Whereas, All drugs sold in the United States have to be approved by the US Food and Drug Administration; and

Whereas, The thalidomide tragedy that occurred in early 1960s in Europe with approximately 10,000 infants being born with limb abnormalities was largely avoided in the United States because FDA inspector Francis Kelsey prevented the approval of the drug for use in the United States. Since that time the FDA has been hypervigilant about approving new medications which has improved patient safety but unfortunately has also been used by pharmaceutical companies to their benefit by making it more difficult to allow the market to work effectively in pharmaceuticals because of decreased competition; and

Whereas, The vigilance of the FDA and required testing of new drugs has increased the cost of development and testing of new medications to approximately $1 billion for each new medicine approved and this cost has led to new medicines not being tested and approved for use in the United States; and

Whereas, In Europe the EMA (European Medicines Agency) does a similar but not identical job in approving new medications in Europe for a smaller expense and therefore more drugs are available in Europe than are available in the United States and often at a significantly lower price; and

Whereas, The cost of pharmaceuticals in the United States is increasing rapidly and is recognized as a major medical problem with many people having difficulty affording their medications and wondering why they cannot obtain drugs approved in Europe which are often considerably less expensive; therefore be it

RESOLVED, That our American Medical Association compare the results of our US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) approval processes in terms of determining the safety and efficacy of pharmaceuticals using whatever data is available in order to determine whether the health of the citizens of the United States would be at risk if drugs approved by the EMA were imported and used as compared to the FDA (Directive to Take Action); and be it further

RESOLVED, That our AMA estimate what the reduction in the cost of medications would be for our patients if they were allowed to import EMA certified medications for use in the United States and thereby increasing competition for some of our current expensive pharmaceuticals. (Directive to Take Action)

Fiscal Note: Not yet determined
Received: 05/01/19
RELEVANT AMA POLICY

Prescription Drug Importation and Patient Safety D-100.983
Our AMA will:
(1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if:
(a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported;
(2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured;
(3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation;
(4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts;
(5) support the in-person purchase and importation of Health Canada-approved prescription drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity; and
(6) advocate for an increase in funding for the US Food and Drug Administration to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the integrity of prescription drug products imported for personal use can be assured.
Citation: BOT Rep. 3, I-04; Reaffirmation A-09; Reaffirmed in lieu of: Res. 817, I-16; Appended: CMS Rep. 01, I-18

Pharmaceutical Quality Control for Foreign Medications D-100.977
Our AMA will call upon Congress to provide the US Food and Drug Administration with the necessary authority and resources to ensure that imported drugs are safe for American consumers and patients.
Citation: Res. 508, A-08;A-16;A-16