POSITION STATEMENT
IMPORTATION OF PRESCRIPTION DRUGS

Position

The American Society of Consultant Pharmacists (ASCP) fully supports access to all needed and appropriate prescription medications, along with pharmacist services to support the appropriate use of these medications, by all consumers—especially older adults. To achieve these goals, ASCP supports access to affordable, high-quality medication and pharmacist services.

ASCP does not support the routine drug importation of prescription medications because importation increases the likelihood of patients using dangerous, ineffective, counterfeit or low-quality medication. Without appropriate testing, quality, safety and potency cannot be assured. Individuals who decide to import medications should engage in testing to ensure the products meet US standards for quality, safety and purity to avoid taking counterfeit, substandard or unapproved medications.¹

ASCP believes the drug importation strategy has three fundamental problems:

- Importation increases the likelihood of exposure to counterfeit or low-quality pharmaceutical products.
- Importation is not likely to result in significant savings to consumers once additional testing requirements are completed.
- Drug importation of prescription drugs does not address the broader issue of access to pharmacist services to ensure that medications are used appropriately.
Background
Prescription medications are an integral component of quality health care. However, an estimated 31 million Americans had no health insurance coverage in 2020.\textsuperscript{2} It is further estimated that about 19\% of Medicare beneficiaries have no supplemental insurance coverage for prescription drugs as of 2016.\textsuperscript{3,4} Prescription medications are often expensive, and individuals who take multiple or high-cost medications may have difficulty obtaining what they need. Recent surveys have estimated that eight percent of Americans do not take their medication as prescribed because of costs; the percentage climbs to ten percent for Medicare recipients.\textsuperscript{5} For these and other reasons, ASCP supports ongoing efforts to lower the cost of prescription drugs.

In response to these concerns, a variety of strategies have been considered to enhance access to prescription medications, especially for the older adult population. In October 2020, the FDA finalized a rule on drug importation that allows for the commercial importation of certain prescription drugs from Canada through time-limited Section 804 Importation Programs (SIPs).\textsuperscript{6} This rule allows for importation program proposals to be submitted to the HHS Secretary by a State or Indian Tribe, and in certain circumstances by a pharmacist or wholesale distributor, with possible co-sponsorship by a State, Indian Tribe, pharmacist, or wholesaler distributor.\textsuperscript{7} In theory, access to lower cost medications by pharmacies and wholesalers will result in less expensive medications for consumers, however this theory is fundamentally flawed as noted below.

The purpose of this document is to provide an evaluation of drug importation and focus on the general concept of importation, not specifically related to a particular legislative proposal.

Arguments/Discussion

ASCP’s specific concerns regarding drug importation are outlined below.

Importation increases the risk that consumers will be exposed to counterfeit or low-quality pharmaceutical products.

In the United States, the FDA and the state boards of pharmacy have effective systems of regulation and oversight to prevent introduction of counterfeit medications. When medications are imported from abroad, American pharmacies and consumers are dependent upon the unknown level of regulation and oversight in these countries. With the high potential for profit in the sale of counterfeit prescription drugs, this issue is a serious concern. As described in a joint letter that ASCP signed with several other pharmacy associations, importation poses unacceptable safety risks to our supply chain and our patients.\textsuperscript{8} Pharmacists and other drug supply chain stakeholders have been working for years to implement the Drug Supply Chain Security Act (DSCSA), which creates a closed supply chain to track and trace prescription drugs as they move from manufacturer to distributor to pharmacist.\textsuperscript{9} These same safeguards do not exist in other countries.
When medications are labeled in another country, the standards applied may not be consistent with FDA regulations. This may increase the risk of medication errors or lead to confusion when labels do not provide needed or accurate information.

Additionally, medications imported to the United States may be exposed to extreme temperature variations during shipping. Shipping to tropical climates in the summer or cold climates in the winter could result in temperature extremes that result in degradation of the active medication. Without research on the effects of these temperature variations, other storage requirements, and adequate regulations and oversight to protect the drug supply, patient care could be endangered.\textsuperscript{10}

*Importation of prescription drugs is not likely to result in significant savings to consumers that justify the risk(s) of importing medications.*

Pharmacies or wholesalers that desire to import and distribute prescription medications would need to conduct adequate testing to ensure safety and purity. Under a 2020 Final Rule from HHS on drug importation from Canada, imported drugs require testing from a qualifying lab related to authenticity and degradation.\textsuperscript{11} The cost of the testing will increase the acquisition costs of the imported medications and may not result in reduced costs for patients, pharmacies and health systems. Following this rulemaking, there was and will continue to be extensive debate on the true cost saving associated with the plan.\textsuperscript{12}

In addition, pharmacies or wholesalers that distribute imported medications would be liable for adverse consequences associated with the distribution of adulterated products to consumers. The fear of liability and potential costs of legal action will serve as a deterrent to implementing importation policies.

The United States Food and Drug Administration (FDA), the agency that oversees the importation program, would need millions of additional dollars to implement safeguards to ensure that imported medications do not represent a threat to public health, a point made in 2017 by the four most recent FDA Commissioners.\textsuperscript{13} The costs for administrative oversight of the program would greatly diminish potential savings that might accrue, and the agency admits in its regulatory impact analysis of the final rule that there is insufficient information to estimate savings.\textsuperscript{14}

*Drug importation of prescription drugs does not address the broader issue of access to pharmacist services to ensure that medications are used appropriately.*

Providing enhanced access to prescription medications without providing access to comprehensive pharmacist services can result in increased health care costs and an increase in medication-related problems. Direct importation by patients removes these critical healthcare specialists from the patient’s care team and creates the potential for dangerous situations including abuse, misuse, ineffective use and addiction.\textsuperscript{15} Positive outcomes result when pharmacists provide medication therapy management services to older adults.\textsuperscript{16 17}
In summary, risks to patient safety and concerns about the true effectiveness of cost-savings outweigh the short-term, perceived benefits of routine drug importation. As an organization committed to patient safety and transforming aging, ASCP cannot support an importation proposal that does not ensure testing of imported drugs and patient access to pharmacists and medication management services.

Approved by ASCP Board of Directors on June 15, 2021


7 ibid


