Written Testimony by

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Submitted on behalf of the Partnership for Safe Medicines To the North Dakota House Human Services Committee

On Senate Bill SB 2209 and SB 2212

Mr. Chairman and members of the committee, I submit this testimony to express my concerns and opposition to passage of SB 2209, which aims to legalize the importation of prescription drugs from Canada. I encourage you to continue your due diligence in studying the issue as is proposed through SB 2212, to examine the public health and safety concerns and the unintended consequences of prescription drug importation.

My concerns and resulting opposition to prescription drug importation is based on my experience as a former Canadian law enforcement officer, combating organized crime groups operating in Canada and along the border with the United States for over three decades. I was a Chief Superintendent in the Ontario Provincial Police and a Director of Intelligence and Enforcement for the Canada Border Services Agency.

While prescription drug importation proposals are well-intentioned to help lower drug prices for average Americans, they are likely to trigger significant, long-lasting and dangerous unintended consequences by greatly expanding the illicit trade in adulterated, substandard and counterfeit drugs.

The Government of Canada has repeatedly stated opposition to any importation proposals, due to the devastating impact this would have on our domestic supply. Our government most recently enacted an interim order on export restrictions for prescription medicines to counter importation proposals and avoid worsening drug shortages.

This lack of genuine supply for any importation program will open the door to foreign and domestic criminals willing to fill the unmet demand with adulterated, substandard or counterfeit drugs. This will include the transshipment of illicit prescription medicines through Canada to make them appear legitimate.

Transshipments provide a significant challenge to law enforcement, since Canadian prescription drugs do not have a Track and Trace system. As such, there is no system in place to trace prescription drugs back to their supply source to verify authenticity and avoid counterfeits, grey market products, adulterated or substandard drugs.

While Canada's pharmaceutical supply chain is very safe, it was built to ensure the safety of drugs entering and being consumed in Canada. Canadian law enforcement and Canadian border agents are resourced to secure the Canadian drug supply, not to protect the safety of prescription drugs for

export or transshipment to the United States. The priority of Canadian law enforcement and border protection is to maintain the safety on inbound packages destined for domestic use.

Canadian Law Enforcement and Border Protection do not routinely inspect outgoing or transshipped packages and cargo, unless presented with actionable intelligence from other law enforcement units or third parties. Transshipments into the United States, including those through Canada already present an avenue for illegal, dangerous, and counterfeit drugs. Legalizing importation schemes from Canada is going to exacerbate this issue.

Criminals are already in the business of supplying fake medicines and have repeatedly shown a disregard for human life and public safety by operating fraudulent Canadian pharmacies, transshipping counterfeit medicines and trafficking in illicit medical supplies. Operation Pangea, an annual global law enforcement operation designed to investigate the online sale of counterfeit and illicit medicines highlights the extent of the issue. During Operation Pangea XIII (conducted March 2020), law enforcement seized over 4.4 million units of counterfeit, adulterated or substandard medicines, medical supplies and devices worth over USD\$14 million and took over 2,500 illegal websites offline. Seized fake medical products related to the COVID 19 pandemic, including unauthorized anti-viral medicines and fake PPE, provided a stark reminder that criminals will exploit every opportunity and every loophole, especially if driven by a lack of genuine supply.

Since legitimate medicines will be unavailable from Canada in sufficient quantities for North Dakota's importation program, criminals will fill that void. Criminals driven by greed will offer medicines that they will claim are Canadian but are anything but. This is not some hypothetical future scenario but has already happened multiple times before.

CanadaDrugs.com is an example of a Canadian online pharmacy operated by two Canadian licensed pharmacists, which was prosecuted by law enforcement for illicit activity. From 2009 – 2012, they sold \$78 million worth of unapproved, misbranded, and counterfeit drugs to the U.S. clinics and patients. These drug products included Avastin, a counterfeit cancer medication, which had zero active pharmaceutical ingredients.

And while the impact of the fraud was significant, the prosecution outcome was minimal. The DOJ and the FDA pursued the criminals with the full range of federal tools available, yet none of the ring leaders went to jail. The DOJ had to settle on a penalty of \$34 million in fines and six-months of house arrest, commensurate with Canadian sentencing guidelines. The lure of high profits combined with minimal risk is too attractive for bad actors not to capitalize on.

It may seem appealing to try and address drug pricing with drug importation, but we need to worry about the unintended consequences of such policies for the United States, as well as Canada. In the interest of the public safety of both or our nations I urge you to dismiss SB 2209 and continue your due diligence by studying the issue first, as proposed by SB 2212. Thank you for allowing me to raise my concerns.

Sincerely,

Don Bell

i "Health Canada issues new Interim Order to prevent bulk exportation of prescription drugs from Canada", accessed at https://www.pharmainbrief.com/2020/11/health-canada-issues-new-interim-order-to-prevent-bulk-exportation-of-prescription-drugs-from-canada/

https://www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations

Wolz, M. (2018, April 13). Canadian pharmacy fined \$34 million for illegal imports. https://www.usnews.com/news/news/articles/2018-04-13/canadian-pharmacy-to-be-fined-millions-for-illegal-imports.