



October 18, 2017

The Honorable Mitch McConnell
Senate Majority Leader
S-230, U.S. Capitol
Washington, DC 20510

The Honorable Charles Schumer
Senate Minority Leader
S-221, U.S. Capitol
Washington, DC 20510

The Honorable John Cornyn
Senate Majority Assistant Leader
517 Hart Senate Office Building
Washington, DC 20510

The Honorable Dick Durbin
Senate Minority Assistant Leader
711 Hart Senate Building
Washington, DC 20510

Dear Leader McConnell, Leader Schumer, Assistant Leader Cornyn, and Assistant Leader Durbin:

On behalf of ASHP (American Society of Health-System Pharmacists), I am writing to convey our opposition to any legislation that would allow for distributors, pharmacies, or individuals to import prescription medications from Canada or other countries.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 44,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, www.ashp.org, or its consumer website, www.SafeMedication.com.

Over recent decades, problems with the integrity of America's drug supply have endangered patient health and resulted in the passage of the Drug Supply Chain Security Act (DSCSA) in 2013. Importation of medications from foreign countries further complicates this issue and would jeopardize the effectiveness of the DSCSA. Our opposition is based ASHP's policy on importation of pharmaceuticals, which advocates for the continuation and application of laws and regulations enforced by the FDA to maintain the integrity of the supply chain, provide for continued patient access to pharmacists' review of medications, preserve the patient-pharmacist-prescriber relationship, and provide for adequate patient counseling and education.¹

While the concept of pharmaceutical importation may seem as simple as a U.S. manufacturer making and shipping drugs to Canada, for example, and Americans purchasing them to be sent back to the U.S., it is somewhat more complex.

¹ IMPORTATION OF PHARMACEUTICALS: To advocate for the continuation and application of laws and regulations enforced by the Food and Drug Administration (FDA) and state boards of pharmacy with respect to the importation of pharmaceuticals in order to (1) maintain the integrity of the pharmaceutical supply chain and avoid the introduction of counterfeit products into the United States; (2) provide for continued patient access to pharmacist review of all medications and preserve the patient-pharmacist-prescriber relationship; and (3) provide adequate patient counseling and education, particularly to patients taking multiple high-risk medications; further, to urge the FDA and state boards of pharmacy to vigorously enforce federal and state laws in relation to importation of pharmaceuticals by individuals, distributors (including wholesalers), and pharmacies that bypass a safe and secure regulatory framework.

American drug companies manufacture and label medications to the standards of the country to which they are sending the drugs, meaning some drugs are of a different strength or form than they would be in the United States. Whereas the FDA could require a drug to be in capsule form in the United States, Canadian regulation could require that the drug be in tablet form. Consequently, these drugs would not be considered legal or approved for the U.S. market.

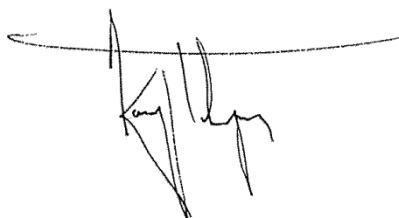
Even medications obtained from a country with high standards, such as Canada, create huge risks. Canadian drugs, like all foreign drugs, are outside the realm of the United States regulatory system; there is no way to verify where they have been, the conditions in which they have been stored, and whether they have been tampered with or contaminated. This lack of regulation creates a problem for both consumers and pharmacists. Consumers do not know if the drug they are taking is safe and effective, and pharmacists cannot accurately check for drug interactions, since they are unaware of the true identity and origin of the drug.

The United States regulatory system is the world's gold standard in maintaining drug supply chain integrity. We caution against the Senate taking actions that may undermine that system by allowing non-FDA-approved medications to enter the supply chain, especially given the investment in the DSCSA to protect the United States supply chain. Once products have the foreign country's distribution system, there is no way to ensure the safety of those medications. This proposed importation measure will make it even more difficult to address safety issues by not only increasing the volume of imports and the number of suppliers, but also failing to address the increased resources that would be necessary to ensure compliance.

Although the drug-importation proposal is a well-meaning policy aimed at enhancing consumer access to medications, a goal we fully support, the unintended consequences outweigh any potential benefit. We recommend instead that the Senate strongly consider measures that would increase competition in the market and that would result in long-term solutions, such as S. 974, the "Creating and Restoring Equal Access to Equivalent Samples" (CREATES) Act of 2017."

Should you have any questions or comments about our position, please contact me or have a member of your team contact Christopher Topoleski, Director of Federal Legislative Affairs, at 301-664-8806 or at ctopoleski@ashp.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kasey K. Thompson', written over a horizontal line.

Kasey K. Thompson, Pharm.D., M.S., M.B.A.
Chief Operating Officer and Senior Vice President