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10 FAQs on Prescription Drug Importation

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The high cost of prescription drugs continues to be a top concern for the public. Policymakers at the federal and state level are pursuing a range of options to lower drug prices for Americans, one of which would allow for the safe importation of prescription drugs from Canada and other countries, based on evidence showing that people often pay more for medications in the U.S. than elsewhere. This proposal is supported by President Trump and many 2020 Democratic presidential candidates, with bipartisan support among the general public (See Figure 1).

Current law allows for the importation of certain drugs from Canada under defined, limited circumstances, and only if the Secretary of the United States Department of Health and Human Services (HHS) certifies that importation poses no threat to the health and safety of the American public. To date, no HHS Secretary has certified the safety of importation. As recently as 2017, four former FDA commissioners signed a joint letter voicing concerns about the ability of HHS to assure the safety of drugs imported from other countries. Nevertheless, many federal and state lawmakers have continued to press for legislation to allow for the importation of prescription drugs from Canada and other countries.[1] Recently, the Trump Administration has proposed two new pathways to allow for the safe importation of drugs from Canada and other countries.

These FAQs provide information about recent efforts to import prescription drugs from abroad. In addition, they provide background on the history of drug importation in the U.S., explain why previous efforts to carry out importation proposals have faced challenges, and describe how current proposals, including recent ones from the Trump Administration, seek to address those concerns.

1. Why is importation of prescription drugs from Canada being considered as a way to lower drug costs in the U.S.?

Many studies have shown that people in the United States often pay more for their prescription drugs than in other developed countries, including Canada. According to one analysis of a subset of single-source brand-name drugs, Canadian drug prices are about 28% of the price in the United States, while another analysis of the 200 top-selling single-source brand-name drugs found Canadian prices are 35% of those in the United States.

Canada's drug prices are generally lower than those in the United States because the Canadian government has various mechanisms to lower the cost of prescription drugs. Since 1987, the Patented Medicine Prices Review Board (PMPRB) has regulated the price of patented (i.e., brand-name) drugs in Canada to ensure that they are not excessive. The PMPRB reviews the prices charged for drugs, and if the Board determines the price of a drug is excessive, it can order a patentee to lower the price of a drug, including requiring a monetary payment for the excess revenue earned from the drug.

2. How does current U.S. law regulate the importation of prescription drugs from other countries?

In order for a drug to be marketed in the United States, it must first receive FDA approval and meet standards set forth in the Food and Drug Cosmetic (FD&C) Act of 1938. Any drug that is "unapproved," meaning it does not meet these standards, is not eligible for importation. Currently, the only type of legally imported drugs are those that are: 1) manufactured in foreign FDA-inspected facilities, the subject of an FDA-approved drug application, intended for use by U.S. consumers, and imported into the U.S. by the drug manufacturer, and 2) those that are U.S.-approved and manufactured in the U.S., sent abroad, then imported back into the U.S. under rare circumstances such as for emergency medical purposes or in the case of product recalls.[2] These importation regulations pertain only to the drug product itself, and are not related to the cost of imported products.

In 2000, Congress enacted the Medicine Equity and Drug Safety (MEDS) Act, which added Section 804 to the FD&C Act, to allow pharmacists and wholesalers to import prescription drugs directly from certain industrialized countries, including Canada, subject to specified limitations and safeguards. The MEDS Act allows such importation, subject to an important requirement: to do so, the HHS Secretary must demonstrate that the program: "poses no additional risk to the public's health and safety," and "results in a significant reduction in the cost of covered products to the American consumer."

The Medicare Modernization Act of 2003 (MMA) amended the Section 804 importation language that was added by the MEDS Act. The MMA specifies that wholesalers and pharmacists can only import prescription drugs from Canada, not other industrialized countries. The MMA also authorizes the Secretary to terminate such importation programs if they do not meet safety standards or result in a significant reduction in costs for consumers. The MMA also requires the HHS Secretary to issue regulations that would grant waivers to individuals to import drugs for personal use under certain circumstances.

Importation of prescription drugs under conditions set forth first by the MEDS Act, and then by the MMA, could allow wholesalers and pharmacists to obtain FDA-approved drugs at lower prices than are available in the U.S. by purchasing them from foreign sellers, and pass these savings on to U.S. consumers.

3. What are the safety concerns related to importation of prescription drugs and why hasn't it been implemented before?

Since 2000, when the MEDS Act first allowed importation subject to certain requirements, HHS Secretaries have been unable to certify an implementation plan, primarily due to safety concerns. According to the HHS taskforce report on drug importation issued in December 2004, the drug distribution network for prescription drugs in the U.S. is a "closed" system that provides the American public with multiple levels of protection against receiving unsafe or poor quality medications. 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.

The report also noted some potential risks and challenges with legalizing importation, including but not limited to: the increasing difficulty of monitoring and ensuring the safety of imported drugs; the additional cost and resources needed for ensuring safety, which may reduce potential savings; the possibility that total savings would be significantly less than international price comparisons suggest; and the likelihood that there would be a reduction in research and development of new drugs. Furthermore, many former HHS Secretaries and FDA commissioners have voiced concerns in recent years about FDA's ability to assure the safety, effectiveness, and quality of imported drugs. According to a 2017 letter to Congress signed by four former FDA commissioners:

> "…Allowing importation of drugs purported to be manufactured overseas in FDA-inspected facilities and drugs purported to be manufactured domestically for export to other countries and reimported from those countries to the United States cannot meet the requirements under the existing closed drug manufacturing and distribution system because the drugs could not be tracked and certified by the manufacturer…Such a program would be very different from importation of consumer products like watches or clothing, where consumers can more easily discern quality and where there are no health consequences of fake products. It could lead to a host of unintended consequences and undesirable effects, including serious harm stemming from the use of adulterated, substandard, or counterfeit drugs. It could also undermine American confidence in what has proven to be a highly successful system for assuring drug safety."

4. What has the Trump Administration proposed regarding importation?

In December 2019, the Administration outlined two pathways for the importation of prescription drugs. The first pathway, which was issued in a Notice of Proposed Rulemaking (NPRM), would authorize states and other non-federal government entities, such as tribal or territorial entities, to implement time-limited importation programs, known as Section 804 Implementation Programs or SIPs, for importation of

prescription drugs from Canada only. States and other entities could submit proposals to the HHS Secretary to manage these SIPs and act as SIP sponsors.

In order for a proposal to be approved by HHS, a SIP sponsor would need to specify: the drugs it seeks to import; the foreign seller in Canada that would purchase the drug directly from its manufacturer; the importer in the U.S. that would buy the drug directly from the foreign seller in Canada; the re-labeler or re-packager of the drug itself that would ensure the drug meets all labeling requirements in the U.S.; the qualifying lab that would conduct testing of the drug for authenticity and degradation; and steps that would be taken by the SIP to ensure the supply chain is secure. SIPs would initially be authorized for 2-year periods with the possibility of 2-year extensions.

Each SIP sponsor would also be subject to post-importation requirements, including providing FDA with data and information on the SIP's cost savings to American consumers. Comments on the proposed rule are being accepted until March 9, 2020.

The second pathway, proposed by the Trump Administration in an FDA draft guidance in December 2019, outlines how manufacturers can import and market FDA-approved drugs in the U.S. that were manufactured abroad and intended to be marketed and authorized for sale in a foreign country. Using this pathway, a manufacturer may be able to obtain an additional National Drug Code (NDC) for drugs imported into the U.S. The rationale, according to the Administration, is that "in recent years, multiple manufacturers have 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 into contracts with other parties in the supply chain. This pathway would highlight an opportunity for manufacturers to use importation to offer lower-cost versions of their drugs." Comments on the draft guidance were due February 21, 2020.

5. Which drugs would be covered under the Administration's proposed importation plan?

Under the first pathway, which would allow states and other entities to facilitate importation of drugs from Canada, only drugs that are currently marketed in the U.S. would be eligible for importation. As under current law, certain types of drugs would be excluded from the definition of a prescription drug eligible for importation including: controlled substances, biological products (including insulin), infused drugs, intravenously injected drugs, and inhaled drugs during surgery. Furthermore, drugs that are subject to risk evaluation and mitigation strategies (REMS), which are high-risk products with serious safety concerns, such as opioids, are not eligible for importation.

Under the second pathway, which would allow manufacturers to import drugs to the U.S. that were manufactured and intended for sale in other countries (not limited to Canada), prescription drugs, including biological products excluded under the first pathway, could be imported and made available to patients. These drugs must also currently be marketed in the U.S. to be eligible.

6. What is the estimated savings from the Administration's importation plan?

The potential cost savings from the first pathway are unknown. In the NPRM itself and in FDA's full preliminary economic analysis of the NPRM, the Administration did not provide an estimate of the expected savings. The preliminary analysis noted that responses by other stakeholders, such as Canadian regulatory agencies and drug manufacturers, could impact the potential benefits of such a program. The analysis also noted that if the Administration's pending proposed rule on international reference pricing, known as the International Pricing Index Model, is finalized first, it has the potential to limit the potential benefits of importation under this pathway, depending on whether drugs eligible under both proposals overlap.

The Administration did not release an estimate of potential savings for importation under the second pathway outlined in the FDA guidance.

7. What are states currently doing regarding importation?

Some states have been actively pursuing legislative action to promote the importation of prescription drugs. Several states, including Florida, Vermont, Colorado, and Maine, have signed into law legislation to establish importation programs for prescription drugs from Canada, and the New Mexico legislature recently passed a bill allowing importation from Canada that is awaiting the governor's signature. In order for any importation plan to go into effect, the HHS Secretary must certify that it meets the safety and cost saving requirements set forth in Section 804 of the FD&C Act. Under each state's respective laws to establish an importation program, they are required to submit a proposal to HHS to demonstrate how its program will meet those safety and cost saving requirements. Thus far, no plan has been certified.

Both Florida and Vermont have taken action to become the first states to implement importation plans. In August 2019, Florida officially submitted its importation proposal to HHS, which was released prior to the Administration's NPRM. Under Florida's importation plan, the program would be overseen by the state's Agency for Health Care Administration through a vendor who would handle the operation of the program and ensure importers are following all state and federal laws relating to importation. Eligible importers would be limited to wholesalers or pharmacists who dispense prescription drugs on behalf of public payers, including Medicaid, the Department of Corrections, and the Department for Children and Families. The state projects savings of over $150 million dollars annually when the program is in full effect.

Vermont submitted its importation proposal to HHS in November 2019, also prior to the release of the Administration's NPRM. Vermont's plan primarily differs from Florida's in that wholesalers would import drugs on behalf of both commercial plans and public payers, rather than just public payers. Both states are awaiting feedback from HHS on their plans. Maine and Colorado are also in the process of developing importation plans for HHS approval. According to their states' respective laws, Maine has until

May 1, 2020 to submit its proposal to HHS, while Colorado has until September 1, 2020. Other states are also considering legislation that would facilitate importation from Canada.

Florida and Vermont's plans were not submitted through the Administration's pathway proposed in the NPRM. In theory, states could move forward with an importation plan if their proposal meets the requirements laid out in Section 804 of the FD&C Act and is certified by the HHS Secretary. However, it is unclear whether HHS will require states to move forward only through the new pathway.

8. Under what circumstances can individuals legally import drugs from other countries, like Canada?

In most circumstances, it is illegal for individuals to import FDA-approved drugs from other countries for personal use. However, based on changes enacted by the MMA, personal importation of prescription drugs that have not been approved by the FDA for use in the U.S. is permitted on a case-by-case basis. Under this statutory authority, FDA has put out guidance that lays out certain circumstances where importation of non-FDA approved drugs for personal use might be allowed. For example, personal importation is generally allowed if the treatment is for a serious condition, there is no effective treatment available in the U.S., and there is no commercialization of the drug for U.S. residents. Typically, only a three-month supply is allowed, and individuals most confirm in writing that the drug is for personal use and provide information about the physician responsible for their treatment.

There appears to be little enforcement by the FDA of the ban against importing FDA-approved drugs for personal use. Even if the personal importation of a drug is technically illegal, current law directs the FDA to exercise discretion in permitting personal importation of drugs when the product is "clearly for personal use, and does not appear to present an unreasonable risk to the user," which is reinforced in FDA guidelines.

9. If there were concerns about the safety of importation before, why are the Administration and states proposing it now?

According to the Administration's proposed rule, FDA in the past has not been asked to evaluate importation in the way HHS is now proposing – solely through SIP programs managed by states and tribal and territorial entities, as described in the proposed rule. Furthermore, the Administration believes that the requirements laid out in the NPRM could enable states and non-governmental entities to facilitate importation of drugs in a way that poses no additional risk to public health. Some of these requirements include: criteria for which drugs are eligible for importation, traceability of drugs in the supply chain, the relabeling of eligible drugs with U.S. labeling, and testing eligible drugs for authenticity and degradation. As required by law, these programs must also demonstrate significant cost reductions to the American consumer.

Furthermore, the Trump Administration as well as Florida and Vermont in their proposals, have noted that since the early 2000s, additional regulations have been put in place that better safeguard the drug supply chain. They say that these regulations, many of which were enacted in the Drug Supply Chain Security Act (DSCSA) in 2013, strengthen their ability to protect the public's health under an importation program. That legislation also outlines steps to build an electronic, interoperable system to identify, trace, and verify drugs in the supply chain, which should be established by 2023.

10. How do stakeholders and the public view these importation proposals?

The Canadian government as well as other stakeholders have expressed reservations about the feasibility of the Trump Administration's proposals under its importation plan. According to Canadian government officials, Canada would be unable to meet the needs of the U.S. market without impacting access to medications for Canadians. The Canadian prescription drug market is small, with Canada consuming only about 2 percent of the global drug supply compared to America's 44 percent. Canada also relies on imported drugs and cannot readily expand its supply to meet the U.S. demand. There is also the risk of creating drug shortages in Canada, which could potentially lead to higher prices for Canadian consumers if the government were to relax price controls.

Industry groups such as PhRMA and BIO say that importation could expose Americans to substandard and counterfeit drugs, and that the additional resources required to ensure the safety of drugs from abroad could outweigh any potential savings for patients. The American Pharmacists Association (APhA) has also expressed concern about the Administration's recent proposals, citing potential risks to patient safety without any clear evidence of cost savings. The Partnership for Safe Medicines, which includes these industry groups as well as others, also has come out against the Administration's plan. The National Consumers League, while not coming out firmly against the plan, stated that it was worried importation could open the door for counterfeit medications.

Other stakeholders, however, have come out generally in favor of the Administration's importation plan. AARP stated that it welcomes the Administration's proposed rule, saying that, "the ability to import lower-priced medicines would help states manage their ever-tightening budgets, save taxpayers' money, and lower drug costs for its citizens." Patients for Affordable Drugs Now said it was pleased the Administration had opened the door for importation, but noted that it is not a solution for lowering drug prices for the majority of Americans. While the National Governor's Association has expressed support for importation in the past, they have not specifically released a statement on the Trump Administration's proposed plan.

The American public is also generally in favor of importation. According to recent KFF polling from October 2019, 78% of the public favors allowing Americans to buy prescription drugs imported from licensed Canadian pharmacies. This proposal has broad support across party lines – 75% of Democrats, 82% of Independents, and 75% of Republicans favor drug importation from Canada (Figure 1). However, it not clear to what extent public opinion would shift if presented with arguments for or against importation.

Figure 1

Majority of the Public Favors Allowing Americans to Buy Prescription Drugs Imported from Canada

Percent who favor allowing Americans to buy prescription drugs imported from licensed Canadian pharmacies:

SOURCE: KFF Health Tracking Poll (conducted October 3-8, 2019). See topline for full question wording and response options.

The American public also supports virtually all proposals to lower prescription drug costs, including the government negotiating with drug companies, and believes lowering prescription drug prices should be a top legislative priority for Congress.

Endnotes

[1] Some examples of these proposals introduced in the 116th Congress are H.R.4 47/ S. 97, "Affordable and Safe Prescription Drug Importation Act," sponsored by the late Representative Elijah Cummings (D-MD) in the House and Senator Bernie Sanders (I-VT) in the Senate, available at: https://www.congress.gov/116/bills/hr447/BILLS-116hr447ih.pdf; https://www.congress.gov/116/bills/s97/BILLS-116s97is.pdf; H. R. 478/ S. 61, "Safe and Affordable Drugs from Canada Act of 2019," sponsored by Representative Chellie Pingree (D-ME) and Senator Chuck Grassley (R-IA) available at: https://www.congress.gov/116/bills/hr478/BILLS-116hr478ih.pdf; https://www.congress.gov/116/bills/s61/BILLS-116s61is.pdf

[2] A drug manufactured in the U.S., then exported abroad, can be imported back into the U.S. under two circumstances: 1) by the HHS Secretary for emergency medical purposes; and 2) by the original manufacturer of the drug. A manufacturer may choose to do this in a situation where a drug has been recalled or damaged or for other standard inventory control practices. See https://www.finance.senate.gov/imo/media/doc/srpt100-303.pdf