

VIA ELECTRONIC DELIVERY

Monday, March 11, 2019

Chairwoman Colleen Burton
Vice Chair Rene Plasencia
Minority Ranking Member Richard Stark
Members of the Health & Human Services Committee
Florida House of Representatives
402 South Monroe Street
Tallahassee, FL 32399-1300



RE: Florida Wholesale Prescription Drug Bill

Dear to Chairwoman Colleen Burton, Vice Chair Rene Plasencia, Minority Ranking Member Richard Stark, and members of Health & Human Services Committee:

The Alliance for Online Safe Pharmacies (ASOP Global; www.BuySafeRx.pharmacy) is a nonprofit organization dedicated to combating illegal online pharmacies and the counterfeit medications that they sell. Our goal is to ensure that the Internet is safer for consumers worldwide through the promotion of legitimate and approved sources of prescription drugs. We are writing today to express our concern with legislation recently introduced in your state to legalize the wholesale importation of prescription drugs in an attempt to lower constituents' out-of-pocket costs for medicine. While working to lower drug expenditures is a laudable goal, this proposed importation policy does not directly address the core issue of domestic prices and overlooks the significant risks to patient safety associated with sourcing drugs from outside the closed and highly regulated U.S. supply chain.

ASOP Global [does not stand alone](#) in our opposition to allowing wholesale drug importation. The healthcare and law enforcement communities oppose it, and past importation schemes in states like Illinois, Maine, Minnesota have shown again and again that the limited savings for consumers did not come close to balancing out the costs incurred by the states to keep the plans up and running. States were simply unable to mitigate the negative impacts of such proposals.

Moreover, wholesaler drug importation from Canada is simply unimplementable. The ongoing and widely reported drug shortage issues in Canada threaten the nation's health care system. To protect the Canadian drug supply, Health Canada would – and has in the past – revoked the license to operate from wholesalers that agree to export Health Canada-approved prescription drugs. Before Congress moves forward with any drug importation proposals, policymakers should seek counsel from Canadian regulators such as Health Canada, the Foreign Affairs Consular at Canadian Embassy in Washington, D.C., Canadian Pharmacist Association, and others.

U.S. consumers buying medications from “Canadian” online pharmacies rarely, if ever, receive the same regulator-approved products provided to Canadian consumers. Indeed, the U.S. Food and Drug Administration (FDA) has found that 85% of drugs promoted as “Canadian” came from 27 other countries, including India, Costa Rica, and Vanuatu. Just as online criminals currently pass themselves off as “Canadian,” allowing even a limited legal means of importation would cause criminals to likewise pass themselves off as meeting the requirements of a new restricted importation policy.

Simple economics drive drug counterfeiters. They make everything from inexpensive generic products for the management of chronic conditions to higher-priced, innovator or breakthrough medicines for cancer and other life-threatening diseases. Counterfeits are often made in unsafe conditions; contain too much, too little, no active ingredients, or one not indicated on the label; and/or may contain dangerous or deadly substances such as fentanyl and other synthetic pharmaceutical products.

In 2018, a plea agreement with the U.S. Department of Justice settled a case against CanadaDrugs.com and its owner Kristjan Thorkelson, a leader in the online pharmacy market. Canada Drugs ceased operations after admitting to importing counterfeit cancer medicines and other unapproved pharmaceuticals into the United States. CanadaDrugs.com operated for 17 years and claimed to provide Americans access to safe, affordable medicines, but as this case evidenced, they did no such thing.

Even without allowing drug importation, the U.S. is already struggling to cope with the influx of foreign drugs on two major fronts: online and through the mail. The internet is awash with illegal online pharmacies posing as “Canadian” and claiming to be selling safe FDA- or Health Canada-approved medicines. At any given time, there are up to 35,000 active online pharmacy websites operating on the open web, of which about 96% are operating out of compliance with state and federal law and relevant pharmacy practice standards. Expanding mechanisms available to import foreign-sourced medicines to the U.S. would exacerbate an already overwhelming and unmanageable safety situation. It is further concerning that FDA Commissioner Scott Gottlieb, M.D. has noted it that estimates show the agency physically inspects less than 0.06% of all packages entering international mail facilities thought to contain drug products.

All former Health and Human Services Secretaries and FDA Commissioners – both Republican and Democrat – over the past two decades have said that they cannot guarantee the safety of imported drugs and have warned that these medications can pose serious health risks to patients. While retaining the authority to do so since 2003, no U.S. health regulatory has approved a scheme permitting the importation of prescription drugs for personal, let alone wholesale, use. While 21 U.S.C. § 381(d)(1) expressly outlaws the importation of prescription drugs, § 384(l)(1) allows a state to propose a program and grants the Secretary of Health and Human Services to approve such a program so long as it does pose additional risk to public health. To date, no such proposal has been approved. Additionally, the [Food and Drug Administration](#) has repeatedly, through various consumer resources, strongly warned against patient safety risks posed by foreign drug importation.

There is no federal agency charged with – or even capable of – providing the necessary oversight and safety enforcement over drugs purchased from foreign drug supplies. Should lawmakers and other health authorities authorize the importation of prescription drugs, we should expect criminals to swoop in, and target patients by offering access, “deals,” and even “cures.”

Patients who purchased FDA-approved medications do not question their quality. Wholesale drug importation puts the burden of ensuring the safety and effectiveness of medicines on the buyer: caveat emptor. Should the current legislation advance, patients would constantly face the threat of purchasing counterfeit, falsified or substandard products. If foreign sellers want to make more affordable prescription drug options available to American consumers that abide by the regulatory approval pathway set forth by the FDA, they can work with those partners to introduce those products into the United States’ legitimate supply chain.

Please do not hesitate to reach out to us if you have any questions or other concerns. We stand ready to serve as a resource going forward.

Respectfully,



Libby Baney, JD

Senior Advisor, ASOP Global

Libby.Baney@BuySafeRx.pharmacy

(202) 312-7438