



**FLORIDA OSTEOPATHIC
MEDICAL ASSOCIATION**



**Epilepsy
Association**



American Senior Alliance*



Dear Governor Ron DeSantis and the Florida Legislature:

On behalf of more than 75 organizations committed to the safety of prescription drugs and protecting U.S. consumers against counterfeit, substandard or otherwise unsafe medicines, we're writing to express our deep concern around proposals announced by Governor DeSantis, Representative Thomas Leek (HB 19), Senator Joe Gruters (SB 1452), and Senator Aaron Bean (SB 1528) to import prescription medications from Canada. Proposals that include unregulated foreign actors in the American healthcare supply chain sacrifice safety to achieve elusive savings that will never materialize and may cost Florida patients their lives.

Whether offered broadly or for a narrow set of medications, there's never a good time to sacrifice safety. No patient is served well by a drug from an unknown source, that has been stored under unknown conditions, and which contains unknown ingredients because it passed through unlicensed, foreign middlemen who operate beyond U.S. law.

Florida's patients have a history of endangerment from Canadian counterfeits and the black market for medicine.

- In October 2017, a couple from Davie was charged with trafficking in counterfeit pills from Canada and China. Two of the members of the gang participated in the ring from jail in Canada. Investigators said the pills were linked with at least four deaths.¹
- In August 2017, a Palm Harbor oncologist was sentenced to nearly six years in prison² for purchasing non FDA-approved medicines from a Canadian wholesaler (Quality Specialty Products) operating as a subsidiary under a licensed Canadian pharmaceutical wholesaler, Canada Drugs that participated in a global counterfeit oncology drug smuggling ring. At the physicians sentencing, one daughter of a patient who died of cancer under the physicians care said³: "I'll spend the rest of my life wondering if my mother would have lived longer if she'd gotten the treatment she deserved."
- In March 2015, 158 different Florida physicians were warned by the U.S. Food and Drug Administration to stop buying medications from Canadian wholesaler TC Medical which sold 22 different kinds of non-FDA-approved and counterfeit medication. Some Florida physicians had to be warned twice.

A more exhaustive list of the nearly 400 Florida physicians and medical clinics that have gotten into trouble endangering their patients with unsafe, foreign-bought medications over the past decade is available on the Partnership for Safe Medicines website.

You may believe that Florida's proposals to import medication from Canada will be different than previous attempts. Structurally, these importation programs cannot be made safe, and historically they have failed to save money while simultaneously endangering patients.

Florida officials have no regulatory authority over Canadian wholesalers.

As is seen by licensed criminal Canadian pharmaceutical wholesalers, Canada Drugs, and unlicensed criminal Canadian pharmaceutical wholesalers, TC Medical, Canadian companies don't require permissions from U.S. Federal or state authorities to sell non-FDA-approved medication into the U.S. to either physicians, clinics, or directly to patients.

Should you move forward with a program to attempt to license them, Florida does not have the enforcement legal authority to inspect or sanction foreign entities you may choose to do business with.

Cost of medical adverse events can be expensive, irreversible and dwarfs any savings.

Some types of treatment, such as the cancer patients of the oncologist in Palm Harbor who were treated with non-FDA-approved medication, have no time for error. Diseases, like cancer, if treated with counterfeit medication will progress to an advanced stage and rob a patient of their life.

¹ <https://www.sun-sentinel.com/news/crime/fl-reg-fentanyl-indictment-20171011-story.html>

² <https://www.justice.gov/usao-mdfl/pr/palm-harbor-oncologist-sentenced-nearly-six-years-treating-patients-unapproved-cancer>

³ <https://www.tampabay.com/news/courts/criminal/palm-harbor-oncologist-to-be-sentenced-today-for-smuggling-chemo-drugs/2332608>

In the case of a medication that prevents a more survivable condition such as a heart attack, the cost of the medical adverse event is significant to the patient in lost wages as well as medical care. Cost estimates of the direct and indirect cost of a heart attack, for example, have been estimated at \$38,000 to \$50,000 per year.

Foreign entities cannot reasonably take on legal and financial liability of patient endangerment.

Pharmacists and pharmacies face significant legal and financial liability for dispensing non-FDA-approved medications.

Canadian export pharmacies are a waiver of liability from harm to the patients who do business with them. This waiver includes mistakes made in dispensing or failure to procure products from safe sources, or handle products in a safe manner.

No U.S. pharmacy insurance underwriter has ever agreed to cover liability of dispensing of non-FDA-approved medications and the legal liability of this is significant.⁴

Canadian suppliers cannot comply with the U.S. Track and Trace system, and can't be sanctioned for failing to do so.

Canada does not have a closed-loop supply chain tracking system to integrate with the U.S. Track and Trace system. Foreign suppliers that supply incorrect information to the Track and Trace system will face no legal sanction because the State of Florida has no regulatory authority over them.

Canadian law enforcement does not actively inspect medicine marked for export to the U.S.

Canadian law does not prohibit the transshipment of drugs from any country – including from countries with low manufacturing standards – into Canada and if importation were made legal, then on to the U.S. In fact, Canadian law explicitly states that the Canadian equivalent to the U.S. Food and Drug Administration does not have to inspect drugs for export.

Impact on Florida law enforcement is significant and unfunded.

Counterfeit medicines made with fentanyl with illegal pill presses are such an enormous problem in Florida that it is one of the only states to explicitly outlaw possession of these machines without authorization.

Counterfeits have made an enormous impact on law enforcement budgets as well, as the rise in deadly counterfeits have skyrocketed expenses for lab testing of suspected substances for law enforcement departments.

Neither proposal we have seen so far has addressed the added costs to law enforcement that would come from creating a pipeline to black market operators in Canada sending medications to Florida.

Canada's drug supply is not sufficient to supply America, much less Florida.

Canadian healthcare professionals and patient groups oppose Americans importing medication from Canada because of the likelihood of shortages and the effect a dwindling supply would have on prices. Contrary to popular belief, prescription drug prices in Canada are actually the second highest in the world. In fact, many generic medications cost less in the U.S. than they do in Canada.⁵

Canadian boards of pharmacy, the Canadian Pharmacists Association, Canadian patient groups, and Canadian wholesalers all oppose American export of Canadian pharmaceuticals.

If American drug importation of Canadian medicines were implemented, "the Canadian shelves would run dry," said Steve Morgan, a Canadian health economist.⁶ PSM's own board President Dr. Marv Shepherd has estimated that it would take about 201 days for Canada's drug supply to run dry if only 20% of Americans shifted their prescriptions to Canada.⁷

Canadian pharmacists aren't allowed to dispense to American patients with an American physician's prescription.

Canadian pharmacists aren't allowed to dispense to Americans without a Canadian physician's prescription. Furthermore, Americans cannot rely on Canadian regulators to police their own pharmacies. In late 2015 the executives of CanadaDrugs.com were indicted by the US Department of Justice for selling \$78 million (US\$) fake cancer drugs, with no active ingredient, to as many as 950 different oncology clinics in America. The fact that the founder of CanadaDrugs.com still possesses a pharmacy license in Canada today is proof that Canadian regulators cannot be trusted to protect American patients.

While the issue of access to medication and financial barriers is urgent and problematic, there are many proposals under discussion nationwide to bring down the patient's cost of medications that work inside the legal supply chain. Proposals that address the role and transparency of middlemen, such as Pharmacy Benefit Managers, limitations on annual consumer out of pocket expenses, ensuring greater access to medicines, and programs that encourage additional generic manufacturers to join the market and bring down prices are all techniques that address prescription costs without sacrificing safety.

We urge you to consider these concerns as you review the topic of importation, and not sacrifice patient safety to achieve savings. Please contact Partnership for Safe Medicines if we can serve as resource to you or your staff on this important topic.

With very best regards,

Alzheimer's & Dementia Resource Center
American Senior Alliance
Epilepsy Association of the Big Bend
Florida Osteopathic Medical Association
Florida Pharmacy Association
Florida Society of Clinical Oncology
Florida State Hispanic Chamber of Commerce

Oncology Managers of Florida
Partnership for Safe Medicines
Pharmacists United for Truth and Transparency
Salud USA
Sickle Cell Foundation
The Epilepsy Association

⁴ <https://www.safemedicines.org/2018/07/drug-importation-and-liability.html>

⁵ <https://nationalpost.com/news/canada/this-is-why-canada-has-the-second-highest-medication-costs-in-the-world>

⁶ <https://www.politico.com/story/2019/02/21/canada-prescription-drugs-1188578>

⁷ <https://www.safemedicines.org/2017/08/u-s-drug-importation-impact-on-canadas-prescription-drug-supply.html>