that an imported drug could be FDA-approved but misbranded because the label does not meet FDA's standards for adequate directions for use); *see also FDA's Administrative Destruction Authority*, *supra* note 59 ("The lack of an English language label may also indicate that the drug is misbranded.").

89. 21 U.S.C. § 381(a).

90. 21 U.S.C. § 381(d).

under the conditions required by the NDA or in FDA-registered manufacturing establishments, or if they are misbranded.[91]

The Prescription Drug Marketing Act of 1987 banned the reimportation of prescription drugs except by the manufacturers.[92] The FDCA was amended in 2017 to add a similar, but not identical, restriction to the import of foreign-made drugs for commercial (but not personal) use, stating that:

> no drug…may be imported into the United States for commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States.[93]

Thus, any importation of FDA-approved drugs for commercial use that is not under the authority of the manufacturer would violate the FDCA.[94]

2. Section 804: Importation of Prescription Drugs

In 2000, the Medicine Equity and Drug Safety (MEDS) Act added Section 804 to the FDCA, which made it legal to import drugs for commercial use at lower prices from several high-income countries, including European countries, without authorization from the drug manufacturers, but only subject to certification from the HHS Secretary that such importation would (1) pose no additional risk to consumers and (2) would help achieve significant savings for consumers.[95] The certification under MEDS never occurred.

In 2003, Section 804 was amended to limit wholesale importation to just Canada, keeping the same certification requirements as MEDS.[96] A new subsection was added—804(j)—

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91. *Id.*

92. 21 U.S.C. § 381(d)(1)(A) ("reimportation" means drugs manufactured in the US, exported, and then brought back into the country).

93. 21 U.S.C. § 381(d)(2).

94. 21 U.S.C. §§ 381(a), (d). As it relates to the personal importation of prescription drugs, it is noteworthy that Congress chose to impose this restriction on imports for "commercial use."

95. Medicine Equity and Drug Safety Act of 2000, Pub. L. 106-387, § 745, 114 Stat. 1549-35.

96. *See* Medicare Prescription Drug Modernization and Improvement Act of 2003, Pub. L. No. 108-73, § 1121, 117 Stat. 2066, 2464-67 (2003) (codified at 21 U.S.C § 384).

which encouraged personal importation and gave the Secretary broad authority to grant waivers to expressly permit it from any country, but specifically requiring that it be permitted it from licensed Canadian pharmacies.[97]

Section 804(b) states that the HHS Secretary "shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States."[98] Section 804 stipulates many requirements, including onerous testing requirements that are not required for drugs imported subject to Section 801; and excludes controlled substances, biologics, and other categories of drugs.[99]

Section 804 does not provide statutory authority to allow drug equivalence determinations based on Health Canada's drug approvals.[100] Instead, it requires the FDA, "to establish its own inspection and screening processes for these particular prescription drug imports."[101] Essentially, that makes drug importation under Section 804 a distinct regulatory framework from the rest of the FDCA.[102]

In 2020, in issuing a final rule, pursuant to Section 804(b), the HHS Secretary certified that importation from Canada would pose no additional risk to public health and achieve substantial savings.[103] The rule, however, weakens the law's potential to impact drug prices.[104] Specifically, it limits wholesale drug importation from Canada to time-limited programs sponsored by states or other non-federal entities, and requires that drugs

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97. 21 U.S.C. § 384(j).

98. 21 U.S.C. § 384(b).

99. Horvath Health Policy, Comment on the Notice of Proposed Rulemaking Concerning Importation of Prescription Drugs (Dec. 23, 2019), https://www.regulations.gov/comment/FDA-2019-N-5711-1221.

100. *See* Bollyky & Kesselheim, *supra* note 6, at 1346.

101. *Id.*

102. FDA-approved prescription drugs can be lawfully imported into the US subject to Section 801(a) and (g) of the FDCA, 21 U.S.C, § 381(a) and (g). Since most drugs sold in the US are imported, ironically, Section 801 is the main artery of the US supply chain. Section 804 is therefore extraneous to the main regulatory framework for importation.

103. Importation of Prescription Drugs, 85 Fed. Reg. 62,094, 62,095 (Nov. 30, 2020) (codified at 21 C.F.R. § 251).

104. *See* Horvath Health Policy, *supra* note 99 ("The [Notice of Proposed Rulemaking] has some very important limitations that may, if not modified, undermine the potential of importation.").

imported under Section 804 come from wholesalers who received those drugs directly from the manufacturer (meaning not from another wholesaler), which makes it easy for manufacturers to cut supplies to Canadian wholesalers that participate in the Section 804 programs.[105]

Lastly, Section 804 is limited to importation from Canada, which has only 38.2 million people,[106] compared to the US which has 337.3 million people.[107] Thus, creating a more robust and sustainable federal system for parallel drug importation requires reaching larger markets.[108]

C. How the FDCA Blocks Imports of Lower-cost Drugs from the EU

Brand name drug prices are much higher in the US than in EU countries. For example, drug prices are 2.80, 3.15, and 3.49 times higher in the US than in Germany, Italy, and France, respectively.[109] Those differentials reflect the prices that drug manufacturers charge wholesalers.[110] In the EU, parallel importation is lawful among EU members and three other countries in the EU Free Trade Area.[111] This means licensed pharmaceutical wholesalers or distributors in one country can

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105. *Id.* at 2 (commenting on the restricted supply chain, Ms. Horvath writes, "we anticipate that manufacturers of prescription drugs will try to bar distributors in Canada from selling Canadian products into the U.S. even when such sales would be legal.").

106. *See The World Fact Book: Canada*, CENTRAL INTELLIGENCE AGENCY, https://www.cia.gov/the-world-factbook/countries/canada (last visited Jan. 4, 2023).

107. *See id.*; *see The World Fact Book: United States*, CENTRAL INTELLIGENCE AGENCY, https://www.cia.gov/the-world-factbook/countries/united-states (last visited Jan. 4, 2023).

108. *See* Jane Horvath, *State Drug Importation Programs Will Work with the FDA, Not Outside Of It,* STAT (Jul. 16, 2019), https://www.statnews.com/2019/07/16/state-drug-importation-programs-fda.

109. Rand Report, *supra* note 9, at xii.

110. *Id.*

111. *Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted*, at 3, COM (2003) 839 (Dec. 30, 2003) ("Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations regarding the protection of human health and life and the protection of industrial and commercial property, provided by article 30 of the EC Treaty.").

sell to those in another country without authorization from manufacturers.[112]

The FDCA prevents the importation for commercial use of lower-cost drugs from Europe because such drugs are deemed "unapproved drugs" and "misbranded drugs."[113] One example of an unapproved drug is the foreign version of an FDA-approved drug called Daraprim. In the UK, GlaxoSmithKline holds the marketing authorization for Daraprim.[114] Vyera Pharmaceuticals holds the marketing authorization in the US.[115] In 2015, the then-CEO of Turing Pharmaceuticals (now Vyera), Martin Shkreli, infamously raised the price of Daraprim from $13.50 to $750 per pill overnight.[116] GlaxoSmithKline's price in the UK at the time was twenty dollars for thirty tablets (less than one dollar/pill).[117] It is and was illegal to import Daraprim from the UK or the EU, because GlaxoSmithKline's Daraprim is considered a new unapproved drug under the FDCA.[118]

Above, this Note provided the example of Januvia, which is an FDA-approved drug sold in the EU but labeled differently from

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112. *Id*.

113. *See supra* Section III.A.

114. *See Daraprim Tablets*, ELEC. MED. COMPENDIUM, https://www.medicines.org.uk/emc/product/938 (last visited Oct. 27, 2022) (click on "7. Marketing Authorisation Holder").

115. *See Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD AND DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm (last visited Nov. 4, 2023), (search by Proprietary Name for "Daraprim.").

116. Andrew Pollack, *Drug Goes From $13.50 a Tablet to $750, Overnight,* N.Y. TIMES (Sept. 20, 2015), https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html.

117. Victoria White, *Turing to lower price of Daraprim amid controversy,* EUR. PHARM. REV. (Sept. 23, 2015), https://www.europeanpharmaceuticalreview.com/news/35167/turing-to-lower-price-of-daraprim-amid-controversy/.

118. *See* Sarata, *supra* note 66, at 1 ("Under current law, the importation of unapproved new drugs, including foreign-made versions of FDA-approved drugs, is generally prohibited."); *see also* 21 U.S.C. § 355; *see also* 21 U.S.C. § 321(g)(1)(B)(GlaxoSmithKline's Daraprim is considered a new and unapproved drug by the FDA because, inter alia, it was not manufactured in the establishment listed in the FDA-approved Daraprim NDA subject to § 355, and it is defined as a "drug" under § 321(g)(1)(B)).

the US label.[119] The price in the UK for one 50 mg tablet is $3.62, compared to about eighteen dollars in the US.[120] It would be illegal for any company to import FDA-approved Januvia for resale except under authorization by Merck Sharp & Dohme Corp,[121] thus preventing commercial imports of Januvia at lower prices.

Therefore, the FDCA prevents the importation of lower-cost FDA-approved and foreign versions of FDA-approved drugs from Europe for commercial use, such as Januvia and Daraprim, respectively. [122]

IV. FOCUS ON EUROPE: THE EMERGENCE OF THE "PLATINUM STANDARD" IN DRUG SAFETY

A. Au Revoir Canada, Hello Europe

For about two decades, the drug importation debate in the US has focused on Canada.[123] Like most high-income countries, Canada has a comparably strong system of pharmaceutical regulation to the US.[124] Following the certification of Section 804

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119. *See* 21 U.S.C. §§ 352, 355 (A drug that is sold in the US is misbranded if its packaging or labeling does not conform to the label requirements pursuant to the drug's FDA application and approval).

120. *Januvia Prices*, PHARMACYCHECKER.COM, https://web.archive.org/web/20221128055656/https://www.pharmacychecker.com/januvia/50%2Bmg/#! (prices on Nov. 28, 2022).

121. *See* 21 U.S.C. § 381(d)(1)(B) (which would not prohibit the import of FDA-approved Januvia for *personal* use).

122. *See supra* notes 86, 87, at 17 (Januvia); *see also supra* notes 120, 121(Daraprim).

123. *See generally* Phil Galewitz, *Trump Approves Final Plan to Import Drugs From Canada 'for a Fraction of the Price,'* KAISER HEALTH NEWS, (Sept. 25, 2020), https://kffhealthnews.org/news/trump-approves-final-plan-to-import-drugs-from-canada-for-a-fraction-of-the-price/?. In summary, the focus on Canada is explained by Canada's proximity to the US to which Americans easily travel to buy cheaper drugs, but also because the provisions, added twenty years ago, of Section 804 (b) of the FDCA, 21 U.S.C. § 384(b), are limited to Canada, at least as applied to wholesale importation.

124. Even drug industry and regulation experts who are known to oppose importation accept that there are other countries with comparable standards in regulatory safety. *See generally* Andrew von Eschenbach, former FDA Commissioner, at the Partnership for Safe Medicines, Interchange 2017, YOUTUBE (Apr. 21, 2017), https://www.youtube.com/watch?v=u3ukGbuyCd4 ("Of the 96 countries around the world that can supply drugs *only* 30% have a

in 2020, several states have waited on the FDA to approve their wholesale importation program application, facing resistance from the Agency.[125] As this Note goes to publication (January 2024), the FDA approved Florida's application to oversee a Canadian wholesale importation program, and still Florida cannot start importing without further vetting by the FDA.[126] Moreover, in addition to the fact that the pharmaceutical industry is "considering all options" to stop the programs, and the Canadian government may simply prevent them, the insurmountable obstacle is that Canada is too small to accommodate broad-based, US drug importation.[127]

In contrast to Canada, the EU stands out as the perfect region to pursue drug importation. Its lead regulator, the EMA, and the EU system have likely surpassed the FDA when it comes to the safe approval, manufacture, and distribution of prescription drugs.[128] The EU, with 451 million people,[129] is much bigger than the US. Further, the EU has the largest wholesale pharmaceutical market in the world by number of market participants, 36,119 businesses, and a market size of €543

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functional regulatory infrastructure that's *comparable* to the one that we have at the Food and Drug Administration.") (emphasis added). In saying "only 30%," Eschenbach affirms that about thirty countries have comparable standards to the FDA; *see also* Agriculture, Rural Development, Food and Drug Administration, And Related Agencies Appropriations Committee; *Hearing before Subcomm. on Ag., Rural Dev., Food and Drug Admin., and Related Agencies of the H. Comm. on Appropriations,* 116th Cong. 30 (2019) ("Canadians have safe drugs and if you go into a brick-and-mortar pharmacy and you purchase a drug, you're getting a safe and effective drug. I have confidence in the Canadian drug regulatory system.") (Statement of FDA Comm'r Scott Gottlieb, MD).

125. *See DeSantis sues FDA in push to import prescription drugs from Canada*, *supra* note 14.

126. Christina Jewett & Sheryl Gay Stolberg, *F.D.A. Issues First Approval for Mass Drug Imports to States From Canada*, NY TIMES (Jan. 5, 2024), https://www.nytimes.com/2024/01/05/health/drug-imports-canada-florida.html ("Before it can distribute Canadian drugs, the state must send the F.D.A. details on those it plans to import.").

127. *See id.*; *See also Readout of Acting Ambassador Kristen Hillman's Meeting With Joe Grogan Assistant to the President for Domestic Policy*, *supra* note 15.

128. *See* discussion *infra* Section IV.B–E.

129. CENTRAL INTELLIGENCE AGENCY, THE WORLD FACT BOOK: EUROPEAN UNION (last visited Jan. 4, 2023) https://www.cia.gov/the-world-factbook/countries/european-union.

billion.[130] Additionally, the market potential size increases to about 520 million persons if you include the UK, which maintains a large parallel pharmaceutical trade market with the EU.[131] Moreover, the EU has decades of experience regulating and benefiting from parallel importation.[132] Finally, the US is already the EU's largest export destination for pharmaceuticals,[133] and this is notably the case for major cost drivers: expensive patented, brand-name drugs.[134]

B. The EU/EMA's Regulatory Ascendance

After two years of consultations and planning between EU member DRAs, the EMA was created in 1995.[135] In part, by virtue of their dynamic collaboration to create a system in which drugs sold in the region would require rigorous, pre-market drug evaluations, one modeled on the FDA's process, the EMA's leadership considered the EMA "comparable to that of the FDA" from the beginning.[136] That claim was also premised on the formation in 1990 of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which brought together regulators and industry from Europe, Japan, and the US.[137]

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130. *Pharmaceutical Wholesaling in the EU - Market Research Report*, IBIS WORLD (Mar. 27, 2022) https://www.ibisworld.com/eu/industry/pharmaceutical-wholesaling/2780/ .

131. *Value of pharmaceutical products imported into the United Kingdom (UK) from the EU-27 from 2016 to 2021,* STATISTA (June 2023), https://tinyurl.com/2e82dfza.

132. *See* Suzanne Elvidge, *An Introduction To Pharmaceutical Parallel Trade In Europe*, LIFE SCI. LEADER (Apr. 29, 2014), https://www.lifescienceleader.com/doc/an-introduction-to-pharmaceutical-parallel-trade-in-europe-0001.

133. *See International trade in medicinal and pharmaceutical products,* EUROSTAT (Mar. 2023) https://ec.europa.eu/eurostat/statistics-explained/index.php?title=International_trade_in_medicinal_and_pharmaceutical_products.

134. *See* Levitt & Mueller, *supra* note 10, at 17–18.

135. Sir Kent Woods et al., *European Medicines Agency: Celebrating 20 Years* 14 (2015), https://www.ema.europa.eu/en/documents/leaflet/european-medicines-agency-20th-anniversary-book_en.pdf.

136. *See id.*

137. Joseph G. Contrera, *The Food and Drug Administration and the International Conference on Harmonization: How Harmonious Will International Pharmaceutical Regulations Become?*, 8 ADMIN. L.J. AM. U. 927,

Daniel Carpenter, a noted national expert on the FDA and drug regulation, and professor of government at Harvard,[138] indicated well over a decade ago that the FDA's prominence may be declining relative to that of the EMA.[139] He reported how EMA officials believe that their standards and procedures for drug regulations are better models for emulation, and that non-Western countries now looked to the EMA as the standard bearer in drug regulation.[140]

C. EU/EMA versus US/FDA

Three important building blocks of a "strong pharmaceutical state" include its ability to facilitate the provision of safe and effective drugs through strong and efficiently enforced regulations relevant to (1) *drug evaluation* for safety and efficacy, (2) *drug manufacturing* to ensure drugs are produced in accordance with Good Manufacturing Practices (GMP),[141] and (3) *drug distribution*, to ensure the pharmaceutical supply chain is protected from falsified (also called "counterfeit") and substandard drugs.[142] Below is a discussion of the US and EU systems on these aspects of drug regulation.

1. Drug Evaluation

The core requirements for evaluating the safety and efficacy of a drug—three phases of increasingly complex and large clinical trials to show that a drug's benefits sufficiently exceed its

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929 (1995) ("The position within the U. S. Food & Drug Administration (FDA) and the industry is that participation by the three major pharmaceutical regulating bodies in the world is fundamental to achieve ICH's goals.").

138. *Daniel Carpenter Freed Professor of Government*, HARVARD UNIV., https://dcarpenter.scholar.harvard.edu (last visited Nov. 5, 2023).

139. *See* DANIEL P. CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 711–712 (2010).

140. *See id.*

141. *See Current Good Manufacturing Practice (CGMP) Regulations*, FOOD & DRUG ADMIN. (Oct. 25, 2023), https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations.

142. *See* CARPENTER, *supra* note 139, at 710–711. Carpenter does not mention "drug distribution" specifically, but since the publication of his book, both the EU and the US have focused extensively on laws and regulations dedicated to safety in this area, e.g., see *infra* notes 166-175.

risks— are essentially the same in the US and EU.[143] The EMA and FDA generally rely on an identical template submitted by drug companies seeking drug evaluations called the Common Technical Document (CTD),[144] which has "reduced the uniqueness of the FDA's New Drug Application and the regulated experiments that it summarizes."[145] The CTD contains key information about a drug for regulatory agencies to evaluate the drug: "Quality (pharmaceutical documentation);…Non-clinical reports (pharmacology/ toxicology);….Clinical study reports (clinical trials)."[146]

The regulatory symmetry between the FDA and EMA extends to the "remarkable similarity in the basic scientific and data interpretation issues raised by the FDA and the EMA during reviews of the same applications."[147] Further, this often leads the two agencies to the same decisions.[148] According to an FDA-EMA interagency study, there was a ninety percent confluence of drug marketing approvals between 2014 and 2016.[149]

While the EMA's reputation as a global leader in drug regulation and international harmonization efforts has strengthened over the past decade,[150] the FDA's reputation is in decline,[151] in part because Congress has weakened the rules for approving and marketing drugs.[152] One example is the FDA's Accelerated Drug approval process, which eschews the standard drug evaluation criteria used in clinical trials, accepting instead

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143. *See* Gail A. Van Norman, *Drugs and devices: comparison of European and US approval processes*, 1(5) JACC: BASIC TO TRANSLATIONAL SCI. 401, 412 (2016).

144. *See* Debbie Jordan, *An overview of the common technical document (CTD) regulatory dossier*, 23 MEDICAL WRITING 101, 105 (2014).

145. *See* CARPENTER, *supra* note 139, at 712.

146. *See id.*

147. Mwango Kashoki et al., *A Comparison of EMA and FDA Decisions for New Drug Marketing Applications 2014–2016: Concordance, Discordance, and Why*, 107 CLINICAL PHARMACOLOGY & THERAPEUTICS 199, 202 (2020) ("The EMA and the FDA had high concordance (91–98%) in decisions on marketing approvals.").

148. *See id.*, at 195.

149. *See id.*

150. *See* CARPENTER, *supra* note 139, at 711–12.

151. *See id.*, at 740.

152. *See* Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357, 2379 (2018).

weaker indicators of efficacy called "endpoints."[153] Its defenders in the industry argue that government policies to curtail the accelerated approval process are a step "backward."[154] Its critics in the activist medical community counter that the FDA is lowering the bar on drug approvals.[155] Testifying before Congress, Reshma Ramachandran, MD, MPP of Yale School of Medicine, looked to Europe (and other countries) stating, "Regulatory authorities in other countries including the United Kingdom, Australia, and Europe who award similar such approvals allow them to expire and require renewal of these conditional approvals every one to two years," recommending that the FDA adopt "a similar approach."[156] The drug safety activists have prevailed to some degree as Congress passed a law to force the FDA to bring greater oversight and enforcement relating to accelerated drug approvals.[157]

Thus, due to (1) the emulation of the FDA by foreign drug regulators, including national drug regulators in the European Economic Community (EEC) members and, in the 1990s, the EMA;[158] (2) international harmonization efforts led by the EMA and FDA (as well as Japan) to harmonize best practices to

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153. *See id.,* at 2379–80.

154. *See* Max Bayer, *Welcome to Scrutiny': BIO Chair Mounts Defense Against More Rigorous Accelerated Approval Process*, FIERCE BIOTECH (June 28, 2022, 10:40 AM) https://www.fiercebiotech.com/biotech/welcome-scrutiny-biotech-industry-mounts-defense-against-more-rigorous-accelerated-approval.

155. *See* Gregg Gonsalves et al., *Opinion: The FDA is in Desperate Need of Some Soul-Searching*, WASH. POST (June 17, 2021, 11:51 AM), https://www.washingtonpost.com/opinions/2021/06/17/fda-aducanumab-alzheimers-drug-approval-erodes-confidence/.

156. *See FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics*: *Hearing Before the H. Energy and Commerce Sub. Comm. on Health,* 116th Cong. 8 (2022) (written statement of Reshma Ramachandran, MD, MPP of Yale School of Medicine), https://www.congress.gov/117/meeting/house/114371/witnesses/HHRG-117-IF14-Wstate-RamachandranR-20220203.pdf.

157. *See generally* Zachary Brennan, *Accelerated Approval Reforms Make the Cut in Year-end Government Spending Bill*, ENDPOINTS NEWS (Dec. 20, 2022, 06:49 AM), https://endpts.com/accelerated-approval-reforms-make-the-cut-in-year-end-government-spending-bill/.

158. *See* CARPENTER, *supra* note 139, at 711.

evaluate drugs;[159] and (3) recent backsliding in the US;[160] the EMA is on par with or exceeds the FDA as a drug evaluator.

2. Drug Manufacturing

The FDA's data indicates that drug manufacturing in the EU is stronger than in the US. An FDA analysis of drug manufacturing establishments in the EU, US, China, India, and the rest of the world for GMP compliance found that only two percent of manufacturing establishments in the EU were required to correct problems, compared to 7 percent in the US.[161]

The EU's drug manufacturing excellence, combined with a global pharmaceutical supply chain, has forced the FDA to accept manufacturing inspections by EU DRAs in lieu of its own.[162] The FDA has assessed the abilities of all EU DRAs to produce safe and effective drugs and found all "capable of conducting inspections that met US requirements."[163] In 2020, the FDA accepted inspection reports on 160 drug manufacturing facilities of EU regulators as a basis to allow for the importation of drugs made in those facilities, up from only twenty-nine in 2018.[164]

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159. *See* Purnhagen, *supra* note 2, at 637–38.

160. *See* Gonsalves et al., *supra* note 155.

161. *See generally Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program*, *Testimony before the H. Energy and Commerce, Subcomm. on Oversight and Investigations*, 116th Cong. 1, 10 (2019) (Statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration), https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019#ftn8 (last accessed Nov. 20, 2022) (These were outcomes as of August 2019 for the most recent inspection of facilities that were in the FDA's catalog as of July 2019.).

162. *See* Bollyky & Kesselheim, *supra* note 6, at 1338.

163. *Mutual Recognition Agreement (MRA): A New World for Pharmaceutical Inspections,* U.S. FOOD & DRUG ADMIN. (Nov. 8, 2021), https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra.

164. U.S. GOV'T ACCOUNTABILITY OFF., GAO-22-103611, DRUG SAFETY: FDA SHOULD TAKE ADDITIONAL STEPS TO IMPROVE ITS FOREIGN INSPECTION PROGRAM 18 (2022).

3. Drug Distribution

Lastly, pursuant to its Falsified Medicines Directive (FMD),[165] the EU has a superior system of monitoring its drug supply chain.[166] In the US, regulations to fulfill the drug "track and trace" mandate created under the Drug Supply Chain Security Act (DSCSA), initially slated to be complete by 2023, are now facing delays until 2026.[167] In contrast, the FMD became operational on schedule in 2019.[168] The FMD requires random serialization codes on drug packaging, the DSCSA does not.[169] Under FMD all supply chain entities scan serialization codes, registered in a central EU hub called the European Medicines Verification System (EMVS);[170] no such US hub exists.[171] FMD requires verification of every product at the retail unit level; the DSCSA only requires verification of products that are returned.[172] The FMD requires anti-tampering devices on drug

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165. Directive 2011/62 of the European Parliament and of the Council Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Product, O.J. (L 174/74) 1.

166. *See generally* Meg Rivers et al., *Serialization on a Global Scale: Deep Dive into the US DSCSA and EU FMD – Packaging: Part 2,* BIOPHRAM (Nov. 15, 2021), https://www.biopharminternational.com/view/serialization-on-a-global-scale-part-2 (noting multiple safety functions integrated within the EU FMD that are absent in the US DSCSA).

167. *See* Michael Mezher, *FDA Delays Enforcement of Some DSCSA Provisions by Three Years*, REGUL. FOCUS (Oct. 26, 2020), https://www.raps.org/news-and-articles/news-articles/2020/10/fda-delays-enforcement-of-some-dscsa-provisions-by; *see also* Erin Hunter, *FDA Announces Delayed Enforcement of DSCSA to 2024*, PHARMACY TIMES (Aug. 28, 2023), https://www.pharmacytimes.com/view/fda-announces-delayed-enforcement-of-dscsa-to-2024#.

168. *See* Grant Courtney, *Introducing the New Report: Benefits beyond the EU Falsified Medicines Directive - The Hospital Setting*, EUROPEAN FED'N OF PHARM. INDUS. AND ASS'N (Sept. 28, 2020), https://www.efpia.eu/news-events/the-efpia-view/blog-articles/introducing-the-new-report-benefits-beyond-the-eu-falsified-medicines-directive-the-hospital-setting/.

169. *See* Rivers, *supra* note 166.

170. *See Eur. Medicines Verification Organisation, EMVO's Mission*, https://emvo-medicines.eu/mission/emvo-mission/ (last visited Nov. 5, 2023).

171. In other words, the DSCSA lacks a central authority or technology platform (like the EMVO) to track unit-level drug packages throughout the supply chain.

172. *See* Rivers, *supra* note 166.

packages; the DSCSA does not.[173] Indicative of the EU's superiority in protecting its drug supply chain is the total absence of recent counterfeit drug incidents experienced at pharmacies in the EU, compared to pharmacies in the US, which have experienced serious recent counterfeit incidents.[174]

Assessing their respective processes and performances in drug evaluations, manufacturing, and distribution, the EU's system for regulating drugs, under the helm of the EMA, is a new platinum standard in drug regulation, one that has surpassed the US gold standard.

D. The EU Experience with Drug Equivalence to Facilitate Parallel Trade and Safety

The push for stronger drug regulations in Europe began in the 1960s and was twofold in its goals: (1) improve drug safety and (2) increase trade among EEC members.[175] In 1986, the European Commission (EC) undertook the "completion of work eliminating obstacles to free circulation of pharmaceutical products" as part of its larger economic integration project.[176]

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173. *See id*.

174. For example, the EU did not experience an apparently massive drug supply chain breach in the US, amounting to an alleged 250 million dollars in counterfeit HIV drugs. *See* Jonathan Stempel & Manas Mishra, *Gilead says counterfeit HIV drugs ended up with patients*, REUTERS (Jan. 19, 2022, 10:49 AM), https://www.reuters.com/breakingviews/gilead-says-counterfeiting-network-sold-250-mln-worth-its-hiv-drugs-2022-01-18; *see also* Kevin Dunleavy, *Feds Probe Ring of Counterfeit HIV Meds Targeting Gilead, GlaxoSmithKline and Johnson & Johnson: report*, FIERCE PHARMA (Mar. 31, 2022, 09:44 AM), https://www.fiercepharma.com/pharma/department-justice-probes-counterfeit-hiv-drugs-including-those-gilead-gsk-jj-report.
Additionally, this year (2023), counterfeit Ozempic was discovered in US pharmacies and sold to patients, *see* Ashley Gallagher, *FDA, Novo Nordisk Warn of Counterfeit Semaglutide Injection Pens*, PHARMACY TIMES, (Jun. 20, 2023), https://www.pharmacytimes.com/view/fda-novo-nordisk-warn-of-counterfeit-semaglutide-injection-pens (but was not found in pharmacies in the EU).

175. *See* Inga Abed, *The Approval Process of Medicines in Europe*, 23 THE EUR. MED. WRITERS ASSOC. 117, 121 (2014).

176. *See Completing the Internal Market: White Paper From the Commission to the European Council, Annex to the White Paper*, at 2 (see PDF page 64), COM (1985), https://op.europa.eu/en/publication-detail/-/publication/4ff490f3-dbb6-4331-a2ea-a3ca59f974a8/language-en (last visited Nov. 18, 2023).

Today, there are three routes to obtaining drug marketing authorizations in the EU.[177] The Centralized Procedure (CP), through which drug companies submit their applications for EMA's evaluation to obtain drug marketing authorizations from the EC.[178] Through the CP, authorized products can be sold throughout the EU.[179] Second, the Mutual Recognition Procedure (MRP), through which the dossier used for a drug marketing approval in one EU country is used to obtain marketing approvals in other countries.[180] Through the MRP, an EU DRA, called the "reference member state," commits to the drug evaluation, informing other "Concerned States" that it has done so, and sharing its evaluation with EU members.[181] EU members can reject the findings of the reference member state "on the ground that the authorisation poses a potentially serious risk to public health."[182] Third, through the Decentralized Procedure, which is similar to the MRP, one national DRA evaluates a drug with no prior approval within the EU.[183] The EU's system is recognized as a model of how international harmonization can create trade in pharmaceuticals while improving safety.[184]

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177. *See EU Marketing Authorisation Procedures, Practical Law UK Practice Note w-001-3304*, Practical Law Life Sciences (Westlaw) (2023) (providing an overview of the three protocols for obtaining marketing authorizations for drugs in the EU), at 2.

178. *Id.*

179. *Id.*

180. *Id.,* at 4.

181. *Id.*

182. *See id.*

183. *See id.*

184. *See* Purnhagen, *supra* note 2, at 634 ("Thus, to improve healthcare on an international level by harmonizing drug authorization systems, there is no need to reinvent the wheel. We can rely on many years of European and nearly twenty years of international harmonization experience with the ICH."); *see also* Fernand Sauer (former Exec. Dir. of the Eur. Med. Agency), *Pharmaceutical Harmonisation in Europe and Beyond*, 1 J. OF PHARMACY AND DRUG DEV. 1, 11 (2019), https://www.researchgate.net/publication/335517993_2019_EU_pharmaceutical_harmonisation_and_beyond#fullTextFileContent.

E. From "Comparable" to "Superior"

Recognizing the EU's superior system of drug regulation is important for moving forward on parallel importation in the US because widespread recognition that other countries, notably Canada, have *comparable* systems to the US has proved insufficient.[185] After all, in 2020, the HHS Secretary acknowledged that Health Canada's system of pharmaceutical regulation was strong enough so that drug imports from Canada would "pose no additional" risk to the public health of Americans.[186] While Florida's Canadian wholesale drug importation program was finally approved under Section 804, serious obstacles to importing remain.[187] Thus, "comparability" may not be enough to overcome the ubiquitous gold standard narrative. Preventing parallel importation from a superior drug supply chain in the EU is less tenable.

V. TOWARD A PARADIGM SHIFT IN UNDERSTANDING THE FDA'S REPUTATION-BASED AUTHORITY

Carpenter's theory of *agency reputation* explains why the perception of the FDA as the gold standard gives it power that exceeds its statutory authority.[188] Under this theory, Carpenter refers to the importance of "audiences," by which he means constituencies such as Congress, the pharmaceutical industry, patients, "scientific and professional organizations," and "institutions of learning."[189] Audience perceptions of the FDA as the gold standard have created its vast power and authority.[190]

The ethos of the FDA's reputation, and of the regulatory paradigm supporting that reputation, is its gatekeeping role as the sole arbiter of whether a drug is sold in the US, which began with the Food, Drug and Cosmetic Act of 1938.[191] The FDA's staunch opposition to drug importation based on equivalence determinations underlies the agency autonomy it closely

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185. *See generally supra* note 124.
186. Importation of Prescription Drugs, *supra* note 103, at 62,096.
187. *See* Jewett & Sheryl Gay Stolberg, *supra* note 126; *see also supra* note 102.
188. *See* CARPENTER, *supra* note 139, at 49.
189. *Id.* at 33.
190. *Id.*
191. *Id.* at 73.

guards.[192] Further, the FDA opposes accepting foreign drug equivalence determinations that could help lower US drug prices because it might undermine its reputation, which could threaten its funding.[193] Thus, the FDA will fight against importation at the expense of "other policy objectives, such as lowering drug prices or facilitating trade."[194]

Under Carpenter's theory, Bollyky and Kesselheim, and some of their peers at prestigious organizations and universities (including Carpenter himself), are "audiences" of the FDA, ones that can affect the FDA's reputation.[195] Accordingly, Bollyky and Kesselheim express concern that comprehensive parallel importation, based on substantive statutory reforms to allow for foreign drug equivalence determinations, may undermine the FDA's authority.[196] Indeed, that concern underlies their proposal for a limited form of using equivalence determinations for foreign versions of FDA-approved generic drugs, which would help alleviate drug shortages and safeguard against generic drug price spikes,[197] but not lower prices on brand-name drugs.

Instead, a paradigm shift is needed so that the basis of the FDA's reputational power evolves to include not just its own capacity for drug evaluations and marketing authorizations, but also its ability to strategically leverage EU drug regulations to help lower prices on patented, brand-name drugs, as this Note proposes, and help alleviate generic drug shortages.

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192. *See* Bollyky & Kesselheim, *supra* note 6, at 1332.

193. *Id.* at 1338 ("To sustain…its funding, the FDA depends on its reputation for protecting consumers from unsafe drugs…[and], [a]ccordingly…has resisted initiatives that might undermine that reputation and subordinate its gatekeeping mission to other policy objectives, such as lowering drug prices or facilitating trade.").

194. *Id.*

195. *See* CARPENTER, *supra* note 139, at 33 (asserting that "Audiences such as scientific and professional organizations, firms, and institutions of learning can grant conceptual power to the regulator by accepting the agency's definitions of technical terms and concepts.").

196. S*ee* Bollyky & Kesselheim, *supra* note 6, at 1393 ("Our generic prescription drug importation proposal is designed not to require major legislative changes to the FDA's current authorities and not to undercut the agency's essential role in evaluating and overseeing the quality, safety, and efficacy of the medicines used in the United States.").

197. *Id.*

The proposed paradigm shift should not be mistaken as promoting deregulation. Rather, this Note embraces a theoretical framework referred to as "information production," articulated by Amy Kapczynski from the Yale Law School's Global Health Justice Partnership.[198] In her opposition to new laws and court decisions favored by conservatives and libertarians, which have a deregulatory effect,[199] she argues that the FDA is indispensable for public protection because it has the expertise, resources, and objectivity to produce information about medicines for public consumption.[200] Her position remains tenable whether the regulator is the FDA, the EMA, or another comparable DRA. For example, the EU's drug marketing approvals are conducted with the expertise, resources, and objectivity to produce information about drugs that can be trusted.[201] Further, the FDA, even if parallel drug importation from the EU is lawful, can still hold the keys to producing information on a drug's safety and efficacy through its own drug evaluations *or* its review of the EMA's evaluations, which it can accept or reject.

The FDA may continue to resist this paradigm shift because of its entrenched bureaucratic imperative for regulatory autonomy.[202] Congress, however, should not wait for the FDA's blessing to amend the FDCA to legalize parallel importation from the EU.

VI. AMENDING THE FDCA: THE PARALLEL DRUG IMPORT COMPETITION ACT (PDICA)

This Note proposes robust legislative and regulatory reforms to make parallel importation (1) lawful, (2) integrated into the US drug supply chain, and (3) safe. This requires amending the FDCA so that the FDA must allow (1) *drug equivalence determinations* leveraging marketing approvals of patented and generic drugs in the EU, (2) *EU drug manufacturing inspections* as a basis for registering an EU manufacturing establishment from which drugs can be imported, (3) *relabeling of imported*

198. *See* Kapczynski, *supra* note 152, at 2357, 2359.
199. *Id.* at 2357–58.
200. *Id.* at 2358–59.
201. *See* Kashoki, *supra* note 147, at 199.
202. *See* CARPENTER, *supra* note 139, at 75.

drugs by parallel drug importers to comply with the DSCSA, and (4) *parallel drug importers* by adding a new establishment category and license. These proposed amendments can go into legislation entitled The Parallel Drug Import Competition Act (PDICA).

A. Repeal the Ban on Commercial Importation

Congress must repeal the law that prevents the commercial importation of prescription drugs without the authorization of the manufacturers of those drugs.[203] This should only be done in coordination with the reforms recommended below.

B. Drug Equivalence Determinations

Legislation to grant drug marketing authorizations in the US based on foreign DRA marketing authorizations already exists in the Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2023 (hereinafter the "Result Act").[204] This Note simply borrows language from the Result Act to meet the goals of the PDICA on drug equivalence determinations, but with a distinctly different goal in mind than the bill's sponsor, Senator Ted Cruz (R-TX). [205] The Result Act includes "Section 524B. Reciprocal Marketing Approval," which would amend the FDCA to create a process for allowing drug equivalence determinations so that drugs can receive FDA marketing authorizations if they have marketing authorizations in

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203. 21 U.S.C. § 381(d).

204. S.1712 - 118th Congress (2023-2024), § 2 [hereinafter Result Act].

205. *See generally* Ted Cruz, *Let's Revive America's Culture of Cures and Innovation*, NAT'L REV. (Oct. 22, 2015, 7:09 PM), https://www.nationalreview.com/2015/10/fda-drug-approval-bottleneck/ (focusing on removing barriers to new treatments); *see also* Press Release, *Sens. Cruz, Lee, Introduce Results Act to Increase Access to Life-Saving Medical Care* (May 23, 2023), https://www.cruz.senate.gov/newsroom/press-releases/release-sens-cruz-lee-introduce-result-act-to-increase-access-to-life-saving-medical-care# ("Healthcare decisions should be made by patients and their doctors–not government bureaucrats. We should allow patients to use life-saving drugs, devices, and medical therapies that other countries are successfully using") [hereinafter Sen. Cruz].

"Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa" or a country of the "European Union."[206]

Senator Cruz's main goal with the Result Act is to fill "unmet medical need[s]" in the US.[207] He wants to force drug marketing authorizations in the US for entirely new drugs (i.e., not just foreign-approved versions of FDA-approved drugs), based on marketing authorizations of foreign regulators.[208] Unmet medical needs in the US where products may exist elsewhere is an important issue, but different from this Note's focus on drug prices.

Instead, the Reciprocal Marketing Approval section of PDICA would allow—but not compel—the FDA to grant drug marketing authorizations for drugs approved for sale in the EU that are already available in the US, including brand and generic (1) foreign versions of FDA-approved drugs and (2) FDA-approved drugs with different labeling—but that cost less—subject to the proper relabeling of those drugs to meet FDA requirements. This would make it lawful for US wholesalers to import drugs such as Januvia or Daraprim from the EU, without permission from the drug manufacturers.

Under the proposed Reciprocal Marketing Approval procedure, Congress would mandate protocols for the FDA to grant marketing authorizations for drugs based on the FDA's expedited review of the bases for their approvals within the EU.[209] Importantly, the FDA would still have the final say over a parallel imported drug's marketing approval in the US. Like under the EU's mutual recognition procedure, the FDA could reject drug marketing approval applications if it determines the authorization would "pose[] a potentially serious risk to public health."[210]

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206. *See* Result Act, § 2(b)(2)(D) (referencing Section 802(b)(1) of the FDCA, which lists countries that the US views as having strong regulatory standards and enforcement capacities).

207. *See* Result Act, at § 2(b)(2)(F).

208. *See* Sens Cruz*, supra* note 205 (exclaiming "The American people should not have to wait years and years for bureaucrats at the FDA to sign off on medicines that are already approved in other trusted countries.").

209. *See* Bollyky & Kesselheim, *supra* note 6, at 1394 (recommending this very same process, but only for generic drugs).

210. *See EU Marketing Authorisation Procedures*, *supra* note 177.

C. Codify Reciprocal Drug Manufacturing Agreements Under Current MRAs

Under its MRA with all EU members, the FDA can choose to accept the inspections of any EU DRA of a drug manufacturing establishment that produced drugs for the US market without its own duplicative inspection.[211] Strengthening and codifying these agreements within the FDCA will remove legal ambiguity pertaining to importing drugs that were manufactured under the EU's authority and subject to marketing authorizations under the PDICA.

Currently, under Section 801 of the FDCA, the HHS Secretary maintains a list of "establishments," "pursuant to subsection (i) of section 360…" that are registered with the FDA, in which prescription drugs are produced and eligible for import into the US.[212] Drugs coming from establishments not so registered are generally prohibited import for commercial use.[213] Thus, it is necessary to amend section 360 so that any drug manufacturing facility inspected by and registered in the EU can be added to the list of FDA-registered establishments, pursuant to a drug marketing approval under the PDICA. Through this revision, Section 801(a) will no longer impede commercial importations of lower-cost drugs from the EU.

D. Safeguarding the US Drug Supply Chain to Prevent Counterfeit Drugs

The most common refrain against drug importation, especially by the industry, is the threat of counterfeit and substandard drugs,[214] often pointing to their prevalence in lower-income countries as a reason that drug importation is "dangerous."[215] The EU's fully implemented system under the FMD powerfully prevents counterfeit drugs from breaching its supply chain.[216] Thus, the regulatory task is creating US rules that ensure drug imports from the EU only include those regulated under the FMD.

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211. *See* U.S. FOOD & DRUG ADMIN., *supra* note 163.
212. 21 U.S.C. § 381(a) (emphasis added).
213. *Id.*
214. *See generally* Outterson, Levitt, and Delauro, *supra* note 54.
215. *See* Longo, *supra* note 55.
216. *See* Courtney, *supra* note 168.

Under the FMD, all drugs sold in the EU contain random serial numbers,[217] which are traceable through the EMVS from manufacturer to patient.[218] Drugs, however, that are exported out of the EU are "decommissioned" by the exporter.[219] Thus, in creating rules for importing drugs from EU wholesalers, the FDA would only allow imports from FDA-registered and EU-licensed wholesalers who must show that the decommissioned and exported drugs are FMD-compliant.

E. Parallel Import License Applications: Exploring the UK Model

Under PDICA, instead of drug manufacturers applying for drug marketing authorizations, applicants will often be licensed parallel drug distributors in the EU. Since Brexit, UK pharmacy wholesalers can import drugs from the EU by obtaining a parallel import license.[220] Its experience provides a potential model to look to and build upon for the US. Generally, to obtain a license, a UK wholesaler must show that the drugs for import (1) were manufactured under GMP, (2) under the authority of an EU drug regulator, and (3) have "no therapeutic difference from the cross-referenced UK product[s]."[221] The UK Medicines and Healthcare Products Regulatory Agency's website details myriad approaches to parallel importation,[222] which US regulators should consult when drafting the PDICA regulations.

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217. *See* Rivers*, supra* note 166.

218. *See Eur. Medicines Verification Organisation*, *supra* note 170 ("The EMVS is in accordance with the EU's Falsified Medicines Directive (FMD) and the Delegated Regulation (DR). It ensures the implementation of a functioning, secure, interoperable and cost-effective system across Europe.").

219. *Eur. Comm. Dir. Gen. for Health and Food Safety, Questions and Answers* 17 (June 2022), https://health.ec.europa.eu/system/files/2022-06/qa_safetyfeature_en_0.pdf. ("When a medicinal product is physically exported outside of the EU, its unique identifier must be decommissioned in accordance with Article 22(a) of Commission Delegated Regulation (EU) 2016/161."). Decommissioning means that drugs exported out of the EU are no longer under its authority.

220. *See Medicines: Apply for a Parallel Import License,* UK MED. AND HEALTHCARE PRODUCTS REG. AGENCY (Dec. 9, 2022), https://www.gov.uk/guidance/medicines-apply-for-a-parallel-import-licence.

221. *See id.*

222. *See* id.

F. Relabeling, DSCSA Requirements and Parallel Distributor Licensure

Importing drugs without manufacturer authorizations, whether FDA-approved drugs or foreign versions of FDA-approved drugs, will require their relabeling to meet the FDA's requirements (so they are in English and have the same warnings as one would find in a US pharmacy), and to comply with the DSCSA to prevent counterfeits from entering the US supply chain.

Opponents of drug importation assert that imported "[drug] products can't be repackaged for sale in the U.S.," arguing that each package's unique standardized numerical identifier "must be applied by the original manufacturer."[223] In other words, they assert, under the DSCSA, parallel importation is unlawful because the only drugs permitted for sale in the US are those with numerical identifiers placed on the packaging by drug manufacturers.[224] Drugs sold in the EU do not have DSCSA numerical identifiers; they have randomized serial numbers in accordance with the FMD.[225]

There are exemptions under the DSCSA to permit the sale of prescription drugs without manufacturer-placed serialization.[226] Section 804's final rule relies on these exemptions to allow wholesale drug importation from Canada.[227] The Section 804 model is sufficient for safe drug distribution but should not be the long-term approach.

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223. Adam J. Fein & Dirk Rodgers, *State drug importation laws undermine the process that keeps our supply chain safe*, STAT (July 17, 2019), https://www.statnews.com/2019/07/11/state-drug-importation-laws-undermine-supply-chain-safety/.

224. *See id.*

225. Directive 2011/62, *supra* note 165, at 3.

226. *See* Drug Quality and Security Act of 2013, Pub. L. No 113-54, § 582(a)(3)(A)(iii), 127 Stat. 606 (the Secretary, through guidance, may "establish a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of this section," e.g., see Importation of Prescription Drugs, *supra* note 103, at 62,102 ("Under the final rule, a Foreign Seller is responsible for relabeling drug products to affix the SSI to or imprint the SSI on each package and homogenous case of the eligible prescription drug(s)," meaning the manufacturer-placed serialization requirement is exempted, so long as the importer meets this requirement).

227. *See* Importation of Prescription Drugs, *supra* note 103, at 62,136.

Instead, the PDICA should integrate parallel drug imports within the DSCSA. Under the FDCA, to distribute drugs within the US, a company must be licensed as a pharmacy wholesaler in a US state.[228] Where a state may not have established a system of wholesale licensure, a wholesaler must be licensed by the HHS Secretary.[229] The law's effect is summed up by the FDA: "Prescription drugs should only be purchased from wholesale drug distributors licensed in the United States."[230] To distribute prescription drugs in compliance with the DSCSA, a wholesaler must be licensed in accordance with 21 U.S.C. § 353(e).[231] Thus, to provide for parallel importation from the EU, the PDICA will add a new wholesaler licensee under 21 U.S.C. 353(e), referred to here as a Foreign Drug Distributor (FDD). Lastly, under PDICA, authorized FDDs would be registered establishments in accordance with Section 360.[232]

Finally, the FDCA will need to permit FDDs to repackage drugs with new National Drug Codes (NDC) and DSCSA-compatible serialization or provide for registered repackagers, receiving drugs directly from FDDs to make those changes. The FDA already provides industry guidance to drug manufacturers for a highly similar purpose: "to obtain an NDC for an FDA-approved drug that was originally intended to be marketed in a foreign country and is also authorized for sale in that foreign country."[233] FDA-registered repackagers can place product identifiers on drug packaging,[234] and so too could FDDs under the PDICA.

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228. 21 U.S.C. § 353(e)(1)(A)(i)(II).

229. *Id.*

230. *Verify Wholesale Drug Distributor Licenses*, U.S. FOOD & DRUG ADMIN. (July 13, 2023) https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses.

231. *See* 21 U.S.C. § 353(e).

232. *See* 21 § 360(i) (stipulating that drug establishments in foreign countries offering drugs for import into the US must be registered with the FDA). This Note recommends that FDDs must register in accordance with § 360 as well, and list those drugs to be offered for import for which it has obtained marketing authorizations.

233. *See* 85 Fed. Reg 61,955, *supra* note 80, at 61,956 (providing guidance for drug manufacturers to apply a different NDC number to a drug from the one under which it was initially registered to then import an eligible drug).

234. 21 U.S. Code § 360eee–1(e)(2)(A).

VII. CONFLUENCE OF INTERNATIONAL LEGAL THEORY AND US LAW ON PARALLEL IMPORTATION

Unlike the EU, which actively supports international law through global treaties and multilateral agreements, the US is known for resisting such agreements because they limit US sovereignty.[235] The proposed reforms in this Note to allow parallel importation find a conceptual home in transnational legal harmonization theory (hereinafter "TLH theory"),[236] are supported by federal law,[237] and reside within America's international law comfort zone.

Under TLH theory, "[T]o the extent that international law is simply one rule binding on more than one country, it is created whenever there is convergence or harmonization in law among countries."[238] Two subcategories of TLH theory conceptually apply to the US allowing parallel drug importation by leveraging the EU's regulatory strength. The first is called "Harmonization of Legal Regulation Relating to Specific Subject," which is simply when two or more countries come together and harmonize standards within a given industry or economic sector.[239] For example, the US and the EU have engaged in harmonization efforts in antitrust and securities to "avoid inconsistent legal actions against corporations operating in both jurisdictions."[240]

In the pharmaceutical sector, international harmonization efforts by the FDA include its active participation with EMA in the ICH, and membership in the EMA-led Pharmaceutical Inspection Co-operation Scheme.[241] Further, drug evaluation and drug manufacturing standards have become notably uniform between the US and the EU.[242] This process, a

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235. *See* Gráinne de Búrca, *International Law Before the Courts: The EU and the US Compared*, 55 VA. J. INT'L L. 685, 686-87 (2015).

236. *See* James D. Wilets, *A Unified Theory of International Law, the State, and the Individual: Transnational Legal Harmonization in the Context of Economic and Legal Globalization*, 31 U. PA. J. INT'L L. 753, 755 (2010).

237. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, § 410, 111 Stat. 2296, 2372-73.

238. Wilets, *supra* note 236, at 757.

239. *Id.*, at 761.

240. *Id.*

241. *International Regulatory Harmonization*, US FOOD & DRUG ADMIN. (Mar. 26, 2020), https://www.fda.gov/drugs/cder-international-program/international-regulatory-harmonization.

242. Kashoki, *supra* note 147.

"convergence or harmonization in law"[243] between the US and the EU in the pharmaceutical sector, furthers the development of international law in accordance with TLH theory.

Another category of TLH theory is called "Harmonization Through Market Forces," which covers international harmonization of standards to facilitate trade between countries where consumers "demand that certain products in the producer country [] are consistent with those of the country in which the products are sold."[244] When it comes to drugs approved for sale in the EU, Americans would receive identical, or virtually identical products (in the case of EU-versions of FDA-approved drugs) through parallel importation.[245] By allowing parallel importation, American consumers and taxpayers would benefit from these international harmonization efforts through lower drug prices and potentially even safer drugs.[246]

Countries will resist international harmonization if it means changing their legal systems or incorporating foreign "governmental theories," or actions that might require compromising their "political systems" or "cultural beliefs."[247] This is often the case with the US, which tightly guards its sovereignty, as evidenced by its refusal to bind itself to The Convention on the Elimination of All Forms of Discrimination Against Women, the International Criminal Court, and many other international agreements.[248] In contrast, there is less cultural or political tension when the matter at issue is whether a drug is safe and effective; it is or it isn't.[249] Thus, conceptually, the US should be able to tolerate greater reliance on, or leveraging of, EU drug laws and regulations that can facilitate trade and lower drug prices.

Finally, while Congress has not yet passed a law permitting parallel drug importation on a scale that would broadly and

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243. Wilets, *supra* note 236, at 757.
244. *Id.,* at 761.
245. *See* discussion *supra* section III.C.
246. *Id.*
247. *See* Purnhagen, *supra* note 2, at 629.
248. *See* Anya Wahal, *On International Treaties, the United States Refuses to Play Ball*, COUNCIL ON FOREIGN REL.: BLOG (Jan. 7, 2022, 5:08 PM), https://www.cfr.org/blog/international-treaties-united-states-refuses-play-ball.
249. Purnhagen, *supra* note 2, at 630-31.

substantially reduce drug prices on most brand name drugs, it did pass a law mandating that the FDA engage in the international harmonization efforts that led to the EU MRA on manufacturing.[250] That law not only required an MRA with the EU but also the FDA's "participation[ion] in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements," and to facilitate trade where the FDA believes standards are appropriately harmonized.[251] Thus, US law convincingly supports the advancement of international law in the area of pharmaceutical safety and trade as conceived by TLH theory.

CONCLUSION

Ironically, Carpenter writes that in developing the gold standard, US drug regulators, as far back as the 1930s, looked to European models and borrowed from them,[252] but there is little dispute that, until recently, the US led the way in modern drug regulation.[253] Now, the EU's parallel importation model in drug regulation provides a roadmap,[254] which, if followed, can lead to lower drug prices and even greater drug safety in the US.

Bollyky and Kesselheim suggest that because it took the FDA over twenty years to conclude "just one" MRA with the EU, forced by an act of Congress to do it, we should temper our expectations when it comes to parallel importation.[255] On the contrary, their observation should lead us to conclude that another act of Congress is urgently needed to make drug importation and lower drug prices a reality. Millions of Americans who cannot afford lifesaving drugs are tired of excuses.

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250. Food and Drug Administration Modernization Act of 1997, *supra* note 237.

251. *Id.*

252. CARPENTER, *supra* note 139, at 137.

253. *Id.* at 43.

254. *See* generally Purnhagen, *supra* note 2, at 623 ("In the past, the United States taught the Europeans how to authorize drugs safely. Now the Europeans can give something back to the U.S. by sharing their knowledge of the harmonization of drug authorization systems.").

255. *See* Bollyky and Kesselheim, *supra* note 6, at 1368.

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* M.A., International Relations (concentration in international law and economic policy), B.A., International Relations and Political Studies, J.D., Brooklyn Law School (Expected 2025). I dedicate this Note to Americans, and everyone living in the United States, who struggle to afford prescription drugs. I want to thank the former Editor-in-Chief of the BJIL, Lucie Couillard Sosa, and her colleagues, for choosing this Note for publication; and the current Editor-in-Chief, Molly Turro, and the Managing Editor, Keely Redhage, for their help in making the Note better. Special to Keely, thank you for forcing me to learn how to Bluebook (although I have much room for improvement). Finally, and critically, I want to thank my wife Rebecca Feldman, my kids, Casper, Max, and Wyatt, my dog, Cole Madison, and my parents, for their love and support. All errors or omissions are my own.