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March 2, 2020

Stephen M. Hahn, MD  
Commissioner  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Importation of Prescription Drugs Proposed Rule, Docket No. FDA-2019-N-5711

Dear Commissioner Hahn:

I write in opposition to the notice of proposed rulemaking that would allow the importation of prescription drugs from Canada.

Importation proposals do not address the root cause of high prices, and it is unclear whether this proposal will result in any meaningful savings to consumers or increase access to medicines.

Instead, the proposal will likely lead to a flood of unvetted, potentially dangerous medicines into the U.S. and could lead to shortages in Canada.

ATR opposes this proposal and urges the administration to withdraw it.

**Canada does not have the scale to successfully import drugs to the U.S.** Canada is roughly one-tenth the size of the U.S. with a [population](#) of 37.5 million and an [economy](#) of \$1.7 trillion. By comparison, the U.S. has a population of 327 million and an economy of \$20.5 trillion.

Given the disparity in size between the two countries, Canada does not have the scale to effectively import drugs to the U.S. In fact, this proposal may destabilize the Canadian supply chain, a concern raised publicly by Canadian officials. For instance, Acting Ambassador to the United States, Kirsten Hillman recently [stated](#):

“The Canadian market is too small to have a real impact on U.S. drug prices. The U.S. consumes 44% of the global prescription drug supply, compared to Canada’s 2%.”

If 40 percent of Canada’s existing prescriptions are [diverted](#) into America, Canadian supply would run out in just 118 days – or 16 weeks.

The Canadian government is responsible for ensuring its citizens have access to medicines, so if this scheme goes into effect, Canadian officials will naturally be incentivized to keep supply of imported drugs low given their responsibility to prevent shortages and keep prices low.

Even if Canada had the scale to import drugs to the U.S. in any meaningful level, many innovative medicines that can be found in the U.S. market could not be imported.

Of the 290 new medical substances were [launched](#) across the world between 2011 and 2018, the U.S. had access to 90 percent of these cures, far exceeding other markets. Canada has access to just 44 percent of cures, but it is far from an outlier. The United Kingdom had 60 percent of medicines, Japan had 50 percent, and Ireland had just 40 percent.



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**It is unclear whether there will be any savings from importation.** The non-partisan [Congressional Budget Office \(CBO\)](#) has previously estimated that importing drugs from Canada would have a “negligible reduction in drug spending.”

Many high cost drugs are excluded from the importation plan, further undercutting the potential to deliver savings. According to the [American Action Forum](#), 42 of the top 50 Medicare Part B drugs by total spend and 31 of the top 50 Medicare Part D drugs by total spend would not be eligible for importation under the proposed plan.

Furthermore, the program requires extensive regulatory review before products can hit the market, as [noted](#) by HHS:

“Eligible prescription drugs would have to be relabeled with the required U.S. labeling prior to importation and undergo testing for authenticity, degradation, and to ensure that the drugs meet established specifications and standards. Notably, these programs would also have to demonstrate significant cost reductions to the American consumer.”

**There are longstanding concerns that importation will flood the market with unsafe, unvetted drugs.** While the administration says their importation plan will be safe, the FDA has long expressed concern over allowing the importation of medicines. Agency officials have repeatedly stated there is no way to assure the safety, authenticity, or effectiveness of imported drugs, or whether the drugs are from the country the packaging claims it to be.

In fact, every single Commissioner of the FDA and every HHS Secretary over the past two decades has acknowledged allowing importation of price-controlled medicines is dangerous and has declined to certify if the practice is safe.

HHS Secretary Alex Azar is no exception – as recently as May 2018, he [labeled](#) importation as “open borders for unsafe drugs in search of savings that can’t be safely achieved.”

This concern is justified -- the FDA has previously estimated that 99.1 percent of drug products entering the U.S. through international mail in 2019 are non-compliant with agency standards, while an [estimated](#) 1 in 10 medicines worldwide are counterfeit.

**Importing Canadian drugs is not a free trade measure -- it will import price controls.** Although importation is often conflated with free trade, this comparison is not accurate.

Free trade means a level playing field where prices are set by the market with no tariffs, barriers, or price controls. Drug importation is the [opposite](#) of free trade because foreign countries frequently utilize a range of arbitrary and market-distorting policies to determine the cost of medicines – by definition such approaches are price controls.

There is no negotiation and foreign governments often force innovators to accept lower prices in a “take-it-or-leave it” proposition. This results in reduced or [restricted access](#) to new medicines and higher prices for those medicines that enter the market.

Importing these market distorting policies will curtail innovation in the long-term as prices will no longer be set by the free market but by government forces.



Over time, the creation of new medicines will be severely curtailed – a threat that the [White House Council of Economic Advisers](#) warned of in a report released in February 2018:

*“If the United States had adopted the centralized drug pricing policy in other developed nations twenty years ago, then the world may not have highly valuable treatments for diseases that required significant investment.”*

**Proposals to import Canadian medicines into the U.S. should be opposed.** Not only will this proposal destabilize the Canadian drug market, it risks opening the door to unsafe, unvetted medicines.

While proposals to lower drug costs deserve consideration, it is unclear the extent to which this proposal will reduce costs given the number of drugs excluded from the proposal and the extensive regulatory review process.

Importation should be not considered a free trade proposal – rather, it should be viewed as a proposal to import market distorting price controls into the U.S.

Onward,

Grover G. Norquist  
President, Americans for Tax Reform

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