

# Prescription Drug Importation: A Politically Feasible Solution to an Economically Challenging Problem

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## I. Economic and Political Context of High Drug Prices

Prescription drugs are expensive. In 2019, patients spent \$67 billion out of pocket on prescription drugs at retail pharmacies.<sup>1</sup> About a quarter of U.S. residents report that it is difficult to afford their prescriptions; patients with low-incomes or poor health encounter this difficulty even more frequently.<sup>2</sup> Beyond the financial impact, the patients' health is suffering, as almost 30% of people with prescriptions not taking medication in some way.<sup>3</sup> Private insurers spent almost \$140 billion on prescription drugs in 2017, the cost of which trickles back to patients through higher premiums.<sup>4</sup> In addition to burden on patients, it is a hefty toll on the government; Medicare Part D and Medicaid spent about \$133 billion on prescription drugs in 2017.<sup>5</sup>

Most people in the U.S. are in agreement that action needs to be taken to lower drug prices.<sup>6</sup> This support has been bipartisan and stayed high for decades.<sup>7</sup> Despite the public support, little federal action has been taken,<sup>8</sup> and as of the time this article was written, no clear

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<sup>1</sup> Murray Aitken et al., *Medicine Spending and Affordability in the United States*, IQVIA INSTITUTE FOR HUMAN DATA SCIENCE (Aug. 2020), <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>.

<sup>2</sup> Liz Hamel et al., *Public Opinion on Prescription Drug and Their Prices*, KAISER FAMILY FOUNDATION (June 15, 2021), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>.

<sup>3</sup> *Id.*

<sup>4</sup> Juliette Cubanski et al., *How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?*, KAISER FAMILY FOUNDATION (May 20, 2019), <https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/>.

<sup>5</sup> *Id.*

<sup>6</sup> Hamel, *supra* note 2.

<sup>7</sup> For instance, Democrats and Republicans have both strongly supported the idea of allowing Medicare to negotiate on drug prices and allowing prescription drugs to be reimported from Canada since at least 2006. Drew E. Altman et al., *The Public's Health Care Agenda for the New Congress and Presidential Campaign*, KAISER FAMILY FOUNDATION (Nov. 26, 2006), <https://www.kff.org/health-costs/poll-finding/the-publics-health-care-agenda-for-the/>.

<sup>8</sup> The last large policy change was in 1984, when Congress passed the Hatch-Waxman Act, Pub. L. No. 98-417, which created new pathways for lower priced generic medication to get marketing approval. See Garth Boehm et al., *Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984*, 3(5) ACTA PHARMACEUTICA SINICA B 297 (2013) (describing how these pathways allowed generics to enter the market quickly and at a much lower cost than before). Since then, generic medications have played a large role in helping make medicines more affordable. See, e.g., Ryan Conrad & Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug*

policy has enough support to be enacted.<sup>9</sup> Federal action would be particularly affective at helping to lower drug prices because IP and drug regulatory policies – the primary levers affecting price – are controlled at the federal level.<sup>10</sup> Together, IP and regulatory policies offer various exclusivity protections that allow a drug manufacturer to prevent competing companies from introducing the same product into the U.S., essentially giving a drug manufacturer monopoly control for an average of 12 to 13 years.<sup>11</sup> In response to federal inaction, states have been experimenting with many policies.<sup>12</sup> However, federal preemption continues to inhibit effective state policies from being enacted.<sup>13</sup>

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*Prices*, U.S. FOOD AND DRUG ADMINISTRATION (Dec. 2019),  
<https://www.fda.gov/media/133509/download>.

<sup>9</sup> Perhaps the most prominent policy discussed recently is allowing Medicare to negotiate drug prices. *E.g.*, H.R. 3, 116th Cong. (2019); Kristi Martin, *Allowing Medicare to Negotiate Drug Prices*, COMMONWEALTH FUND (May 5, 2021), <https://www.commonwealthfund.org/publications/explainer/2021/may/allowing-medicare-negotiate-drug-prices>. Although H.R. 3, the most prominent bill, specifies Medicare to negotiate with drug manufacturers, it would also allow private insurance companies to take advantage of these rates. *Id.* However, the political will is lacking even among Democrats to pass this legislation. Alice Miranda Ollstein & Susannah Luthi, *Pelosi Drug Price Plan Threatened by Centrist Defection*, POLITICO (May 11, 2021, 7:15 PM), <https://www.politico.com/news/2021/05/11/pelosi-drug-prices-democrats-487229>.

<sup>10</sup> Drug regulations are primarily governed by the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq., while IP policy is codified in Title 35 of the United States Code. Both sets of law grant originator or brand name medications periods of exclusivity, where patients only have access to that medication (and not other medications with the same active ingredient). This essentially grants monopoly protection for the first approved drug with a given active ingredient, allowing a drug manufacturer to set whatever price it likes for many years. *See, e.g.*, Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316(8) JAMA 858-871 (August 2016), <https://jamanetwork.com/journals/jama/article-abstract/2545691> (explaining how monopoly protection from IP and regulatory law is a primary driver of the high cost of prescription medicines in the U.S.).

<sup>11</sup> David Blumenthal, *It's the Monopolies, Stupid!*, COMMONWEALTH FUND (May 24, 2018), <https://www.commonwealthfund.org/blog/2018/its-monopolies-stupid>. Sometimes the period of exclusivity can be even higher, as some additional FDA designations (like orphan drug status) come with exclusivity extensions. Bo Wang, Jun Liu, & Aaron S. Kesselheim, *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175(4) JAMA INTERNAL MEDICINE 635, 636 (Apr. 2015), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2109854>.

<sup>12</sup> *See, e.g.*, Jaime S. King et al., *Recent Action in Pharmaceuticals*, THE SOURCE ON HEALTHCARE PRICE & COMPETITION, <https://sourceonhealthcare.org/pharmaceuticals/> (last visited July 9, 2021) (providing a database of state drug pricing legislation). Some states have chosen to limit the maximum copays an insurer can charge for certain essential medicines, including insulin. *E.g.*, 215 Ill. Comp. Stat. § 5/356z.41(c). Although this helps reduce how much a person might pay directly for medication, it does not reduce the amount of money spent on prescription drugs in the whole system (i.e. the insurer is still paying the same amount), and so the patient might face increased costs in other ways (for example, higher premiums). Other states are trying to ensure that drug manufacturer discounts go directly to the consumer and not to other entities in the distribution chain except for patients. *E.g.*, Ark. Code. § 4-86-111(b)(1). However, this again does not limit how much a drug manufacturer can charge for its products and so does not necessarily reduce overall system spending on pharmaceuticals.

<sup>13</sup> In addition to federal IP and regulatory law blocking state policies, the Dormant Commerce Clause has proved to be a large barrier as well. This is because the distribution of prescription drugs from drug manufacturer to patients is highly complex and takes place across states. *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, KAISER FAMILY FOUNDATION (March 2005), <https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>. For example, Maryland attempted to bar “excessively high”

Despite the political difficulties in changing federal law and the legal limitations on state action, one policy has emerged as both politically possible and potentially effective, which is importing prescription drugs from Canada. It is widely recognized that the U.S. has the highest prescription drug prices in the world;<sup>14</sup> in many other countries like Canada, medicines can be purchased at a tenth of the price.<sup>15</sup> This is usually because other countries take a more aggressive policy position to regulate the price of medicines.<sup>16</sup> Canada has a prescription drug price review board which analyzes drug prices and prohibits egregious price hikes.<sup>17</sup> Given that many of the same medications are sold in Canada (and other countries) as the U.S., but at much lower prices, one policy idea has been to import (or in some cases, reimpose), prescription drugs from abroad. Often, discussions of importing prescription drugs explicitly or solely mention importing from Canada.<sup>18</sup>

A prescription drug importation scheme is a potent policy because it has both the political will to be implemented and the potential to be effective. Unlike other policy ideas like allowing Medicare to negotiate drug prices or changing exclusivity time periods granted by the FDA, federal law does not need to be changed to implement a drug importation policy.<sup>19</sup> In 2003, Congress passed the Medicare Modernization Act of 2003, which gave the Secretary of Health and Human Services the authority to promulgate regulations allowing prescription drug importation.<sup>20</sup> Although several administrations declined to take advantage of this power, in 2020 Secretary Alexander Azar did promulgate rules to allow and govern the importation process. Although the pharmaceutical lobby has since filed suit against HHS over these rules, the Biden administration has notably decided to continue to defend the drug importation

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priced drugs from being sold, but the law was struck down in violation of the dormant commerce clause. *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018).

<sup>14</sup> Dana Sarank et. al, *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?*, COMMONWEALTH FUND (Oct. 5, 2017), <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct-paying-prescription-drugs-around-world-why-us-outlier>.

<sup>15</sup> For instance, in 2018, the price of insulin in Canada was \$12, while in the U.S. the price was \$98. Doug Irving, *The Astronomical Price of Insulin Hurts American Families*, RAND Corporation (Jan. 6, 2021), <https://www.rand.org/blog/rand-review/2021/01/the-astronomical-price-of-insulin-hurts-american-families.html>.

<sup>16</sup> E.g., David Gross et. al, *International Pharmaceutical Spending Controls: France, Germany, Sweden, and the United Kingdom*, 15(3) *Health Care Fin. Rev.* 127 (1994), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193451/>.

<sup>17</sup> For more information on Canada's process to oversee drug pricing, see *Compendium of Policies, Guidelines and Procedures*, Canadian Patented Medicine Prices Review Board, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492&lang=en> (last updated Feb. 2017).

<sup>18</sup> It is not immediately obvious why Canada has become policymakers' go-to importation country. Part of the reason may be political; Americans have been able to easily cross the border and fill individual prescriptions for a long time. Over time, this has likely made Canada more well-known for its lower drug prices than other countries, and so it easier for politicians to refer to.

<sup>19</sup> For example, Medicare has a statutory restriction barring the Secretary of Health and Human Services from interfering with negotiating over drug prices. 42 U.S.C. § 1395w-111(i). This would need to be legislatively changed to implement the policy allowing Medicare to negotiation for drug prices.

<sup>20</sup> Medicare Modernization Act of 2003, Pub. L. 108-173 (2003).

regulations.<sup>21</sup> Under the new HHS regulations, states play an important role in the importation process.<sup>22</sup> Excitingly, both Democrat and Republican-led states have begun passing laws to create importation programs.<sup>23</sup> Should prescription drugs be imported into the U.S., patients will have access to much cheaper medication.

## II. Overview of the Current Drug Importation Regulations

As a general rule in the U.S., prescription drug importation is only allowed when a drug manufacturer is importing its own product into the country.<sup>24</sup> This is true regardless of whether the prescription drug was originally manufactured outside of the U.S., or the prescription drug was made in the U.S., shipped outside the country, and now being imported.<sup>25</sup> Although limited to drug manufacturers, this exception allows huge quantities of prescription drugs to enter the U.S.<sup>26</sup>

One unofficial exception to this rule is the personal importation exception; the FDA has used its discretion to allow individuals traveling to Canada to bring back prescription drugs. After all, by buying a medicine directly at a regulated pharmacy, the risk is eliminated that the medicine might be tampered with in transit,<sup>27</sup> and thus making some importation safety concerns moot. Congress explicitly gave the FDA discretion to allow personal importation of this kind in 2003, under the Medicare Modernization Act of 2003.<sup>28</sup> Stories have flourished of

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<sup>21</sup> Matt Dixon & Sarah Owerhole, *Biden Administration Sides with Florida and Colorado Drug Imports*, POLITICO (May 29, 2021), <https://www.politico.com/states/florida/story/2021/05/28/biden-administration-sides-with-florida-on-canadian-drug-imports-1384579>.

<sup>22</sup> *Infra* Part III.

<sup>23</sup> For example, Florida and Colorado have both passed importation policies. Dixon, *supra* note 21. This stands in sharp contrast to more politically polarized policies, like Medicaid expansion under the ACA, which Republican-led states have resisted adopting. *Status of State Medicaid Expansion Decisions: Interactive Map*, KFF (Feb. 24, 2022), <https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/>.

<sup>24</sup> 21 USC § 381(d)(1)(A); 21 USC § 381(d)(1)(B).

<sup>25</sup> The latter is known as being reimported. *Id.*

<sup>26</sup> *China Is the Top Source of U.S. Pharmaceutical Imports, with India and Mexico Also Major Sources*, PUBLIC CITIZEN (April 7, 2020), <https://www.citizen.org/article/china-is-the-top-source-of-us-pharmaceutical-imports/>.

<sup>27</sup> Some commentators worry that if patients order drugs through an online pharmacy, or the medicines were delivered via mail, that a patient might not receive what they expect. Jim Greenwood, *Importing Drugs from Other Countries Undermines Safety*, STAT NEWS (July 14, 2017), <https://www.statnews.com/2017/07/14/drug-importation-safety/>.

<sup>28</sup> 21 USC § 384(j)(1) (“Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should...exercise discretion to permit individuals to make such importations in circumstances in which...the importation is clearly for personal use; and...the prescription drug or device imported does not appear to present an unreasonable risk to the individual.”); The FDA has since published guidelines which reiterate this discretion. “FDA personnel may allow entry of shipments when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to

patients traveling from the U.S. to Canada and bringing back cheaper medicine.<sup>29</sup> Although the FDA does not give individuals a blanket license to import prescription drugs without restraint, there do not seem to be many cases of the FDA preventing personal importation of this sort.<sup>30</sup>

The problem is that allowing this style of small-scale personal importation is not an effective policy solution. To start with, it relies on patients being able to travel into Canada to purchase and bring back medication. This can be feasible for residents of states like Vermont or Maine, which border Canada, but is much less feasible for residents of non-border states like Florida, which account for hundreds of millions of people.<sup>31</sup> Even for U.S. residents who are close to a Canadian pharmacy, the U.S.-Canadian border might be closed, as has been the case with Covid-19.<sup>32</sup> When the border closure is not a barrier, the time and expense of the trip could be a barrier to many patients who cannot afford to spend many hours on a trip to Canada every couple of months.<sup>33</sup> Lastly, U.S. insurance does not help cover the cost of prescription drugs purchased at Canadian pharmacies, as those pharmacies would be out-of-network. Although medications in Canada are generally listed at a lower price than they are in the U.S.,<sup>34</sup> a patient might be able to access some medications at a lower cost in the U.S. than in Canada with insurance. Taken together, these barriers minimize the potential savings through personal drug importation as fewer patients are realistically able to take advantage of lower Canadian prices.

Thus, to make drug importation effective at scale, HHS has promulgated rules to create a system of prescription drug importation from Canada, carving out an exception to these rules.<sup>35</sup> There are three primary entities, as defined by the HHS rules, in this importation

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individuals to bring in such shipments.” *Regulatory Procedures Manual Chapter 9: Import Operations and Actions*, U.S. FOOD AND DRUG ADMINISTRATION (April 2022), <https://www.fda.gov/media/71776/download>.

<sup>29</sup> Emily Rauhala, *As Price of Insulin Soars Americans Caravan to Canada for Lifesaving Medicine*, WASHINGTON POST (July 31, 2019), [https://www.washingtonpost.com/world/the\\_americas/as-price-of-insulin-soars-americans-caravan-to-canada-for-lifesaving-medicine/2019/06/14/0a272fb6-8217-11e9-9a67-a687ca99fb3d\\_story.html](https://www.washingtonpost.com/world/the_americas/as-price-of-insulin-soars-americans-caravan-to-canada-for-lifesaving-medicine/2019/06/14/0a272fb6-8217-11e9-9a67-a687ca99fb3d_story.html); Nicholas Florko, *See One Woman’s Complicated, Costly Journey to a Canadian Strip Mall Pharmacy – All for Cheaper Insulin*, STAT NEWS (March 4, 2020), <https://www.statnews.com/2020/03/04/photo-essay-journey-to-canada-for-insulin/>.

<sup>30</sup> *Personal Importation*, U.S. FOOD & DRUG ADMINISTRATION (Nov. 10, 2020), <https://www.fda.gov/industry/import-basics/personal-importation#whatis>.

<sup>31</sup> Florida alone has over 18 million residents, to say nothing of the millions of people who live in other states which don’t border Canada. *State Population Totals and Components of Change: 2010-2019*, U.S. CENSUS BUREAU, <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html> (last updated November 4, 2021).

<sup>32</sup> Covid-19: Current Border Measures and Requirements, Government of Canada, <https://www.cbsa-asfc.gc.ca/services/covid/menu-eng.html> (last updated April 1, 2022); Sandra MacGregor, *Trudeau Extends Canada-U.S. Border Closure Yet Again, Until July 21*, FORBES (July 19, 2021), <https://www.forbes.com/sites/sandramacgregor/2021/06/19/trudeau-extends-canada-us-border-closure-yet-again-until-july-21/?sh=31e8151a3eaa>.

<sup>33</sup> FDA guidance suggests that no more than a 3-month supply of a medication could be permitted to be personally imported. *Personal Importation*, U.S. FOOD & DRUG ADMINISTRATION (Nov. 10, 2020), <https://www.fda.gov/industry/import-basics/personal-importation#whatis>. This means patients seeking cheaper medicines in Canada could need to travel 4 times every year to get their medications.

<sup>34</sup> Irving, *supra* note 15.

<sup>35</sup> 85 Fed. Reg. 62126 (Oct. 1, 2020) (codified at 21 C.F.R. pt. 251).

system: the Section 804 Importation Program Sponsors (SIP sponsors), foreign sellers, and importers.<sup>36</sup> SIP sponsors are responsible for providing regulation and oversight to the an importation program; a sponsor must be a state or Indian tribe.<sup>37</sup> Foreign sellers are Canadian manufacturers, distributors, or other entities that have a Drug Establishment License.<sup>38</sup> Lastly, importers are U.S. wholesalers or pharmacists.<sup>39</sup>

At a high-level, the importation programs are very simple: importers purchase eligible prescription drugs<sup>40</sup> from foreign sellers, with SIP sponsors in charge of overseeing and implementing safety precautions.<sup>41</sup> There are many restrictions placed on these programs, some of which are for safety reasons.<sup>42</sup> For example, importation proposals may only designate one foreign seller and one importer to start.<sup>43</sup> However, additional foreign sellers and importers may be incorporated into the importation program later on.<sup>44</sup> Additionally, the importers are required to test a sampling of the imported prescription drugs to ensure the drug is what it is supposed to be.<sup>45</sup>

### III. Drug Importation (In)Action

As of April 2022, no state importation plan has been approved by the FDA, even though five states have submitted plans over the past two years.<sup>46</sup> However, significant logistical work has been accomplished in the meantime. For instance, Florida has contracted with a wholesaler

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<sup>36</sup> 21 C.F.R. § 251.2 (2020).

<sup>37</sup> 21 C.F.R. § 251.2 (2020). Two years after the start of any importation program under these rules, if the Secretary determines that programs without a state or Indian tribe sponsor can assure safety, the FDA will be able to approve programs without a government sponsor. *Id.*

<sup>38</sup> 21 C.F.R. § 251.2 (2020). Under Canadian law, a Drug Establishment License is required to participate in certain activities, including manufacturing, importing, distributing, wholesaling, packaging, and testing prescription drugs. Food and Drug Regulations (C.R.C. c. 870) C.01A.004 (1). [https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,\\_c.\\_870/page-112.html#docCont](https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-112.html#docCont)

<sup>39</sup> 21 C.F.R. § 251.2 (2020).

<sup>40</sup> Eligible prescription drugs are those which are approved for sale in both the U.S. and Canada. 21 C.F.R. § 251.2 (2020). Some exclusions apply to this, including medicines which are not typically meant to be taken at home, like those taken intravenously. *Id.* Interestingly, all biologics are ineligible to be imported. *Id.*

<sup>41</sup> For instance, SIP sponsors must ensure that distribution chain is maintains the safety of the prescription drugs, 21 C.F.R. § 251.14 (2020), and must submit reports to the FDA regarding importation data. 21 C.F.R. § 251.19 (2020).

<sup>42</sup> *E.g.*, biologics cannot be imported, *infra* note 55, and program sponsors must submit periodic reports to the FDA, 21 C.F.R. § 251.19 (2020).

<sup>43</sup> 21 C.F.R. § 251.3(b) (2020).

<sup>44</sup> 21 C.F.R. § 251.3(b) (2020); 21 C.F.R. § 251.8 (2020).

<sup>45</sup> 21 C.F.R. § 251.17(d) (2020).

<sup>46</sup> These states are Florida, Colorado, Vermont, Maine, and New Mexico. Adriel Bettelheim, FDA MULLS DRUG IMPORTATION WITH STATES, AXIOS (April 12, 2022), [https://www.axios.com/fda-mulls-drug-importation-with-states-b2f50bea-00b6-47fd-8f6d-4ccc408ac8a7.html?utm\\_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm\\_medium=email&\\_hsmi=209771218&\\_hsenc=p2ANqtz-8VVGXGWNXXRvay1LXUYBZEYcgzmlr8kUbHSv7Vfoi1YR\\_mKmcuNGLsJCCIC-r9nWPWJjk9MLxhX-ebwJQQRJVaF0bI\\_Pw&utm\\_content=209771218&utm\\_source=hs\\_email](https://www.axios.com/fda-mulls-drug-importation-with-states-b2f50bea-00b6-47fd-8f6d-4ccc408ac8a7.html?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=209771218&_hsenc=p2ANqtz-8VVGXGWNXXRvay1LXUYBZEYcgzmlr8kUbHSv7Vfoi1YR_mKmcuNGLsJCCIC-r9nWPWJjk9MLxhX-ebwJQQRJVaF0bI_Pw&utm_content=209771218&utm_source=hs_email).

to provide importation services.<sup>47</sup> One possible reason for delay in approval is that the Biden administration may be wavering on how much political support to give this policy. Although the Biden administration has chosen to defend the regulations against PhARMA's lawsuit, the Biden also defended the regulations on the grounds that state importation plans might not be approved in the foreseeable future.<sup>48</sup> This suggests that the Biden administration may be concerned about fully supporting this policy until many of the political and policy hurdles standing in the way of making drug importation effective can be cleared.

The most prominent critique of the drug importation policy is that a lack of supply of prescription drugs in Canada might make such a policy ineffective. Commentators have said for years that the relatively small volume of prescription drugs in Canada compared to the volume that would be required to fulfill U.S. demand.<sup>49</sup> And now, Canada instated an export ban on prescription drugs to the U.S., fearing that importation would cause shortages.<sup>50</sup> Canada health authorities report that on any given day, 5-15% of prescription drugs approved in Canada are experiencing a shortage.<sup>51</sup> As of March 2022, Canada has not given any indication that it will lift this ban.

That said, this concern may be overexaggerated. Some states, such as Florida, will only import drugs that are in surplus or in excess of what's normally made, which would prevent a shortage from occurring.<sup>52</sup> Additionally, it remains unclear which prescription drugs in Canada are actually experiencing shortages. These drugs may not be drugs that U.S. states want to import, either because they are not frequently prescribed or because the price difference is insignificant for a particular prescription drug.

#### IV. Current Problems with the Regulations

Although the promulgated regulations highlight the progress made in implemented a drug importation policy, the current regulations have some serious drawbacks. The first problem with the regulations is the categories of prescription drugs not eligible to be

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<sup>47</sup> Aaron Kunkler, *An Update on the Florida Prescription Drug Importation Plans*, STATE OF REFORM (Nov. 10, 2022), <https://stateofreform.com/news/florida/2021/11/an-update-on-the-florida-prescription-drug-importation-plan/>.

<sup>48</sup> Reply in Support of Defendants' Motion to Dismiss the First Amended Complaint, *Pharmaceutical Research Manufacturers of America v. U.S. Department of Health and Human Services*, No. 1:20-cv-03402-TJK (D.C. Cir. Oct. 28, 2021).

<sup>49</sup> *Health Care and the 2004 Elections: Prescription Drug Costs*, KFF (Sept. 2, 2004), <https://www.kff.org/health-costs/issue-brief/health-care-and-the-2004-elections-prescription/>.

<sup>50</sup> Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply), Government of Canada (Nov. 27, 2020), <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html>.

<sup>51</sup> For a complete list of which drugs are experiencing a shortage, see Drug Shortages Canada, Government of Canada, <https://www.drugshortagescanada.ca/> (last accessed March 2, 2022).

<sup>52</sup> Kunkler, *supra* note 47.

imported.<sup>53</sup> Notably, there are categories currently excluded that should be included: biologics and intravenously infused drugs. Biologics are medicines manufactured through a biologic process, and tend to be much more expensive than traditional small-molecule and chemically manufactured drugs.<sup>54</sup> Many novel and cutting edge medicines are biologics, including expensive and effective cancer treatments, as well as insulin medications, which are required by millions of Americans. However, biologics are not considered eligible for importation under the current regulations.<sup>55</sup> Similarly, intravenously injected drugs are not considered eligible.<sup>56</sup> Intravenously injected drugs can be either small-molecule or biologic in nature; many expensive cancer drugs are intravenously injected, along with other expensive medicines. By categorically excluding these categories of medicines from the importation program, millions of Americans are unable to access more affordably priced doses of their medications.

Second, the regulations only allow importation from Canada.<sup>57</sup> As previously discussed, one of the most prevalent critiques of this policy is that Canada, given its much smaller population relative to the U.S., would be unlikely to practically meet the U.S. demand for prescription medication. Strictly limiting importations to be from Canada plays into the narrative that drugs imported from abroad are dangerous. Although the FDA notes that “medicines from outside the legitimate U.S. drug supply chain do not have the same assurance of safety, effectiveness and quality as drugs subject to FDA oversight,”<sup>58</sup> this assertion is overblown. First, it’s important to note that there are at least some safe and effective prescription drugs outside the U.S.. Many countries, including Canada, have laws carefully regulating the production, marketing approval, and distribution of prescription drugs.<sup>59</sup> Similar to the U.S., Canada also imports many prescription drugs from abroad, and similarly conducts inspections and regulates foreign manufacturing plants to ensure the safety of prescription drugs.<sup>60</sup> Although there are plenty of legitimate safety concerns related to drug importation, such as the prescription drug being misbranded or not containing the correct active ingredient,

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<sup>53</sup> 21 C.F.R. § 251.2(2) (2020).

<sup>54</sup> *What Are “Biologics” Questions and Answers*, U.S. FOOD & DRUG ADMINISTRATION (Feb. 6, 2018), <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers>.

<sup>55</sup> 21 C.F.R. § 251.2(2)(ii) (2020).

<sup>56</sup> 21 C.F.R. § 251.2(2)(iii) (2020).

<sup>57</sup> This is because foreign sellers in the importation programs must be established within Canada. *Id.*

<sup>58</sup> <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports>

<sup>59</sup> For instance, in Canada, the Food and Drugs Act governs the approval, manufacturing, and distribution of prescription drugs. Further, it gives the government power to promulgate regulations, including relating to “the sale or the conditions of sale of any food, drug, cosmetic or device,” R.S.C. 1985, c. F-27, s. 30(1)(b)(iii), as well as “the method of manufacture, preparation, preserving, packing, storing and testing of any food, drug, cosmetic or device in the interest of, or for the prevention of injury to, the health of the purchaser or consumer.” R.S.C. 1985, c. F-27, s. 30(1)(e). The regulations accompanying the Act are found in Can. Reg. 870.

<sup>60</sup> Alan Cassels, *Most of Our Prescription Drugs Are Manufactured Overseas – But Are They Safe?*, 184(14) CANADIAN MEDICAL ASSOCIATION JOURNAL 1648 (Oct. 2, 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3470633/>.



these arguments do not apply to well-regulated countries like France, Germany, and Japan. Second, many prescription drugs, such as Eli Lilly's insulin products,<sup>61</sup> are manufactured in the U.S. and exported to places like Canada;<sup>62</sup> re-importing these medicines poses little threat since they have been consistently regulated by the FDA and Canada Health.

## V. Opportunities for Improvement

The first area for improvement with this policy is to expand the list of available countries to import from beyond Canada. This would help the United States, as the country would have access to a larger number of prescription drugs to import, and thus would be better able to meet the U.S. demand. This would also help Canada, as the export burden could be shared across many countries, lessening the burden felt by any one particular country. Unfortunately, it is unlikely that HHS could administratively expand the list of importing countries. The Secretary of HHS is given the power to promulgate rules about importing prescription drugs "from Canada", but no other countries are explicitly mentioned in the enabling statute.<sup>63</sup> Given this, it's unlikely that HHS has currently has the power to amend the regulations to include additional countries.

Relatedly, many very expensive and widely used prescription drugs are not eligible for importation. Biologics, which include widely used insulin medications and very expensive specialty cancer drugs, are excluded from the list of eligible imports.<sup>64</sup> This category of drugs accounts for a large portion of prescription drug spending in the U.S.; insulin alone is essential for about 8.3 million Americans.<sup>65</sup> Although biologics only accounted for 2% of the number of prescriptions in the U.S. in 2017, biologics represent 37% of all spending on prescription drugs.<sup>66</sup> Changing the statute to allow the importation of biologics could help provide significant cost savings within the U.S., and significant financial relief to patients.

Lastly, there is an opportunity to incentivize Canadian partnership with drug importation. One idea is that Canada collect an export tax on prescription drugs imported by the U.S.. Given that prescription drugs tend to be about 218% more expensive in the U.S. than in Canada,<sup>67</sup> a nominal tax of 5-10% could mean significant revenue (with volume) for Canada,

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<sup>61</sup> D. Beran et. al, *A Perspective on Global Access to Insulin: A Descriptive Study of the Market, Trade Flows and Prices*, DIABETIC MEDICINE (March 15, 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6593686/pdf/DME-36-726.pdf>.

<sup>62</sup> *Id.*

<sup>63</sup> 21 U.S.C. § 384(b).

<sup>64</sup> 21 U.S.C. § 384(a)(3)(B).

<sup>65</sup> Tara O'Neill Hayes, *Understanding the Insulin Market*, AMERICAN ACTION FORUM (March 3, 2020), <https://www.americanactionforum.org/research/understanding-the-insulin-market/>.

<sup>66</sup> Andrew Mulcahy, *Biosimilar Drugs Could Generate \$38.4 Billion in Savings over Five Years*, RAND CORPORATION (Jan. 10, 2022), <https://www.rand.org/news/press/2022/01/10.html>.

<sup>67</sup> Andrew Mulcahy et. al, *International Prescription Drug Price Comparisons*, RAND CORPORATION (2021) [https://www.rand.org/pubs/research\\_reports/RR2956.html](https://www.rand.org/pubs/research_reports/RR2956.html).

while still preserving significant cost savings for the U.S.. The exact financial arrangement could take many forms in light of international free trade agreements and other treaties to lower taxes on global trade. Whatever the form, this economic incentive could help make this arrangement mutually beneficial for both countries.

As previously discussed, there is great concern in Canada that a U.S. drug importation plan could exacerbate prescription drug shortages in the country. This concern has been so great that Canada has placed a ban on exporting prescription drugs to the U.S..<sup>68</sup> Accordingly, building a partnership with Canada to ensure a robust supply of prescription drugs remains for Canada will be helpful to make this policy effective.

Any new prescription drug shortages in Canada would primarily be the fault of drug manufacturers, not state importation plans. After all, as businesses, drug manufacturers should be responding to supply and demand to increase output. Moreover, any net increase in manufacturing output should be nominal, since the global need for prescription drugs would not be increasing; only where the drugs are purchased would be changing. Thus, a new shortage in Canada would be caused by manufacturers not participating in the free market.

One course of action that drug manufacturers could take is to limit the sales of their prescription drugs within Canada. On the far end of the extreme, a drug manufacturer could stop selling their drug entirely in Canada as a way to boycott the importation programs; this has happened before in other countries when unfavorable pharmaceutical policies were implemented.<sup>69</sup> A less drastic measure would be to place a cap on sales within Canada, such that only enough units are sold to supply the people in Canada.

Another possible outcome would be for manufacturers to limit sales to participating wholesalers and importers. As previously mentioned, under U.S. law, a state must have an agreement in place with a wholesaler before HHS will approve the state's drug importation program.<sup>70</sup> There are many wholesalers currently licensed in Canada; it's unlikely that they would all be engaged in a state drug importation program. One option available to drug manufacturers is to stop selling to any wholesalers who have an agreement to partake in a state drug importation program.

To solve the problem of drug manufacturers refusing to increase sales to wholesalers who wish to import drugs into the U.S., the FTC should recognize the anticompetitive effects of drug manufacturers refusing to increase sales to wholesalers and use its existing authority under the Federal Trade Commission Act to remedy this problem. The FTC has broad authority

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<sup>68</sup> *Supra* note 50.

<sup>69</sup> Amy Kazmin & Andrew Jack, *Abbott Pulls New HIV Drug in Thailand*, FINANCIAL TIMES (March 13, 2007), <https://www.ft.com/content/5a5a88c2-d1a6-11db-b921-000b5df10621>.

<sup>70</sup> *Supra* notes 41-45 and accompanying text.

to prevent “unfair methods of competition” which it has historically used to rectify traditional antitrust violations, and broader anticompetitive behavior.<sup>71</sup>

On its face, refusal to sell, or increase sales, of insulin is anticompetitive because it artificially preserves the high price of insulin in the U.S.. Should a lower-priced insulin product enter the U.S. market, competition would require sellers to make a choice: either lower the cost of their products, or lose market-share. The big three drug manufacturers, as for-profit entities, will aim to maximize profits and so want to avoid such a choice by preventing the lower-priced insulin from entering the U.S. market altogether. Of course, this not only harms competition, but consumers as well. Although the full analysis of this anticompetitive nature and the FTC’s powers to intervene are beyond the scope of this paper, it’s worth noting that the FTC has recently recognized the importance of exercising a larger scope of authority granted by the FTC Act, which could help include new applications of existing authority to situations like this.<sup>72</sup>

## VI. Conclusion

The excessive price of prescription drugs in the U.S. demands new action. Although far from a silver bullet, the importing prescription drugs from Canada has the political will behind it to implement it, and with the right implementation, could help drive down prices. That said, several changes to the current U.S. policy would make the state importation plans much more effective. Expanding the eligible countries to import from and the prescription drugs eligible to be imported would significantly widen the sustainability and impact of this policy. Relatedly, enhancing the policy to create incentives for Canadian support of this policy could help lift barriers, while U.S. enforcement of existing competition laws could help ensure there is sufficient supply in Canada to import.

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<sup>71</sup> J. Howard Beales, *The FTC’s Use of Unfairness Authority: Its Rise, Fall, and Resurrection*, FEDERAL TRADE COMMISSION (May 20, 2003), <https://www.ftc.gov/news-events/news/speeches/ftcs-use-unfairness-authority-its-rise-fall-resurrection>.

<sup>72</sup> In 2015, the FTC issued a statement on how it would self-limit its enforcement of anticompetitive business activities. Statement of Enforcement Principles Regarding “Unfair Methods of Competition” Under Section 5 of the FTC Act, Federal Trade Commission (August 15, 2015), [https://www.ftc.gov/system/files/documents/public\\_statements/735201/150813section5enforcement.pdf](https://www.ftc.gov/system/files/documents/public_statements/735201/150813section5enforcement.pdf). More recently, the FTC has rescinded this because “the Statement [] doubled down on the Commission’s longstanding failure to investigate and pursue ‘unfair methods of competition.’” *FTC Rescinds 2015 Policy that Limited Enforcement Ability Under the FTC Act*, FEDERAL TRADE COMMISSION (July 1, 2021), <https://www.ftc.gov/news-events/press-releases/2021/07/ftc-rescinds-2015-policy-limited-its-enforcement-ability-under>.