

US to set up plan allowing prescription meds from Canada

July 31 2019, by Ricardo Alonso-Zaldivar



In this Tuesday, July 16, 2019, file photo, Health and Human Services Secretary Alex Azar pauses while speaking during a Cabinet meeting at the White House, in Washington. Azar says he and President Donald Trump are working on a plan to allow Americans to import lower-priced prescription drugs from Canada. (AP Photo/Alex Brandon, File)

The Trump administration said Wednesday it will set up a system allowing Americans to legally and safely import lower-cost prescription drugs from Canada for the first time, reversing years of opposition from federal health authorities amid a public outcry over high prices for life-sustaining medications.

The move is a step toward fulfilling a 2016 campaign promise by President Donald Trump, and it weakens an import ban that stood as a symbol of the political clout of the pharmaceutical industry. It's unclear how soon consumers will see benefits, as the plan has to go through time-consuming regulatory approval and later could face court challenges from drugmakers.

It comes as the industry is facing a crescendo of consumer complaints over costs, as well as legislation from both parties in Congress to rein in costs, along with a sheaf of proposals from the Democratic presidential contenders. Ahead of the 2020 election, Trump is feeling pressure to deliver on years of harsh rhetoric about the pharmaceutical industry.

Making the announcement Wednesday, Health and Human Services Secretary Alex Azar said the administration's decision recognizes that prescription drug manufacturing and distribution is now international.

"The landscape and the opportunities for safe linkage between drug supply chains has changed," Azar said. "That is part of why, for the first time in HHS's history, we are open to importation. We want to see proposals from states, distributors, and pharmacies that can help accomplish our shared goal of safe prescription drugs at lower prices."

Most patients take affordable generic drugs to manage conditions such as high blood pressure or elevated blood sugars. But polls show concern about the prices of breakthrough medications for intractable illnesses like cancer or hepatitis C infection, whose annual costs can run to

\$100,000 or much more. And long-available drugs like insulin have seen price serial increases that forced some people with diabetes to ration their own doses.

Azar, a former drug industry executive, said U.S. patients will be able to import medications safely and effectively, with oversight from the Food and Drug Administration.

One prong of the administration's proposal would allow states, wholesalers and pharmacists to get FDA approval to import certain medications that are also available here. Another part would allow drugmakers to seek approval for re-importation of their own drugs. This second provision would cover cutting-edge biologic drugs as well mainstays like insulin.

It's unclear how soon consumers will see results. Azar spoke of a regulatory process lasting "weeks and months" and he also called on Congress to pass legislation that would lend its muscle to the effort, even short-circuit attempts to overturn the changes in court.

"The FDA has the resources to do this," said acting FDA Commissioner Ned Sharpless. "The agency is interested in considering any reasonable that maintains the bedrock of safety and efficacy for the American consumer."



In this Wednesday, July 10, 2019, file photo, President Donald Trump speaks about kidney health, accompanied by Health and Human Services Secretary Alex Azar, left, in Washington. Azar says he and Trump are working on a plan to allow Americans to import lower-priced prescription drugs from Canada. (AP Photo/Alex Brandon, File)

The importation idea has backers across the political spectrum.

Sen. Chuck Grassley, R-Iowa, chairman of the panel that oversees Medicare said on Twitter that importation would lower prescription drug costs. He and Democratic presidential candidate Sen. Amy Klobuchar of Minnesota have a bill to facilitate importation.

During Tuesday night's Democratic presidential debate , multiple

candidates talked about the need to lower prescription drug costs. Sen. Bernie Sanders, Vermont Independent, noted the disparity in U.S. and Canadian prices. "I took 15 people with diabetes from Detroit a few miles into Canada and we bought insulin for one-tenth the price being charged by the crooks who run the pharmaceutical industry in America today," he said.

Pressure on the industry is rising across many fronts.

In the Senate, Trump is supporting Grassley's bipartisan bill to cap medication costs for Medicare recipients and require drugmakers to pay rebates to the program if price hikes exceed inflation. Democrats in the House are pressing for a vote on a bill allowing Medicare to directly negotiate prices on behalf of millions of seniors enrolled in its prescription drug plan. Separately, the Trump administration is pursuing a regulation that would tie what Medicare pays for drugs administered in doctors' offices to lower international prices.

Looking to his reelection campaign, Trump has made lowering prescription drug prices one of his top goals. As a candidate, he had called for allowing Americans to import prescription drugs, and recently he also backed a new Florida law allowing state residents to gain access to medications from Canada with FDA approval. That idea was incorporated in Wednesday's plan.

Drug prices are lower in other economically advanced countries because governments take a leading role in setting prices. But in the U.S., Medicare is not permitted to negotiate with drug companies.

Some experts have been skeptical of allowing imports from Canada, partly from concerns about whether Canadian suppliers have the capacity to meet the demands of the much larger U.S. market.

But consumer groups have strongly backed the idea, arguing that it will pressure U.S. drugmakers to reduce their prices. They also point out that the pharmaceutical industry is a global business and many of the ingredients in medications sold in the U.S. are manufactured abroad.

The drug industry lobby, Pharmaceutical Research and Manufacturers of America, has successfully blocked past efforts in Washington to allow importation. It argues patients would be at risk of receiving counterfeit or adulterated medications.

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