

DPAC Opposes Drug Importation Over Safety and Economic Concerns

DPAC's Statement

The Diabetes Patient Advocacy Coalition (DPAC) is an alliance of people with diabetes, caregivers, patient advocates, health professionals, disease organizations and companies working collaboratively to promote and support public policy initiatives to improve the health of people with diabetes. DPAC's guiding principles focus on 3 key areas:

- *Safety (enforce established safety standards on devices, medications and practices for diabetes care)*
- *Quality (advance the standards of care for diabetes management)*
- *Access (access to health care and quality diabetes products for all 29M Americans with diabetes)*

Considering the rising costs of U.S. healthcare, it is not surprising that government and individuals are looking for innovative pathways to get needed prescription medicines at lower prices. Many states are introducing bills to investigate or allow for the importation of drugs from Canada. DPAC opposes these bills for two reasons: first, there is no effective way to ensure that the drugs coming from Canada meet the strict safety regulations set by the FDA, and second, there is no guarantee that any cost savings would be passed on to the consumer.¹²

RECENT HISTORY

The Medicare Modernization Act gave the Secretary of Health and Human Services the power to legalize drug importation if and only if two criteria were met: the Secretary must be able to certify that the imported drugs would (1) pose no additional risk to public health and safety, and (2) generate cost-savings for American consumers.³ Since the law was passed in 2003, no Secretary has been able to make such a certification, and the practice remains illegal. Additionally, no state has been able to implement a system of drug importation that meets the needs of consumers without being a danger to their health.⁴

¹ Harvard Business Review, Importing Cheap Drugs From Canada Won't Reduce U.S. Drug Costs, <https://hbr.org/2016/02/why-importing-cheap-pharmaceuticals-from-canada-wont-work>

² The Hill, Drug importation from Canada increases patient risk with no guarantee of lower prices, <http://thehill.com/blogs/pundits-blog/healthcare/326773-drug-importation-from-canada-increased-patient-risk-with-no>

³ Harvard Business Review, Importing Cheap Drugs From Canada Won't Reduce U.S. Drug Costs, <https://hbr.org/2016/02/why-importing-cheap-pharmaceuticals-from-canada-wont-work>

⁴ Forbes, The FDA is Right; Prescription Drug Importation is Dangerous, <https://www.forbes.com/sites/dougschoen/2017/01/23/the-fda-is-right-prescription-drug-importation-is-dangerous/#7a78cddd3fe2>

It is a fact that many individuals purchase prescription drugs from Canadian pharmacies through mail order or physically crossing the border. A recent poll showed that about 8% of U.S. citizens purchase prescription drugs from Canada or other countries in order to obtain lower purchase prices.⁵ Currently, U.S. law limits individual purchases of prescription medicines from other countries not to exceed a lifetime 90-day supply. However, this law is rarely enforced.⁶ Despite the prevalence of this practice, there are very real safety and economic concerns to consider.

SAFETY

Most people with diabetes who buy imported medicines do so through online “Canadian pharmacy” websites, which are often illegitimate or illegal with no oversight. 85% of drugs sold on “Canadian pharmacy” websites are not actually from Canada.⁷ Instead, these drugs come from countries that lack safety guidelines, allowing prescription medications to be stored at unsafe temperatures, formulated with unsafe ingredients, or may be completely counterfeit. The U.S. FDA and Health Canada, which is the equivalent of FDA, have exportation and importation laws that are enforced for the safety of their citizens.⁸⁹

Though many consumers believe that they can spot a counterfeit or tampered-with prescription drug from labeling or packaging, improvements in counterfeiting technology has made it cheaper and easier to produce fake packaging and labels, making it nearly impossible for consumers and even authorities to detect counterfeits.¹⁰ Additionally, life-essential medications, like cancer and diabetes prescription drugs are counterfeited more often because of the high price counterfeiters can charge for them.

In 2006 more than a million counterfeit blood glucose test strips were sold to U.S. consumers in 35 different states. Nobody along the U.S. supply chain was able to tell the counterfeit test strips from real ones.¹¹ In September 2017, the INTERPOL, working with the FDA, confiscated more than 51 million dollars worth of fake and illicit drugs including dietary supplements, pain reduction pills, epilepsy medication, erectile dysfunction pills, and anti-psychotic medications.¹²

⁵ New England Journal of Medicine, The Price of Crossing the Border for Medication, <http://www.nejm.org/doi/full/10.1056/NEJMp1704489?rss=searchAndBrowse&>

⁶ Harvard Business Review, Cheap Drugs from Canada Won't Reduce U.S. Drug Prices, <https://hbr.org/2016/02/why-importing-cheap-pharmaceuticals-from-canada-wont-work>

⁷ The Hill, Drug importation from Canada increases patient risk with no guarantee of lower prices

⁸ Forbes, The FDA is Right; Prescription Drug Importation is Dangerous, <https://www.forbes.com/sites/dougschoen/2017/01/23/the-fda-is-right-prescription-drug-importation-is-dangerous/#7a78cddd3fe2>

⁹ Pew Trusts, Case Studies: How Unsafe Drugs Can Reach Patients, http://www.pewtrusts.org/~media/legacy/uploadedfiles/phg/content_level_pages/issue_briefs/casestudyunsafe_drugs_v2.pdf.pdf

¹⁰ NIH, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/>

¹¹ NIH, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/>

¹² FDA, Millions of Medicines Seized in Largest INTERPOL Operation Against Illicit Online Pharmacies, <https://www.fda.gov/ICECI/CriminalInvestigations/ucm577828.htm>

These fake medications can have deadly consequences, as was the case when a woman in Nigeria died of hyperglycemia after being treated with fake insulin.¹³

Consumers may believe the drugs they receive are safe because they think the Canadian government inspects and certifies them. However, Canada does not regulate or certify the safety of drugs flowing through its borders to U.S. consumers.¹⁴ The U.S. FDA also does not regulate these drugs, as it is left out of the illegal supply chain completely. This means that there is no agency, government or otherwise, certifying the safety or authenticity of these drugs.

COST SAVINGS

Proponents of legalizing drug importation often say that the practice would strengthen the drug markets or free trade. Unfortunately, that is not true. Any lower cost generic drugs already cost less in the U.S. than in other developed countries and make up nearly 90% of U.S. drug sales. Importation would not reduce costs in a meaningful way.¹⁵

Drug reimportation is when U.S.-manufactured drugs are sold to other countries and then sold back to U. S. consumers at the price negotiated between particular government and the manufacturers. These contracts may impose export limits or regulatory caps on the quantities of drugs distributed to that country.¹⁶ Even if U.S. citizens were to see any cost savings from drug reimportation, countries may not be able to export the quantities above what is needed for their own population.

DPAC believes that drug importation is not an effective or long-term solution to address drug pricing. Drug importation is dangerous because the drugs imported are not inspected by any organization, and are often from countries that have lax manufacturing and handling rules. Additionally, legalizing drug importation will not lead to meaningful savings for patients. DPAC looks forward to working with stakeholders to find an alternative solution that will keep people with diabetes safe and provide affordable access to prescription drugs.

¹³ NIH, Is the Drugstore Safe? Counterfeit Diabetes Products on the Shelves,
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/>

¹⁴ The Hill,
<http://thehill.com/blogs/pundits-blog/healthcare/326773-drug-importation-from-canada-increased-patient-risk-with-no>

¹⁵ The Hill,
<http://thehill.com/blogs/pundits-blog/healthcare/326773-drug-importation-from-canada-increased-patient-risk-with-no>

¹⁶ Harvard Business Review, Cheap Drugs from Canada Won't Reduce U.S. Drug Prices,
<https://hbr.org/2016/02/why-importing-cheap-pharmaceuticals-from-canada-wont-work>