Importing Competition to the U.S. Prescription Drug Market: Current Practice and Potential

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June 2019

This paper was funded by a grant from the The Commonwealth Foundation
Federal and State Prescription Drug Importation Will Improve Market Competition

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The Florida legislature moved quickly this Spring to pass a bill that allows the state to import lower cost prescription drugs. Recently, in a show of support, the Trump administration directed Secretary of Health and Human Services (HHS) Azar to help Florida create a program that HHS can approve.¹ Colorado, Maine and Vermont also enacted importation laws last month and last year, respectively.

These state laws will be important test cases of how existing federal law will be used to permit safe importation of lower cost prescription drugs by entities other than manufacturers or the Food and Drug Administration (FDA). Existing law permits both wholesale and personal importation of prescription drugs from Canada with the approval of the HHS Secretary.

State and federal policymakers increasingly see importation as a mechanism by which to improve market functioning--creating more market competition based on price -- as demonstrated by the variety of bi-partisan federal bills, state law and pending legislation, as well the Administration’s own policies to expand prescription drug importation.

Administration Proposals are Consistent with State Proposals

In addition to working with Florida, the Administration is developing importation policies of its own. The FDA plans to import generic drugs when the US supply is sufficient but lacking price competition.² FDA recently finalized guidance for using imported (lower cost) biologics for purposes of developing (lower cost) biosimilar products for the US market.

Importation and safety

People may not know that drug importation is an idea with history. Since about 2010, the FDA has facilitated the importation of medically critical drugs that are in short supply until domestic manufacturing reaches adequate capacity to end the shortage. A Canadian company, CanaRx, has worked with about 500 U.S. cities, counties, school districts, and private employers since about 2004 to help employees find the lowest cost source for their prescription drugs in Canada, Australia, or Great Britain.³ Government and private employers incentivize employees to use CanaRx for prescription fulfillment through no, or lower drug copayments for purchases through CanaRx. U.S. public and private employers have been using CanaRx seemingly without incident since about 2004.

Importation is almost commonplace already. At least 40 percent of the prescription drugs used in the U.S. are manufactured abroad, and our products are considered very safe.⁴ This data is from 2014 and the volume of importation has only grown since then as our pharmaceutical industry has become truly global in manufacturing and distribution.
Five former FDA commissioners issued a statement arguing against importation of all
drugs.\textsuperscript{v} But the Commissioners were addressing an open-borders approach for
individual/personal importation, rather than government-administered, limited wholesale
importation in certain situations where market competition is stymied. State importation plans
are government-administered and generally limited in scope, with strong savings and safety
components. Existing federal laws, regulations, and standards would enable safe, controlled
approaches.

Former FDA Commissioner Gottlieb has noted that any drug manufactured overseas for
the U.S. market is made in the same FDA-registered plant that makes the drug for markets in
other countries.\textsuperscript{vi} He restated the point in congressional testimony --, he noted that FDA
concerns have more to do with internet pharmacies than with drugs manufactured and licensed in
other countries, and managed by regulated entities in those countries.

Many improvements to the safety and security of the drug supply chain have occurred as
the pharmaceutical industry has become global. U.S. laws which are driving technology that
creates more secure distribution systems – even as that distribution system grows outside U.S.
borders. The most important piece of drug supply safety legislation in recent years is the Drug
Quality and Security Act (DQSA) of 2013. Title II, the Drug Supply Chain Security Act, is
designed to improve detection and removal of potentially dangerous drugs from the supply chain
according to the FDA. The DQSA is forcing development of an interoperable electronic system
to identify and trace pharmaceuticals from the pharmacy back to the point of origin.

U.S. standards for manufacturing and handling of prescription drugs are similar to those
of many other countries. Because of that alignment, the EU and the FDA will accept each
other’s inspection findings for manufacturing plants within their borders. The US also has a
long-standing reciprocity agreement with Canada for information sharing on compliance rather
than deeming compliance across the two countries.

States are proposing importation plans that are government administered, generally
limited in scope, and have strong savings and safety components.

\textbf{Recommendations for safe and effective importation}

State-administered prescription drug importation requires new administrative structures
to assure that the program does not put the public at greater risk than our existing drug supply
system. The system has to assure savings as well, after accounting for new administrative costs
that may result. In order to meet these goals, state-administered importation programs should:

- Adapt and apply existing federal laws, regulations, and standards that enable safe,
  controlled approaches to importation.
- Avoid significantly adding to FDA workload.
- Finance added FDA workload and state staffing through new or increased licenses
  and fees for participating supply chain vendors.
- Be managed or overseen locally/regionally by States or non-profits to relieve resource
  pressure on the FDA.
• Directly impact patient drug costs. Savings cannot be converted into profits for the supply chain and insurers. The mark-up on the imported products should be managed in part through utterly transparent pricing throughout the supply.

• Permit the importation costly biologics, which are driving US spending growth but are excluded from importation under current federal law.

Importantly, better US price competition will not undermine industry incentive or ability to create new drug products. Academic researchers have found that the return on investment for oncology products averages $14.80 for each R&D dollar spent. Researchers also found that for the ten oncology drugs studied, the median R&D cost for the drugs was $648 million and the median reported revenue was $1658.4 million. There is room to lower prices and retain sufficient funds for R&D.

Importation, when implemented safely and effectively, is one part of a larger strategy needed to increase price competition.

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vi The Commissioner’s talk can be accessed at https://www.brookings.edu/events/u-s-market-for-biosimilars-fda-scott-gottlieb/.
