

## ASOP CANADA CONCERNED BY IMPACT OF NEW U.S. DRUG IMPORTATION PROPOSALS ON CANADIAN DRUG SUPPLY AND SHORTAGES

## TORONTO (January 25, 2019)

The Alliance for Safe Online Pharmacies Canada is expressing significant concern following the introduction of the Sen. Bernie Sanders, Reps. Elijah Cummings, Ro Khanna, Peter Welch, Joe Neguse, and other cosponsors in the House and Senate of the <u>Affordable and Safe Prescription Drug Importation Act</u> (S.97) (H.R.447) and of the <u>Safe and Affordable Drugs from Canada Act of 2019</u> (S.61) from Senators Chuck Grassley (R-IA) and Amy Klobuchar (D-MN). These bills will not result in a long-term nor sustainable solution to meet U.S. demand for life-saving medicines and may result in harm to U.S. patients by allowing infiltration of unapproved, substandard and counterfeit medicines. The bills fail to consider Canadian regulations and practice standards with respect to Health Canada-approved products and Canadian physician, pharmacy and pharmacist practice and would exacerbate Canada's drug shortage challenges.

Canadians access a supply of medicines geared to the size and clinical need of our population. If our domestic supply is exhausted due to an increase in orders from the United States, manufacturers may not be able to satisfy the unexpected increase in demand. Indeed, as the chart in Figure A shows, there is a significant supply mismatch should any of the proposed drug importation bills ever be successful. In turn, Canadians would be subject to significant drug shortages and limits in access to appropriate and necessary care. Due to domestic factors, Canada has experienced a wave of drug shortages in recent months, placing a strain on Canadian patients, families, hospitals and health professionals. The exportation of Canadian medicines to the U.S. threatens to exacerbate Canada's drug shortage issues and poses a risk to the proper functioning of our health system.



In addition, Canadian pharmacies fill prescriptions of medicines that are approved by Health Canada and suited for sale within Canada. The medications approved by Health Canada for Canadian consumers are not approved by the U.S. Food and Drug Administration (FDA) for that purpose. We are proud that Canada hosts one of the safest and most secure pharmaceutical supply chains in the world. However, the safeguards put in place to ensure the identity, efficacy, and safety of prescription medications no longer apply outside Canada's closed and tightly regulated domestic supply chain. Our border officials cannot be held responsible for determining the safety of products entering the United States.

We are concerned the proposed legislation does not address regulations with respect to pharmacy and

pharmacist practice in Canada. In Canada, pharmacists are obligated to provide patient care and assess the medication needs of the patient and legal practice is not just the packaging of a drug pursuant to a prescription. Furthermore, according to Canadian federal and provincial legislation prescription in Canada is only legal when issued by a Canadian physician (or other licensed Canadian prescriber). However, the proposed legislation only describes a prescription issued by a U.S. physician. This practice would seem to condone "co-signing" activity by a Canadian licensed practitioner which is in direct conflict of professional standards of care and ethics.

Furthermore, sending consumers online to look for Health Canada-approved medicines increases the risk of U.S. patients accessing unapproved, substandard, and counterfeit medicines from unknown foreign sources. As noted by ASOP Global, U.S. consumers buying medications from alleged 'Canadian online pharmacies' rarely, if ever, receive the same regulator-approved products provided to Canadian consumers. Indeed, FDA has found that 85% of the drugs being promoted as "Canadian" came from 27 other countries around the globe. U.S. laws that encourage U.S. consumers to find safe Canadian online pharmacies will lead to more illegal sites misrepresenting themselves as licensed Canadian pharmacies, creating a greater patient safety threat on both sides of the border.

As these are only a few of the concerns highlighting patient safety, patient care and legal drug distribution pursuant to the proposed legislation, we encourage Senators Grassley and Klobuchar, and all U.S. legislators to consult with Canadian physician, pharmacy and pharmacist regulators and Health Canada officials regarding the compliance of Canadian regulations to the sale, distribution and exportation of medicines from Canada to U.S. patients. In addition, we encourage U.S. legislators to consider the enhanced risk and undue harm posed by the *Safe and Affordable Drugs from Canada Act of 2019* to both Americans and Canadians that rely on steady access to safe medicine.

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About ASOP Global and ASOP Canada

## ABOUT ASOP GLOBAL

The Alliance for Safe Online Pharmacies (ASOP Global), a 501(c)(4) non-profit organization headquartere d in Washington, D.C. with activities in U.S., Canada, Europe, India, Latin America and Asia, is dedicated t o protecting consumers around the world, ensuring safe access to medications, and combating illegal online drug sellers. ASOP Global has an expansive membership including non-profit pubic health organizations, international members, pharmacy members, as well as pharmaceutical manufacturers.

The Alliance for Safe Online Pharmacies Canada is dedicated to keeping Canadians safe from illegal onlin e sellers and protecting the integrity of Canada's pharmaceutical supply chain. A list of our members and observers can be found <a href="here">here</a>.