Benefits Insights

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Prescription Drug Importation

The cost of prescription drugs in the United States is the highest in the developed world and is rising quickly. In fact, Americans often pay more for prescription drugs than individuals in comparable countries. According to a 2021 RAND Corporation study, U.S. prescription drug prices were 256% of those in the combined 32 comparison countries. It's no surprise many Americans struggle to afford the prescription drugs they need.

Addressing the lack of affordable prescription drugs is a top public health priority in the United States. Prescription drug importation is one option some U.S. policymakers are pursuing to lower drug prices for Americans. While prescription drug importation has bipartisan support among the general public, it remains a controversial issue, with benefits and risks that must be examined.

This article explores prescription drug importation and its potential impacts on U.S. drug prices.

What Is Prescription Drug Importation?

Prescription drug importation is the practice of purchasing prescription drugs from another country and importing them to the United States. The goal of this process is to save money on prescription drug costs, as prices for many drugs are lower in other countries. Currently, it's illegal to import prescription drugs into the United States from other countries except under limited circumstances. However, there have recently been proposals to legalize prescription drug importation to lower drug prices, increasing Americans' access to affordable medications.

What Is the Current State of Prescription Drug Importation?

U.S. law currently permits certain drugs from Canada—but no other country—to be imported and sold in the United States under limited circumstances. For an imported prescription drug to be sold in the United States, it must meet the standards established in the Food and Drug Cosmetic Act of 1938 and be approved by the Food and Drug Administration (FDA). Only FDA-approved drugs manufactured in an FDA-inspected facility, intended for U.S. consumers and imported into the United States by drug manufacturers are permitted. In rare circumstances, prescription drugs approved and manufactured in the United States and sent abroad may be imported back into the country. An example is when the importation is under the direction of the secretary of the U.S. Department of Health and Human Services (HHS) for emergency medical purposes and by the original drug manufacturer in situations where a drug has been damaged, recalled or for inventory control.

Even though U.S. federal law allows prescription drug importation from Canada, the HHS secretary must still certify to Congress that importation will provide significant savings for U.S. consumers and not threaten the general public's health and safety before any drugs can be imported and sold. In 2020, the Trump administration issued a final rule and final FDA guidance for prescription drug importation. This allowed states, territories and Native American tribes—and some wholesalers and pharmacists—to implement time-limited importation programs, permitting them to import certain drugs that are currently marketed in the United States from Canada. Under the administration's final rule, states must submit their importation proposals to the HHS secretary for approval.

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Similar to the Trump administration's efforts, President Joe Biden issued an executive order in July 2021 directing the FDA to work with states to import prescription drugs from Canada. This proposal currently has strong bipartisan public support. Some states, including Florida, Vermont, Colorado and Maine, have enacted laws establishing prescription drug importation programs. However, to date, no plans have obtained the required certification by the HHS Secretary, largely due to safety concerns.

Recently, a U.S. district court dismissed a lawsuit by pharmaceutical industry members to stop state governments from importing prescription medications from Canada. This ruling may encourage more states to consider importing medications from Canada as a strategy to lower the costs of prescription drugs from Americans.

Can Individuals Import Prescription Drugs for Personal Use?

Except in limited circumstances, individuals generally cannot import FDA-approved drugs for personal use. Permission to import prescription drugs that have not been approved by the FDA is granted on a case-by-case basis and is usually only allowed to treat serious health conditions where there is no effective treatment available in the United States.

However, some Americans purchase lower-cost prescription drugs from other countries, even though this is illegal in most situations. For example, according to a poll conducted by Kaiser Family Foundation in 2016, approximately 8% of respondents said they or someone in their household had imported a drug at some point. This equates to nearly 19 million Americans illegally importing medications. This willingness to import medications illegally is a strong indication that many Americans are unable to afford the high costs of prescription drugs and are desperate for solutions.

Will Prescription Drug Importation Lower U.S. Drug Prices?

The goal of prescription drug importation is to lower drug prices for Americans. If successful, it could improve the health and well-being of the American public. However, despite its admirable goal, prescription drug importation remains controversial, with many doubting its merits.

The argument in favor of prescription drug importation is that it offers a way to provide safe, low-cost drugs to many Americans, which could improve access to needed and life-saving medications. Wholesale drug importation may also increase competitiveness among U.S. drug manufacturers, resulting in cost savings and lower prices. Canada's single-payer health care system is government-run and allows the government to negotiate directly with drug companies to reduce prices. So, allowing these lower-cost drugs to be marketed and sold in the United States may force U.S. drug companies to reduce their prices to remain competitive.

However, many are skeptical that prescription drug importation will fix the issue of high prescription drug costs in the United States. Currently, many high-cost drugs, like biologic products (e.g., insulin) and narcotics, cannot be imported. These exclusions could limit the potential cost savings from importation. Additionally, since any drugs imported to the United States would first go through Canadian negotiations with manufacturers, there's no guarantee that prices would be lower. Before Canadian drugs could be sold in the United States, they would likely need to be inspected, tested, repackaged, relabeled and tracked. This would likely require significant government oversight, potentially leading to increased costs.

Importing prescription drugs from Canada could also increase demand for those drugs in Canada, driving up prices. Every year, drug manufacturers typically allocate the number of drugs to be sold in each country individually. This is done by assessing past drug sales and estimating anticipated increases for the following year. Manufacturers are unlikely to increase Canada's allotment of prescription drugs so those drugs can be redistributed to the United States, especially since the United States is a larger and more lucrative market than Canada. There are also concerns over whether importing drugs from Canada could meet U.S. demand. Further, it's difficult to ensure the effectiveness, quality and safety of imported drugs.

Overall, lowering prescription drug costs is a priority for the American public. While there are questions about whether prescription drug importation will lower U.S. drug prices, it's an option policymakers and states continue to explore to lower prices. As such, prescription drug importation could

have major impacts on the prices of prescription drugs for many Americans in the near future.

Summary

Reducing the cost of prescription drugs in the United States is critical. Prescription drug importation offers one way to potentially increase access and affordability to necessary and life-saving drugs for many Americans. This is a developing issue that employers should continue to monitor closely.

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