

Testimony of the Partnership for Safe Medicines
Shabbir Imber Safdar, Executive Director
315 Montgomery St, Suite 900, San Francisco, CA 94104
editors@safemedicines.org / (703) 679-7233
Re: Maine bills LD 1272 / LD 1387

Chairwoman Sanborn, Chairwoman Tepler, members of the committee, thank you for giving me an opportunity to address you today. My name is Shabbir Safdar, I am the executive director of the Partnership for Safe Medicines, a 16 year old nonprofit coalition of patients, healthcare professionals like pharmacists, wholesalers, and manufacturers that are entirely focused on the counterfeit problem.

My members agree on almost nothing about the healthcare system except one thing: counterfeits are very real and very dangerous.

My staff spends its time studying counterfeit incidents in America. We interview victims of counterfeits or their surviving families.

I'm here today to talk about your wholesale importation bill. I'm not going to spend any time on the personal importation bill. This approach wasn't legal when this body passed it in 2013 and I don't think it's legal now. Soon after it was passed a foreign company in Canada sent counterfeits into Maine including a fake blood thinner and managed to evade prosecution by simply refusing to be tried in America. That's documented in this handout in your packet.

But wholesale importation is one of about a dozen policies that policymakers propose when addressing the very serious challenge of healthcare affordability. And I know from talking to policymakers that the phrase you hear the most from every person in the healthcare system is "I think you should do something about healthcare costs, just not THIS idea."

But I want you to notice that of all the proposals to bring down drug prices, only one of them goes outside the legal supply chain and risks safety: importation.

The only proposal that has been dismissed as unsafe, unimplementable, and unlikely to save money by five different FDA commissioners, including the most recent, is importation. It's not implementable, for example:

It is not legal today for a Canadian wholesaler to export Canadian medicine to the United States.

They aren't allowed to export medicine into another country that isn't legal in that country, and Canadian medicine is literally illegally mislabeled and misbranded when inside the U.S. You can't find a Canadian wholesaler who will do this who actually is concerned with being compliant with the law. You can probably find many who don't care, but that's not safe.

Importing medicine from Canada breaks Track and Trace.

Every proponent who wants to import medicines from Canada for Americans insists that it will be a part of the "track and trace" system. We are currently five years and tens of millions of

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dollars into a ten year implementation of Track and Trace and it does not include Canadian pharmacies or wholesalers. Furthermore Canada does not have its own Track and Trace system for us to leverage either.

Canadian patients don't want it.

There are currently over 1,700 drugs in shortage in Canada. For this reason Canadian patient groups have opposed American importation schemes. I don't believe Maine can implement any kind of large scale importation system over the objection of Canadian voters. The population difference between Canada's 37 million residents and America's 300+ million should tell you that this system only works if you include the black market.

Committee members, I urge you to focus on the healthcare cost savings measures that operate inside the legal, regulatory framework. Importation is the only cost proposal that breaks the regulated supply chain and sacrifices safety and that should be a disqualifier.

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Of the many action items politicians have recently debated to reduce healthcare costs, there is only one that sacrifices safety to achieve cost savings: foreign drug importation. It is never acceptable to sacrifice safety to achieve cost savings.

The precious time used to debate and attempt to implement this policy delays confronting the very real, and often politically unpopular ways of addressing the cost of healthcare. PSM urges policymakers to focus on safely implementable solutions for healthcare costs besides foreign drug importation, because foreign drug importation as proposed is not implementable safely or affordably. Here are ten clear reasons why:

#10: Canadians are not inspecting medicine bound for the United States. Today a great deal of the medicine that Americans think they are getting from Canada is actually transshipped through Canada. It comes from the third world black market manufacturers in China, Turkey, or Pakistan, and arrives at an international mail facility in a major city such as Toronto. Instead of passing through Canadian customs, it is reshipped to America. Canadian authorities have been explicit that they will not inspect these packages and this is a route acknowledged by the FDA that is the source of much of the counterfeit medication in America.

#9: It breaks Track and Trace.

Every proposal to import medicines from Canada for Americans insists that it will be a part of the Drug Secure Supply Chain Act implementation called "track and trace". But the only people that say that are people who have no knowledge of how this system actually works. We are currently five years and hundreds of millions of dollars into a ten year implementation of Track and Trace and it does not include Canadian pharmacies or wholesalers. Furthermore Canada does not have its own Track and Trace system for us to leverage either.

Simply insisting that these medicines will be protected by Track and Trace is a policy promise that cannot be fulfilled.

#8: Counterfeit medicines rob patients of their only chance at treatment.

Patients dealing with a serious illness are already racing the clock to arrest the progress of their disease. Providing them with medications that may be counterfeit means that their disease will progress unchecked. For a patient with cancer, a sub-therapeutic or outright placebo treatment will allow that cancer to spread through their body making it untreatable and losing the one window they might have had for arresting it.

For HIV patients taking drug cocktails, a sub-therapeutic dose of one of the medicines in the cocktail will allow the virus to develop an immunity to the entire cocktail. When this happens

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those medicines are no longer usable for the rest of the patient's life and there aren't an infinite number of medicine options for HIV patients.

#7: We're already struggling to keep rogue medicines out of our drug supply.

In the past ten years we have seen many criminals sell counterfeit products to Americans. Multiple criminal rings, including some with Canadian pharmaceutical retail and wholesale licenses, have been caught selling fake medicines to American patients and medical clinics. Four different criminal rings (Gallant, Canada Drugs Wholesale, Ozay Pharmaceuticals, and Medical Device King) successfully did business with medical practices in almost every state in the U.S. We still don't know how many thousands of American patients were harmed and will probably never know the full scope.

#6: It's difficult to regulate people and businesses that don't fear prosecution.

One of the biggest flaws with states licensing foreign pharmaceutical wholesalers and pharmacies is that states cannot legally sanction them like businesses in their own state. The foreign actors have no assets and no physical presence in the state proposing importation. Unlike the pharmacies regulated by the state board of pharmacy, they cannot order a foreign pharmacy to stop selling spoiled product, shut dangerous facilities, or suspend workers with poor safety records.

Manitoba Canada resident Kris Thorkelson, who plead guilty to a scheme involving counterfeit cancer medication, simply refused to come to the U.S. for trial after his 2014 indictment. Extradition proved impossible and in 2018 the U.S. gave up and agreed to a plea bargain that involved no jail time for him.

#5: Importation has been tried in seven states and failed to save money, burned state funds, and endangered patients.

IL, MO, KS, VT, WI, MN, and ME have all attempted to create importation schemes in the last fifteen years. None of these programs are still in existence now. All of them had documented patient endangerment issues that made them less safe than the existing drug supply chain. Furthermore when the first six shut down they all had very low utilization due to the fact that changing insurance coverage and the power of the generics market had eliminated their cost savings.

In Maine, the program was shut down by a federal judge after a very high profile lab tested counterfeit blood thinner was sold into Maine by a criminal Canadian vendor.

#4: Importation will worsen the opioid crisis and endanger law enforcement.

In every state today there exists a new threat that is driving the opioid crisis: counterfeit pills made with fentanyl. These counterfeits pills are killing Americans who don't realize the dangers posed by counterfeit medicines because historically our drug supply has been so safe.

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Worse, the presence of fentanyl has posed a hazardous materials danger to first responders because under certain circumstances fentanyl exposure can create the conditions for an overdose.

This is why drug importation is opposed by the National Sheriffs Association, the Major County Sheriffs Association, the International Association of Chiefs of Police, National Association of Drug Diversion Investigators, among others.

#3: Importation is opposed by healthcare professionals and regulators on both sides of the border.

Importation is opposed by: boards of pharmacy in both Canada and the US, both the American and Canadian Pharmacist Associations, both the American and Canadian pharmaceutical wholesalers association, by several Canadian health ministers, by every FDA commissioner and HHS secretary since 2003, by American patient groups concerned they will get sub-therapeutic medication, and by Canadian patient groups concerned that importation will create even more shortages and create price spikes.

#2: Canadian patients don't want it.

There are currently over 1,700 drugs in shortage in Canada, mostly because Canada makes very little of the medicine they take. Because most of it is imported, they have little control over the supply. Canada also has the second highest drug prices in the world. For this reason Canadian patient groups have opposed American importation schemes. They see increased shortages and price spikes as the consequence of allowing Americans to order their medication.

#1: 37 million Canadians cannot supply 300+ million Americans with medicine.

On its face, the size difference between the countries should tell you that importation is a non-starter. Canada will not be a willing partner to allowing America to raid it's drug supply at the expense of the Canadian populace. The only way to make importation from Canada work is to involve the black market at which point we can all agree that this is not safe importation.

For more information on the structural flaws in foreign drug importation programs, please see:
<https://www.safemedicines.org/policymakers-media>