

TO: Sen. Laurie Monnes Anderson, Chair

CC:

Sen. Dennis Linthicum, Vice Chair

Sen. Elizabeth Steiner Hayward

Members of the Health Care Committee

RE: SB 409

There are few professionals who are more cognizant of the cost of healthcare and its impact on patients than pharmacists. Whether in an institutional health-system setting or in a retail pharmacy, the act of delivering medications and collecting payment is one that pharmacists carry out every day. We are not opposed to proposals that will reduce drug cost, but we are concerned with patient safety. Our drug knowledge combined with our understanding of pharmaceutical manufacturers, insurance companies, and Pharmacy Benefit Managers (PBMs), puts us in a position to be experts in the many factors at that will can affect patient safety. Proposing importation of drugs from Canada could lead to the bypass of essential safety checks and will likely have little effect on the entities that have a strong influence on drug prices.

With their unique position, pharmacists are acutely aware of the need to address issues related to access to medications. And pharmacists are also aware of what goes into creating this country's secure drug supply chain – one of the safest in the world. Pharmacists are exposed to licensing, safety, regulation, and pharmaceutical pedigree issues to a degree that many other professions do not see or experience.

To that end, we are concerned about the wholesale and retail foreign drug importation proposals in SB 409. The US medicine supply chain is incredibly complex, and that complexity creates many different cost drivers that ultimately determine the final price a patient pays for medicine. To address this, legislators at all levels have touted dozens of proposals to address all those different cost drivers.

However, only foreign drug importation proposals sacrifice patient safety to achieve cost savings. Importation of drugs from Canada compromises the safety and integrity of medication dispensed to U.S. residents.

We have seen top leaders in healthcare publicly oppose foreign drug importation in both wholesale and retail form. These representatives include four former FDA Commissioners¹, the American Pharmacists Association²,

¹ March 2017 as published in the Washington Post

² January 2019, Joint NACDS/APhA position statement regarding foreign drug importation

Prepared by the Oregon State Pharmacy Coalition Joint Legislative Committee ~ Submitted by Bill Cross and Niki Terzieff

the Canadian Pharmacists Association³, the American Society of Health-System Pharmacists⁴, the National Association of Chain Drug Stores⁵, the National Association of Boards of Pharmacy⁶, nearly two dozen Canadian patient advocates⁷ and many more American ones⁸, several U.S. state pharmacy associations⁹, the Canadian Association for Pharmacy Distribution Management¹⁰, and state and provincial boards of pharmacy in the U.S.¹¹ and Canada¹².

Canada has a much smaller population than the U.S., and the potential impact on drug pricing may or may not be significantly measurable. Canada has a different healthcare system than the U.S., and the prices they pay is a result of their single payer system, rather than some special pricing method. If Canada is shipping drugs to the U.S., the pharmaceutical companies can simply raise prices in Canada or pressure Canadian pharmacies to not trade with the U.S.

The reasons for concerns regarding safety include the following: a lack of likely cost savings, the inability to ensure safety, the lack of patient counseling and education, the irreversibility of damage to patients of inevitable counterfeits, the inability to hold foreign criminal actors accountable when they traffic in counterfeits, a potential additional liability for dispensing a counterfeit medicine that harms a patient, and the loss of integrity in the Drug Supply Chain Security System known commonly as "track and trace." These are problems with any foreign drug importation proposal, and they are systemically a piece of any proposal that attempts to include foreign entities in the pharmaceutical supply chain, entities which are outside of our ability to regulate.

We also have concerns regarding the ability and costs of creating another regulatory responsibility for the Oregon Board of Pharmacy. Creating and regulating a foreign importation wholesale operation is not within the current expertise and scope of the Board's activity, and this function would have to be created and staffed with the appropriate experts in drug supply chain and quality currently provided by the FDA. Compliance with 21.USC.384 outlined in Section 2 (line 12-17) would be duplicative of the FDA regulations and expensive to create and maintain. These costs would impact the possible savings that could be passed to the patient.

³ January 2007 letter from Canadian Pharmacists Association, the Ontario Pharmacists' Association, the Best Medicines Coalition, and the Canadian Association for Pharmacy Distribution Management, Letter to Tony Clement, the Canadian Minister of Health

⁴ October 2017 letter to Senate leadership

⁵ Ibid NACDS/APhA joint position statement

⁶ February 2017 Letter to Congress

⁷ March 2017 Best Medicines Coalition position statement on American importation proposals

⁸ February 2017 Partnership for Safe Medicines joint letter to Congress from healthcare advocates

⁹ Ibid.

¹⁰ January 2007 joint letter (above)

¹¹ March-June 2017 Letters opposing importation from state boards of pharmacy (AZ, CA, KY, LA, OK, VA, WV)

¹² March-April 2017 Letters opposing importation from provinces of Newfoundland and Labrador and Manitoba.

The requirements of section 2(3) to test purity would require costly staff, expertise and equipment to provide would be necessary since the products imported could circumvent the FDA and Canadian regulatory bodies.

The reporting requirements of section 2 (7-15) would also add costs to the program and reduce the savings to the patient. These requirements are innovative but the process and cost of this kind of health plan reporting is unknown.

Although the drug-importation proposal is a well-meaning policy aimed at enhancing consumer access to medications, a goal we fully support, the unintended consequences outweigh any potential benefit. We stand ready to work with the committee to find other solutions that address medication cost without sacrificing patient safety.

Should you have any questions or comments about our position, please contact Bill Cross at bill@wvcross.com

The Oregon Pharmacy Coalition

[note, you can find all the letters referenced at: https://www.safemedicines.org/opposing-drug-importation-2000]