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Current Issues in Public Policy

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SAFETY FIRST: THE WELLNESS AND WALLET DANGERS OF CANADIAN DRUG IMPORTATION.

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INTRODUCTION[2]

High drug costs plague the United States. Because of these high costs, patients avoid the doctor, do not take their medication as prescribed, substitute their medication, or even illegally trade medication. Over recent years, drug prices have skyrocketed to even more outlandish costs in the United States, making politicians more eager than ever to be the ones who solve this crisis. In 2019, it is projected that 345.7 billion dollars were spent on prescription drugs in the United States.[3] Patient out-of-pocket costs grew from "$56 billion in 2014 to $61 billion in 2018," and were expected to be even higher in 2019.[4]

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[2] This Article was written during the process of the Safe Importation Action Plan introduction as an idea by the Trump administration to when it was formally introduced as a proposed rule in Fall 2020. As of the time of publishing, the Biden Administration has not made any moves toward Federal drug importation legislation, however states are still moving forward with plans under the Trump Administration proposal discussed in this Article. *See* Phil Galewitz, *States Move Ahead with Canada Drug Importation While Awaiting Signal from Biden*, KAISER FAM. FOUND. (Jan. 29, 2021), https://khn.org/news/article/states-move-ahead-with-canada-drug-importation-while-awaiting-signal-from-biden/.

[3] *Prescription Drug Expenditure in the United States from 1960 to 2019*, STATISTA (Apr. 2020), https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960/.

[4] *See Medicine Use and Spending in the U.S.*, IQVIA (May 9, 2019), https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023.

One concrete example of drug costs skyrocketing is insulin. In 2012, the average cost of insulin annually for a type 1 diabetic was $2,864.[5] This price was almost doubled to $5,705 in 2016 for the exact same products,[6] and continued to climb before state legislatures and courts stepped in to stop the insulin manufacturers from price gouging.[7] Due to this major jump, patients in the United States were "rationing… the life-saving medication" which then led to "protests outside company headquarters of insulin makers."[8]

This major cost issue for all prescription medications is what the Safe Importation Action Plan intends to overhaul. By importing prescription drugs from Canada, the Trump administration projected major cost savings for Americans. Canada was chosen specifically because they, like many countries other than the United States, "regulate prices for drugs… through controls on reimbursement, limits on overall spending, or limits on the rate of return on capital."[9] As of July 2019, "at least ten U.S. states, including Florida, have passed or proposed laws to allow such imports, but actual shipments would not be legal without

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[5] Robin Respaut & Chad Terhune, *U.S. Insulin Costs Per Patient Nearly Doubled From 2012 to 2016: Study*, REUTERS (Jan. 22, 2019), https://www.reuters.com/article/us-usa-healthcare-diabetes-cost/u-s-insulin-costs-per-patient-nearly-doubled-from-2012-to-2016-study-idUSKCN1PG136.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] U.S. DEP'T OF HEALTH & HUM. SERVS., REPORT ON PRESCRIPTION DRUG IMPORTATION 70 (Dec. 2004), https://wayback.archive-it.org/org-745/20130927185442/http:/archive.hhs.gov/importtaskforce/Report1220.pdf [hereinafter HEALTH & HUMAN SERVICES, REPORT ON PRESCRIPTION DRUG IMPORTATION].

federal approval."[10] The issue of high drug prices and the desire to lower prices is bipartisan,[11] but the Safe Importation Action Plan has sparked quite a bit of conversation regarding its implementation. On one hand, the United States healthcare system cannot have its' cake and eat it too – unfettered imports may decrease costs, but it will severely impact safety due to the closed United States drug system (discussed more in depth later in this Article). However, the United States closed system allows drug costs to stay high and climb higher because there is no arbitrage in place for manufacturers to fight on pricing (also discussed more in depth later in this Article).

This Article will proceed in two parts: Part I will discuss the controlling Food, Drug, and Cosmetic Act, the Medicare Act, and the process drug companies must take to introduce new medications into the United States market. The Food, Drug, and Cosmetic Act prohibits interstate shipment of unapproved drugs due to the threat of misbranding or adulteration. The Medicare Act, however, authorizes

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[10] Allison Martell, *Exclusive: Canada Warns U.S. Against Drug Importation Plans, Citing Shortage Concerns,* REUTERS (July 18, 2019), https://www.reuters.com/article/us-canada-pharmaceuticals-exports-exclus/exclusive-canada-warns-us-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LN.

[11] Meredith Freed, Tricia Neuman & Juliette Cubanski, *10 FAQ's on Prescription Drug Importation,* KAISER FAM. FOUND. (Oct. 8, 2020), https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/?utm_campaign=KFF-2020-Medicare&utm_source=hs_email&utm_medium=email&utm_content=83797463&_hsenc=p2ANqtz-8P7KUEG7UEZCuu1fEfPgcn-19QK7CNUZmhiZDP5PG05V3SStuKyoNxnAPlfpG4Yybb4G555LTEWFxIYqNib_-Zbjkij0VEie6fX1E6jYvBy-bksVM&_hsmi=83797463.

the Secretary of Health and Human Services to import drugs from Canada as long as they can certify that 1) it will pose no additional risk to public health and safety, and 2) it will generate cost-savings for American consumers. Lastly, drugs must go through an extensive application process to receive a track-and-trace number to protect the United States market against adulterated, counterfeit, and misbranded drugs.

Part II will review the Trump Administration's Safe Importation Action Plan.[12] First, both pathways in the 2019 plan will be discussed. Pathway 1 will allow states, wholesalers, or pharmacists to submit plans for how they will import from Canada. They must show no additional risk to public health and achieve cost savings, and the Secretary must approve through the Medicare Act power. Pathway 2 would allow manufacturers to import versions of FDA approved drugs sold in foreign countries into the U.S. with a new drug coding number. This was expected to allow manufacturers to sell the same drug chemically while foregoing extra costs imposed through patents and other controlling laws and regulations.[13] Lastly, various opinions will be highlighted on both sides of the political isle and on both sides of the two countries' boarders.

I. BACKGROUND

The Federal Food, Drug, and Cosmetic Act § 331, New Drug requirements in 21 U.S.C. § 355, and the Medicare Modernization Act

[12] The Safe Importation Action Plan was proposed in July 2019, and the Final Rule from HHS was introduced September 2020.

[13] In the finalized rule on October 1, 2020, Pathway 2 was eliminated. This Article still discusses Pathway 2, as it could serve as a reference relied on by the Biden Administration when re-writing importation regulations in the near future.

21 U.S.C. §384 (I)(1) are all at issue regarding any drug importation plan. As an overarching ban, Congress expressly prohibited the interstate shipment of any adultered or misbranded drugs as outlined in the Federal Food, Drug, and Cosmetic Act.[14] Furthermore, according to the Food and Drug Administration's website, individual importation of drugs into the United States is illegal (except in certain circumstances) due to the different approval processes laid out by Health Canada and the Food and Drug Administration in the United States.[15] To import a drug without violating the Food, Drug, and Cosmetic Act, the drug must go through the approval process laid out in the New Drug requirements. Lastly, even after a drug is approved according to the New Drug requirements, the Medicare Modernization Act requires the Secretary of Health and Human Services to certify it is safe and will save money. The need and want to lower prescription drug prices in the United States has been consistent, however there are no drugs certified for importation by the Secretary of HHS currently.[16] The risks have always outweighed the reward in this sector, which is why it is unlikely that importation now would be any different.

A. Federal Food, Drug, and Cosmetic Act § 331

Although the Safe Importation Action Plan reportedly has the support of the U.S. Food and Drug Administration (FDA), the statutes enforced and previous letters by the FDA and its commissioners are

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[14] 21 U.S.C.S. § 331.

[15] *Is It Legal for Me to Personally Import Drugs?,* U.S. FOOD & DRUG ADMIN. (Jan. 26, 2021), https://www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs.

[16] *See* Freed et al., *supra* note 11.

important to discuss as they are seemingly in contrast to the Plan.[17] The Federal Food, Drug, and Cosmetic Act § 331 is a prohibitive code regarding foods, drugs, and cosmetics.[18] This act expressly prohibits the interstate shipment of unapproved new drugs, which includes importation of items not approved by the FDA.[19] When interpreting the statute, Congress heavily emphasizes the risk of misbranded or adulterated "food, drug, device, tobacco product, or cosmetic."[20] Risk from imported drugs can come in the form of mislabeling, or misbranding, contamination, lack of research and development and knowledge about the drug in the United States, or even simply less-than-favorable packaging conditions.[21]

The FDA's mission statement is as follows:

> The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. [The] FDA is responsible for advancing the public

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[17] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (2020); 21 U.S.C. § 355 (2020); 21 U.S.C. § 384 (I)(1) (2020); Letter from Robert M. Califf, MD, MACC et al., to Members of Congress (Mar. 16, 2017) (on file with the author) ("[I]mportation represents a complex and risky approach—one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products.").

[18] 21 U.S.C. § 331 (2020).

[19] *Id.*

[20] *Id.*

[21] *Id.*

> health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. [The] FDA also plays a significant role in the Nation's counterterrorism capability. [The] FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.[22]

It is necessary to keep the FDA's mission of protecting public health and advancing public health when evaluating the Safe Importation Action Plan, paying close attention to the attention to detail the FDA process requires and how speed is usually at odds with this process.[23]

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[22] *What We Do*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2018), https://www.fda.gov/about-fda/what-we-do.

[23] This Article will not discuss the COVID-19 vaccine progression and speed. However, it is important to note that during the COVID-19 pandemic, these FDA processes were sped up unlike ever before by using the "emergency use authorization" for distribution in the United States. *See Pfizer-BioNTech COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Feb. 3, 2021), https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine; *see also Moderna COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Feb. 3, 2021), https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine.

The Courts have also recognized how important a liberal construction of the Food, Drug, and Cosmetic Act is to a healthy and safe society within medicine.[24] The overarching view of the Courts is that this Act should be read "consistent[ly] with the Act's overriding purpose to protect public health."[25] Courts should be advancing the agency's public interest with "constructive cooperation," not making judgements against the Act.[26] It is important to note that there is the need for a *Chevron* analysis by the court when construing the FDC Act because the Food and Drug Administration asserted jurisdiction to regulate a public concern matter, but this Article will not analyze this matter.[27] Each time the Act is cited or applied to a specific issue, the Courts state it should be seen as "a working instrument of government and not merely as a collection of English words."[28] Even the risk of adulteration is of concern, so "the FDA is empowered to regulate manufacturing processes and conditions" that may give rise to such issues.[29] A product is adulterated "if it has been . . . packed . . . under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."[30]

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[24] Nutritional Health All. v. FDA, 318 F.3d 92, 97 (2d Cir. 2003).

[25] *Nutritional Health All.*, 318 F.3d at 97; United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 246 (2d Cir. 1977); United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969).

[26] *Nova Scotia Food Prods. Corp.*, 568 F.2d at 246.

[27] *See* Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837 (1984) (The analysis of the Court of an agency's interpretation is as follows: if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction. The Court cannot impose its own interpretation of the statute.).

[28] United States v. Dotterweich, 320 U.S. 277, 280 (1943).

[29] *Nutritional Health All.*, 318 F.3d at 100.

[30] *Id.*

With both Congress and the Courts making sure this Act is elastic in protecting the public from health risks, it can be understood that pharmaceutical manufacturers, importers, and every other entity in the chain of distribution must be extremely cognizant of public health. Importation through the Safe Importation Action Plan must be highly regulated, or not occur at all, in order to keep the public safe at all costs due to the major concerns of the FDA regarding adulteration, misbranding, poor packaging, a lack of research and development and the like.

B. New Drug requirements in 21 U.S.C. § 355

Approval of a new drug is arduous, but for good reason. Safety of the American people is of the utmost concern. Title 21 of the United States Code section 355 starts as an overall restriction on delivery in the United States for the introduction of a new drug unless an application has been filed pursuant to the code.[31] New drug applications must be filed pursuant to 21 U.S.C. § 355(b) or (j).[32] The application, or the abbreviated application, requires extensive research, years of testing, proof of non-violation of an existing patent, the Secretary of HHS to provide guidance and an investigation, a certification pursuant the Public Health Service Act regarding clinical trials, and many more.[33]

"New drug" is defined as either:

1) A "the composition . . . that . . . is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and

[31] 21 U.S.C. § 355 (2020).

[32] *Id.* § 355(a).

[33] 21 U.S.C. § 355 (2020)

> effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . .” [34] or “[a]ny drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.”[35]

To go a step further, a “new drug” within the Act “may arise by reason of a new or different recommended use for the drug even though the same drug may not be a new drug when used for another disease.”[36] An HHS report on drug importation states “this definition is broad enough to include all prescription drugs offered for sale into the U.S. from abroad,” suggesting the fact that all drugs from Canada, even if already sold in the United States, would statutorily be required to go through the new drug application and scrutiny.[37]

C. Medicare Modernization Act 21 U.S.C. § 384 (I)(1)

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[34] *Id.* § 321.

[35] *Id.*

[36] Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 137 (3d Cir. 1973); Merritt Corporation v. Folsom, 165 F. Supp. 418 (D.D.C. 1958).

[37] HEALTH & HUMAN SERVICES, REPORT ON PRESCRIPTION DRUG IMPORTATION, *supra* note 9, at 34 n.5.

The largest hurdle to jump, after passing the Food, Drug, and Cosmetic Act, and the New Drug requirements, is the Medicare Modernization Act requirement of certification from the HHS Secretary. This certification provides that new drug plans to import from Canada cannot be implemented until the Secretary of Health and Human Services (HHS) certifies to Congress that 1) the new drug poses no additional risk to the public's health and safety, and 2) that the result of introduction will be a significant reduction in the cost of covered products to the American consumer.[38]

The Secretary of HHS would need to be de-briefed by the FDA regarding the medication, as the FDA is the agency with the information regarding the drug.[39] However, the Secretary of HHS is autonomous in this decision.[40] In addition, "the Secretary, after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States."[41] The main question to be asked regarding the Safe Importation Action Plan is: can the Secretary of HHS delegate its power as given in the Medicare Modernization Act to States, wholesalers, pharmacists, or whoever else decides to submit a plan to the FDA for importation from Canada?

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[38] 21 U.S.C. § 384 (l)(1) (2020).

[39] *See generally id.* (Author extrapolates the need for a briefing from the FDA for the Secretary of HHS due to the need for certification from the Secretary but the procedural processes requiring the FDA receive most of the drug information from importers.).

[40] *Id.*

[41] *Id.* § 384 (b).

In *Vermont v. Leavitt*, after having its importation plan struck down by the Secretary after refusing to certify, Vermont challenged the Secretary's power under the nondelegation doctrine.[42] Vermont claimed the Act is in violation of the nondelegation doctrine because it "improperly delegates legislative power to the Executive Branch."[43] However, the court stated:

> "Under the Medicare Modernization Act's certification provision, the ***Secretary [of HHS]*** must consider whether importation would pose an additional risk to the public's health and would result in a significant reduction in the cost of covered products. If the ***Secretary*** certifies that importation from Canada is safe and cost-effective, then the Medicare Modernization Act's importation program becomes effective. As a result, the Medicare Modernization Act's certification provision provides clear guidance to the ***Secretary of Health and Human Services*** by directing the ***Secretary*** to consider safety and cost-effectiveness. This is not unbridled discretion."[44]

This case excerpt makes it clear that the Secretary is the party that must certify this Canadian importation, not other parties who may submit importation plans. In the December 2019 proposed safe importation rule, the "FDA proposes to implement section 804 through time-limited

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[42] Vermont v. Leavitt, 405 F. Supp. 2d 466, 475 (D. Vt. 2005).

[43] *Id.*

[44] *Id*. at 476 (*emphasis added*).

[importation plans], which would be authorized by the FDA in 2-year increments and managed by [importation plan] sponsors, with the possibility of extensions for 2-year periods."[45] Because it has been decided that the Secretary of HHS has this certification power, not the FDA, this section of the Safe Importation Action Plan remains unresolved and needs to be rewritten if the plan is to go forward.

In addition, to introduce a new drug into the U.S. market, 21 U.S.C. § 355 must be followed. There is an entire application process which includes certifications of the effectiveness, patent checks to ensure none are being infringed upon, trials of the drug in accordance with 42 U.S.C.S. § 282, and many other steps to ensure that the drug is safe, effective, marketed correctly, and prescribed correctly.[46]

II. PLAN OVERVIEW

Through the Safe Importation Action Plan, President Trump and his administration attempted to "lower prices and reduce out of pocket costs for American patients."[47] The legislations goal to lower costs of prescription drugs is bipartisan,[48] however the way to achieve this goal is convoluted. According to the Health and Human Services Secretary

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[45] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,801 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251).

[46] 21 U.S.C. § 355 (2020); 42 U.S.C. § 282 (2020).

[47] Press Release, U.S. Dept. of Health & Human Services, HHS Announces New Action Plan to Lay Foundation for Safe Importation of Certain Prescription Drugs (July 31, 2019), https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html [hereinafter Press Release, Health & Human Services].

[48] 165 CONG. REC. H8820–21 (daily ed. Nov. 13, 2019).

Alex Azar, this plan "is the next important step in the Administration's work to end foreign freeloading and put American patients first."[49] The Food and Drug Administration's Acting Commissioner Ned Sharpless, M.D., has also stated that the "proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House . . . ."[50]

A. Preliminary Pharmaceutical Information

The distribution system for pharmaceutical drugs starts with the manufacturer. These manufacturers are the laboratories and factories who create the medication. Once the drug exists, a wholesaler is given permission by the manufacturer to sell the pharmaceuticals in bulk to retailer entities. These sales usually include a contract on the retailer limiting price, so the wholesaler and manufacturer make a profit, and a contract on limiting buyers, so the drug is not sold where the manufacturer does not want it to be sold. One of the many reasons these limiting contracts exist is so that the manufacturers can keep track of who is buying, what areas have access, the amount of access that area has, and how much profit is expected to be made in order to work on research and development or expansion. Tracking and tracing pharmaceutical drugs are extremely important in keeping the United States safe and is discussed later in this Article.

The Safe Importation Action Plan describes two pathways in which drugs can be provided to consumers safely and for a lower cost. Pathway 1 relies on 21 U.S.C. § 384 (also known as § 804 of the Federal Food, Drug, and Cosmetic Act) to authorize States, wholesalers, or pharmacists to submit plans outlining how they would import Canadian

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[49] Press Release, Health & Human Services, *supra* note 44.
[50] *Id.*

pharmaceuticals to the United States to HHS for review.[51] Pathway 2 relies on 21 U.S.C. § 381 (also known as § 801(d) of the Federal Food, Drug, and Cosmetic Act) to authorize manufacturers of the FDA approved pharmaceuticals to import identical but foreign-sold product into the United States.[52] The implicated and relevant statutes were discussed in Section I. As indicated in the Notice of Proposed Rule Making for the Safe Importation Action Plan, the plans shall be submitted to the FDA, who will then authorize the Sponsors through time-limited increments all through the FDA's discretion.[53]

Eligible prescription drugs, according to the proposed rule, include:

> "drug[s] subject to § 503(b) of the FD&C Act that has a marketing authorization from HPFB (Health Products and Food Branch of Health Canada) and, but for the fact it bears the HPFB-approved labeling, also meets the conditions in an FDA-approved NDA (new drug application) or ANDA (abbreviated new drug application), including those relating to the drug substance, drug product, production process, quality controls, equipment, and facilities."[54]

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[51] U.S. FOOD & DRUG ADMIN., SAFE IMPORTATION ACTION PLAN 1 (Dec. 31, 2020), https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.

[52] *Id.* at 3.

[53] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,801 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251).

[54] *Id.* at 70,803.

Each drug would essentially need to be eligible to be "sold legally on either the Canadian market or the American market with appropriate labeling."[55] A large factor in determining which drugs are eligible to be imported is that the drug must already be "marketed in the United States currently."[56] Lastly, a cost comparison between the sale in Canada and the sale in the United States of the drug "may be necessary to establish that importation has resulted in a significant reduction in the cost of covered products to the American consumer."[57] As previously noted, the Secretary of HHS must be able to certify that, as the result of introduction, there will be a significant reduction in the cost of covered products to the American consumer.[58]

Importation by individual states, however, could potentially uproot the entire track-and-trace U.S. system. Labeling requirements ("track-and-trace" systems) were created through 21 U.S.C. § 355(e) "for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs."[59] Each prescription drug type is given a numerical identifier that allows for easier "identification, validation, authentication, and tracking and tracing of the prescription drug."[60] The numerical identifier includes the FDA national drug code, plus a unique serial

[55] *Id.*
[56] *Id.* at 70,804.
[57] *Id.*
[58] 21 U.S.C. § 384 (I)(1) (2020).
[59] *Id.* § 355 (e).
[60] *Id.*

number, in order to trace the drug all the way back to its original manufacturer.[61]

Canada does not require a unique serial number, which could undermine this United States national numerical identifier system.[62] National Drug Code (NDC) codes, unique 10 digit numbers in the United States, are what is used in the United States labeling system.[63] These 10 digits identify "the labeler, product, and the trade package size of the drug."[64] The labeler code for manufacturers, repackagers, or distributors is assigned by the FDA, and the product and package codes are assigned by the labeler.[65] NDC codes are then aggregated with another unique serial number in order to trace the drug all the way back to its original manufacturer as part of the United States track-and-trace system.[66] Jane Horvath, creator of the model for state importation, states her planned model does not conflict with track-and-trace, but in

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[61] Adam J. Fein & Dirk Rodgers, *State Drug Importation Laws Undermine the Process That Keeps Our Supply Chain Safe*, STATNEWS (July 11, 2019), https://www.statnews.com/2019/07/11/state-drug-importation-laws-undermine-supply-chain-safety/.

[62] *Id.*

[63] *National Drug Code (NDC) – An Overview*, LIBERTY MANAGEMENT GROUP LTD. (April 10, 2019), https://www.libertymanagement.us/fda-news/2019/04/10/national-drug-code-ndc-an-overview/; *See also National Drug Code Directory*, U.S. FOOD & DRUG ADMIN. (Dec. 18, 2020), https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.

[64] *National Drug Code Directory*, *supra* note 63.

[65] *Id.*

[66] Fein & Rodgers, *supra* note 61.

fact, "build[s] on the safety requirements of the federal supply chain."[67] However, Horvath's non-conflict conclusion about her own plan is debatable due to the previously explained intricacies of NDC numbers, like many other creators assumed non-conflict conclusions.

NDC numbers, proper labeling, and the U.S. track-and-trace system are extremely important for several reasons. The most applicable reason is the codes that the United States use are unique to the country, meaning the United States drug distribution system is closed.[68] A closed system, as the FDA states, is beneficial to catching counterfeit drugs because every drug sold is able to be traced and accounted for.[69] Because of the FDA's regulations and processes in distribution, "medicines on the U.S. market are widely regarded as the safest in the world."[70]

Manufacturers would include entities who own "approved NDA or ANDA for an eligible prescription drug… a person who owns or operates an establishment that manufactures an eligible prescription drug… [or the] holder of a drug master file… [used to] authenticate an

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[67] Jane Horvath, *State Drug Importation Programs Will Work with the FDA, Not Outside of It,* STATNEWS (July 16, 2019), https://www.statnews.com/2019/07/16/state-drug-importation-programs-fda/.

[68] *Imported Drugs Raise Safety Concerns,* U.S. FOOD & DRUG ADMIN. (Mar. 1, 2018) https://www.fda.gov/drugs/drug-information-consumers/imported-drugs-raise-safety-concerns.

[69] *Id.*; Freed et al., *supra* note 11 ("Importation, according to the taskforce report, would create an opening in this closed system that would increase the opportunity for counterfeit, substandard, or unapproved products to enter the supply chain, introducing additional risks to American consumers.").

[70] Holly Campbell, *4 Facts on Why Drug Importation is Bad for Patients,* PHRMA (Oct. 6, 2015), https://catalyst.phrma.org/4-facts-on-why-drug-importation-is-bad-for-patients.

eligible prescription drug."[71] These manufacturers would allow foreign sellers, which are defined as "establishment[s] within Canada [who are] engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States," to sell their product.[72] In order for an establishment to classify as a foreign seller, it is "required to be licensed by Health Canada as drug wholesalers," be registered to sell approved drugs in Canada, and be registered with the FDA.[73]

On the United States side, importers include state or FDA-licensed wholesale drug distributors or state-licensed pharmacists who own an eligible prescription drug at the time of importation.[74] Each entity would play an essential part in getting the drug into the United States and the plan to do so would be laid out in the sponsor's proposal. The different pathways described below outline similar but separate ways a sponsor could achieve their goal of selling in the United States.

These pathways to drug importation from Canada were proposed by the Trump Administration, which, unlike the President, have not been removed from the White House.[75] The issue of high prescription drug prices is bipartisan, which leads to the conclusion that the Biden Administration will likely propose some sort of plan as well.[76]

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[71] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,804–05 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251).

[72] *Id.* at 70,804.

[73] *Id.*

[74] *Id.*

[75] Galewitz, *supra* note 2.

[76] Juliette Cubanski et al., *A Status Report on Prescription Drug Policies and Proposals at the Start of the Biden Administration*, KAISER FAM. FOUND. (Feb. 11, 2021), https://www.kff.org/medicare/issue-brief/a-status-report-on-

In the meantime, states are "moving ahead with efforts to import drugs from Canada," as they were under the Trump Administration.[77] The Trump Administrations Safe Importation Action Plan should not be considered as a framework or used as a reference for the Biden Administration in attacking high prescription drug prices.

B. Pathway 1

Pathway 1, where States, wholesalers, or pharmacists are authorized to submit plans on importation from Canada, requires assurance that their plan would provide that "the drug is what it purports to be and that [it] meets the cost requirements of the rulemaking."[78] References are made in this pathway of the plan to "drug quality, record keeping, testing, and protections against counterfeiting," which is an extraordinary feat for 1 state, 1 wholesaler, or 1 pharmacist to accomplish. In addition to that list of requirements, "additional safety requirements" including track-and-trace numbers, labeling requirements, registration for foreign sellers, and electronic information for shipment into the United States must be addressed by applicants.[79] Lastly, "post-importation requirements" must be consistently met after the plan is in place including "adverse event reporting, procedures to facilitate recalls, and CGMP for certain manufacturing activities such as relabeling."[80]

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prescription-drug-policies-and-proposals-at-the-start-of-the-biden-administration/ ("President Biden supported prescription drug importation during the campaign.").

[77] Galewitz, *supra* note 72.

[78] U.S. FOOD & DRUG ADMIN., SAFE IMPORTATION ACTION PLAN, *supra* note 51, at 1.

[79] *Id.* at 1–2.

[80] *Id.* at 2.

The cost requirement of Pathway 1 is a noteworthy hurdle for states, wholesalers, or pharmacists to jump. Under the Notice of Proposed Rulemaking for the Safe Importation Action Plan, cost requirements are categorized as additional post-importation requirements.[81] However, the sponsor would also need to include why and how much cost savings are projected before importation, clashing with the original requirement in the Notice of Proposed Rulemaking.[82] Cost savings would be shown by comparing the cost of the drug in the Canadian market to the cost of the drug approved by the FDA and sold in the United States to the American consumer.[83]

Furthermore, the plan references the fact that under the Medicare Modernization Act of 2003, the Secretary of HHS must certify "to Congress that the implementation of this section [allowing importation] will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer."[84] Notwithstanding the fact that this certification has never been attempted before due to the extremely limiting language of "no additional health risk," the various upfront requirements for proposers, as well as the ongoing monitoring involved, seem to point to no cost savings that the Secretary can certify as "significant."[85] In the Final Rule, the Secretary makes this very certification by issuance of the Final Rule, however it is a blanket use

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[81] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,797 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251).

[82] *Id.* at 70,802.

[83] *Id.* at 70,804.

[84] 21 U.S.C. § 384(l)(1) (2020).

[85] *Id.*

of authority that has never been done before and unlikely to protect the American people.[86]

According to the Importation of Prescription Drugs Final Rule, importation plan sponsors are to submit their full proposal to the FDA.[87] It is recommended that states team up with wholesalers, pharmacists, or any other sponsor to "introduce valuable flexibility… and allow [importation plan sponsors] to benefit from the experience of pharmacists and wholesalers, while preserving the advantages that accrue from sponsorship by at least one State or other governmental entity."[88] Other benefits from co-sponsorship with a state could include

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[86] Importation of Prescription Drugs, 85 Fed. Reg. 62,094, 62,095-96 (Oct. 1, 2020) (to be codified at 21 C.F.R. pts. 1, 251); Complaint at 37, PhRMA et al. v. HHS et al., Case 1:20-cv-03402 (D.D.C. Nov. 23, 2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Commercial-Importation-Complaint.pdf ("In a letter dated September 23, 2020, Secretary Azar wrote to congressional leaders to certify "that implementation of section 804(b)-(h) through the final rule Importation of Prescription Drugs . . . poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer.… Both that letter and the Final Rule are devoid of information about the actual effects of implementing Section 804(b)–(h) on public health and safety or costs to American consumers…").

[87] Importation of Prescription Drugs, 85 Fed. Reg. at 62,095; *see also* Importation of Prescription Drugs, 84 Fed. Reg. at 70,805 (proposed Dec. 23, 2019).

[88] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,801 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251); *see also* 85 Fed. Reg. 62,094, 62,099 (We continue to believe, as discussed in the NPRM (84 Fed. Reg. 70,796 at 70,801), that co-sponsorship could introduce valuable flexibility. . . .").

"enhanced accountability and . . . . [protection of] the public health" through state licensure and regulation that is already in place.[89]

C. Pathway 2

In Pathway 2, manufacturers of drug products that have already been approved by the FDA can propose plans to import copies of that drug that are sold in foreign markets into the United States. 21 U.S.C. §381, regarding reimportation, is implicated, even though this is not exactly reimportation of pharmaceuticals.[90] 21 U.S.C. §384, the main section used under Pathway 1, is also used as a hurdle for Pathway 2 proposals due to the apparent presumption in the Plan that implementation could be more efficient and effective under Pathway 1.[91] In the NPRM issued December 23, 2019, the FDA states that they will omit this pathway if they do not receive comment justifying an allowance for manufacturers to proceed without state co-sponsorship.[92] In the Final Rule, this pathway was omitted but is still important to discuss as the Biden Administration moves forward with addressing high prescription drug prices.[93]

Pathway 2 was offered as an option for manufacturers due to statements that the Administration had reviewed that "stated (either publicly or in statements to the Administration) that they wanted to offer lower cost versions but could not readily do so because they were locked

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[89] 84 Fed. Reg. at 70,801.

[90] U.S. FOOD & DRUG ADMIN., SAFE IMPORTATION ACTION PLAN, *supra* note 51, at 3.

[91] *Id.* at 4.

[92] 84 Fed. Reg. at 70,802.

[93] *See generally* 85 Fed. Reg. 62,094 (proposed Oct. 1, 2020).

into contracts with other parties in the supply chain."[94] In layman's terms, Pathway 2 is a way for manufacturers to get around their distribution contracts that limit prices and buyers, which were legally entered into and should be legally protected. Essentially, after the manufacturer has shown the imported drug is the same as the FDA approved drug, through manufacturing records and correct labeling, the FDA will authorize that reimported drug to be identified with a different National Drug Code in order to sell the drug at a lower price.[95] Pathway 2 creates problems stemming from contract law which will not be discussed in depth in this Article. However, it is important to highlight that if Pathway 2 or a similar workaround were to be enacted, these contracts would essentially become moot. The contracts at issue would become powerless and thus irrelevant because importing the exact same drug (but with a different national drug code number than the one identified in the contract) would be possible through the Safe Importation Action Plan.[96]

OPINIONS ON THE PLAN

As expected, the Safe Importation Action Plan proposed by President Trump, the FDA, and HHS has stirred up quite a bit of conversation from both sides regarding implementation. Those against implementation argue that this plan will break open the closed prescription system of the United States and highlight lack of cost savings, unknown origins of these imported drugs, as well as arbitrage concerns. The implementers see this plan lowering prescription drug prices in the United States, stopping the free-rider problem, and argue

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[94] U.S. FOOD & DRUG ADMIN., SAFE IMPORTATION ACTION PLAN, *supra* note 51, at 3.

[95] *Id.*

[96] *Id.*

that this plan is a necessary first step. This section will highlight opinions against the plan and will discuss the in-favor defenses to the attacks on the plan.

A. Safety

First, a large concern that comes up in virtually every conversation regarding importation revolves around the safety of consumers in the United States. The United States Chamber of Commerce issued a statement arguing that "the 'Safe Importation Action Plan' described today by HHS would make American patients less safe, without improving the affordability of medicines."[97] After stating that the desire to lower costs is shared by both parties, the Executive Vice President and Chief Policy Officer Neil Bradley stated "the approaches outlined in this proposal to encourage and facilitate importation of drugs manufactured for foreign markets, will have significant and perverse consequences, including exposing patients to the substandard, falsified, and counterfeit medicines that proliferate in the global marketplace."[98] The Biotechnology Innovation Organization (BIO) argues that while patients in the United States deserve affordable out-of-pocket costs, "under no circumstance should we risk patient safety to achieve this goal, yet that's exactly what this dangerous importation scheme will do."[99] Even the FDA, one of the organizations

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[97] *See U.S. Chamber Insists on Maintaining the Safety and Integrity of the American Supply of Medicines*, U.S. CHAMBER OF COM. (July 31, 2019), https://www.uschamber.com/press-release/us-chamber-insists-maintaining-the-safety-and-integrity-of-the-american-supply-of.

[98] *Id.*

[99] *Importation Scheme Will Jeopardize Patient Health, Do Little to Lower Drug Costs*, BIO (Dec. 18, 2019), https://www.bio.org/press-

proposing this current plan, has an entire section on their website entitled "Imported Drugs Raise Safety Concerns."[100] On their website, the FDA states that they do not have the authority to approve drugs sold in Canada, and if certain drugs are only manufactured in Canada specifically for importation into the United States, Health Canada may not even regulate the drugs or the company at all.[101] According to the United States Health and Human Services Task Force on Drug Importation, a letter from Assistant Deputy Minister of Health Canada Diane Gorman to Richard Carmona, Surgeon General of the U.S. Public Health Service further stated:

> "Many Americans import prescription drugs from Canada or Mexico, due to their proximity to the United States. Canadian Federal and provincial law is based on the premise that each country is responsible for the safety of drug products made available to its own citizens. Health Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future."[102]

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release/importation-scheme-will-jeopardize-patient-health-do-little-lower-drug-costs; *Policy*, BIO, https://www.bio.org/policy (last visited on Mar. 10, 2021) ("BIO advocates for laws, funding and other governmental actions that ensure that biotechnology companies are able to focus on their research whether it be developing next-generation drugs, the next major advancement in agriculture or fuel to move the world . . . .").

[100] *Imported Drugs Raise Safety Concerns*, *supra* note 68.

[101] *Id.*

[102] HEALTH & HUMAN SERVICES, REPORT ON PRESCRIPTION DRUG IMPORTATION, *supra* note 9, at 60–61 (this Task Force Report on Prescription Drug Importation was created in response to a plan similar to the

For the FDA, Health Canada not ensuring safety for United States citizens causes "potential health risks with imported drugs" including "quality assurance concerns… counterfeit potential… presence of untested substances… risks of unsupervised use… labeling and language issues… [and] lack of information."[103]

However, in the current NPRM regarding the Safe Importation Action Plan, these concerns are glossed over briefly and followed up with a comparison to the importance of cost savings.[104] Safety and health in the context of the NPRM is concerned that American people are "not taking their medicines as prescribed due to the expense" and "rationing… or delaying" medications and treatments because of costs.[105] As important and concerning as those aforementioned

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Safe Importation Action Plan that was introduced in the United States in 2004.).

[103] *Imported Drugs Raise Safety Concerns*, *supra* note 68.

[104] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,799 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251) ("The Agency takes seriously its responsibility to ensure that the medicines Americans use are safe and effective… Most Americans (79 percent) say the cost of prescription drugs is 'unreasonable.'" . . . "Congress has given FDA, as part of the Agency's mission to promote and protect the public health, responsibility for implementing laws intended to strike a balance between encouraging and regarding innovation in drug development and facilitating robust and timely market competition."). While the Final Rule does mention safety, it does not allude to or resolve any concrete safety concerns (especially concerning substitution, falsification, and counterfeited medications). *See generally* 85 Fed. Reg. 62,094 (proposed Oct. 1, 2020).

[105] 84 Fed. Reg. 70,796, 70,799–80.

ramifications of high costs are, at least the medications the patients are receiving, when they do receive them, are not substituted, falsified, or counterfeit.[106]

CATO argues Health Canada sets standards for Canada, and the European Union has allowed manufacturing and sale(s) in between member countries without any issue.[107] CATO supports the safe importation action plan insofar as it is a small step in the correct direction.[108] The article concludes with CATO stating that the HHS Secretary should open up importation from multiple countries in order to protect Canada's market and force pharmaceutical companies into regulating their own prices.[109] Nevertheless, "bait and switch" techniques increase the possibility of Canada being a middle-man for other countries with different standards of safety and efficacy to ship in to the United States.[110]

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[106] *U.S. Chamber Insists on Maintaining the Safety and Integrity of the American Supply of Medicines*, *supra* note 97.

[107] Jeffrey A. Singer, *Trump Plan for Pharmaceutical Importation a Small Step in the Right Direction,* CATO INSTI. (Aug. 1, 2019, 10:17 AM), https://www.cato.org/blog/trump-plan-pharmaceutical-importation-small-step-right-direction.

[108] *Id.*

[109] *Id.*

[110] Press Release, U.S. Food & Drug Admin., FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries (Dec. 16, 2005), http://www.safemedicines.org/wp-content/uploads/FDA-Operation-Reveals-Many-Drugs-Promoted-as-_Canadian_-Products-Really-Originate-From-Other-Countries-captured-January-2017.pdf [hereinafter Press Release, U.S. Food & Drug Admin.]; *see also* Allyson Funk, *What You Don't Know About Importation From Canada,* PHRMA (Feb. 17, 2017), https://catalyst.phrma.org/what-you-dont-know-about-importation-from-canada.

In fact, an FDA operation named "bait and switch" revealed that 85 percent of drugs being marketed as Canadian actually came from 27 other countries around the globe.[111] The issue that is appropriately highlighted from this operation is the high possibility that the pharmaceuticals are not even of Canadian origin, with at least somewhat comparable processes in public health and safety through Health Canada. This issue particularly pertains to certain online pharmacies that have been set up and subsequently shut down by the Courts. One example of this breach in safety is Andrew Strempler's RxNorth.com pharmacy that was found to have sold "foreign and counterfeit medicines to U.S. customers."[112] The pharmaceutical companies owned by Strempler "sold cheaper, foreign drugs from price-controlled markets such as Canada and the U.K. … But a crackdown by drug makers forced Mr. Strempler and other pharmacists to look for supplies further afield… that turned out to be counterfeit."[113]

Arguing in favor of importation from Canada, Horvath, the drafter of the National Academy for State Health Policy importation model, stated "almost half of the drugs Americans consume now come from overseas FDA-registered manufacturing plants… that supply U.S. drugs."[114] Regardless of what the arguably biased creator of this importation plan argues, Strempler's mission is exactly the same as the Safe Importation Action Plan. Although the importation models would

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[111] Press Release, U.S. Food & Drug Admin., *supra* note 110.

[112] Christopher Weaver, *Former Internet Pharmacist Sentenced in Fake Drugs*, WALL ST. J. (Jan. 9, 2013), https://www.wsj.com/articles/SB10001424127887324442304578232133556180830.

[113] *Id.*

[114] Horvath, *supra* note 67.

be different, the consequences from Strempler's importation could likely be the same as the Safe Importation Action Plan.

Hitting a bit closer to the mark of the real concern about safety in importation than the NPRM, Former FDA Commissioner Scott Gottlieb, who previously expressed skepticism that foreign drug importation could be done safely or generate substantial savings for American consumers, tweeted just one day after his expressed concern:

> "On close review of the 'importation' plan unveiled today, the proposed rule places stringent conditions on the importation of drugs. While it may sharply limit who can actually import Canadian drugs under this framework, it maintains critical FDA safeguards to protect consumers."[115]

The framework Gottlieb references in the NPRM is a long and arduous process, as explained above within the Notice of Proposed Rulemaking. This then begs the question – who will actually save money from this importation if so many stringent conditions must be met?

Next, relying on a Kaiser Family Foundation (KFF) Health Tracking Poll conducted in 2016, it is argued that importation is already

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[115] Scott Gottlieb (@ScottGottliebMD), TWITTER (Dec. 18, 2019), https://twitter.com/scottgottliebmd/status/1207317144993697792; Scott Gottlieb (@ScottGottliebMD), TWITTER (Dec. 17, 2019), https://twitter.com/ScottGottliebMD/status/1207093162470182912 (Scott Gottlieb tweeted a thread on December 17, 2019, one day before the quoted tweet, stating "Our closed drug system doesn't allow imports of unapproved foreign drugs for key historical reasons. The 1987 Prescription Drug Marketing Act required wholesalers to provide a drug pedigree. It was response to widespread counterfeits, many from small shady wholesalers…").

happening, so the Safe Importation Action Plan should pass.[116] This Article will only address the hollow argument that importation is already happening regarding the KFF Poll. This poll relied on states where only eight percent of people have themselves, or someone in their household, bought prescription drugs from Canada or other countries outside the United States in order to pay a lower price.[117] This percentage could be due to the fact that people do not want to answer honestly about their foreign pharmaceutical purchasing because it is illegal.[118] However, safety issues should not be thrown by the wayside for the entire United States just because a reported eight percent of individuals are already importing prescription drugs for personal use.

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[116] *See generally* Rachel Bluth, *Faced With Unaffordable Drug Prices, Tens Of Millions Buy Medicine Outside U.S.*, KAISER HEALTH NEWS (Dec. 20, 2016), https://khn.org/news/faced-with-unaffordable-drug-prices-tens-of-millions-buy-medicine-outside-u-s/ (citing *Kaiser Health Tracking Poll: November 2016*, THE HENRY J. KAISER FAM. FOUND., 8, https://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline); *see also Pharmaceutical Bulk Purchasing,* NAT'L CONF. STATE LEGIS. (Mar. 2, 2020), https://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx (describing prescription drug cost and access solutions already in place); Drew E. Altman, *President's Message,* KAISER FAM. FOUND. (Aug. 2019), https://www.kff.org/presidents-message/ ("KFF is an endowed, non-profit organization filling the need for trusted, independent information on national health issues… headquartered in San Francisco, without any connection to Kaiser Permanente.").

[117] *Kaiser Health Tracking Poll: November 2016*, THE HENRY J. KAISER FAM. FOUND., 8, https://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline.

[118] Bluth, *supra* note 116.

B. Cost Savings

The next main argument against the implementation of the Safe Importation Action Plan is that it will not actually save pharmaceutical companies, manufacturers, importers, pharmacists, and consumers any money. This is due to the arduous tasks imposed on the process of importation and the fallacy created by international reference pricing. As background, it is believed that prices are high because the FDA regulations interrupt the free-market regime based on property and contract principals with the imposition of requirements regarding research and development for safety and efficacy.[119] On average, it takes companies 12-15 years from discovery to FDA approval, which is costly.[120] This cost is then shifted directly to consumers in the U.S. market.

The NPRM and the Final Rule start with the importation plan sponsor specifying the eligible prescription drugs included in the importation that are approved by both Health Canada and the FDA.[121] Next, the sponsor needs to identify the foreign seller in Canada that would purchase the drug from its manufacturer, making sure that they are a licensed Health Canada wholesaler and registered with the FDA.[122] The importer in the United States who would be buying directly from the foreign seller would also need to be identified.[123] Both the foreign

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[119] Roger Pilon, *Drug Reimportation: The Free Market Solution* NO. 521, 2, 3 (CATO Inst. Pol. Analysis Aug. 4, 2004), https://www.cato.org/sites/cato.org/files/pubs/pdf/pa521.pdf.

[120] *Id.* at 3.

[121] Importation of Prescription Drugs, 85 Fed. Reg. 62094 (proposed Oct. 1, 2020) (to be codified at 21 U.S.C. 384(b) through (h)).

[122] *Id.*

[123] *Id.*

seller and the importer would be subject to the supply chain requirements specified in the Food, Drug, and Cosmetic Act.[124] The foreign seller would then need to make certain that proper serial numbers were placed on each package matching the case it was being sold in.[125] The importer would then ensure that a NDC code was on each package and case, while keeping records linking each package to each foreign seller.[126] These records would be submitted to the FDA at least 30 days before (the) arrival of the eligible prescription drug in the United States.[127] The importer would also be required to file an entry for consumption in an electronic data interchange system; if noncompliant, the drug could be refused entry, meaning that all of the money expended thus far would be wasted.[128] The importer would then need to test the drug in a United States laboratory for authenticity, degradation, and other statutory requirements under Section 804 of the Food, Drug, and Cosmetic Act.[129] The results of this testing would be subject to review by the FDA and if accepted, the drug would need to be relabeled before distributed.[130] The NPRM and Final Rule requires each sponsor to provide the FDA with data including cost savings to

[124] *Id.*

[125] *Id.*

[126] *Id.* at 62,094–95.

[127] Importation of Prescription Drugs, 85 Fed. Reg. 62,094, 62,095 (Oct. 1, 2020) (to be codified at 21 U.S.C. 384(b) through (h)).

[128] *Id.*; Importation of Prescription Drugs, 84 Fed. Reg. at 70,797.

[129] Importation of Prescription Drugs, 84 Fed. Reg. at 70,797; Importation of Prescription Drugs, 85 Fed. Reg. at 62,095.

[130] Importation of Prescription Drugs, 84 Fed. Reg. at 70,797; Importation of Prescription Drugs, 85 Fed. Reg. at 62,095.

American consumers.[131] Importers would be required to provide dates on of adverse events, medication errors, field alerts, and other reports to the manufacturer and to the FDA.[132] These reports would be subject to the FDA's discretion regarding recall at the cost of the sponsor.[133] An extremely long process like this would mean that manufacturers, sponsors, and anyone else involved in the plan proposal process would not be making as much money as what may be needed. An extremely arduous process like this would also mean that there will be large amounts of money expended on creating these plans.

On the regulation side, importation commercially "would require new legal authorities, substantial additional resources, and significant restrictions on the types of drugs that could be imported, which could increase the costs of imported drugs."[134] However, when similar failed plans have been introduced in the past, "neither [the] FDA nor CBP (United States Customs and Border Protection) have received additional resources or authorities to process these shipments."[135] The HHS report states, "It is difficult to predict the actual cost of an importation program without specific information on the type of program. However, it is clear that any program would need substantial

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[131] Importation of Prescription Drugs, 84 Fed. Reg. at 70,797; Importation of Prescription Drugs, 85 Fed. Reg. at 62,095.

[132] Importation of Prescription Drugs, 84 Fed. Reg. at 70,797–98.

[133] *Id.*

[134] HEALTH & HUMAN SERVICES, REPORT ON PRESCRIPTION DRUG IMPORTATION, *supra* note 9, at 23 (This report was published by HHS in December of 2004 after an importation plan similar to the Safe Importation Action Plan was proposed. Although the discussion is about that previous Plan, the data is able to be extrapolated to the current 2020 Importation Plan.).

[135] *Id.* at 32.

resources for infrastructure, IT needs, personnel, and associated required measures."[136]

Currently, inspections by the FDA are conducted by staff but packages are flagged by Information Technology (IT) systems.[137] FDA inspections consist of commercial shipment inspections and personal shipment inspections.[138] Commercially, each shipment is entered into a database called OASIS.[139] After this OASIS review, certain shipment sponsors "may be required to submit additional information or undergo physical inspection."[140] In 2004 (when a previous failed importation plan was introduced), of 197,420 lines of commercial pharmaceutical product, approximately 5,124 detentions occurred.[141] Each detention then requires individual physical inspection by FDA personnel which

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[136] *Id.*

[137] *Id.* at 52 ("To date, physical inspections have been conducted on a very small percentage of imports. In order to ensure these are done in a risk-based or "directed" manner, information technology (IT) systems are critical.").

[138] *Id.* at 53–54.

[139] *Id.* at 53.

[140] HEALTH & HUMAN SERVICES, REPORT ON PRESCRIPTION DRUG IMPORTATION, *supra* note 9 at 53–54.

[141] *Id.* at 54 ("A line represents a broker's entry of an imported product. Each line can represent a varying amount of drug product. For example, one line could be ten boxes or 200 boxes of the same drug product. The total number of lines for commercial pharmaceutical products was approximately 197,420 in FY 2003 out of over nine million total lines of imported products under FDA's jurisdiction. For FY 2004, FDA estimates that there will be 234,930 lines of pharmaceutical products."); *Id.* at 55, Figure 5.1 (Although this data is older, data and projections included in this report illustrate detentions of unapproved drugs based on lines in OASIS, as well as inspections by FDA personnel, as increasing dramatically each year.).

includes both investigations and testing.[142] Because "laboratory analysis is critical for providing the data needed by [the] FDA to evaluate authenticity, assess risk, develop an appropriate response to protect the public from harm, support criminal prosecutions," and provide more manpower to conduct physical inspections, "there are not sufficient resources available to ensure adequate inspection of current levels of prescription drugs entering the U.S for personal importation."[143] Insufficient resources and an insufficient infrastructure in place means a need for an overhaul, which will cost money that will cut into the bottom line of the Secretary's already baseless certification.

In 2005-2006, it was estimated by the Congressional Budget Office that an importation plan for prescription drugs would cost approximately $1.5 billion dollars over a four-year period.[144] However, the total prescription drug expenditure would be reduced by only one percent (1%), or $50 billion over a nine-year period, stemming mostly from importing patent protected brand-name drugs.[145] Even though the reduction in expenditure seems large, the cost to the American people regarding unsafe, untraceable, and uncontrolled prescription drugs largely outweighs it, especially when considering the other expenditures involving policing and monitoring these international orders.

In addition, international reference pricing is used to compare United States drug prices with other countries resulting in major disparities.[146] This is misleading because the United States healthcare

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[142] *Id.* at 54.

[143] *Id.*

[144] FTC REAUTHORIZATION ACT OF 2005, S. Doc. No. 1392, at 2, 8 (109th Sess. 2005).

[145] *Id.*

[146] *See* Kevin Haninger, *Setting the Record Straight on International Reference Pricing*, THE CATALYST (July 16, 2019),

market is much different than that of other countries in which the government is the primary payer of health care.[147] In countries where the government is the primary or only payer, pharmaceutical companies are forced to accept the low offered price, or face restrictions in coverage, discriminatory policies to their company, or threats by the government to break patent protections on valuable new medicines.[148] Practices like these "force artificially low prices, delay patient access to new medicines and keep[s] some innovative treatments off [of] the market entirely."[149] Because the price is artificially low, comparing the United States pricing to other countries' government-controlled health care prices is misleading as "restrictions in accessing new medicines and treatment options" are significant.[150]

Entities in favor of implementation argue that countries in which the government is the primary payer of health care have forced drug companies to shift their costs to the United States to subsidize drug development, creating a free-rider issue.[151] They argue that other countries should not be able to free-ride on the research and development dollars provided by America.[152] The United States subsidizes drug research and development by paying for the majority of

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https://catalyst.phrma.org/setting-the-record-straight-on-international-reference-pricing.

[147] *See id.*

[148] *Id.*

[149] *Id.*

[150] *Id.*

[151] Singer, *supra* note 107.

[152] *Id.* ("[Pharmaceutical companies] charge much higher prices to US consumers who, in effect, subsidize new drug development for patients in Canada and other countries.").

it, while other countries do not scratch the surface of what the United States pays.[153] This surface level analysis makes sense – the United States pays more to pharmaceutical companies, and because other countries are paying less, it is assumed that the United States is taking the hit for all countries involved. This analysis provides for the conclusion that this is unfair to the United States.

However, "nearly 90% of new medicines launched since 2011 are available in the United States compared to just 50% in France, 48% in Switzerland and 46% in Canada . . . ."[154] This access was not taken into account in the analysis provided above, where it is said that the result to the United States is unfair since the U.S. pays more for prescription drugs from pharmaceutical companies. Differential pricing like this allows drugs to be sold cheaply in low-income countries to improve access, while maintaining high prices in market-rich countries to support innovation.[155] No matter how the issue of free-riding is looked at, the amount of cutting-edge prescription drugs the United States consumer has access to due to research and development expenditures outweighs the extra money spent. This conclusion is especially true when the United States consumer is projected to save very little per prescription, compounded with other issues of supply and demand.[156] If the issue of free-riding on the United States' money and

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[153] Haninger, *supra* note 146.

[154] *Id.*

[155] Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets* 1–2, YALE J. HEALTH POL., LAW & ETHICS (Dec. 2004), https://www.who.int/intellectualproperty/news/en/Submission5.pdf.

[156] FTC REAUTHORIZATION ACT OF 2005*, supra* note 144, at 8 (explaining how inflation effects the overall strength of the U.S. dollar compared to other countries currency, as well as the issue that relative value of the U.S. dollar

its eradication is so important, the United States should not create another free-rider issue in its own free-rider solution. By importing from Canada, the United States would essentially be free riding on Canada's governmental price control infrastructure.[157]

The final cost savings component this Article will discuss is Canadian arbitrage. Arbitrage is defined as "buyers in a lower-priced market re-sell[ing] the product to consumers in a higher-priced market," making a personal profit.[158] Arbitrage is the "nemesis" of differential pricing, as discussed previously with international drug reference pricing, because it "assumes the first purchaser is the ultimate user."[159] Due to the assumption of differential pricing, "neo-classical economic theory predicts that arbitrage will erode price-differentiated markets, moving all sales towards an equilibrium price."[160] To work against this theory of eventual equilibrium, "IP laws support pharmaceutical differential pricing by creating legally enforceable rights such as

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may reduce the type of prescription drugs it makes sense to import economically, creating potential supply issues). A portion of cost savings projected by the Congressional Budget Office was also projected to go to transportation costs, relabeling, repackaging, and export and import firms. *Id.*

[157] *See generally* Natalie O. Pearson & Simran Jagdev, *Trump's 'Crazy' Drug Import Plan Stirs Backlash in Canada*, BLOOMBERG (Aug. 1, 2019), https://www.bloomberg.com/news/articles/2019-08-01/trump-s-crazy-drug-import-plan-stirs-supply-fears-in-canada; *Home,* GOV'T OF CANADA: PATENTED MEDICINE PRICES REVIEW BOARD (July 13, 2020), http://pmprb-cepmb.gc.ca/home.

[158] Outterson, *supra* note 155, at 9.

[159] *Id.*

[160] *Id.*

patents, trademarks and copyrights… [and] the government may also seize counterfeit or improperly diverted drugs."[161] The FDA has always taken the position that it is legal for an individual to physically visit a Canadian pharmacy for their own use and then bring back the pharmaceuticals, in certain circumstances.[162] However, it has been illegal for companies to import from Canada, evidenced by officials "aggressively enforcing against U.S. companies involved in trade."[163] Relating to the Safe Importation Action Plan, Canadian arbitrage would essentially become a normal, legalized practice. Lower cost would be achieved for the United states but would "potentially [harm] innovation through reduced cash flow to pharmaceutical companies."[164] The harm would occur because "the first mover (a PhRMA company) incurs all research costs (including failed programs)…" which can be in the millions of dollars and can take years to bring a newly patented product to the market.[165] This could lead to pharmaceutical companies stopping innovation due to the cost.

C. Canadian Issues

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[161] *Id.* at 11.

[162] *Personal Importation,* U.S. FOOD & DRUG ADMIN. (Aug. 3, 2018), https://www.fda.gov/industry/import-basics/personal-importation#whatis.

[163] Outterson, *supra* note 155, at 75 (Officials include the Customs Department in postings, the state Boards of Pharmacy in challenges against prescription centers, and state pharmacy investigators in undercover operations.).

[164] *Id.* at 9.

[165] *Id.* at 5 (This publication goes on to state the assumption that patents support innovation is openly challenged, however in footnote 12 there are exceptions in patents for pharmaceuticals, which is what this Article is discussing.).

Up to this point, this Article has discussed projected issues regarding the United States. However, it is important to remember that the Safe Importation Action Plan proposes legalizing "importation of certain prescription drugs shipped from Canada" specifically.[166] This proposal focuses on drugs being approved by Health Canada's Health Products and Food Branch, foreign sellers licensed by Health Canada, Health Canada inspection records, and the like.[167] Canada's response to this major involvement has not been nearly on the same page as the United States' Trump administration. It can be assumed that Canada will respond in the same way to the Biden Administration.[168]

The Notice of Proposed Rule Making states "regulatory harmonization between Canada and the United States has also increased bilaterally through the United States-Canada Regulatory Cooperation

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[166] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,797 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251).

[167] *Id.* at 70,797, 70,805.

[168] *See* Complaint at 27, PhRMA et al. v. HHS et al., Case 1:20-cv-03402 (D.D.C. Nov. 23, 2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Commercial-Importation-Complaint.pdf ("The Government of Canada submitted comments opposing the NPRM. In particular, the Government of Canada noted that its drug market was "too small to meet American consumer demand for prescription drugs or have an impact on high drug prices." Government of Canada, Comment Letter on NPRM at pp.1, 3. The Government of Canada predicted that importation would increase "pressure on the Canadian drug supply, exacerbating drug shortages and limiting access to needed medicines in Canada." *Id.* at 2. Accordingly, the Government of Canada warned that it would "employ all necessary measures to safeguard its drug supply and preserve access for Canadians to needed prescription drugs." *Id.* at 3.").

Council and through international organizations such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Pharmaceutical Inspection Co-operation Scheme initiatives, of which both FDA and Health Canada are members."[169] In addition, the Notice of Proposed Rule Making mentions that "In August 2019, the FDA and Health Canada announced a series of joint meetings in advance of each bi-annual ICH face-to-face meeting to seek the public's input on areas where harmonized ICH guidelines would be beneficial."[170] However, as explained below, these collaborative one-off meetings do not serve as Canada's greenlight for United States importation from their prescription drug market.

i. Canadian Drug Shortages

The major argument against United States importation from Canada is Canadian drug shortages. Drug shortages are an issue in the United States as well.[171] In the United States, the impacts of drug shortages include higher hospital expenses, increased labor costs, safety risks with compromised clinical outcomes, medication errors or death,

[169] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,800 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251).

[170] *Id.*

[171] *Drug Shortages: Root Causes and Potential Solutions,* U.S. FOOD & DRUG ADMIN., (Nov. 2019), https://www.fda.gov/media/132058/download (a written, bipartisan request from Congress "ask[ing] for assistance in addressing the Nation's drug shortage crisis.").

issues with quality-control, diminished supplies of alternative drugs, and others.[172] In Canada, the risks are similar.[173]

In dealing with their own drug shortages, according to an April 2019 briefing for Canadian officials, "Canada does not support actions that could adversely affect the supply of prescription drugs in Canada and potentially raise costs of prescription drugs for Canadians," while citing shortages as a main issue.[174] When a similar drug importation plan was proposed by the administration of the United States in 2005, the "Canadian government promised a bill that would restrict drug exports in response to similar U.S. proposals…" to show their opposition.[175]

The Canadian Pharmacists Association released a statement "calling on the federal government [of Canada] to clearly express its

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[172] C. Lee Ventola, *The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies*, 36 PHARM. & THERAPEUTICS 11, 740–57 (Nov. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/.

[173] *Consequences?,* CANADIAN DRUG SHORTAGE, https://www.canadadrugshortage.com/consequences/ (last visited Mar. 10, 2021); Jessy Donelle et. al., *Assessing Canada's Drug Shortage* Problem, C.D. HOWE INST. NO. 515, 3 (Jun. 2018) https://www.cdhowe.org/sites/default/files/attachments/research_papers/mixed/Commentary_515.pdf.

[174] Allison Martell, *Exclusive: Canada Warns U.S. Against Drug Import Plans, Citing Shortage Concerns,* REUTERS (July 18, 2019), https://www.reuters.com/article/us-canada-pharmaceuticals-exports-exclus/exclusive-canada-warns-us-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LN (citing briefing for Canadian officials obtained under the freedom of information laws.).

[175] *Id.*

opposition to U.S. drug importation, and immediately develop an action plan to respond to these proposals including restricting exportation of drugs from Canada to the US."[176] This bright-line opposition comes from the fact that "drug shortages have 'greatly increased' in the last 3-5 years" for Canadian residents.[177] Abacus Data conducted a survey in November 2018 which resulted in the conclusion that "one in four Canadians have either personally experienced or know someone who has experienced a drug shortage in the last 3 years."[178] Due to the shortages, "15-21% of Canadians have looked into taking other approaches to procuring medication – online purchasing, or procuring drugs from a family member or elsewhere informally."[179] According to Kelly Gindrod, associate professor at the University of Waterloo's School of Pharmacy, "there is almost no transparency around the true causes… Pharmacists are told there's a 'disruption of manufacturing' or a 'delay in shipping,' but there are no explanations of why there are

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[176] *Canadian Pharmacists Association Renews Call for Federal Government to Protect Drug Supply in Light of U.S. Drug Importation Developments,* CANADIAN PHARMACISTS ASS'N, (July 31, 2019), https://www.pharmacists.ca/news-events/news/canadian-pharmacists-association-renews-call-for-federal-government-to-protect-drug-supply-in-light-of-u-s-drug-importation-developments/.

[177] *Id.*

[178] *CPhA Drug Shortages,* ABACUS DATA, (Nov. 2018), *https*://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/DrugShortages_AbacusSurvey_November2018.pdf; *About Abacus,* ABACUS DATA, https://abacusdata.ca/about/ (last visited Feb. 28, 2021) (Abacus Data is a Canadian-based "research and strategy firm that helps organizations respond to the disruptive risks and opportunities in a world where demographics and technology are changing more quickly than ever.").

[179] *CPhA Drug Shortages, supra* note 178.

disruptions or delays."[180] If Canada, a country of about thirty-seven million residents, is already experiencing drug shortages, they cannot seriously be the "drugstore of the United States," a country of about 327 million residents.[181]

Notwithstanding the blatant opposition from Canada, the Final Rule states in a response to potential Canadian drug shortages,

> The final rule affords significant flexibility to SIPs to choose which eligible prescription drugs to import and in what quantities. This flexibility could allow SIPs to make adjustments in response to the supply of eligible prescription drugs available for importation. In addition, several potential SIP Sponsors have indicated in comments that they believe they can implement a SIP that, if authorized by FDA, will achieve a significant reduction in the cost of covered products to the American consumer with no additional risk to the public's health and safety.[182]

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[180] Natalie O. Pearson & Simran Jagdev, *Trump's Canada Drug Import Plan Can't Happen Without Big Pharma,* BNN BLOOMBERG (Aug. 13, 2019), https://www.bnnbloomberg.ca/trump-s-canada-drug-import-plan-can-t-happen-without-big-pharma-1.1300777.

[181] Wayne Winegarden, *Trump's Drug Importation Policy is Folly, Just Ask Canadians*, FORBES (Aug. 7, 2019), https://www.forbes.com/sites/waynewinegarden/2019/08/07/trumps-drug-importation-policy-is-folly-just-ask-canadians/#31ab35b0e0fb.

[182] Importation of Prescription Drugs, 85 Fed. Reg. 62,094, 62,097 (proposed Oct. 1, 2020).

This run-around response echoes the overall tone of the Final Rule for drug importation from Canada. Under this plan, the U.S. will not consider the health, safety, and needs of Canada and will override Canada's own government to try to access their already limited prescription drug supply.[183] The Final Rule then sprinkles in the so-called validity of this decision by referencing back to the Secretary certification language, although it is also completely unsupported as discussed previously.

Canada is experiencing these shortages due to their price controls.[184] The Patented Medicines Prices Review Board (PMPRB) "protects and informs Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive…"[185] The PMPRB keeps prices down by "regulat[ing] the prices that patentees charge wholesalers, hospitals or pharmacies for patented drugs – known as the factory gate price…"[186] According to Forbes, United States "patients have access to nearly 90% of all of the medicines that were launched between 2011 and 2017… In comparison, Canadians have access to less than 50% of these medicines…"[187] As a satirical suggestion, Forbes author Wayne Winegarden goes as far to state "if the U.S. truly wanted to have access to 'Canadian prices' on drugs, then we could simply

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[183] *See generally id.*

[184] Winegarden, *supra* note 181.

[185] *Home,* GOV'T OF CANADA: PATENTED MEDICINE PRICES REVIEW BOARD, *supra* note 157.

[186] *Are You a Consumer?*, GOV'T OF CANADA: PATENTED MEDICINE PRICES REVIEW BOARD, (Mar. 19, 2018), http://pmprb-cepmb.gc.ca/view.asp?ccid=490.

[187] Winegarden, *supra* note 181 (the United States access percentage is "the highest access rate in the world.").

implement the same policies that Canada has implemented… [but] if the U.S. implemented price controls such as exist in Canada and other foreign countries, then we should expect to have significantly diminished access to cutting edge medicines."[188]

The "fear-mongering campaign" of supply issues for Canada is rooted in the fact that "Canada's supply chain is beholden to the drugmakers."[189] A group including wholesalers and distributors, as well as a group including hospitals and pharmacies, "stand to lose from diverting drugs south" to the United States.[190] The main disincentive in diverting drugs south to the United States is being "cut off by the manufacturers."[191] Many pharmacies in Canada have entered into agreements to not "intentionally sell to non-Canadians,"[192] assumedly because of the price differences between different drugs in different countries. On the other hand, Canadian pharmacies must tread lightly because "Canada is a small market for the drugmakers and a finicky one requiring bilingual labels in French and English, and special sizes and colors just for Canada."[193] Due to the finicky hoops manufacturers already need to jump through for Health Canada, Dani Peters, a senior adviser at the Canadian branch of the Alliance for Safe Online

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[188] *Id.*

[189] Pearson & Jagdev, *Trump's Canada Drug Import Plan Can't Happen Without Big Pharma, supra* note 180.

[190] *Id.*

[191] *Id.* ("It's not an idle threat: in the early 2000s, amid a boom in online and mail-order Canadian pharmacies, GlaxoSmithKline Plc and Pfizer Inc. threatened to cut off supplies to those caught shipping drugs south of the border.").

[192] *Id.*

[193] *Id.*

Pharmacies, states Canada is "not an important market enough and it might just be too risky so [manufacturers] might cut back [on their supply to Canada]."[194]

However, despite Canada's own input, some entities argue that the Canadian drug shortage is a non-factor in importation to the United States. The National Academy for State Health Policy argues "the majority of [Canadian drug] shortages involve generic drugs," and U.S. consumers will have the "greatest potential savings" when importing "high-cost, brand-name prescription drugs."[195] The study that The National Academy for State Health Policy relies on states, "The majority (77 percent) of drug shortages involve generic drugs, *although a significant proportion (23 percent) also affected innovator drugs*."[196] The surveys conducted by pharmacists, physicians and various specialties have also "documented the extent of the drug shortage affecting the majority of practitioners in every province, and find it *present over a wide array of products*."[197] In addition, the difference in percentage could be attributed to "the relative prescription volume of generic and innovator drugs," meaning more people tend to be

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[194] Pearson & Jagdey, *Trump's Canada Drug Import Plan Can't Happen Without Big Pharma, supra* note 180 (Alliance for Safe Online Pharmacies members include pharmacies, distributors, and wholesalers).

[195] Johanna Butler, *Q&A: The Facts About Canadian Drug Shortages*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Feb. 10, 2020), https://nashp.org/qa-will-canadian-drug-shortages-impact-state-importation-programs/; *About NASHP,* NAT'L ACAD. FOR STATE HEALTH POL'Y, https://nashp.org/about/ (last visited Feb. 21, 2021) ("The National Academy for State Health Policy is a nonpartisan forum of policymakers throughout state governments, learning, leading and implementing innovative solutions to health policy challenges.").

[196] Donelle et al., *supra* note 173, at 3 (emphasis added); *See also About NASHP*, *supra* note 195.

[197] Donelle et al., *supra* note 173, at 2 (emphasis added).

prescribed generic drugs so more people will report that there are shortages, as opposed to less innovator, or brand-name, drug prescriptions, so less reports on shortages.[198] Notwithstanding the results of the study being potentially contradictory, the position that the National Academy for State and Health Policy is taking is a problematic one because Canada, including their government and large think tanks, still take issue with the United States importing prescription drugs from their country.[199]

ii. Raised Canadian Drug Prices

The bipartisan issue that the Safe Importation Action Plan attempts to remedy for the United States is high prescription drug prices. As explained earlier, Pathway 2 is a way for pharmaceutical manufacturers to get around their distribution contracts which limit what drugs can be sold in the United States, creating contract legal issues.[200] This relates to an issue that could arise in Canada, as Canadian pharmacies are also under contract with manufacturers to not

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[198] *Id.* at 6–8.

[199] Pearson & Jagdev, *Trump's Canada Drug Import Plan Can't Happen Without Big Pharma, supra* note 180; Winegarden, *supra* 181; Martell, *supra* note 174; *Canadian Pharmacists Association Renews Call for Federal Government to Protect Drug Supply in Light Of U.S. Drug Importation Developments*, *supra* note 176.

[200] *See* U.S. FOOD & DRUG ADMIN., SAFE IMPORTATION ACTION PLAN, *supra* note 51, at 3. In the Final Rule, Pathway 2 has been eliminated, however it is still referenced IN THIS ARTICLE due to the pending litigation (PhRMA et al. v. HHS et al.) and potential Biden Administration measures being taken.

"intentionally sell to non-Canadians."[201] The elements of a contract that are legally enforceable are: "*mutual assent*, expressed by a valid offer and acceptance; adequate consideration; capacity; and legality."[202] The major problem for Canadians is that Canada's hospitals and pharmacies are in these sell-nothing-to-the-south agreements with manufacturers in order to keep prices low in their country.[203] If the agreement is broken, there is nothing stopping manufacturers from either cutting ties with the smaller country completely, or creating a new contract with inflated prices due to the knowledge that drugs will be exported to the United States anyway.[204] According to Jacalyn Duffin,[205] and as discussed above, Canadian hospitals and pharmacies are "resourced to serve the Canadian public" and they are already "scrambling to keep [their] supplies."[206] Duffin goes on to pose the rhetorical question asking who, of the "scrambling" to keep up hospitals and pharmacies, "is going to sell [pharmaceuticals] to [the United States]?"[207] The answer according to Duffin can be assumed to be none.

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[201] Pearson & Jagdev, *Trump's Canada Drug Import Plan Can't Happen Without Big Pharma, supra* note 180.

[202] *Contract Definition,* CORNELL L. SCH. LII, https://www.law.cornell.edu/wex/contract (last visited Mar. 10, 2021) (*emphasis added*).

[203] Pearson & Jagdev, *Trump's Canada Drug Import Plan Can't Happen Without Big Pharma, supra* note 180.

[204] *See id.*

[205] Pearson & Jagdev, *Trump's Plan To Import Medicines Stirs Outrage,* BLOOMBERG LAW (Aug. 1, 2019), https://bnanews.bna.com/pharma-and-life-sciences/trumps-crazy-drug-import-plan-stirs-supply-fears-in-canada
(Jacalyn Duffin is "a medical historian and professor emerita at Queen's University who doesn't receive funding from the pharmaceutical industry.").

[206] *Id.*

[207] *Id.*

CONCLUSION

The Safe Importation Action Plan proposed by President Trump and his administration should not be the final step. It could even be argued to say that this Importation Plan is a smoke and mirrors show for political reasons, rather than an actual effort to do so, since lowering prices is bipartisan and President Trump is campaigning for a second term in office.[208] Obviously, this effort by the Trump Administration did not work as the inauguration of Joe Biden took place January 20, 2021. However, while not on the same page as the Trump administration, the Biden administration is "in the same book" and will

[208] Nicholas Florko, *Trump Administration Unveils Two Proposals to Permit Drug Importation,* SCI. AM. (Dec. 18, 2019), https://www.scientificamerican.com/article/trump-administration-unveils-two-proposals-to-permit-drug-importation1/ ("The move comes as something of a last-ditch effort from the Trump administration, which has either abandoned most of its other big ideas to lower drug prices, or seen them struck down in the courts. It comes, too, as Democratic presidential candidates continue to emphasize promises for even more drastic steps aimed at reining in the pharmaceutical industry."); Press Release, PhRMA, PhRMA Statement on Administrations Importation Plan (Dec. 18, 2019), https://www.phrma.org/Press-Release/PhRMA-Statement-on-Administrations-Importation-Plan ("At a time when there are pragmatic policy solutions being considered to lower costs for seniors at the pharmacy counter and increase competition in the market, it is disappointing the Administration once again put politics over patients. The Administration chose to proceed with an importation scheme that could endanger American lives, could worsen the opioid crisis and has been called unworkable by Canadian officials.")

likely modify from the Safe Importation Plan model. [209] Notwithstanding the pretextual nature of the Canadian importation rule, importation from Canada cannot work if Canada is not on board. The Canadian government and Canadian health care providers seem to be against importation full-stop, which raises the concern of the bite behind the bark of this Final Rule to import and should signal to the Biden Administration that the Trump Safe Importation Action Plan is not a suitable starting point for drafting new plans.[210]

According to the National Academy for State Health Policy, a group in favor of implementation as previously disclosed, even states that there are "questions that need responses" from the Safe Importation Action Plan pathways.[211] The question of red-tape federal government delays in state actions is at the forefront,[212] which relates back to the

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[209] Ian Lopez, *Biden's HHS on 'Different Page' About How to Curb Drug Prices*, BLOOMBERG L. (Jan. 21, 2021), https://news.bloombergtax.com/international-trade/bidens-hhs-on-different-page-about-how-to-curb-drug-prices (quoting Ian Spatz, senior advisor at Manatt Health, healthcare consulting firm).

[210] Letter from Alliance for Safe Online Pharmacies Canada et al. to Minister Petitpas Taylor (July 25, 2019), https://buysaferx.pharmacy/wp-content/uploads/2019/07/Health-Canada-Stakeholder-Letter_Importation.Minister.FINAL072519.pdf; Martell, *supra* note 174; *PhRMA Statement on Administrations Importation Plan*, *supra* note 201 ("Moreover, Canadian officials have said that the policy is unworkable, and they will not risk shortages by diverting their medicine supply to the United States…").

[211] Trish Riley, *Will Trump's Drug Importation Plan Provide a Pathway for State Action?,* NAT'L ACAD. FOR STATE HEALTH POL'Y (Aug. 5, 2019), https://nashp.org/will-trumps-drug-importation-plan-provide-a-pathway-for-state-action/.

[212] *Id.*

cost of implementation as compared to actual savings. The question of what "originally intended for sale in Canada" means,[213] coined as the "poison pill" of the plan, also needs clarification because the language is much more restrictive than that of the initial federal law establishing importation programs.[214] Finally, the issue of safety, which is in jeopardy due to the very nature of importation breaking open the "closed

[213] Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,820 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1, 251) (The Notice of Proposed Rule Making for the Safe Importation Action Plan mentions the phrase "originally intended for sale in Canada" as a fact to include in the proposed plan by importers. This would allow pharmacists, healthcare providers, and patients to use the National Drug Code number for the United States version or the imported Canadian version to track adverse events, quality concerns, medication errors, or field alert reports. This website would be created and maintained by the drug importer, with names and National Drug Code numbers of each drug that it imports.); U.S. FOOD & DRUG ADMIN., SAFE IMPORTATION ACTION PLAN, *supra* note 51, at 2 ("The NPRM would propose that drugs eligible for importation must be drugs authorized for sale in Canada that are versions of FDA-approved prescription drugs.").

[214] Riley, *supra* note 211; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 117 Stat. 2066, 2464 (2003) (codified as amended at 21 U.S.C. § 384) (The original federal law for importation states: "The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.").

system" of prescription drugs in the United States,[215] needs to be addressed more thoroughly than in the Notice of Proposed Rule Making.

The FDA's mission statement references "protecting the public health by ensuring the safety, efficacy, and security of human… drugs," but is also proposing this Safe Importation Action Plan that seriously calls the mission statement into question.[216] This juxtaposition should be looked at and thought over more thoroughly in conjunction with controlling law and precedents that have been set regarding importation. The Final Rule of the Safe Importation Action Plan should be withdrawn by HHS and not used as a guide for the Biden Administration. Even though lowering drug prices is a bipartisan opinion, hasty law-making, like the Safe Importation Action Plan, is not the way this issue should be met.

[215] 21 U.S.C. § 331 (a) (2020); Vermont v. Leavitt, 405 F. Supp. 2d 466, 472 (D. Vt. 2005); Campbell, *supra* note 70; *see generally Policy*, *supra* note 99.
[216] *What We Do*, *supra* note 22.