

PATIENTS MOVE US.

February 11, 2021

North Dakota State Senate State Capitol 600 East Boulevard Bismarck, ND 58505-0360

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

Dear Senator,

The Healthcare Distribution Alliance (HDA) offers this letter to indicate our opposition to Senate Bill (SB) 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 HDA, I would like to express our concerns with SB 2209 due to its potential negative impacts on the pharmaceutical supply chain. These impacts include the possible introduction of counterfeit product into the US supply chain, ultimately endangering patient safety, and the establishment of an arduous and permanent licensure assessment in support of a nonexistent program.

The amended legislation attempts to allow the North Dakota Department of Health to contract with another state for the importation of prescription drugs from Canada. To support this effort, the legislation also requires the North Dakota Board of Pharmacy to increase licensure fees on certain entities to any amount up to \$1,000 which will then continuously be appropriated to the Department of Health in order to implement and operate the wholesale prescription drug importation program – of which there is none.

To date, no state has successfully developed a Canadian Drug Importation Program. In fact, four recent FDA Commissioners wrote an open letter to Congress expressing their continued concerns with a drug importation program stating that "such importation represents a <u>complex and risky approach</u> – one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers." ¹

Furthermore, the National Association of Boards of Pharmacy also <u>expressed concern with state and federal importation efforts</u>, 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

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

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

Licensure by the Board of Pharmacy is intended to protect, preserve and promote public health and welfare of the citizens of North Dakota; however, under the legislation the Board will be required to earmark additional licensure funding to support a program that is opposed by many of those same entities due to safety concerns. Those same concerns that have been echoed by U.S. Secretaries of Health and Human Services, FDA Commissioners, the National Association of Boars of Pharmacy and their Canadian counterparts.

The North Dakota Senate passed Senate Bill 2212 on February 10th, requiring the state to study the feasibility of an importation program. Rather than rushing through a proposal allowing North Dakotans to rely on another state's pharmaceutical importation program as proposed in SB 2209, we encourage the state legislature to study the topic over the interim and determine both the feasibility, cost savings and potential consequences of implementing such a program.

We encourage you to vote no on the passage of this legislation. Please contact me at <u>Llindahl@hda.org</u> or (303) 829-4121 if you have any questions or would like to discuss this issue further.

Thank you,

Leah Lindahl

Senior Director, State Government Affairs

Healthcare Distribution Alliance

Leon D. Linchahl

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