

Importation of Prescription Medicines

HDA'S POSITION

HDA opposes permitting the importation of pharmaceuticals sold or designated for sale in foreign countries into the United States. Importation significantly increases the likelihood of counterfeit or adulterated prescription medicines entering the U.S. marketplace and places U.S. patients at risk.

- Importation of medicines runs counter to the goals and requirements of the DSCSA, which was enacted by Congress in 2013.
- Limiting importation from a specific country or countries neither diminishes the likelihood of counterfeit or adulterated drugs entering the U.S., nor will it ensure significant reductions in the costs of prescription drugs.
- HDA does not support importation through Internet pharmacies, particularly given the increasingly sophisticated technology that is being used by counterfeiters. In fact, HDA supports efforts to combat illegal online drug sellers and believes that an importation proposal would further undermine the U.S. Food and Drug Administration (FDA) efforts to prevent such illicit activities.

ISSUE

The U.S. pharmaceutical supply chain is a sophisticated, efficient and highly secure system, and was further strengthened in 2013 by the passage of the Drug Supply Chain Security Act (DSCSA, or Title II of the Drug Quality and Security Act) (Public Law 113-54). The law provides for a federal traceability solution for prescription medicines, which by 2023, will lead to the establishment of FDA-regulated electronic, unit-level traceability requirements across the entire supply chain for prescription drug products. Drugs sold or designated for sale in other countries likely will not conform with U.S. traceability regulations, thereby exposing the U.S. supply chain and patients to unnecessary health risk with no promise of decreased costs for prescription drugs.

Drug approval by the FDA is contingent upon the strictest guidelines for product integrity, good manufacturing practices, scientific data analysis and public safety. Although there are a number of drugs available for sale in Europe, Canada or other countries that may be priced at a lower cost for a variety of reasons, it is important to recognize that other countries' regulatory agencies have different approval guidelines, dosage recommendations and quality assurances. While the FDA is currently working to expand its relationships with other regulatory entities, the agency cannot guarantee an American consumer that a drug marketed and available abroad will be the same product his or her physician's prescription is written for, nor can it fully attest to its safety.

Both branded and generic drugs are susceptible to counterfeiting, containing insufficient or too much of an approved medicine's active ingredient or to being contaminated by unsanitary manufacturing conditions. Patients can be placed in harm's way due to the presence of substandard/spurious/false-labeled/ falsified/ counterfeit (SFFC) medicines in other countries, including purchases made from illegal Internet drug sellers, whose nature often hides the true origin of products. Illegal online drug sellers may disregard state and federal laws and pharmacy practice standards, promising lower prices on medications. The U.S. supply chain, regulated by the FDA, devotes significant resources to ensuring good manufacturing practices, product authenticity and the safe and secure distribution of drugs through authorized parties from the point of manufacture to the point of dispensing. HDA members are an essential part of this closed distribution system, working daily with supply chain partners, law enforcement and government regulators to help ensure prescription medicines are safely delivered to legal, licensed pharmacies within the U.S.

Importation of Prescription Medicines *continued*

Given the action Congress has taken to enhance security within our pharmaceutical supply chain, allowing for importation of prescription drug products, even from a specific country, increases the likelihood of counterfeit or adulterated drugs entering the U.S. Patient safety and product integrity will suffer as a result of prescription medicine importation. Before considering importation of potentially dangerous products from other countries — whether through personal importation, Internet purchasing, or other avenues — Congress should consider the implications of introducing such risk to the pharmaceutical supply chain.

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.