My state wants to implement drug importation? What does that mean? What should I do?

Importing Canadian medicine to reduce cost burdens for Americans is an unworkable policy idea that never works but also seems to never quite die. The problem with implementing these programs is they aren't sustainable, and they have always brought with them patient safety issues.

Your role in protecting patients

If your state is hoping to implement Canadian drug importation, your role as a patient advocate or healthcare professional is to minimize the danger to patients in the process. The program will fail and will almost certainly cost the state money it need not have spent. But drug importation programs that fail also hurt people. Minimizing that by asking the state to modify the program is the goal.

How would importation work in my state?

Canadian drug importation done by states in bulk is enabled by a 2003 federal law and federal regulations finalized in 2020 that govern how any such program works. What can be imported is very limited (no insulin, no biologics, no IV medicine) and requires expensive testing, repackaging and relabeling.

For a state or tribe to get permission from HHS to setup a bulk importation program, they submit an application that includes: a licensed Canadian wholesaler, a U.S. importer, the vendors used for testing, repackaging and relabeling, and the exact medicines they wish to import.

Were they to get approval from HHS, the state would purchase the identified medicines from the Foreign seller, import them to the U.S. importer, have them tested, repackaged, and relabeled, and then begin to distribute them within the state. All recalls, destruction of medicine becomes the fiscal responsibility of the state. Additionally, the FDA is not doing testing, inspections, or enforcement so that also falls to the state.

Problems with the idea of importing medicine from Canada

The plan to import medicine from Canada is based on a number of things that aren't true. Ultimately if you try and implement the program anyway, it ends up being both expensive and not safe. Below we've outlined the myths, the facts, the risks, and suggestions you can make to

try and minimize patient safety failures. **If the state takes any safety suggestions it won't make the program work, it will just put fewer people in danger as it fails.**

Myth: The medicines imported under this program will be protected by Track and Trace (T&T).
Fact: Canada doesn't have any kind of Track and Trace system or anything similar.
Risk of proceeding anyway: Counterfeits in the supply chain.

Politicians are fond of claiming medicines will be protected by T&T. In the U.S., T&T means each unit of sale of medicine gets a serial number and barcode on the factory floor. We have this system because criminals are fond of lying about where they get medicine and forging paperwork. Their workaround is to put a barcode on the medicine when it enters the U.S. and "trust" that the Canadian vendor bought it directly from the factory.

Safety Suggestions: In the absence of a Canadian T&T system, the state should ask Health Canada to certify the provenance of each purchase before shipments. As the lead regulator for all Canadian wholesalers they have the legal right to demand paperwork, under penalty of fraud, that certifies the wholesaler purchased the medicine directly from the manufacturer. Health Canada's certification should be published.

Myth: Canada can and will supply medicines to U.S. states for our importation programs.
Fact: Canada does not make most of its own medicines and already experiences significant drug shortages. The federal government has objected to this idea at every turn and has discouraged their wholesalers from participating in this program.
Risk of proceeding anyway: Scarcity creates opportunities for criminals to sell counterfeits. The struggles to get hard-to-source PPE during the pandemic have created an industry of counterfeiters selling fake PPE. If we proceed to try and buy medicine from Canada anyway, we are likely to get counterfeits.
Safety Suggestions: We should not purchase any medicine that has been in shortage in the last five years. Health Canada should have a chance to weigh in on every purchase and choice of Canadian wholesaler so we don't choose someone with a poor track record.

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Myth: Drug importation can be done safely and the state has the facility to regulate it.
Fact: Four FDA commissioners, major pharmacy associations (APHA, ASHP, NACDS, NABP) and leading law enforcement associations have all come out against drug importation. The state and its enforcement officers will bear all the burdens of regulation, enforcement, recalls, and safety. States do not possess the tools to inspect international facilities, inspect all foreign shipments or ensure foreign criminals are brought to justice inU.S. courtrooms.
Risk of proceeding anyway: States do not have the legal right to enter Canadian facilities or force operation shutdowns. Much like Minnesota and Maine found out, a vendor violating the rules of an importation agreement is difficult to inspect and if they need to answer in U.S. court, they will be difficult to extradite.
Safety Suggestions: The program should not proceed unless the state identifies a lead enforcement agency, ensures they have full civil and criminal powers and provides additional resources for enforcement of safety.

Myth: U.S. purchasers of Canadian medicine are entitled to Canadian pricing when purchasing from Canadian wholesalers. Medicine purchased for state Medicaid or 340B programs is entitled to rebates.
Fact: Medicine imported from Canada is not entitled to rebates. Medicaid administrators in both Maine, Vermont and Colorado have said they already get many medicines cheaper because of their existing pricing net rebates.
Risk of proceeding anyway: We will invest precious state money in a program without a clear guarantee of the prices we will get from Canadian wholesalers and be committed to vendors who can charge anything they want.
Safety Suggestions: Ensure that the state has contractually-binding price agreements from Canadian wholesalers before spending state money on an importation program or applying to HHS.

Myth: State importation programs are cheap to setup and pay for themselves quickly.
Fact: Colorado has appropriated US$3mm for their program and does not have a Canadian vendor, price quotes for medicine purchase, testing, repackaging, or relabeling, or an application into HHS. Florida issued an RFP for a vendor to manage their importation program for

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US$10mm per year and nobody bid. Former importation programs that used state tax dollars in both Illinois and Minnesota were shut down because they failed to find savings.
Risk of proceeding anyway: We risk robbing other state programs of precious funds.
Safety suggestions: Many states proposing importation played fast and loose with their calculations of savings when passing legislation. Before the state commits to significant budget dollars, we should have quotes in hand from Canadian wholesalers, testing labs, and repackaging and relabeling vendors so we can accurately determine if we will save money. Until we have these, we should not commit state budget dollars.

Myth: Canadian medicines are universally cheaper than U.S. medicines.
Fact: Many generics are cheaper in the U.S. than Canadian equivalents, and many U.S. generics are cheaper than Canadian brand-name versions.
Risk of proceeding anyway: In excitement to import cheaper Canadian versions of brand names, we may overlook existing savings. Colorado published its intent to import brand name medicine from Canada despite there being US$47mm of savings in the first to be had just by purchasing the generic version instead.
Safety Suggestions: Importing medicine from Canada brings safety risks. No brand name medicine should be imported from Canada if a cheaper generic is already available in the U.S.

Myth: Testing, repackaging, and relabeling only adds 45% to the cost of the Canadian price of the medicine
Fact: Testing, unless you do it to an unsafe standard, is likely to eat up all the arbitrage savings according to a peer-reviewed journal article. Additionally the federal regs require repackaging and relabeling to be done within a certified facility that's within thirty miles of a port of entry.
Risk of proceeding anyway: The state program will likely be forced to cut corners like testing to a low, unsafe standard to save money.
Safety Suggestions: Insist that testing, which is required by federal law and regulations, be conducted to a statistical level of 99.99% confidence and reliability. Insist on binding price quotes for testing, repackaging, and relabeling from eligible vendors before committing any significant state tax dollars to this program.