



# Policy Proposal: Importation of Prescription Drugs

A series that examines policies to manage drug spending

## What problem is this policy meant to address?

Allowing prescription drugs to be purchased and imported from abroad has the potential to lower health care costs in the U.S. In the short term, patients could access some medicines at lower prices, since brand pharmaceuticals are generally more expensive in the United States than in other high-income countries, in part because some nations have taken steps to limit drug prices. In the long term, increased competition from imported drugs could put pressure on drug companies to reduce the price of their products in the U.S.

## How could this policy work?

Some proposed policies would allow pharmacies, wholesalers, and patients to purchase prescription drugs from other countries if the Food and Drug Administration has approved a version of the same drug for use in the U.S., which is currently illegal.<sup>1</sup> For example, the Affordable and Safe Prescription Drug Importation Act, introduced in 2017, would allow these entities to purchase drugs and biologics from sellers in Canada who are certified by the U.S. secretary of health and human services (HHS).<sup>2</sup> Individuals with a valid prescription from a U.S. health care provider could import up to a 90-day supply of drugs for personal use from pharmacies licensed to dispense drugs in Canada.<sup>3</sup> The legislation would also, after two years, give the secretary authority to allow importation of drugs from member countries of the Organization for Economic Cooperation and Development that meet certain regulatory standards comparable to those in the U.S. Controlled substances and compounded drugs would not be eligible.

The Congressional Budget Office (CBO) estimated that potential savings from a similar policy—the Pharmaceutical Market Access Act of 2003, which would have allowed pharmacists, wholesalers, and individuals to import drugs from 25 countries, among them Australia, Canada, Japan, and a number in Europe<sup>4</sup>—could have produced total savings of \$40 billion over 10 years in the U.S., including savings of \$2.9 billion for the federal government.<sup>5</sup> (This estimate does not take into account any savings in the Medicare Part D program, as it was signed into law in late 2003.) The CBO also estimated that savings from the policy would be minimal if imports were permitted only from Canada.<sup>6</sup>

Another proposed policy, the Pharmaceutical Supply and Value Enhancement Act, or Pharmaceutical SAVE Act, would allow the temporary importation of off-patent drugs for which a “noncompetitive market”—one in which fewer than five versions of an off-patent drug (approved at least 10 or more years ago) are available for at least two consecutive months<sup>7</sup>—exists in the U.S. The drug’s manufacturer would be required to certify an intention to seek FDA approval. There are no published estimates of potential savings attributable to this policy.

## What should policymakers consider?

Current law requires FDA to determine that each drug is safe and effective before it can be marketed in the U.S., approving not just the drug itself, but also the manufacturing location, source of active ingredients, processing methods, and many other factors that may affect the product's safety or effectiveness.<sup>8</sup> In some rare cases, in response to a drug shortage, FDA has allowed the temporary importation of certain approved drugs from unapproved sources. In these instances, the agency evaluates the foreign products to ensure that they are of adequate quality and do not pose significant risks to U.S. patients.<sup>9</sup> In addition, a 2003 federal law gave the HHS secretary the authority to permit importation of prescription drugs from Canada if the secretary certifies to Congress that they would pose no additional risk to the public's health and safety, and would result in a significant reduction in the cost of the drugs to Americans.<sup>10</sup> However, the secretary has never made such a certification.

Because the importation of drugs from foreign sources would bypass current FDA review processes by creating a separate certification process, it could increase safety risks. For example, some U.S. consumers have placed prescription orders online with pharmacies that falsely promoted themselves as Canadian,<sup>11</sup> and FDA identified a number of cases where consumers purchased counterfeit prescription drugs through websites that were operated by Canadian pharmacies.<sup>12</sup>

To reduce the potential risks associated with importing unapproved drugs, FDA would need additional resources and capacity. In a 2004 congressional hearing, FDA's then-commissioner speculated that a program to ensure the safety of imported drugs could cost hundreds of millions of dollars annually.<sup>13</sup> Funding would need to come from congressional appropriations or fees on industry, which could reduce the net savings from importation.

Also unclear is how imported drugs could comply with established measures to ensure that counterfeit and diverted drugs do not enter the pharmaceutical supply chain. The Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act of 2013) requires that pharmaceutical manufacturers and repackagers put a unique product identifier on most prescription drug packages and outlines steps to build an electronic, interoperable system for identifying and tracing prescription drugs as they are distributed in the United States.<sup>14</sup>

Importing drugs into the U.S. could also affect foreign markets, and pharmaceutical manufacturers might alter their pricing strategies. To mitigate decreased U.S. revenue, manufacturers could seek to increase their prices abroad. In addition, the U.S. market's large size could strain the supply of pharmaceuticals, resulting in drug shortages in other countries if importation were to be implemented on a large scale.

## Endnotes

- 1 21 U.S.C. § 331.
- 2 Affordable and Safe Prescription Drug Importation Act, S. 469, 115th Cong. (2017), <https://www.congress.gov/bill/115th-congress/senate-bill/469/text?q=%7B%22search%22%3A%5B%22the+Affordable+and+Safe+Prescription+Drug+Importation+Act%22%5D%7D&r=1>.
- 3 Currently under the FDA's Personal Importation Policy, the agency may at times exercise enforcement discretion under certain circumstances. Food and Drug Administration, "Personal Importation Policy (PIP) Frequently Asked Questions (FAQs)," accessed March 27, 2017, <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/UCM297909.pdf>.
- 4 Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. (2003), <https://www.congress.gov/bill/108th-congress/house-bill/2427>.
- 5 Congressional Budget Office, "H.R. 2427: The Pharmaceutical Market Access Act of 2003," accessed Feb. 14, 2017, <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/costestimate/hr24270.pdf>.
- 6 Congressional Budget Office, "Would Prescription Drug Importation Reduce U.S. Drug Spending?" last modified April 29, 2004, <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf>.
- 7 Pharmaceutical Supply and Value Enhancement Act, S. 3455, 114th Cong. (2016), <https://www.congress.gov/bill/114th-congress/senate-bill/3455/text>.
- 8 Congressional Research Service, "Prescription Drug Importation: A Legal Overview" (Dec. 1, 2008), <https://www.everycrsreport.com/reports/RL32191.html>.
- 9 Food and Drug Administration, "FDA Acts to Bolster Supply of Critically Needed Cancer Drugs," last modified Feb. 24, 2012, <https://wayback.archive-it.org/7993/20161024102821/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm292658.htm>.
- 10 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 384(l) (2003).
- 11 Food and Drug Administration, "FDA Operation Reveals Many Drugs Promoted as 'Canadian' Products Really Originate From Other Countries," last modified Nov. 14, 2013, <https://wayback.archive-it.org/7993/20161022203236/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm108534.htm>.
- 12 Food and Drug Administration, "FDA Warns Consumers Not to Buy or Use Prescription Drugs From Various Canadian Websites That Apparently Sell Counterfeit Products," last modified April 5, 2013, <https://wayback.archive-it.org/7993/20170113092239/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108722.htm>.
- 13 Options for Safe and Effective Prescription Drug Importation: Hearing Before the Committee on Commerce, Science, and Transportation, U.S. Senate, 108th Cong. (2004) (statement of Mark McClellan, commissioner of the U.S. Food and Drug Administration), <https://www.gpo.gov/fdsys/pkg/CHRG-108shrg76522/pdf/CHRG-108shrg76522.pdf>; "\$58 Million for Canadian Rx Importation Based on Outdated Estimate," Inside Washington Publishers *FDA Week*, March 19, 2004.
- 14 Food and Drug Administration, "Drug Supply Chain Security Act (DSCSA)," last modified Jan. 18, 2017, <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/>.

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