



## US drug importation plan hits snag

The Biden administration says it has “no timeline” for deciding if states can import cheap drugs from Canada. Susan Jaffe reports.

President Joe Biden’s administration said last week that it won’t decide whether to allow states to import drugs from Canada anytime soon, if ever. Biden supported drug importation during the presidential campaign, as did his opponent, Donald Trump, to mitigate sky-rocketing drug costs in the USA.

Americans pay more per capita for prescription drugs than any other country, according to a National Academies of Sciences, Engineering, and Medicine study.

Biden’s declaration came in the administration’s response to a lawsuit seeking to block an importation programme created by Trump. “Although two proposals [to import Canadian drugs] have been submitted to the FDA, no timeline exists for the agency to make a decision”, lawyers for the administration argued. Opposition to the programme “rests upon ‘contingent future events that may not occur as anticipated, or indeed may not occur at all’”, they wrote, quoting a previous court ruling.

The case filed by the Pharmaceutical Research and Manufacturers Association of America (PhRMA), which represents brand-name drug makers, claims that Trump’s programme would restrain drug development, would not yield significant savings, and would expose more Americans to the risks of counterfeit foreign medicine.

So far, six states want to participate in the programme, including Florida and New Mexico, which have submitted formal applications to the Department of Health and Human Services (HHS) showing how cheaper Canadian drugs can be imported safely and yield savings for patients. If the Food and Drug Administration (FDA), which is part of HHS, is persuaded, they will be able to proceed.

Department of Justice lawyers for the Biden administration asked a federal district court judge last week to dismiss the case because the drug companies’ objections are premature. No state plan has been approved, and given the obstacles, approval may never come.

But inaction is no reason to dismiss the PhRMA lawsuit, said Nicole Longo, the group’s spokeswoman. “I don’t think we can speculate about what the administration’s position is on importation and whether or not they would approve a state importation plan.”

The Department of Justice’s legal brief describes several obstacles to the states’ plans along with any harm PhRMA says they pose. First, states might not be able to find a Canadian exporter. The Canadian Government has been reluctant to share its drug supply with its southern neighbour, home to ten times more people than Canada. Late last year Canadian health officials prohibited distribution of any drug for use outside Canada if doing so would “cause or exacerbate a shortage of the drug”.

Second, states might be unable to assure HHS that their plans “will result in a significant reduction in the cost to the American consumer”, as required by the HHS rule setting criteria for state importation. For example, Florida’s proposed importation plan would provide cheaper Canadian drugs for patients covered by Medicaid health insurance and other state health programmes, who are currently charged very low, if any, copayments for prescriptions. The state budget—rather than patients—would save as much as \$150 million in the plan’s first year.

“These obstacles were known to the Trump administration but they didn’t talk about them”, when the

programme was announced, said Rachel Sachs, associate professor of law at Washington University School of Law (St Louis, MO, USA), who specialises in health law and drug pricing. “They might very well make it more difficult for the Biden administration to implement the rule even if they wanted to.”

Florida’s Republican governor, Ron DeSantis, has said his state’s application meets all the requirements, including an agreement with a Canadian drug distributor, and should be approved “immediately”. Democratic governors in Colorado and Maine also hope to submit successful applications.

When the President talks about cutting drug prices, importation has not been among his remedies. Instead, his proposed budget includes allowing the federal Medicare programme—not private insurance companies—to negotiate directly with drug makers for lower prices for some high-cost medicines. Manufacturers would also be required to pay rebates if drug prices grow faster than inflation. Both strategies could generate savings of over half a trillion dollars in 10 years.

Meanwhile, Americans continue to buy drugs from Canadian pharmacies for personal use even though federal law prohibits it. Using its enforcement discretion, the FDA is effectively saying the law applies, but they will not enforce it against individuals, said Sachs.

Whether states or individuals are buying, “importation is not the comprehensive solution we need for high drug prices in the USA”, said David Mitchell, president of Patients for Affordable Drugs, an advocacy group. “Lower prices for everyone in this country is the solution [and] that requires comprehensive reform.”

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