

ASOP GLOBAL STATEMENT ON HHS DRUG IMPORTATION ANNOUNCEMENT

WASHINGTON – December 18, 2019 – In response to today’s announcement by Health and Human Services Secretary Alex Azar on the White House’s plan to allow U.S. consumers to import drugs from Canada, the [Alliance for Safe Online Pharmacies](#) (ASOP Global), issued the following statement:

While ASOP Global appreciates and supports efforts to find new ways to increase patient access to safe, affordable prescription medicines, the proposed importation policy does not directly address the core issue of domestic prices and overlooks the significant risks to patient safety associated with sourcing drugs from outside the highly regulated U.S. supply chain.

Today’s NPRM proposes that stakeholders may submit proposals to “import Health-Canada approved drugs.” However, fearing drug shortages and higher prices of their own, Canadian government officials, patient-advocacy groups and healthcare professionals have been vocal in their disapproval of drug importation bills. See [video here](#).

Canada simply does not have a sufficient quantity of drugs to fill America’s needs. Canada’s current pharmaceutical supply system, the subject of national price negotiation and regulation, is designed to serve the Canadian population of 36 million people. In contrast, the four states that have passed importation legislation - Florida, Vermont, Maine and Colorado combined have a population of 29 million people- more than 80% of Canada’s total population.

Moreover, drug importation from Canada is unrealistic in practice. The ongoing and widely reported drug shortage issues in Canada threaten the nation’s health care system. To protect the Canadian drug supply, Health Canada may – and has in the past – revoked the license to operate from wholesalers that agree to export Health Canada-approved prescription drugs. Before the Trump Administration moves forward with a final rule and implementation, policymakers should seek counsel from Canadian regulators such as Health Canada, the Foreign Affairs Consular at the Canadian Embassy in Washington, D.C., the Canadian Pharmacist Association and others. ASOP Global’s Canada Chapter members stand ready to provide perspective on the issues as they impact Canadian safety and drug supply.

Even before today’s importation schemes are implemented, Americans may be put at risk even by today’s announcement. ASOP Global appreciates and applauds the FDA’s acknowledgment of the dangers of rogue online pharmacies “often run by sophisticated criminal networks that knowingly and unlawfully cause the importation of adulterated, counterfeit, misbranded and unapproved drugs into the United States.” See NPRM discussion, pages 18-19.

Despite that warning, we fear that news of today’s actions may lead consumers to go online looking for “import Canadian medicines,” as Americans are so accustomed these days to buying nearly everything online. When they do, Americans will find dozens if not hundreds of sellers offering promises of safe Canadian products. We urge consumers to not believe the hype. As the draft FDA rule states, “Consumers go to these websites believing they are buying

safe and effective medications, but often they are being deceived and put at risk by individuals who put financial gain above patient safety.” *Id.*

It is widely known that the open internet is awash with illegal online pharmacies posing as “Canadian” and claiming to be selling safe U.S. Food and Drug Administration (FDA)- or Health Canada-approved medicines. *Id.* At any given time, there are up to 35,000 active online pharmacy websites operating on the open web, of which about [94.8% are operating out of compliance](#) with U.S. state and federal law and relevant pharmacy practice standards. 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.

And let us not forget the [CanadaDrugs case](#), where a licensed Canadian wholesaler was indicted and plead guilty to making millions selling misbranded and/or counterfeit cancer medications to Americans. While the NPRM seeks to distinguish this case from what is being proposed (*Id.*), ASOP Global fears the draft regulation opens the door to copy-cat criminals following this business model, getting rich while skirting safety laws and endangering Americans.

Additionally, major loopholes in the U.S. Postal System allow mass quantities of counterfeit pills – many of which have been laced with deadly fentanyl and other synthetic opioids – from foreign sources to slip into the U.S. illegally through International Mail Facilities (IMFs). If drug importation is authorized at the state level, the inevitable increased volume of drugs from other countries would stress an already overburdened postal safety system.

ASOP Global is not alone in its concerns. Republican and Democrat, for two decades HHS Secretaries and FDA Commissioners for have opposed importation proposals for many of these same reasons– including President Trump’s former [FDA Commissioner Scott Gottlieb](#).

Finally, it is important to remember that past importation efforts in states like Illinois, Maine, Minnesota and Vermont have failed.

While ASOP Global applauds all efforts to increase patient access to safe, affordable medicines, importation remains an implausible answer. ASOP Global welcomes the opportunity to provide data and insights showing why importation is not the solution and offer alternatives for keeping Americans safe when looking for medicines online.

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ABOUT ASOP GLOBAL

The Alliance for Safe Online Pharmacies (ASOP Global) is a 501(c)(4) non-profit organization headquartered in Washington, D.C. with activities in U.S., Canada, Europe, Latin America and Asia. ASOP Global is dedicated to 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 public health organizations, international members, pharmacy members, as well as pharmaceutical manufacturers.