Insight

Obstacles to Success of the Drug Importation Plan

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Executive Summary

- As part of its efforts to reduce drug costs, the Trump Administration released a proposal to establish protocols for the importation of prescription drugs from Canada, but this proposal is unlikely to have any meaningful impact on Americans' prescription drug costs.
- The proposal only allows drug importation from Canada—a country one-tenth the size of the United States and whose citizens use fewer drugs than Americans—and as a result the supply of drugs that could be redirected to the United States is limited.
- Besides the supply issues, the legal restrictions on the types of drugs eligible for importation severely limits any potential savings: 42 of the top 50 drugs in terms of total spending in Medicare Part B may not imported, while 31 of the 50 most expensive drugs per claim in Medicare Part D may not be imported.

The Proposal

A top priority of the Trump Administration has been lowering drug costs. As part of this effort, it has finally released a long-awaited proposal to establish protocols for the importation of prescription drugs from other countries. First, a proposed rule was published outlining the regulatory process that will govern the importation of prescription drugs from Canada. Second, the Food and Drug Administration (FDA) issued draft guidance detailing how pharmaceutical companies may voluntarily import into the United States their drugs originally intended for sale in other countries.

The administration suggests that a manufacturer may be interested in importing its own drugs in order to bypass existing contract terms with insurers or pharmacy benefit

managers that may prohibit it from lowering the price of a given drug. If a manufacturer wishes, it may import a drug and obtain a different national drug code, which allows it to price the drug differently from an identical drug that was originally made available for sale in the United States. It seems unlikely that many manufacturers will take up this opportunity, so this paper focuses instead on the proposed rule for importing drugs from Canada.

Section 804 of the Food, Drug, and Cosmetics Act—a statute long in force—already allows for the importation of prescription medicines so long as the Secretary of Health and Human Services can certify that importation will not threaten or undermine public health and safety *and* will result in a significant cost reduction to American consumers. No secretary has ever previously made such a certification.

This importation plan is limited to drugs from Canada. To be imported, each country's respective drug approval agency—the FDA in the United States, and the Health Products and Food Branch in Canada—must approve the drug for sale, meaning that the United States will not rely on a foreign drug approval agency to guarantee safety. The FDA may currently approve a drug for sale in other countries while a market exclusivity provision prevents it from approving the drug for sale in the United States. Under this plan, such protections would remain and a drug would not qualify for importation until any exclusivity protection expired.

As a further safety measure, the plan limits the supply chain for these products to three entities: the manufacturer, the foreign seller, and the importer, each of which must be licensed and registered with the appropriate entity and subject to various supply chain security requirements. Under the plan, a qualifying laboratory must test the imported drug for authenticity, degradation, and other quality standards.

Six Challenges Facing the Importation Plan

There are a number of reasons why such a plan is unlikely to provide American consumers access to significantly lower prices for their prescription medications.

1. *Canada has a much smaller population and lower utilization of prescription drugs, and as a result the number of drugs available for importation is likely to be very low.*

According to the Centers for Disease Control and Prevention, 69 percent of Americans aged 40-79 used at least one prescription drug, while 65.5 percent of Canadians did; 22.4 percent of Americans in this age group used at least 5 each month, while 18.8 percent of Canadians used that many.[1] While the percentage of Canadians using prescription drugs appears to

be only slightly less than the share of Americans, the difference in population size results in significant differences on a nominal basis.

There are only 19.2 million Canadians over age 40.[2] Based on the above statistics, 12.6 million Canadians over age 40 use at least 1 prescription drug (assuming the rate holds for those over age 79); only 3.6 million use more than 5 prescription drugs per month. Meanwhile, there are 156.1 million Americans over age 40.[3] An estimated 107.7 million therefore use at least 1 prescription drug; 35 million take at least 5 prescriptions each month. In other words, for each Canadian using a prescription drug, there are 8.5 Americans, and nearly 10 times as many Americans use 5 or more prescription medications as Canadians. Even if we imported all of the drugs used by Canadians, there would not be nearly enough to offset much of Americans' consumption.

2. *Canadian authorities have a duty to ensure their citizens get the drugs they need before allowing any to flow to the United States, and Canadian drug exports could lead to shortages there.*

Given the population differential, any meaningful exportation of Canadian drugs into the United States could cause a shortage for Canadian citizens, and Canadian health officials are unlikely to let that happen. The administration's plan requires Canada's cooperation—and it has already expressed opposition.[4]

3. *Drug companies will do everything in their power to limit supply and ensure there is no excess.*

Like Canadian officials, drug companies will also be looking for ways to prevent drugs from being exported to the United States at lower prices. Drug manufacturers control the supply of their drugs; they can limit the supply to a given country to ensure there is no excess to be exported. They could also require in their contracts that the buyer not export any of the supply to another country.

4. *Many other countries do not have drugs that are the most expensive in the United States, and thus these drugs are not available for importation.*

Other countries have largely secured lower prices for medicines by refusing to purchase drugs if the government decides the price is too high. In the United States, 89 percent of all 290 new drugs and 96 percent of the 82 new cancer medicines launched between 2011 and 2018 were available within three months of their global launch; in the 14 countries that the administration is considering for its International Pricing Index proposal, only 48 percent of all new medications and 57.1 percent of new cancer medicines are available, and it took an

average of 16 months and 17.8 months, respectively, for those drugs to become available in those countries after initially being available elsewhere.

Regarding Canada specifically, less than half of all new medicines and only 56 percent of new cancer medicines are available, and there was a delay in their availability of 13 months, on average. [5], [6]

5. *The plan excludes from importation the vast majority of the most expensive drugs, severely limiting the ability to achieve significant savings.*

As stated in the rule, "Section 804(a)(3) excludes several categories from the definition of prescription drug, including controlled substances, biological products, infused drugs (including a peritoneal dialysis solution), intravenously injected drugs, and drugs that are inhaled during surgery. The proposed regulation excludes these categories from the definition of 'eligible prescription drug.' In addition, we propose to exclude drugs that are subject to risk evaluation and mitigation strategies (REMS)."

The drugs described above that would be ineligible for importation are the types of drugs that are typically the most expensive and drive the high spending on prescription drugs in the United States. For example, 31 of the top 50 Part D drugs in terms of average spending per claim are biological products, with an average cost of $47,341 in 2018. Those drugs would not be eligible for importation. Regarding Part B drugs, 42 of the top 50 drugs in terms of total spending are either biologicals or intravenous-injection drugs and would not be eligible for importation. Those top 50 drugs accounted for 81 percent of total Part B drug spending. Excluding most of these drugs dramatically limits any potential cost savings. Of note, even insulin—which accounts for billions in annual spending, and which has received significant attention recently—could not be imported. Even if other countries had as robust a drug market as the United States and the new, expensive drugs were available there, most of the products that drive high drug spending still could not be imported.

6. *If drug importation does not achieve significant cost reductions, then the importation is illegal under the authority used for this proposal.*

Current law requires that any importation plan result in "significant reductions" in the cost to consumers. The proposed rule, however, states that cost estimates cannot be made at this time because regulators are unable to estimate the volume or value of drugs that may be imported.[7] If the drug importation does not achieve significant cost reductions, then the importation would be illegal under the authority that the rule uses.

As explained, there are numerous reasons why importing Canadian drugs is unlikely to

achieve significant costs savings. Further, any savings that *may* be achieved via the ability to purchase cheaper imported drugs will be offset at least partially by the significant costs incurred during the importation process. Participating entities will face numerous and costly regulatory requirements. Besides the shipping and handling costs (particularly for medicines that require storage at a particular temperature), the costs of testing the drugs to ensure their quality and authenticity will also be expensive. Finally, the paperwork burden required to comply with the regulations will be significant and may require participating companies to hire additional workers. It is not guaranteed that any initial cost savings on the price of the drug itself will exceed the costs of importing that drug.

The proposed rule also fails to quantify what will constitute "significant reductions" in the cost to the consumer; without a benchmark, it will be hard to know whether this requirement is being met, and thus whether the endeavor is legal. Perhaps that's intentional.

[1] https://www.cdc.gov/nchs/products/databriefs/db347.htm

[2] https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1710000501

[3] https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk#

[4] https://www.reuters.com/article/us-canada-pharmaceuticals-exports-exclus/exclusive-canada-warns-us-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LN

[5] https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_IPIModelComments.pdf

[6] https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/IPI-Model—Comparison-of-Cancer-Medicine-Availability—012819.pdf

[7] https://www.fda.gov/media/133553/download