OFFICE OF LEGISLATIVE RESEARCH
Objective Research for Connecticut's Legislature

Issue Brief

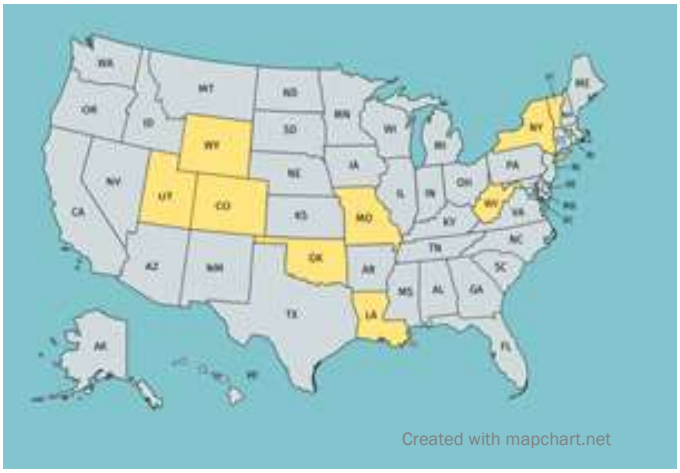
Importing Prescription Drugs

Summary

The federal Medicare Prescription Drug, Improvement, and Modernization Act Of 2003 authorizes a wholesaler or pharmacist to import prescription drugs from Canada under certain conditions with the approval of the Department of Health and Human Services (HHS) (P.L. 108-173 § 1121). The primary purpose of this authorization is to import prescription drugs at a lower cost in order to pass the savings on to U.S. consumers. To date, HHS has not acted on this law by approving an importation program. The law also authorizes HHS to allow individuals to import drugs without penalty in certain circumstances.

Federal law allows the importation of drugs from Canada only if it poses no additional public health and safety risk and results in significantly reduced costs to the American consumer (21 U.S. Code § 384).

Although the federal law was passed fifteen years ago, the rising cost of prescription drugs has caused renewed focus on importation as a strategy for addressing the issue. In fact, in July 2018, the HHS Secretary directed the federal Food and Drug Administration (FDA) to establish a drug importation working group to address prescription drug price spikes.



State Action

In May 2018, Vermont passed the nation's first drug importation law, which establishes a state drug importation program to act as an importing wholesaler under the federal law. The program cannot be implemented until (1) the state adopts new legislation funding it and (2) HHS approves it. The law is based on the National Academy for State Health Policy's (NASHP) model drug importation legislation.

According to NASHP, six other states also introduced drug importation legislation this year: Colorado (SB 80), Louisiana (HB 384), Missouri (SB 722), Utah (HB 163), West Virginia (HB 4294), and Wyoming (SF 88). In addition, at least two other states introduced similar legislation in 2017: New York (A 9553) and Oklahoma (SB 1381).

Federal Research on Prescription Drug Importing

After the federal law passed in 2003, HHS, the Congressional Research Service (CRS), and the Congressional Budget Office (CBO) conducted in depth analyses of the possible impact and consequences of a drug importation program. These analyses are still utilized by a variety of stakeholders in today's policy discussion. We summarize some key findings below.

A 2004 HHS Task Force on Drug Importation report cautions that the existing system of drug regulation should "be modified only with great care to ensure continued high standards of safety and effectiveness of the U.S. drug supply." The report also notes that

1. national savings from drug importation would be a small percentage of overall drug spending;
2. most generic drugs are less expensive in the U.S. than abroad;
3. importation would adversely impact new drug development by U.S. companies;
4. importation would have significant legal challenges, including over intellectual property rights; and
5. importation may cause significant liability challenges, especially when consumers have no recourse against foreign entities.

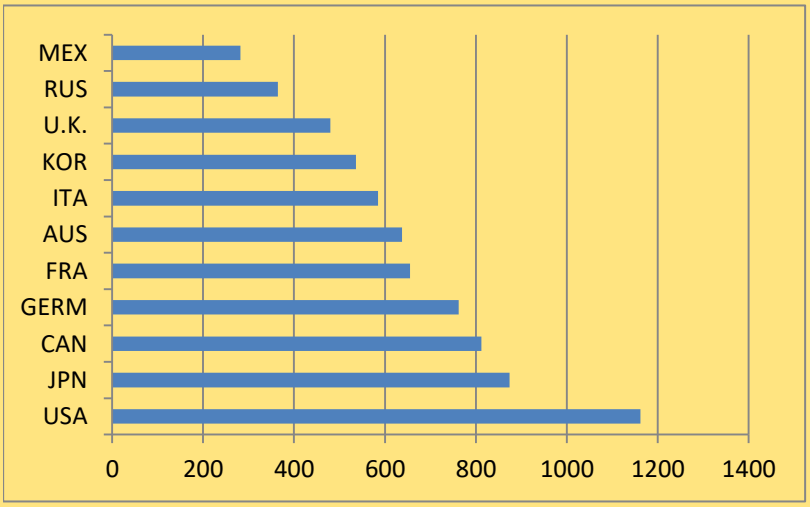
A 2004 CBO report notes that reduced drug spending would be partially offset by an increased cost of ensuring the drugs' safety and by other market forces which may cause manufacturers to reduce foreign drug supplies. A 2008 CRS report, notes that drug importation laws are driven by rising drug prices but cautions that there are several unknown variables, including the ability to provide safe medications, the amount of any savings, and the impact of international trade agreements and state and federal antitrust laws.

Importing Drugs as an Individual

Although federal law generally prohibits individuals from importing drugs, the FDA may make exceptions and the FDA "does not typically object" to drugs imported by an individual for personal use if certain criteria are met. Additionally, federal law authorizes HHS to (1) grant individuals waivers to import drugs, (2) exercise discretion in enforcing the law against individuals importing for personal use, and (3) focus enforcement efforts on cases that pose a significant threat to public health (21 U.S.C. § 384(j)).

For more information, see the FDA website: "Is it legal for me to personally import drugs?

Per Capita Pharmaceutical Spending in Select Countries, Measured in U.S. Dollars (2015)



Pharmaceutical spending generally constitutes prescription and over-the-counter costs. (*Source: OECD (2018), Pharmaceutical spending (indicator). doi: 10.1787/998febf6-en; Accessed on 25 July 2018)*

Learn More

Congressional Research Service, "Prescription Drug Importation: A Legal Overview"

Congressional Research Service, "Patents and Prescription Drug Importation"

HHS Task Force on Drug Importation

Congressional Budget Office, "Would Prescription Drug Importation Reduce U.S. Drug Spending?"

OFFICE OF LEGISLATIVE RESEARCH

Analyst: Alex Reger
Connecticut General Assembly
860-240-8400 | www.cga.ct.gov/olr