



Testimony in Opposition of LD 1387 & LD 1272
Maine Joint Committee on Health Coverage, Insurance and Financial Services
April 17, 2019

The Biotechnology Innovation Organization (BIO)
Washington, DC

Chairwomen Sanborn and Tepler and distinguished members of the Committee on Health Coverage, Insurance and Financial Services, the Biotechnology Innovation Organization (BIO) would like to express our concerns with LD 1387 & LD 1272. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

LD 1272 would require the Department of Health and Human Services to design a wholesale Canadian prescription drug importation program, as specified. BIO is concerned this bill would compromise the safety of the pharmaceutical supply chain, notwithstanding evidence that such a program would result in 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.

Studies have found that any improved access or cost savings resulting from importation are likely to be minimal.¹ 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."²

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

¹ Report of the HHS Task Force on Drug Importation. 2005. Available at: <https://www.surgeongeneral.gov/news/testimony/t01262005.html>.

² Ibid.

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. In fact, every head of HHS and the FDA for the last 18 years has opposed importation because of the risks it poses to the safety of the American drug supply.³

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.

LD 1387 would allow for individual importation of drugs which BIO has concerns would compromise patient safety. It is important to remember the Federal Food and Drug Administration (FDA) has repeatedly said that it cannot guarantee the safety of prescription drugs imported from Canada. More than half 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 2014.⁴ 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."⁵ Neither the FDA nor the State of Maine can guarantee the safety of medicine imported from Canada.

Furthermore, LD 1387 & LD 1272 would hamper existing efforts to protect consumers. The Drug Supply Chain Security Act established a 10-year plan, already underway, for the FDA to establish an electronic system to track and 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.

For these reasons, we respectfully oppose LD 1387 & LD 1272. If you have any questions, please do not hesitate to contact me at agochenaur@bio.org or 202-870-9747.

Respectfully Submitted,

/s/

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³ Partnership for Safe Medicines, Infographic, 2018. Accessed: <https://www.safemedicines.org/2018/07/who-opposes-drug-importation-every-head-of-the-fda-and-hhs-since-2000.html>

⁴ Health Canada, https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html Accessed March 25, 2019.

⁵ Ibid.