Experts and leadership from The Partnership for Safe Medicines were in Tallahassee, Florida on Monday, March 25th for a Senate hearing on an ill-advised Canadian drug importation bill. During the hearing, our team heard many false or misleading statements about the proposal to take medicine out of the Canadian medicine supply and ship it to Florida. Here's a fact check of the most egregious ones.

| HEALTH CANADA WILL INSPECT MEDICINE FOR EXPORT TO FLORIDA | | |
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| What the bill sponsor said | The facts | |
| []"Health Canada is the equivalent of the FDA in our country," [Senator] said in an attempt to reassure the committee. | Along with repeated official statements from Health Canada over the years, two different Canadian health officials over two decades have clearly stated that this is not a role Canada has done or ever will do for the United States. | |
| They will even, [he] said, test the product before | | |
| export. Extra testing, he added, will be applied to drugs from a third country that Canada then ships to the United States.[] -Published on Floridapolitics.com 3-25-2019 The [Senator] says when it comes to the safety of Canadian imported drugs, Florida consumers can trust that they will be vetted by Health Canada – what he | "Health Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future." [] "The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter." Letter from Diane C. Gorman, Assistant Deputy Minister of Health Canada to U.S. Surgeon General Richard H. Carmona, 2004 | |
| calls the country's equivalent of the U.S. Food and Drug Administration. | "Canadian authorities do not inspect every shipment of products | |
| -Published on WJCT.com Public Media on 3-25-2019 | headed for the U.S. marketplace to ensure that packages don't contain adulterated, counterfeit or illegal drugs. Canada does not | |
| "The safety chain has several different levels. One is Health Canada. That is our primary defense right there. Our primary defense of safety is Health Canada." | have the resources to undertake such comprehensive searches, and the Canadian and U.S. governments are not currently set up to facilitate such a program. Canada's health-inspection regime is | |

Bill sponsor, <u>Transcript of Senate Committee hearing</u> 03-25-2019, See 1h26m17s mark.

designed to ensure the safety of medications for Canadians, not for other countries."

<u>Statement of Leona Aglukkaq, Canada's minister of health</u> 2008-2013

Washington Post, May 12, 2017

SHORTAGES

What the bill sponsor said

Senator asked: "I have heard a lot of discussion that Canada itself is going through a drug shortage, do they have sufficient meds to supply the United States?"

[..]

[Bill sponsor] answered: "Yes, that is one of the arguments that Florida has 21 million people, Canada has 37, will they be able to take care of Florida. And we're not going to get all our drugs there. We have a very limited number of drugs."

<u>Transcript of Senate Committee hearing 03-25-2019</u>, See 1h34m10s mark.

The facts

The legislation in question only allows importation from Canada, so there is nowhere else to get them. Additionally, shortages are a real problem in Canada. Not only have experts from The Partnership for Safe Medicines previously published peer-reviewed research that shortages are a risk for Canadians if Americans pass drug importation, but in a previous week a member of his own party raised this question at a hearing for the House version of the bill as well.

Rep. Rene Plasencia, R-Orlando, also asked about potential unintended consequences of the bill, raising issues like whether Canada's existing supply of pharmaceuticals might accommodate Florida's population of 20 million.

Tampa Bay Times, March 12, 2019

Canada is experiencing record drug shortages this year, with 1,762 medicines in actual shortage right now, according to DrugShortagesCanada.ca, a Health Canada website.

Additionally, patient groups in Canada have gone on the record objecting to U.S. importation schemes since 2016.

If pharmaceuticals meant for Canadians are exported to the United States, supplies will quickly be depleted. In fact, there are indications that this could happen in as soon as 38 days, given the population of the United States in comparison to Canada's.

It is not viable for Canadian supplies to meet the needs of those in the United States even in the immediate short term, let alone on an ongoing basis. Increased importation is not sustainable as a method to address domestic prescription drug cost and supply issues in the United States.

[..]

The BMC [Best Medicines Coalition] urges policy makers in the United States to shift their focus to meaningful, long term reforms which will deliver affordable and accessible health care and pharmaceutical products to American patients within the context of the United States' health care system.

<u>Letter from 23 Canadian patient advocacy groups (Best Medicines Coalition), March 2016</u>

DRUGS WE BUY FROM CANADA WILL BE PART OF THE TRACK AND TRACE PROGRAM

| What the bill sponsor said | The facts |
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| "We also in the United States enjoy a program called the track and trace program, which tracks and traces every ingredient and recipe of every drug that we enjoy here in the United States." Transcript of Senate Committee hearing 03-25-2019, See 1h27m10s mark. | The U.S. Track and Trace system is only about halfway through its ten year implementation and not completely deployed yet. |

| "If it is not going to be safe, then that same Commissioner [Azar] is going to say no. But we are going to demonstrate that it does go through the FDA's track and trace program." <u>Transcript of Senate Committee hearing 03-25-2019</u> , See 1h45m22s mark. | | |
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| TRACK AND TRACE AND TESTING OF FINAL PRODUCTS | | |
| What the bill sponsor said | The facts | |
| Senator asked: "How much incoming medical product is being inspected at the borders, and how much testing will be done at the borders and how do you how much testing will be done at the borders to know this won't be adulterated product?" Bill sponsor answered: "We are going to go from our current law standards, which means if it comes from Canada, our current law says under track and trace that we are doing every other batch. If it comes from a country that is from somewhere else, that goes through Canada and then comes here, we are testing every batch." Transcript of Senate Committee hearing 03-25-2019, See 1h43m24s mark. | The Drug Supply Chain Security Act passed in 2013 that implements Track and Trace does not have any mention of standards for testing of medications, and certainly no metrics that test "every other batch" from Canada and "every batch that goes through Canada". It's a long piece of legislation, but you won't find anything in the law about it. | |
| FLORIDA'S RIGHT TO INSPECT MANUFACTURING FACILITIES IN OTHER COUNTRIES | | |
| What the bill sponsor said | The facts | |

"Florida still has the right to inspect manufacturing plants in Canada and elsewhere, should Canada be an importer of drugs coming from somewhere else."

<u>Transcript of Senate Committee hearing 03-25-2019</u>,
See 1h36m20s mark.

One of the big challenges for states or even the U.S. federal government trying to implement drug importation is that foreign entities on foreign soil are not legally reachable. If you happened to watch NARCOS on Netflix, you saw this when the U.S. DEA agents had to constantly work through their Colombian counterparts because they couldn't simply search or arrest people in someone else's country.

This was expressed well in the testimony in the Florida House on HB 19 when former head of the U.S. FDA's Office of Criminal Investigations George Karavetsos testified about the challenges of attempting to regulate a foreign national or foreign corporate entity outside U.S. borders. You can watch George's testimony on Florida's capitol TV station from March 18th, 2019 at

https://thefloridachannel.org/videos/3-18-19-house-appropriations-committee/ See 56m55s mark.