

Colorado blames Biden team and drugmakers for delaying Canadian imports

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Colorado officials say their plan to import cheaper medicines from Canada has been stymied by opposition from drugmakers and inaction by the Biden administration, according to a state report obtained by KFF

Health News.

The Dec. 1 report, prepared for the [state legislature](#) by Colorado's Department of Health Care Policy & Financing, says that [state officials](#) approached 23 drugmakers in the last year about an importation program. Only four agreed even to discuss the proposal; none expressed interest in participating.

"Generally, the challenges that remain are outside state authority and rely on action by FDA and/or [drug manufacturers](#)," the report reads.

Lawmakers in both parties, at the state and national level, have sought for decades to legalize importing drugs from Canada. Since 2020, when President Donald Trump's administration opened the door to Canadian drug imports with regulations issued just weeks before he lost reelection, only a few states have filed applications with the Food and Drug Administration to create importation programs.

The FDA hasn't yet ruled on any of them. Colorado filed its application in December 2022. Florida, which applied in 2020, has been waiting nearly three years for a decision from the Biden administration on its importation plan, pushed by Gov. Ron DeSantis, now a Republican presidential candidate.

FDA spokesperson Cherie Duvall-Jones said the FDA has not acted on states' importation applications because it has not determined whether they would save significant money for consumers without posing risks to [public health](#).

U.S. consumers pay some of the highest prices in the world for brand-name pharmaceuticals. Drugs are generally less expensive in Canada, where the government controls prices.

Under Trump, the [federal government](#) declared that importing drugs from Canada could be done safely—satisfying for the first time a condition spelled out in a 2003 law.

But Colorado officials cited another catch: The rule didn't take into account that states would have to negotiate directly with drug manufacturers, which oppose selling their brand-name drugs in the United States at Canadian prices.

"As the federal Final Rule did not contemplate the need for this negotiation step, we have urged FDA to release further guidance regarding how states can operationalize the program with this in mind, but to date, no guidance has been released," the Colorado report said.

Unlike many other Trump administration health policies, Biden hasn't revoked or revised the importation rule. But his administration hasn't shown much support for the idea, either. Health and Human Services Secretary Xavier Becerra told KFF Health News last December that he wouldn't commit to the FDA ruling on any state application in 2023.

The president has repeatedly suggested that under his watch Americans would be able to import drugs from Canada.

During his 2020 campaign, Biden said he'd allow for the importation of drugs the government certified as safe. In 2021, he ordered the FDA to work with states to import prescription drugs from Canada. In a 2022 speech about how he planned to reduce drug prices, he cited Colorado estimates of how much people in the state could save through importation.

FDA officials responded to Colorado's application in March by asking for more information and a smaller list of drugs to target, to prove that importation could save money. Colorado's initial application listed 112

high-cost drugs. The state estimates residents and employers could save an average of 65% on the costs of those medicines, including drugs for diabetes, asthma, and cancer.

Colorado said it plans to submit an updated application early next year. By then, it's possible the FDA will have ruled on Florida's application.

The Colorado and Florida importation proposals differ. Colorado's program is intended to directly help consumers obtain cheaper medicines. Florida's plan aims to cut spending on drugs in government programs such as Medicaid, the prison system, and facilities run by the state Department of Children and Families.

The drug industry has argued the Trump administration didn't properly certify that drugs imported from Canada would be safe, jeopardizing Americans' health. Canada's government, too, has expressed concern that U.S. imports would lead to shortages and higher prices in its country.

Drug manufacturers "will do anything to protect their golden goose that is United States consumers and patients who pay the largest amount for drugs in the world," said Colorado state Sen. Sonya Jaquez Lewis, a Democrat, pharmacist, and leading advocate for drug importation.

The White House and Congress, she said, should force drugmakers to negotiate with states to start importation programs.

In its initial response to Colorado's application, the FDA listed several types of information it still needed, including plans on labeling and drug eligibility, according to a March letter from the FDA to the state. Another problem, the FDA said, The state planned to import medicines across the U.S. border in Buffalo, New York. The FDA said the only port of entry it allows for medicines is in Detroit.

Colorado officials told the FDA in March that without federal approval of its application, it was having difficulty securing commitments from drug manufacturers to obtain medicines.

"It has been made clear that potential partners will be more interested in committing to participate once our program has been approved by the FDA," Kim Bimestefer, executive director of the Colorado Department of Health Care Policy & Financing, wrote to the FDA.

"While we understand the [regulatory framework](#) does not permit for a provisional approval, we know that showing progress towards an approved program will aid in our negotiations with drug manufacturers," she added.

Another complication is that the FDA's rule doesn't allow states to buy drugs directly from secondary drug wholesalers. Instead, they must purchase medicines directly from manufacturers, said Marc Williams, a spokesperson for the Colorado agency.

That's proven challenging because drug manufacturers have prohibited the export of products intended for sale in Canada to the U.S., Williams said.

"Without their permission and a supply agreement directly with a manufacturer, Colorado is unable to buy and import these lower-priced drugs that would save people money," he said.

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