



## Insight

# The Challenges Facing the Trump Administration's Drug Importation Plan

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### Executive Summary

- The Trump Administration recently finalized a rule to allow for the importation of certain prescription drugs from Canada.
- There are myriad reasons this policy is unlikely to result in any significant increase in access to more affordable medications, including Canada's limited supply, drug manufacturers' ability to prohibit exportation to the United States, and the fact that some of the most expensive drugs are excluded from the importation policy.
- Policymakers could better serve the American people by working on proposals that have a better chance of producing meaningful results.

### Background

As part of its efforts to reduce drug costs, the Trump Administration has been working on a proposal to allow for the importation of drugs from foreign countries, since drugs are typically much cheaper abroad than they are in the United States. This effort reached a new milestone last week when the Food and Drug Administration (FDA) issued a long-awaited final rule, along with accompanying guidance and two requests for proposal (RFPs) on how to broaden the scope of the rule. The rule allows for the importation of certain prescription drugs from Canada, while the RFPs seek input on how individuals and manufacturers might also be able to import drugs, including insulin, from other countries.

Previous [research](#) from the American Action Forum noted the numerous ways in which such an endeavor was likely to be unsuccessful, all of which still apply today. Specifically, the Canadian population is one-ninth that of the United States, and fewer Canadians use prescription drugs than Americans, both of which mean their drug supply is significantly smaller than ours; Canadian authorities have an obligation to provide an adequate supply to their citizens and have already expressed an unwillingness to allow exports; drug manufacturers have no reason to provide an excess supply; the law prohibits the importation of much of the most expensive medicines; and Canada does not have access to more than half of the new medicines Americans do. In short, relying on Canada for access to more affordable medicines is a fool's errand. In fact, in May 2018, Health and Human Services (HHS) Secretary Azar referred to importation plans as a "gimmick" that the Congressional Budget Office on numerous occasions has declared would have no meaningful effect.<sup>[1]</sup> Azar went on to explain that "Canada's drug market is simply too small" and "drug companies won't sell Canada or Europe more just to have them imported here."<sup>[2]</sup>

Nonetheless, the administration, under Secretary Azar's direction, has issued a [final rule](#) to allow for importation that will be effective at the end of November.

## Summary of the Rule

This rule will allow for the establishment of Section 804 Importation Programs (SIPs)—so-named for the section of the Food, Drug, and Cosmetics Act (FD&C Act) which allows for drug importation). SIPs will be time-limited programs (up to two years) authorized by the FDA for the importation of drugs from Canada, by a state or Indian tribe, pharmacists, or wholesale distributors (or a combination of such entities).

Any imported drug must be legally available for sale in both the United States and Canada (and FDA labeling requirements must be met before sale to the consumer but not required prior to importation). The following products, however, are prohibited from importation by law: biologics, intravenous drugs, controlled substances, infused and parenteral drugs, and drugs inhaled during surgery. Drugs must be tested for authenticity, degradation, and compliance with established specifications and standards. Manufacturers must provide the importer with whatever protocols necessary to support required testing, including a validated stability-indicating assay to test for degradation. Testing will be subject to FDA review and acceptance.

A SIP proposal must initially identify a single seller and importer, but over time, if the sponsor can demonstrate consistent accordance with program rules, the sponsor will be eligible to add additional sellers and importers to the program. The Canadian seller must be licensed to sell wholesale drugs by Health Canada and registered with the FDA as a Foreign Seller, and the importer must be a U.S.-licensed wholesale distributor or pharmacist. The rule establishes supply chain security requirements with which all parties must comply. Unique identifiers will be used to track each shipment and case of drugs. Importers must request approval for an importation at least 30 days in advance of the shipment's arrival, which must come through a Customs and Border Protection port of entry.

SIP sponsors will be required to report to the FDA and to the manufacturer any adverse events, field alerts, and other reports as necessary. Any necessary recalls are the responsibility of the SIP sponsor. The SIP sponsor must also report to the FDA regarding consumer cost savings, as importation is only allowed under the FD&C Act if doing so provides “significant reductions” in costs to consumers.

### *Cost and Burden Considerations*

It is worth noting several relevant aspects of the rule's implementation plan and the administration's official expectations for the rule. The administration is choosing to have each state submit its own plan and administer its own program, each responsible for ensuring compliance from its partners and with drug testing and labeling requirements, rather than have a single federally run importation plan. There will be significant waste and inefficiency as a result of this state-by-state approach.

There are several escape hatches for the agency to terminate review or authorization of a SIP, including when “continued monitoring of the SIP imposes too much of a burden on FDA or HHS resources...or is inconsistent with FDA or HHS prioritization of resources.” This outlet may very well come into play in those instances (which are likely to be many) in which a SIP is unable to identify a Foreign Seller, which the rule allows a SIP to do after its plan has already been submitted for approval. The FDA would likely be better off not allowing a plan to be submitted until all necessary steps have been taken, including identifying all necessary stakeholders.

Finally, the rule states that the administration is unable to determine the amount of possible savings. In fact, the rule is declared to be not economically significant, which indicates the government does not believe it will have an economic effect of at least \$156 million (the current threshold after adjusting for inflation). This finding is

surprising, however, given how strongly the administration has touted this plan as a key pillar in its strategy to bring down drug prices. This finding also suggests that the rule may not be able to be implemented, as the law allowing for drug importation requires that doing so provide “a significant reduction” in costs to consumers.

## **Guidance on Manufacturer Importation of Certain Drugs**

Additionally, the FDA finalized [guidance](#) for drug manufacturers on how they can import certain drugs, including biologics, originally intended for sale in other countries. This authority is granted under Section 801 of the FD&C Act, which allows drug manufacturers to choose to import their own drugs into the United States under certain conditions. Such drugs must be FDA-approved, authorized for sale in the United States, and appropriately labeled according to FDA guidelines. Any drugs imported under this authority will receive a National Drug Code (NDC), which is used to identify a particular drug, separate from the NDC given to the same drug manufactured and originally intended for sale in the United States.

The stated intent of this guidance is to create a new pathway for manufacturers to introduce drugs to the U.S. market free from existing pricing contracts. This pathway could allow manufacturers to offer their products at a lower price without violating rebate contract agreements with [pharmacy benefit managers](#) (PBMs) or insurers. It is unclear, however, whether any manufacturers are interested in doing so; as a result, this guidance is expected to have little, if any, impact.

## **Individual Importation**

The FDA is also seeking proposals regarding [waivers for individual](#) prescription drug importation programs. These waivers would allow individuals, rather than states, to order imported prescription drugs for themselves from the following countries: Australia, Canada, countries in the European Union or the European Economic Zone, Israel, Japan, New Zealand, Switzerland, South Africa, and the United Kingdom. To help ensure patient safety, individuals would not be able to purchase and receive the drug directly; the drugs would be delivered to a licensed U.S. pharmacy for dispensing to the individual, assuming the individual presents in-person the waiver approval granted by HHS.

In order to receive approval, applicants would be required to show an ability to maintain supply chain security and safety, to ensure the drug is FDA-approved and was manufactured in an FDA-licensed facility, to ensure the drug is properly labeled, and to ensure the drug does not enter the U.S. wholesale market, identifying the specific pharmacy to which the drug will be sent for dispensing, and any other requirements FDA imposes. Further, the applicant will have to show that importation will result in a significant cost reduction to the individual. All the same exclusions on the types of drugs that may be imported will apply as under the Canadian importation plan. HHS would set up an online portal through which those seeking a waiver may apply.

## **Reimportation of Insulin**

In recognition of the fact that the exclusion of biological products includes a prohibition on the importation of insulin along with a declaration that the [rising price of insulin](#) constitutes an emergency, the FDA is also seeking proposals to make use of an allowable exception for the [reimportation of insulin](#). Under Section 801 of the FD&C Act, insulin products may be *reimported* (meaning they were made in the United States originally), but only by the manufacturer. Only when required for emergency medical care is reimportation by a third party allowed.<sup>[3]</sup>

A new study conducted by the RAND Corporation found that the United States consumes 31.6 percent of insulin by volume worldwide and accounts for 83.8 percent of sales in U.S. dollars; both of these figures are outliers relative to other countries' population size, but particularly the sales value.[4] For all insulin types combined, U.S. prices are 8.1 times greater than those in all non-U.S. OECD countries combined; this finding does not account for rebates that reduce the net price, however, which RAND notes may reduce the price differential by 50 percent.[5]

While millions of patients could benefit from lower drug prices, the prospects of finding supplies available for reimportation are as slim as the prospects for importing drugs more generally from Canada, for the exact same reasons. The manufacturers control supply to other countries and have no incentive to provide excess supply if they know it can be reimported at a lower price. While a small number of individuals may have success for some time, it is imaginable that manufacturers would amend their contracts with other countries to condition their supply on an agreement to not allow reimportation to the United States.

Of course, no action can be taken regarding either of these RFPs until the Secretary certifies to Congress that this process will not pose a risk to the public's health and safety and consumers will see a significant cost reduction.

## **Conclusion**

The administration has finally released its long-awaited importation rule, but it is too soon to declare any victory in the effort to lower drug prices. Besides the fact that this rule will not take effect for 60 days, there are numerous legal, economic, and logistical reasons why this plan is unlikely to result in any meaningful increase in access to lower-cost medicines. The administration even acknowledges that the rule is not likely to be economically significant, and, if importation cannot produce significant savings, it cannot legally be permitted. The administration could better serve the American people by focusing on efforts with a greater likelihood of success.

[1] <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>

[2] <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>

[3] <https://www.hhs.gov/sites/default/files/insulin-reimportation-programs.pdf>

[4] <https://aspe.hhs.gov/system/files/pdf/264056/Comparing-Insulin-Prices.pdf>

[5] <https://aspe.hhs.gov/system/files/pdf/264056/Comparing-Insulin-Prices.pdf>