Prescription Drug Importation

AMCP has concerns with legislative proposals that would allow the commercial importation of prescription drugs for sale in the United States.[1] AMCP understands such proposals are being offered to address the growing inaccessibility to affordable prescription drugs; equalize global pricing disparities; and encourage the international community to share reasonably in the costs of pharmaceutical research and development. However, as an organization representing health care professionals, AMCP cannot support these proposals until there are adequate resources to monitor the importation of prescription drugs, ensuring that their quality and safety have not been compromised.

Generally, legislative language related to importation would allow pharmacies and drug distributors to purchase FDA-approved pharmaceuticals for sale in the United States. The rationale behind such proposals is to use the international pharmaceutical market as a source of low-cost prescription drugs. AMCP supports the goals of improving access to prescription drugs at lower prices and reducing overall health care costs. Subject to acceptable provisions held in place, the general populace could benefit from the importation of prescription drugs for sale insofar as such legislation makes it possible for the consuming public to purchase prescription drugs at a cost lower than what is asked today. However, the anticipated savings generated through importation programs is uncertain.

Several factors may influence whether significant savings will be realized from the importation of prescription drugs. How the import price compares with domestic price will vary depending on the specific drug. For example, while certain brand-name (innovator) products sold in Canada have been shown to be priced considerably lower than in the United States, the price differential of other drugs, particularly generics, are minimal. Such a program will also depend on the foreign availability of the product.

Foreign supplies of domestically produced drugs may be inadequate to support large-scale importation, thus limiting the potential savings available to American consumers. Moreover, how the importation might affect the exporting country's pharmaceutical market, such as drug shortages or drug price increases, must be considered. Finally, savings may not be fully realized because of the additional costs manufacturers must assume for significant importation, such as registration fees, the transporting of products, and investments in technology to secure the supply chain.

The impact importation legislation would have on the drug distribution system warrants study, as allowing importation may pose unintended financial and health consequences for American consumers. AMCP believes that government intervention in the marketplace results in increased overall consumer prices, increased numbers of uninsured, and decreased pharmaceutical innovation. Allowing the importation of pharmaceuticals may result in these negative effects and bring downstream cost-shifting by manufacturers to compensate for lost profits.

Legislation permitting prescription drug importation also presents potential patient safety issues. For instance, quality and integrity cannot be assured with reimported products and implementing any appropriate safeguards addressing these concerns is a challenge. Prudent importation legislation must ensure maintenance of quality assurance standards throughout the international drug distribution system. In order to guarantee patient safety, agencies such as the Food and Drug Administration, the U.S. Customs and Border Protection, and the U.S. Immigration and Customs Enforcement must have the technological and financial resources to address these safety concerns.

AMCP believes that until more conclusive data are available as to the likely impact of importation on the cost of drugs and the risks posed to the American citizens, AMCP will oppose legislation that would allow the importation of prescription drugs in the United States.

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[1] Most bills introduced in Congress have addressed commercial importation, i.e., importing drugs manufactured outside of FDA-approved sites, as well as reimportation, i.e., importing drugs that were manufactured in the United States and exported to foreign countries. Drugs that are manufactured outside of FDA-approved sites are required to meet further conditions before importation is allowed. This statement applies to both importation and reimportation.