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

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Federal and State Prescription Drug Importation Will Improve Market Competition

By Jane Horvath

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.[i] 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.[ii] 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.[iii] 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.[iv] 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.[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.[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.

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.[vii] 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.[viii] 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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[i] https://www.politico.com/states/florida/story/2019/05/06/trump-directs-azar-to-work-on-florida-drug-import-plan-1008710, accessed May 8, 2019.

[ii] https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html accessed April 30, 2019

[iii] https://www.npr.org/sections/health-shots/2019/03/06/700374420/u-s-cities-skeptical-of-fda-warnings-against-medicine-imports-from-canadian-firm accessed April 30, 2019

[iv] . U.S. Government Accountability Office. *FDA has Improved Its Foreign Drug Inspection Program but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices.* December 2016. https://www.gao.gov/assets/690/681689.pdf Accessed April 29, 2019.

[v] McClellan M, Califf R. Former FDA commissioners letter opposes reimportation. Duke Margolis Center for Health Policy. https://healthpolicy.duke.edu/news/former-fda-commissioners-letter-opposes-reimportation. Published March 17, 2017. Accessed March 23, 2019.

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

[vii] https://www.academia.edu/38247163/WHOTechnicalReportPricingofCancerMedicinesandItsImpact Accessed April 29, 2019.

[viii] Tay-Teo, K. "Comparison of Sales Income and Research and Development Costs for FDA Approved Cancer Drugs by Originator Companies." JAMA Network Open. (2019) 2(1):e186875. January 4, 2019