January 29, 2019

The Honorable Laurie Monnes Anderson
Chair, Senate Committee on Health Care
State Capitol
900 Court St NE
Salem, OR 97301

Dear Senator Monnes Anderson:

The Oregon Bioscience Association and Biotechnology Innovation Organization (BIO) respectfully oppose SB 409, which would require the Board of Pharmacy to design a wholesale Canadian prescription drug importation program, as specified. This bill would compromise the safety of the pharmaceutical supply chain and have a negative impact on biopharmaceutical innovation, despite evidence that such a program would have minimal cost savings. The United States is the standard-bearer for ensuring drug safety and efficacy, as well as the world leader in innovative drug development. Importing medicines from foreign countries would undermine public health and do little to reduce prescription drug costs.

Establishing a wholesale importation program of prescription drugs from Canada would expose patients to counterfeit, adulterated, or unapproved drugs. Drugs imported from abroad will effectively lack oversight by any health authority, and there is a high likelihood that such drugs would display deceptive or incorrect packaging and labeling.

The federal Food and Drug Administration (FDA) has repeatedly said that it cannot guarantee the safety of prescription drugs imported from Canada. According to a 2017 report of the non-partisan Congressional Research Service, 80 percent of all prescription drugs sold in Canada are from foreign sources. Health Canada, the agency in charge of ensuring the safety of Canada's drug supply, admits that while the facilities that import these drugs are subject to inspections, it only did three outside inspections in 2011, and 14 in 2014.[i] In addition, of the 442 domestic inspections in 2014 and 2015, i.e., inspections of facilities within Canada, nearly 3,100 "observations" were made that constituted mostly quality violations. Of that number, 1,517 were categorized as "critical" or "major."[ii] Neither the FDA nor the Utah Board of Pharmacy can guarantee the safety of medicine imported from Canada.

SB 409 would hamper existing efforts to protect consumers. The Drug Supply Chain Security Act establishes a 10-year plan, already underway, for the FDA to establish an electronic system to trace prescription drugs and biologics distributed in the United States for the protection of consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. Allowing a parallel foreign drug supply chain from Canada will threaten these consumer protection efforts.

Studies have found that any improved access or cost savings resulting from importation are likely to be minimal.[iii] Independent studies by the Department of Health and Human Services (HHS) Task Force on Drug Importation and the U.S. Department of Commerce

have concluded that importing prescription drugs from foreign countries poses safety risks to American consumers and does not result in overall net cost savings. Any public savings would be diminished by the cost of the regulatory schemes necessary in trying to ensure the safety of the drugs imported. Moreover, in 2005, the Surgeon General testified that the HHS Task Force on Importation found:

- "Total savings to drug buyers from legalized commercial importation would be one to two percent of total drug spending and much less than international price comparisons might suggest. The savings going directly to individuals would be less than 1% of total spending. Most of the savings would likely go to third party payers, such as insurance companies and HMOs."
- "Under legalized importation, intermediaries may capture a large part of the potential savings."
- On average, foreigners pay 50% more on generic drugs than they do in the United States.[iv]

Studies have found that importation schemes would have a negative impact on biopharmaceutical innovation. The HHS Task Force on Importation found that importation would likely have a negative effect on investment in research and development. These schemes would make it difficult for companies to earn any return on their investments and limit their ability to reinvest in life-saving research. Fifty-seven percent of all innovative medicines are discovered and developed in the United States. Estimates of lost benefits, due to reduced R&D spending, include four to 18 fewer products per decade; it also could cost consumers $5 billion to $20 billion per decade without including gains from having a greater variety of generics in the future. These reduced benefits may significantly offset savings from legalized importation.[v]

The US Secretary of Health and Human Services has had the authority to import drugs from other countries, as long as the public health and safety is not jeopardized and doing so would generate savings for the public. Yet, in the ten years the Secretary has had this authority, no administration—Republican or Democrat—has exercised it because of the simple fact that such guarantees cannot be made.

For these reasons, we respectfully urge your no vote on SB 409.

Sincerely,

Julie Black
Interim Executive Director
Oregon Bioscience Association

Brian Warren
Director, Government Affairs
Biotechnology Innovation Organization

[i] "Drug Regulation in Canada," Congressional Research Service, January 2017.
[ii] Ibid.

[iii] Report of the HHS Task Force on Drug Importation. 2005. Available at: https://www.surgeongeneral.gov/news/testimony/t01262005.html.
[iv] Ibid.
[v] Ibid.