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Q&A: Drug Importation Proposals

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Recent legislative proposals and other policy initiatives aim to facilitate the sale of lower-cost foreign pharmaceuticals in the U.S. Generally speaking, these proposals would permit the importation of prescription drugs into the United States from Canada and other countries. This Q&A addresses various topics related to such importation proposals, including their potential effect on patient safety and the security of the U.S. drug supply chain.

I. Background: U.S. Regulation of Drug Supply Chain

Q. How does the FDA currently ensure the safety and security of drugs in the U.S. supply chain?

A. Since 1965, the FDA has had explicit authority to prevent and address counterfeiting and distribution of counterfeit drug products.[1] Generally speaking, under current law, anyone other than the manufacturer of a prescription drug is prohibited from importing that drug into the country.[2] The Medicare Prescription Drug Improvement and Modernization Act of 2003 authorized the importation of prescription drugs, but with the requirement that the HHS Secretary certify that any imports: (1) pose no additional risk to public health and safety; and (2) generate cost savings for American consumers.[3] To date, no Secretary has made this certification. Congress has periodically given the FDA more authority to regulate the security of the U.S. drug distribution system. Most recently, in 2013 Congress passed the Drug Supply Chain Security Act (DSCSA),[4] which requires actors in the supply chain to create an electronic, interoperable track and trace system that would allow drug product tracing to the individual unit level.

Q. What does it mean that the U.S. has a "closed distribution system"?

A. It is often said that the U.S. drug supply chain is a "closed system." This means that the distribution network is made up of a secure web of manufacturers, suppliers, and retailers subject to FDA regulation, including premarket approval and postmarketing oversight by FDA. That is, an FDA-approved drug will be manufactured in an FDA-registered and FDA-inspected facility, using FDA-approved methods, and marketed subject to FDA regulations.[5] The intent of a "closed" system is to protect patients from receiving unsafe, ineffective, or substandard medications.[6] Critical to this goal is preventing counterfeit medicines from infiltrating the U.S. supply chain.

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[1] Drug Abuse Control Amendments of 1965, 79 Stat. 226 (superseded by the Controlled Substances Act, 84 Stat. 1236, 1242, 1281-81 (1970)).
[2] 21 U.S.C. § 381(d)(1).
[3] P.L. 108-173, §§ 1121-23, 117 Stat. 2066, 2464, 2469 (codified at 21 U.S.C. §§ 331, 333, 381, 384).
[4] Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act), P.L. 113-54, 127 Stat. 587 (2013).
[5] *See* HHS Task Force on Drug Importation, "Report on Prescription Drug Importation at VIII," (2004), *available at* https://archive.hhs.gov/importtaskforce/Report1220.pdf (hereinafter "HHS Task Force Report").
[6] FDA, "FDA Statement Before the Nevada State Board of Pharmacy," (Apr. 20, 2006), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm175852.htm.

II. Recent Drug Importation Proposals

Q. What do importation legislative proposals aim to do?

A. Though the details vary slightly from proposal to proposal, the primary effect of importation proposals is similar: if enacted, an importation program would remove certain barriers to importation under the Federal Food, Drug, and Cosmetic Act (FFDCA). Recent proposals would allow pharmaceutical distributors and pharmacists to import into the U.S. cheaper prescription drugs from Canada and other countries.

Q. Has Congress tried to pass similar measures in the past?

A. Yes. For several years, Congress has proposed similar versions of importation legislation.[7] These proposals have faced stiff opposition from regulatory officials and lawmakers and ultimately failed to pass. Dr. Robert Califf, at the time the FDA Commissioner, stated in November 2015 that "[a]uthorizing importation would compromise the closed drug distribution system in the United States and undermine these laws, thus making it easier for unapproved drugs, which may include counterfeit or other substandard drugs, to reach American patients, putting their treatment at risk."[8]

Q. How would drug importation proposals, if enacted, change the current landscape?

A. A drug importation program would by necessity amend current law, which prohibits anyone other than the manufacturer of a prescription drug from importing that drug into the United States.[9] Under such a program, the FDA would not be able to evaluate the safety and effectiveness of imported prescription drugs that have not been subject to the U.S. regulatory process.[10] FDA officials have acknowledged that even if a drug is labeled as coming from a "reputable source" like Canada, the product often originates from other countries, and the FDA has no ability to ensure the safety of these reimported drugs.[11]

Q. How could foreign regulatory bodies ensure the safety of drugs entering the U.S. pursuant to an importation program?

A. Foreign regulatory bodies lack both the ability and the incentive to ensure the safety of exported and transshipped drugs. In general, they lack the monitoring and oversight capabilities needed to ensure that drugs intended for import into the U.S. are safe.[12] They also lack the expertise to assess the adequacy of directions for use and labeling for U.S. patients and providers.

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[7] *See, e.g.*, H.R. 5186, Drug Importation Act of 2002; Amendment SA 2107 to S. 3187, page S3536-37 (2012) (to allow the importation by individuals of safe and affordable drugs from Canada).
[8] Dr. Robert Califf, "Questions for the Record," HELP Committee Hearing on the Nomination of Dr. Robert Califf to Serve as FDA Commissioner (Nov. 17, 2015).
[9] 21 U.S.C. § 381(d)(1).
[10] *See* Dr. Robert Califf, "Questions for the Record," HELP Committee Hearing on the Nomination of Dr. Robert Califf to Serve as FDA Commissioner (Nov. 17, 2015).
[11] Testimony from Dr. Andrew Von Eschenbach, FDA Commissioner, before the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations (Jan. 29, 2008), *available at* https://www.gpo.gov/fdsys/pkg/CHRG-110hhrg47433/html/CHRG-110hhrg47433.htm.
[12] *See* PhRMA, "4 Facts on Why Drug Importation Is Bad for Patients," *available at* catalyst.phrma.org/4-facts-on-why-drug-importation-is-bad-for-patients (hereinafter "PhRMA Fact Sheet").

Most foreign governments impose a lesser level of regulation on exported products, and many countries do not regulate at all products that are transshipped through their countries.[13] Even if foreign agencies were able to monitor the safety of exported or transshipped drugs, they lack incentive to do so: each foreign health agency is dedicated first and foremost to ensuring the safety of drugs for its own citizens. Officials from Health Canada, a regulatory body with relatively high safety standards, have said in the past that they cannot be expected to monitor the safety of imported products pursuant to an importation program.[14]

III. Policy Implications

Q. What is the rationale behind importation proposals, according to their proponents?

A. Importation proposals are tied to efforts to combat high drug prices. Proponents view an importation program as an alternate way for the sick and aging populations to obtain affordable prescription drugs.[15] However, many policymakers also recognize the need to balance affordability with safety.[16]

Q. Could importation affect patient safety?

A. Yes, to the extent these importation proposals increase the volume of counterfeit drugs in the U.S. supply chain. The very nature of drug manufacturing presents several opportunities for counterfeiting or otherwise tampering with a product—a single pill may pass through a dozen countries during the manufacturing process. This, combined with a lack of regulatory oversight, increases the likelihood that drugs coming from foreign countries and lacking U.S. FDA approval could have been tampered with or otherwise mishandled (*e.g.*, lack of proper temperature control, or improper labeling) before importation.[17] The World Health Organization (WHO) estimates that 10 percent of medicines worldwide are counterfeit.[18] This number could rise as counterfeiters become more sophisticated and able to utilize new technologies to make phony products appear genuine. Counterfeit medicines are dangerous for a number of reasons: they may contain the wrong, not enough, or no active ingredient; or they may contain a toxic, harmful substance.[19] Counterfeit drugs could lead to accidental overdoses and deaths, and at the very least could put patients' treatments at risk.[20] These patients could unknowingly not receive the therapy they need, or could face harmful side effects from potentially toxic counterfeits.

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[13] *See* HHS Task Force Report at 60.
[14] HHS Task Force Report at 60-61.
[15] *See* "Senate to Vote on Sanders Amendment to Lower Rx Prices," (Jan. 11, 2017), https://www.sanders.senate.gov/newsroom/press-releases/senate-to-vote-on-sanders-amendment-to-lower-rx-prices.
[16] *See* Califf Questions for the Record ("FDA is concerned that the risks of unapproved products from foreign sources outweigh any potential cost savings.").
[17] *See* PhRMA Fact Sheet.
[18] PhRMA Fact Sheet.
[19] *See* World Health Organization Fact Sheet, "Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products" (updated Jan. 2016), *available at* http://www.who.int/mediacentre/factsheets/fs275/en/.
[20] The World Health Organization (WHO) estimates that over 120,000 people die in Africa each year as a result of counterfeit anti-malarial drugs alone, either because the drugs contained no active ingredient or were otherwise substandard. *See* Matthew Wall, "Counterfeit drugs: 'People are dying every day,'" BBC News (Sept. 27, 2016), *available at* http://www.bbc.com/news/business-37470667.

Q. What could an importation program, if enacted, mean for the security of the U.S. drug supply chain?

A. Importation programs could compromise the integrity of supply chain by allowing untraceable and potentially dangerous counterfeits to enter the U.S. drug distribution system. Under the current system, prescription drugs are subject to strict FDA regulation and oversight. Allowing importation of foreign drugs without a guarantee that they meet FDA standards could undermine the robust patient protections that Congress and the FDA have established over several decades. Importation programs could also undermine patients' confidence in the safety and effectiveness of the drugs available in the U.S. The infographic in Appendix A illustrates how an importation program lacking foreign and domestic oversight could compromise the U.S. supply chain.

IV. Additional Information

Q. How can an interested individual or organization find out more about importation proposals?

A. Interested individuals and organizations can also track the status of importation bills by using the search function at www.congress.gov.

Appendix A

Source: Allyson Funk, "The Catalyst: What You Don't Know About Importation from Canada," PhRMA (Feb. 17, 2017), *available at* http://catalyst.phrma.org/what-you-dont-know-about-importation-from-canada.