

Imported drugs are unlikely to lower US prices any time soon

The US Food and Drug Administration has approved Florida's plan—the first in the nation—to buy drugs from Canada, but opponents threaten its future. Susan Jaffe reports.



Americans pay some of the highest prices in the world for prescription drugs, but the decision by the US Food and Drug Administration (FDA) to allow Florida to import cheaper medications from Canada won't cut prices any time soon. Although the ruling represents a shift in the decades-long fight for drug importation, opposition from the US pharmaceutical industry, Canadian health officials, and others is expected to block implementation at every stage.

"This is the first time the FDA has approved a broad drug importation plan", said Stacie Dusetzina, Professor of Health Policy at the Vanderbilt University School of Medicine. "However, that doesn't mean that importation is going to really be possible, based on some of the other barriers that are in place. Specifically, Canada has not agreed to importation of their drugs. And manufacturers are also resistant to the idea of having drugs imported. So even if Canada were a willing partner, manufacturers may not be willing to sell Canada enough drugs to supply drugs to the US."

The FDA's ruling on Jan 5, 2024, focused on a Florida proposal submitted 3 years ago to import drugs from Canada and was compelled by court order after the state sued the FDA to act on its application. According to a 2021 RAND analysis, US prices for brand-name drugs were 344% higher than prices in 32 member nations of the Organisation for Economic Co-operation and Development, including Canada, France, Germany, Italy, Japan, and the UK.

Instead of adopting some form of the negotiation process those countries use to reduce prices, the US Congress agreed in 2000 to allow wholesalers and pharmacists to purchase less

costly FDA-approved drugs from those countries if the FDA certified that those drugs were safe. In 2003, Congress restricted importation to drugs only from Canada but the FDA continued to decline to issue a safety certification. Finally, in 2020, the FDA under the Trump Administration invited US states to propose importation programmes showing how they would ensure that the foreign drugs were safe and would generate savings. A 2021 Biden Administration executive order further encouraged the FDA to work with US states and Native American Tribes to develop these programmes.

Championed by Florida Governor and US Republican presidential candidate Ron DeSantis, the state's importation application persuaded the FDA that it "will significantly reduce the cost of covered products to the American consumer without posing additional risk to the public's health and safety", S Leigh Verbois, the FDA's Director of the Office of Drug Security, Integrity and Response, wrote in a letter to DeSantis. The letter outlined further steps that should be taken before importation can begin.

Only 2 months after Trump promoted drug importation in 2020, Health Canada, the Canadian Government agency that oversees the nation's health-care system, took steps to protect its drug supply from being diverted to the USA, a spokesperson said. Health Canada prohibits drugs intended for the Canadian market from being sold for use outside of Canada if doing so could cause or worsen a drug shortage in Canada. "This includes all drugs that are eligible for bulk importation to the USA, including those identified in Florida's bulk importation plan, or any other US state's future importation programmes", officials warned in a response to the FDA ruling.

Florida's plan would initially restrict Canadian imports to specific drugs purchased by the state's health department, prison system, and other agencies for beneficiaries under their care. This first phase would only import medications used to treat some conditions, such as HIV, AIDS, prostate cancer, diabetes, hepatitis C, and mental illness. Eventually, it would be expanded to beneficiaries of Florida's Medicaid programme, which provides health care to low-income families. If fully implemented, the state expects to save up to US\$183 million annually. At least eight other states are also interested in following Florida's lead.

In addition to Canada's opposition, the pharmaceutical industry claims that no importation plan can completely prevent unsafe counterfeit or adulterated drugs from entering the USA. "Ensuring patients have access to needed medicines is critical, but the importation of unapproved medicines, whether from Canada or elsewhere in the world, poses a serious danger to public health", said Stephen Ubl, President and CEO of the Pharmaceutical Research and Manufacturers of America.

"Drug manufacturers don't have to play along," said Nicholas Bagley, a professor at the University of Michigan Law School and a health-law expert. "They can sell drugs into Canada with restrictions on resale [to the US]." That strategy could derail importation.

"If we want to get real about regulating drug prices in this country, we can", he said. But the FDA's importation decision "is closer to political theatre than a meaningful shift in pharmaceutical policy".

Susan Jaffe

For the **RAND analysis** see https://www.rand.org/pubs/research_briefs/RBA1296-1.html

For the **FDA's letter** see <https://www.fda.gov/media/175237/download?attachmentapproval>