Concerns for Patient Safety and Counterfeits with Drug Importation

HB1441 – Representative Anna Moeller, D-Elgin

Please Vote No!

HB1441: Creates the Wholesale Importation of Prescription Drugs Act, which allows participating pharmacies to purchase Canadian drugs from the state without FDA manufacturing safeguards.

Background:

- Currently, there are no states that have an active drug importation program.
- Through an extensive safety net of federal and state laws, the US ensures prescription drugs are manufactured, stored, shipped, dispensed, and used in a safe manner. Importing medications from foreign suppliers undermines these processes.²
- The FDA has repeatedly cautioned against the risk to patient safety posed by the importation of prescription medications.²

10% of drugs worldwide are counterfeit.¹

Why we should care:

- Introducing different looking pharmaceutical medications, from foreign sources into the US, may confuse patients and healthcare professionals as well as having different packaging, indications for use, and dosage forms.³
- Vermont is the only state to have passed a drug importation program, but no data has been produced from the program, since the program is not active until January 1, 2020.³
- Vermont's Agency of Human Services determined that a compliant drug importation program will require substantial upfront investment and appropriations.... that may outweigh the proposed savings.8
- HB1441 does <u>NOT</u> mention the regulation of biologics or biosimilars, which require a much higher attention to detail than other chemically compounded medications.



- Many Canadian pharmacists, wholesalers, healthcare regulators, and economist are opposed, as it will cause a
 depletion of Canadian drug supply in the short-term.^{4,5}
- Relying on Canadian manufacturers would lead to shortages within Canada, forcing increased manufacturing and importation, which will lead to increased medication costs in the future.
- Drug shortages in Canada are as frequent there as in the United States.⁶

Canadian importation <u>does not address the root cause</u> of high domestic drug prices and the manipulative practices of middle men Pharmacy Benefit Managers on prescription drug costs and the increase in *pharmacy deserts*.





References:

- World Health Organization (WHO); "Counterfeit medicines: an update on estimates"; Geneva: WHO International Medical Products Anti-Counterfeiting Task Force (2006).
- 2. Food and Drug Administration; "Importing Prescription Drugs;" available at: https://www.fda.gov/Drugs/Drugs/afety/ucm170594.htm
- 3. Gobeille, A. Wholesale Importation Program for Prescription Drugs Legislative Report. Vermont Agency of Human Services (2018). https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.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.
- Gooi M, Bell CM. Differences in generic drug prices between the US and Canada. Appl Health Econ Health Policy. 2008;6(1):19-26. https://www.ncbi.nlm.nih.gov/pubmed/18774867.
- Rawson NSB, Binder L. Importation of drugs into the United States from Canada. CMAJ Can Med Assoc J. 2017;189(24):E817-E818. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478407/pdf/189e817.pdf.
- Safe Savings Tip: Generic Norvasc Is Over 75% Cheaper In The U.S. Than In Canada. Partnership for Safe Medicines. https://www.safemedicines.org/2017/10/safe-savings-tip-generic-norvasc-is-over-75-cheaper-in-the-u-s-than-in-canada.html. Published October 16, 2017.
 Accessed March 5, 2019. (image citation)
- 8. Schlanger SJ, Vermont Report Finds that the Costs of Prescription Drug Importation May Outweigh Savings. FDA Law Blog (2019), http://www.fdalawblog.net/2019/01/vermont-report-finds-that-the-costs-of-prescription-drug-importation-may-outweigh-savings.