

Resolution Concerning the Prohibition of Imported Prescription Drugs

WHEREAS, the use of safe and legal prescription drugs improves the quality of care and helps patients live healthier, longer, and more productive lives while keeping them out of more costly acute care settings in the long term, and

WHEREAS, the Food, Drug, and Cosmetic Act (FDCA) governs the manufacture, sale, and distribution of drugs in interstate commerce, and under the FDCA, every new drug must be approved by the Food and Drug Administration (FDA) prior to marketing, and also under the FDCA, approvals are specific to each product, and all prescription drugs must be accurately labeled and may not be dispensed without an order from a licensed practitioner, and

WHEREAS, virtually all prescription drugs imported into the United States, other than those imported by the original manufacturer, pose serious safety concerns and violate these provisions of the federal law; such as those recently uncovered by a U.S. Customs and FDA investigation, which found that 88% (1,019 of 1,153) contained unapproved drugs, such as mislabeled, misbranded, expired, and mishandled drugs that might cause patient health problems, and

WHEREAS, the importation of drugs from foreign countries opens the currently secured distribution system established by the FDCA, thereby increasing the likelihood that counterfeit drugs, dangerous narcotics and deliberately contaminated material would endanger the health of U.S. citizens, and

WHEREAS, national pharmacy groups with a focus on patient health and safety have stated that the safety of imported drugs cannot be guaranteed and may result in patient harm, and

WHEREAS, the FDA's Personal Importation policy, which merely states as a matter of FDA enforcement discretion, an individual may import small quantities of drugs which are intended for serious conditions and which are not available domestically, does not alter the requirements of the federal law, and

WHEREAS, consumers victimized by imported drugs have included the most vulnerable patients including seniors, children, and the underserved.

NOW, THEREFORE, BE IT RESOLVED that the American Legislative Exchange Counsel supports the FDA's efforts to ensure the safety and quality of prescription drugs and opposes the illegal importation of non-FDA approved prescription drugs because of safety concerns.

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