NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

January 28, 2019

The Honorable Senator Laurie Monnes Anderson
Chair, Oregon Senate Health Care Committee
Salem, OR

Oppose SB 409 - Prescription Drug Importation Practices Would Jeopardize Patient Safety in Oregon

Senator Monnes Anderson and Honorable Members of the Senate Health Care Committee:

On behalf of our members operating pharmacies in the state of Oregon, the National Association of Chain Drug Stores (NACDS) is writing to share our strong concerns with SB 409, legislation that would establish a commercial prescription drug importation scheme in the state of Oregon at the expense of patient safety. We strongly urge lawmakers to vote against this bill.

The proposed legislation would direct the State Board of Pharmacy to design a wholesale prescription drug importation program and to act as a licensed wholesaler to import drugs from licensed, regulated Canadian suppliers. Such a proposal would violate federal law against drug importation, undermine federally mandated security protections of the drug supply chain, and would increase the risk of counterfeit drugs in a state's drug supply chain. Moreover, historically, both FDA Commissioners and the Canadian government have raised serious concerns regarding the danger to public safety posed by allowing commercial importation.

Commercial Importation Weakens the Drug Supply Chain Security Act (DSCSA)
In 2013, Congress passed the DSCSA to track and trace prescription drugs from manufacturer to receipt by the dispenser. Through tracking prescription drugs, the law aims to prevent counterfeit drugs from entering the United States supply chain. If Oregon were to allow commercial importation from Canada, this would undermine the safety and security protections of the DSCSA. It is impossible to fully enforce the DSCSA over foreign facilities, manufacturers, wholesalers, and dispensers. The importation scheme outlined in SB 409 would create loopholes within the DSCSA regulatory framework, easily allowing counterfeit drugs to reach the state's citizens.

FDA and Canadian Safety Concerns Regarding Commercial Importation
Throughout the past 15 years, through speeches, testimony, letters, and other consumer resources, FDA has repeatedly sounded the alarm as to the risk to patient

safety posed by importation.[1] Moreover, the current FDA commissioner, Dr. Scott Gottlieb, and four former FDA commissioners have made previous statements opposing drug importation, noting that broad drug importation exposes the U.S. supply chain to foreign counterfeit drugs.[2,3] The Canadian government also shares the FDA's concerns.[4] The importation program outlined in SB 409 ignores the serious safety concerns repeatedly raised by Canada and the federal government.

Drug Supply Chain Integrity Issues

A state importation scheme must assure that imported drug products are not counterfeit or diverted. Otherwise, with counterfeit drugs, people will get sick and potentially die. According to the World Health Organization, 10% of drugs worldwide are counterfeit, so the risk of illness and death is very real.[5] Under our present system, the federal government restricts and regulates access to the drug supply. However, the importation program proposed in SB 409 would circumvent these restrictions. Even if products are thought to be from a particular country that has high manufacturing or quality standards, the products may in fact be diverted, through Canada, from a country that does not. Commercial importation will generate "black markets" for pharmaceuticals, raising serious questions about the quality of these drugs.

The Lack of an Adequate, Consistent, and Safe Supply of Foreign Drugs

There are questions of whether international sources of pharmaceutical supply will be adequate and consistently reliable, as well as safe. A commercial importation scheme would provide only a sporadic supply of international drug products. Moreover, imported drugs from Canada and elsewhere would pose safety concerns as drug products sold abroad – albeit containing the same active pharmaceutical ingredients as those sold here – often have different shapes, sizes, colors, and even trade names. They can be made with different inactive ingredients, while some are sold in different doses because the patients in other countries have different dose-response relationships. Introducing different-looking foreign pharmaceutical products into the U.S. system will confuse patients and health professionals. The lack of stability and clarity places patient safety at risk.

Considering the numerous concerns and challenges inherent to the importation program proposed under SB 409, NACDS strongly urges Oregon lawmakers to vote

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[1] Food and Drug Administration; "Importing Prescription Drugs;" available at: https://www.fda.gov/Drugs/DrugSafety/ucm170594.htm, last accessed May 16, 2017.

[2] Gottlieb, Scott; "What Trump Should Have Said on Drug Prices;" *Forbes*; March 04, 2016. Accessed March 15, 2017. https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#540c85a92e74.

[3] Califf, R.M., Hamburg, M.B., McClellan, M. & Von Eschenbach, A. (March 2017); Open letter to members of Congress. https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final.pdf.

[4] HHS Task Force Report citing Letter from Diane C. Gorman, Assistant Deputy Minister, Health Canada, to Richard H. Carmona, U.S. Surgeon General, pg. 60-61. June 1, 2004.

[5] World Health Organization (WHO); "Counterfeit medicines: an update on estimates"; *Geneva: WHO International Medical Products Anti-Counterfeiting Task Force* (2006).

against this measure. We appreciate the opportunity to present the concerns of our members in Oregon on this very important issue.

Sincerely,

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