

STATEMENT ON PRESCRIPTION DRUG IMPORTATION PROPOSALS

Prescription Drug Importation is Not a Viable Solution to High Prescription Drug Costs

FEBRUARY 2019

Policymakers, rightfully so, have sought to lower prescription drug costs for ordinary Americans. Some of the proposals being considered would allow for importation of prescription drugs from other countries where they are currently being sold at cheaper prices. These proposals have ranged from allowing personal importation to the creation of a wholesale (i.e. bulk) purchasing program from Canada.

While the National Association of Boards of Pharmacy® (NABP®) appreciates these important efforts to increase patient access to affordable medications, we must also ensure that those medications are safe. Allowing Americans to import foreign medicines would put patients in this country at risk of harm from the infiltration of unapproved, substandard, falsified and counterfeit medicines into the U.S. supply chain. Based on our nearly 20 years of experience, NABP believes drug importation proposals would have detrimental public health and patient safety consequences.

PROPOSED BILLS ADVOCATE ILLEGAL PROFESSIONAL CONDUCT AND ARE UNIMPLEMENTABLE

According to Canadian federal and provincial laws, a prescription in Canada is only legal when issued by a Canadian physician (or other licensed Canadian prescriber). Most, if not all, drug importation proposals only describe 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. Canadian law prohibits the filling of prescriptions issued by U.S. practitioners.

Moreover, proposals that call for drug importation through verified wholesalers in Canada are unimplementable. 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 would – and has in the past – revoked the license to operate from wholesalers that agree to export Health Canada-approved prescription drugs. Before Congress moves forward with any drug importation proposals, policymakers should seek counsel from our Northern neighbors such as Health Canada, the Foreign Affairs Consular at Canadian Embassy in Washington, D.C., Canadian Pharmacist Association, and others.

WHY CONGRESS SHOULD NOT SEND PATIENTS TO 'CANADIAN' ONLINE PHARMACIES

As seen with persistent law enforcement actions across the nation, illicit and dangerous drug sellers pose a continuous and growing public health threat and demonstrate how difficult it is for law enforcement to protect patients from dangerous medicines bought from unsafe sources. Counterfeit and substandard medicines aren't just an issue with controlled substances such as opioids. Counterfeit medications seized include insulin, anti-inflammatories, fertility drugs, antibiotics, antivirals and birth control, and other medications used for chronic conditions, health maintenance and infections. These drugs are often manufactured in unsafe conditions; contain too much, too little, or no active ingredients; and/or may be made using dangerous and sometimes deadly substances, including fentanyl and other poisons. The sale of counterfeit drugs is lucrative, generating over \$200 billion a year in profit for global criminal networks.

U.S. consumers buying medications from Canadian online 'pharmacies' rarely, if ever, receive the Health Canada-approved products afforded to Canadian customers. Instead, Canadian pharmacy websites sell U.S. patients medicines manufactured in places where buyers would not even drink the water in India, Turkey, or Southeast Asia. NABP and many other patient safety advocates have found that the dangers of drugs dispensed outside of FDA's or Health Canada's drug approval process are significant. Outside these closed and tightly regulated drug supply chains, the safeguards put in place to ensure the identity, efficacy, and safety of prescription medications no longer apply.



- 1. Sending consumers online hoping they will find a safe site is a big gamble, and policymakers would be gambling with patient lives. Even finding a legitimate online pharmacy that sells U.S. FDA-approved medicines to U.S. consumers is tricky, given there are 35,000 active online pharmacies operating today and 96% of them violate applicable laws.
- 2. Further, NABP is unaware of any Canadian online pharmacies that consistently dispense Health Canadaapproved medicines to U.S. consumers. To put it bluntly, sending consumers online to look for Health Canadaapproved medicines is reckless. Indeed, FDA has found that 86% of the drugs being promoted as 'Canadian' actually came from 27 other countries around the globe, including India, Costa Rica and Vanuatu.

"None of us, acting in our roles as former FDA Commissioners, were able to conclude that a wider policy of routine importation would increase access to safe and effective drugs for the American public."

- Former FDA commissioners Robert Califf, MD, Margaret Hamburg, MD, Mark McClellan, MD, PhD and Andrew Von Eschenbach, MD in a 2017 open letter to Congress
- 3. Even if there were Canadian online pharmacies that consistently dispensed Health Canada-approved medicines to US patients (which is not the case today), how would a US consumer distinguish these sites from the thousands of other, dangerous sites selling counterfeit, adulterated, and unapproved products? Even with the full force of U.S. law enforcement going after illegal sites, thousands of illegal online pharmacy websites based offshore would continue to dupe U.S. consumers into believing they are buying from a "real" Canadian online pharmacy. Proscriptive statutes, enhanced penalties, and additional enforcement resources do nothing to protect U.S. consumers from illegal foreign actors who blatantly disregard US laws and hide in jurisdictions that will not extradite criminals.

NABP and many other patient safety and public health advocates have found that the dangers of drugs dispensed outside of FDA's drug approval process are significant. Outside these closed and tightly regulated drug supply chains, the safeguards put in place to ensure the identity, efficacy, and safety of prescription medications no longer apply. As stakeholders in the public health ecosystem, we have a collective responsibility to educate, inform and protect American patients from well-evidenced dangers related to unapproved, substandard, and counterfeit medicines from unregulated foreign sources.

ABOUT THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP is the only professional association that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Bahamas, Australia and 10 Canadian provinces.

NEARLY 20 YEARS OF EXPERIENCE WITH ONLINE PHARMACIES

Since 1999, NABP has been monitoring and reviewing internet pharmacy websites. The Association's efforts began that year with the establishment of the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, which accredits US pharmacies that dispense prescription drugs via the internet. In 2004, NABP launched the Veterinary-VIPPS® program to accredit US pharmacies that dispense prescription veterinary drugs via the internet. In 2010, NABP launched the e-Advertiser ApprovalCM Program, which identified internet advertisers that offer limited pharmacy services or other prescription drug-related services online. Most recently, in 2014 NABP launched the .Pharmacy Top Level Domain Program to provide an easier and more secure way for patients to identify legitimate online pharmacies and pharmacy-related resources. For more about NABP's programs, visit www.safe.pharmacy.