HDA
Healthcare Distribution Alliance

PATIENTS MOVE US.

March 9, 2021

North Dakota Legislative Assembly
House Human Services Committee
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: Healthcare Distribution Alliance (HDA) Opposition to SB 2209

Chairman Weisz, Vice Chair Rohr and Members of the House Human Services Committee,

The Healthcare Distribution Alliance (HDA) offers this letter to indicate our opposition to Senate Bill 2209, relating to the importation of prescription drugs from Canada. HDA is the national trade association representing healthcare wholesale distributors — the vital link between the nation's pharmaceutical and healthcare manufacturers and more than 180,000 pharmacies, hospitals, and other healthcare settings nationwide. On behalf of the industry, HDA would like to express our concerns with SB 2209 due to the potential impact on pharmaceutical supply chain and risk to patient safety.

The U.S. pharmaceutical supply chain is the most sophisticated, efficient, and highly secure drug supply chain system in the world. The security of the supply chain was further strengthened in 2013 by the passage of the federal Drug Supply Chain Security Act (DSCSA). This law outlines steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. This will enhance the Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve the detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Under the confines of DSCSA, any drug distributed in the U.S. must be distributed to and from an authorized trading partner and must be a serialized product incorporating the National Drug Code, Serial Number, Lot Number and expiration date. It is important to note that drugs that are sold or designated for sale in Canada as well as other countries do not conform with U.S. traceability regulations, simply affixing a new label on an imported product will not ensure the product adheres to the full FDA standards set forth by DSCSA prior to its importation. Allowing for the importation of drugs from Canada, or other countries, would hinder the intent of the DSCSA statute, and therefore increase the risk of illegitimate or counterfeit medications entering the U.S. market.

These concerns have been well noted. Four FDA Commissioners wrote an open letter to Congress in March 2017 expressing their continued concerns with a drug importation program stating that "such

importation represents a complex and risky approach – one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers." [1]

The National Association of Boards of Pharmacy also expressed concern with state and federal importation efforts, noting in an October 2020 statement that "allowing Americans to import medications from Canada and other foreign countries opens an additional point of vulnerability in the US prescription drug supply chain. Specifically, each separate proposal effectively creates a new and distinct prescription drug supply chain that will require state regulatory oversight and monitoring, only with fewer protections. This patchwork approach is a step away from the tightly regulated supply chain and safeguards currently in place to ensure the efficacy and safety of prescription medications. The National Association of Pharmacy Regulatory Authorities, NABP's counterpart in Canada, has expressed concern that exportation of medicines out of Canada will threaten the supply available to its citizens. This, in turn, will increase the opportunity for counterfeit medications to enter its supply chain, endangering both US and Canadian patients."[2]

Furthermore, the legislation requires the North Dakota Board of Pharmacy to increase licensure fees on supply chain entities to fund the importation program which has yet to be established and may never come to fruition. Licensure by the Board of Pharmacy is intended to protect, preserve and promote public health and welfare of the citizens of North Dakota. Licensure fees should help the Board achieve these goals, not implement a theoretical program that would potentially harm the patients they are working to protect.

Ultimately, allowing for importation of prescription drug products increases the likelihood of counterfeit or adulterated drugs entering the country. Due to these concerns, we ask that you oppose both SB 2209. We encourage the state legislature to study the topic over the interim to determine the feasibility, cost savings and potential consequences of implementing such a program rather than rushing through a proposal allowing North Dakotans to rely on another state's pharmaceutical importation program.

In addition to my testimony, I have also included a study conducted by the Healthcare Distribution Alliance Foundation in partnership with Accenture entitled "The Risks and Realities of Commercial Drug Importation," the study concludes that "proposed importation policies likely place the integrity of the commercial supply chain at risk." Please contact me at Llindahl@hda.org or (303) 829-4121 if you have any questions or would like to discuss this issue further.

Thank you,

Leah D. Lindahl

Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance

[1] Open letter to Congress authored by four FDA commissioners opposing drug importation, (March 2017) https://www.documentcloud.org/documents/3519007-FDA-Commissioners-Drug-Reimportation.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals

[2] NABP Position Statement on New Federal Importation Rules, (October 2020) https://nabp.pharmacy/mailbag/october-1/#memo-1