

TAXPAYERS PROTECTION ALLIANCE

Food & Drug Administration
United States Department of Health and Human Services
Fishers Lane, Rm. 1061,
Rockville, MD 20852.

RE: Docket No. FDA-2019-N-5711 for “Importation of Prescription Drugs.”

The Taxpayers Protection Alliance (TPA), a non-partisan advocacy organization representing millions of taxpayers and consumers, writes today to the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) in strong opposition to the [Notice of Proposed Rulemaking](#) (NPRM) to allow importation of certain prescription drugs from Canada. If enacted, this NPRM would jeopardize the health of American patients, introduce counterfeit drugs into the domestic medical pipeline, reduce life-saving innovation, and have close to no impact on drug prices paid by consumers.

The United States (U.S.) has a [closed drug distribution system](#) that makes domestic pharmaceutical products the safest in the world. Importation would open this system and severely compromise the integrity and safety of the domestic drug supply chain, presenting an opportunity for malicious actors and criminal organizations to increase the flow of substandard, adulterated or counterfeit drugs—including deadly fentanyl—into the country.

Canada operates under a single-payer, socialized healthcare system that forces the country to import nearly eighty-five percent of its drugs from abroad and limits its capacity to enforce proper drug safety regulations and oversight. In turn, patients are exposed to an increased risk of counterfeit and unsafe medications.

A 2018 report by the respected Fraser Institute (a Canadian think tank) [determined that](#) “*Masquerading as curative medicines, counterfeit pharmaceuticals are increasingly prevalent and profitable. Moreover, there is anecdotal evidence that the trade is being used to fund criminal organizations and terrorism.*” The study notes that these deadly products are growing in prevalence in Canada, as “*counterfeiting prescription drugs can be ten times as profitable as trafficking heroin*” Allowing increased access to these products into the United States could only lead to negative healthcare outcomes.

It is for these serious concerns regarding safety that not a single HHS Secretary has been able to [certify that importation is safe](#) or that it would provide significant cost savings to American patients and taxpayers. To that end, in 2017, a bipartisan group of four former FDA Commissioners wrote a [letter](#) to Congress stating that importation could “lead to a host of unintended consequences and undesirable effects, including serious harm stemming from the use of adulterated, substandard or counterfeit drugs.”

Any increase in the supply of potentially deadly counterfeit goods into the U.S. should be unacceptable from a public policy perspective. However, this is made significantly worse by the fact that there is no evidence it would lead to lower prices for consumers. The nonpartisan Congressional Budget Office found a possible reduction of just one percent of total U.S. prescription drug spending when it last [evaluated importation in 2005](#).

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[Recent data](#) from Canadian Health Policy Institute shows that exporting to the U.S. would deplete the Canadian drug supply in a matter of months for both prescription and name brand drugs. U.S. importation policies are therefore likely to receive significant resistance from Canadian health officials, which would in turn lead to inevitably higher prices to compensate any projected decrease in domestic supply for Canadians. Further, Kirsten Hillman (Canada's acting ambassador to the U.S.) even [stated](#) that her country's "market for pharmaceuticals is too small to have any real impact on U.S. drug prices."

To make matters worse, under the NPRM, all Canadian drugs must be approved by the FDA, which does not currently possess the infrastructure or capacity to handle such an increase in demand. This would inherently lead to increased spending of taxpayer dollars, further offsetting any marginal benefit in drug price reductions, and driving resources away from the approval of new drugs in the United States. This will result in delays in approval time leading to unnecessary suffering as drugs take longer to make it to market.

In 2016, then-FDA Commissioner, Scott Gottlieb, [noted](#) that previously proposed importation schemes "would have added so much costs to the imported drugs that they wouldn't be much cheaper than drugs sold inside our closed American system." We need only look to Europe to see that "parallel trade" schemes result in massive profits for middlemen [leveraging price arbitrages](#), and this savings is not passed along to the patients such proposals are seeking to help.

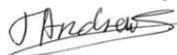
In a matter of even greater significance, the U.S. has experienced a catastrophic opioid epidemic that has seen [deaths related to fentanyl](#) increase by 430 percent in the last three years. Because fentanyl-laced counterfeit or adulterated drugs are [often mislabeled and disguised](#) as legitimate prescription medicines, the increased exposure for Americans to such drugs as a result of this importation proposal could be even more devastating to patients and the entire economy. Domestic law enforcement agencies [are already overburdened](#) dealing with the current epidemic, and importation would make this situation significantly worse.

As such, on behalf of consumers across the United States, TPA urges HHS and the FDA to heed the advice of a [2004 report](#) co-authored by current HHS Secretary Azar, arguing that importation is a "gimmick" and would not lower costs. The administration must rescind its proposal and seek free market solutions such as rebate reforms, increased transparency, and promotion of a more robust generics market through enhanced incentives for domestic suppliers to enter markets lacking adequate competition.

In addition, common sense solutions to bring down the cost of drugs such as enacting comprehensive FDA reform and [reducing the \\$3 billion cost of the approval process](#) will lead to immediate reductions in prescription drug costs, without the potentially disastrous consequences of policies such as those in the NPRM. These solutions will ease shortages and dramatic price increases without sacrificing the safety of the world's best drug supply.

TPA thanks HHS and the FDA for the opportunity to submit these comments. We are happy to testify or provide further information in this matter.

Yours Sincerely,



Tim Andrews
Executive Director

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