

Drug Importation from Canada: The Wrong Prescription

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On May 25, 2022, the Center for Drug Evaluation and Research of the U.S. Food & Drug Administration (FDA) released a Guidance for Industry to clarify its Final Rule on the “Importation of Prescription Drugs.”¹ Issued by then Secretary of Health and Human Services (HHS) Alex M. Azar II in 2020, the Final Rule sets out the relevant regulations for the “importation of certain prescription drugs from Canada.”² The stated objective of the Final Rule is “to achieve a significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public’s health and safety.”² In a rare case of concordance with and continuation of a Trump-era initiative, President Biden issued an Executive Order wherein he called on the Commissioner of the FDA to implement the Final Rule and “work with States and Indian Tribes that propose to develop Section 804 [prescription drugs] Importation Programs [SIPs].”³ In this commentary we review the intricacies of the drug importation program, discuss its relative shortcomings, and propose that it be replaced with a root-cause approach to capping the national prescription drug costs.

Well prior to his election, President Biden pledged to address the ever-escalating U.S. prescription drug costs and to do so through the importation of more affordable Canadian counterparts. To advance this goal, President Biden has recently called on the federal government to work “with states and Tribes to import safe, lower-cost prescription drugs from Canada.”⁴ Advantage was to be taken of Section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA) which makes it possible for governmental entities (SIP Sponsors), together with pharmacists and wholesalers (SIP Co-Sponsors), if any, to import eligible prescription drugs from Canada for up to two years.⁵ To qualify, such prescription drug importation programs must offer a “significant reduction in the cost” to U.S. consumers while guarding against the imposition of any and all risks to the health and safety of the public.⁵ Importation-eligible (FDA-compliant) prescription drugs are limited to those that have been approved by the Health Products and Food Branch of Health Canada, the department responsible for federal health policy in Canada.⁵ Importation-ineligible prescription drugs include controlled substances, biologics, and medications that are infused, inhaled, or else require intrathecal or intraocular administration.⁵ Drugs that are subject to Risk Evaluation and Mitigation Strategy (REMS) are similarly precluded.⁵

States with drug importation laws

At the time of this writing, a total of six states (Colorado, Florida, Maine, New Hampshire, New Mexico, and Vermont) have enacted drug importation laws. A total of five states (North Dakota, Oregon, Utah, West Virginia, and Wyoming) attempted but failed to enact comparable statutes. Other states have yet to act on comparable legislative initiatives which, in some cases, are under the purview of exploratory committees. Federal approval for the importation of drugs from Canada requires that states that have enacted drug importation laws propose a re-importation program for consideration and certification by the Secretary of HHS. It is in this context that FDA and HHS representatives held a recent meeting with state and National Academy for State Health Policy counterparts. Going forward, the FDA will continue to proactively engage with those states that are interested in the development of drug importation programs.

The statutory foundation for the importation of prescription drugs dates back to the Medicine Equity and Drug Safety (MEDS) Act of 2000 (Pub. L. 106-387) wherein the FDCA was amended to include Section 804 titled “Importation of Prescription Drugs.” In so doing, the MEDS Act made it possible for U.S.-based pharmacists and drug wholesalers to import prescription drugs from specified countries. Activation of such newly minted importation programs requires the Secretary of HHS to affirm that the programs pose “no additional risk to the public’s health and safety” and that they “result in a significant reduction in the cost of covered products to the American consumer.” Section 804 of the FDCA was further modified in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Pub. L. 108-173) to specify that U.S.-based wholesalers and pharmacists may import prescription drugs only from Canada but not from other industrialized countries.

Challenges to importation of drugs

The plans to remedy the high costs of prescription drugs in the U.S. via the importation of more affordable Canadian counterparts face a number of significant challenges and uncertainties. First, participation by U.S. States and Tribes has proven limited thus far. This reality is borne out by the fact that only six U.S. states have heretofore enacted drug importation statutes. Second, Canadian accedence to the exportation of prescription drugs to the U.S. remains

uncertain. As noted by Justin Trudeau, the Prime Minister of Canada, ensuring the safe and adequate supply of prescription drugs for Canadians is his first priority. The passage of prohibitory legislation by the Parliament of Canada cannot be ruled out as well. Third, the Canadian health care system is given to intermittent prescription drug shortages which could well be exacerbated by the U.S. importation plan. Anticipating just such a contingency, the Canadian government now prohibits the exportation of drugs that could give rise to or exacerbate a prescription drug shortage. Fourth, significant doubts remain as to the capacity of the small Canadian pharmaceutical marketplace to accommodate the demands of its much larger U.S. counterpart. Implementation of the importation plan could well exacerbate drug shortages in Canada. Fifth, consideration must be given to the possibility that the relief anticipated from the importation program may not be realized in that a significant proportion of high-priced prescription drugs are importation-ineligible. Finally, if a significant volume of drugs were imported to Canada, it is possible that the pharmaceutical industry would attempt to reduce its supply to the Canadian market or otherwise disrupt this trade through alterations in packaging or other means.

Conclusion

An importation program from Canada is not a sustainable recipe for capping the homegrown prescription drug costs. Instead, a focused root-cause approach is called for. Reform initiatives along these lines could include international price referencing, bulk discount negotiations, competitive bidding, and value-based pricing. Judging from the experience of other developed nations, combinations of the aforementioned strategies have frequently seen to the reduction of the national prescription drug costs. Oversight by the Federal Trade Commission of anticompetitive practices designed to keep biosimilar generic options off the market must also be enhanced. Four former FDA Commissioners said it best when they urged “Congress and the many others concerned about the cost of drugs to deal directly with the issues driving the cost of medicines and not to place false hope in measures that will place patients who need treatment at risk and jeopardize public health.”⁶ Whereas any and all reform initiatives are likely to face difficult political headwinds in this Congress and in the foreseeable future, one would be well advised not to pretend that drug importation can substitute for a well-thought-out legislative redress.

References

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