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Prescription Drug Importation

In the context of rising drug prices, the possibility of importing prescription drugs from other countries at lower prices is again being debated. Generally, the importation or reimportation of a prescription drug that does not meet Food and Drug Administration (FDA) requirements is prohibited. The policy debate has centered on creating a new legal option for the import of lower-cost prescription drugs into the United States.

Prescription Drug Regulation

FDA, under the Federal Food, Drug, and Cosmetic Act (FFDCA), regulates prescription drugs. In order to market a new drug in the United States, a manufacturer must obtain approval from FDA by submitting a new drug application (NDA), or in the case of a generic drug, an abbreviated NDA (ANDA). To get approval, the manufacturer must (1) demonstrate the drug's safety and effectiveness according to criteria specified in law and regulation, (2) ensure that its manufacturing facility passes FDA inspection, and (3) obtain approval for the drug's labeling. Drugs made in foreign countries that are imported into the United States for commercial distribution must comply with the same FFDCA requirements as domestically manufactured drugs, including registration and premarket approval. A drug manufacturer may import drugs produced abroad that have not yet received approval (e.g., drugs intended for further processing) by complying with FDA and U.S. Customs and Border Protection (CBP) requirements. See CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, and CRS Report R46507, *FDA's Role in the Medical Product Supply Chain and Considerations During COVID-19*.

Prescription Drug Importation

Foreign-made versions of FDA-approved drugs that have not been evaluated through the FDA process are typically considered unapproved new drugs and are illegal. The FFDCA provides for the circumstances under which an unapproved drug may be imported into the United States. This section discusses the circumstances under which importation is prohibited, as well as the circumstances under which it is allowed.

Importation That Is Prohibited Under Current Law

Under current law, the importation of unapproved new drugs, including foreign-made versions of FDA-approved drugs, is generally prohibited. This would entail bringing into the United States an unapproved drug manufactured outside of the United States. Even in cases where the drug is a foreign-made version of an FDA-approved drug (i.e., the same active ingredient made by the same manufacturer), FDA has stated that it is highly unlikely that the version for the foreign market would meet all of the requirements in the FFDCA for approval. Current law prohibits the introduction

into interstate commerce of a drug that is unapproved, adulterated (e.g., held under insanitary conditions), or misbranded (e.g., the labeling does not include adequate directions for use) [FFDCA Sections 505(a), 301(a), (d)].

Commercial Use. FFDCA Section 801(d)(1)(B) explicitly prohibits the importation for commercial use of unapproved drugs manufactured outside of the United States, with two exceptions: (1) as authorized by the Secretary of Health and Human Services (HHS) pursuant to a drug shortage, and (2) pursuant to the authority at FFDCA Section 804, both of which are discussed in the next section. This prohibition does not apply to drugs when, although manufactured outside of the United States, the manufacturer has authorized them to be marketed in the United States and has labeled them according to relevant FFDCA requirements.

Reimportation. Current law also prohibits the *reimportation*—importing an exported U.S.-manufactured drug back into the United States—of a U.S.-manufactured drug by anyone other than the manufacturer (FFDCA Section 801(d)(1)(A)). Reimportation of a U.S.-manufactured drug by anyone other than the original manufacturer is illegal even if it meets all of the requirements for approval under the FFDCA because it could have been mishandled or otherwise adulterated when it was outside of the reach of FDA. FFDCA Section 801(d)(2) allows for an exception to this prohibition, allowing for the HHS Secretary to authorize the reimportation of a U.S.-manufactured drug where required for emergency medical care, or under FFDCA Section 804, as described below.

The provision prohibiting the reimportation of U.S.-manufactured drugs was put in place in 1987 in an effort to ensure a “closed system” for all prescription drugs marketed in the United States. Proponents of this prohibition argued that it protected against the possibility of prescription drugs that were manufactured in the United States and then exported from being brought onto the American market in possibly subpotent, mislabeled, adulterated, expired, or counterfeit form. Manufacturer reimportation was permitted to allow for standard inventory control practices within the industry.

Importation That Is Allowed Under Current Law

FFDCA Section 804. Section 804 gives the HHS Secretary authority to promulgate regulations to establish a drug importation program under which pharmacists and wholesalers could import *unapproved* prescription drugs from Canada into the United States, with certain qualifications. Specifically, the provision provides that the program cannot become effective until the HHS Secretary certifies that the importation program would pose no additional risk to the public's health and safety and would offer “significant reduction in the cost” to U.S. consumers.

Until recently, no Secretary had given such approval. However, on September 23, 2020, former HHS Secretary Alex Azar made the requisite certification in a letter to Congress. HHS subsequently promulgated a final rule to implement Section 804 (described further below).

Drug Shortages. Current law allows FDA to take various actions when a drug is in shortage, including expediting application review and facility inspection. One available option (now under FFDCA Section 801(d)(1)(B)) is that the HHS Secretary may choose to exercise enforcement discretion and allow the *temporary* and tightly controlled importation and distribution of unapproved drugs to alleviate a drug shortage while domestic production gets back up to speed. This is generally done very rarely, only after other options (e.g., diverting manufacturing to another facility, working with a facility to address quality issues) are considered. In response to Hurricane Maria, for example, FDA used “regulatory flexibility and discretion” to allow for the temporary importation of drugs not approved for use in the United States and manufactured in other countries (e.g., Ireland, Mexico, and Canada).

Personal Importation Policy (PIP). As outlined in FDA guidance, the agency allows some personal importation of unapproved drugs on a case-by-case basis, but one of the criteria that FDA lists in allowing this personal importation is that there can be no existing effective treatment available in the United States. Current law generally does not permit individuals to import or reimport prescription drugs for their own use; instead, it directs the Secretary to exercise discretion to permit importation on a case-by-case basis by an individual for drugs that are clearly for personal use, if such use does not appear to present an unreasonable risk to the individual. FFDCA Section 804(j) provides a statutory basis for the FDA waiver authority outlined in the PIP guidance, although the FDA issued the guidance prior to the establishment of Section 804. FDA has generally allowed individuals to bring into the United States a 90-day supply of unapproved drugs for personal use where effective treatment is not available in the United States, it is for the treatment of a serious medical condition, and there is no commercialization of the drug to U.S. residents. FDA’s PIP is not intended as a way for consumers to bring lower-priced prescription drugs into the United States; rather, FDA intended this enforcement discretion to allow individuals to get treatments not otherwise available in the United States.

Safe Importation Action Plan

In July 2019, HHS and FDA announced the “Safe Importation Action Plan,” proposing two pathways to allow or facilitate the importation of unapproved drugs. In October 2020, HHS promulgated a final rule pursuant to FFDCA Section 804 to implement the first pathway (21 C.F.R. Part 251). The rule allows states and tribes to submit to HHS for review proposals for, and FDA to authorize, time-limited Section 804 Importation Programs (SIP) to permit the importation of certain prescription drugs from Canada, specifically Health Canada-approved versions of drugs marketed in the United States under an NDA or ANDA. Consistent with the statutory language of Section 804, certain drugs are ineligible for importation, including biologics (e.g., insulin) and intravenously injected drugs,

among others. Although then-Secretary Azar made a certification, the final rule requires SIP sponsors to demonstrate that their program will adequately ensure the protection of public health and to explain how it will result in a significant reduction in the cost of covered products to consumers. Proposals must specify the eligible drugs to be included in the SIP, which would have to bear the required U.S. labeling and undergo testing for quality and authenticity, in addition to meeting other supply chain requirements. SIP proposals also must identify the foreign seller in Canada that will purchase the eligible prescription drug directly from its manufacturer, as well as the U.S. importer that will purchase the drug directly from the foreign seller. Both the foreign seller and importer are subject to applicable U.S. registration, licensure and supply chain security requirements. FDA also issued final guidance to implement the second pathway (under FFDCA Section 801(d)(1)(B)) to facilitate importation of foreign-made versions of FDA-approved drugs under their existing U.S. approval. The guidance applies to drug manufacturers, offering them an option to import drugs that may provide lower-cost alternatives to U.S. consumers. This is in contrast to the final rule, which creates a mechanism for importation by entities other than the drug manufacturer and does not require a manufacturer’s authorization. Also unlike the final rule, the guidance applies to small molecule drugs and biologics and is not limited to importation from Canada. In July 2021, Executive Order 14036 directed FDA to work with potential SIP sponsors; FDA has published materials related to the final rule and the required cost analysis on its website.

Drug Importation Policy

Legislation to expand legal drug importation was introduced in the 117th Congress, and a provision addressing both commercial and personal drug importation was included in the Senate user fee bill (S. 4348). Some stakeholders express support for policies that would allow commercial and personal importation of lower-cost drugs in a way that ensures drug safety and integrity. On the other hand, proposals to expand drug importation have been opposed by several former FDA Commissioners and HHS Secretaries, as well as by the pharmaceutical industry, citing safety concerns. Despite the promulgation of regulations implementing Section 804 and publication of final guidance as noted, it remains unclear to what extent or if these policies will be successfully implemented; to date, although a handful of states have submitted SIP proposals to FDA (e.g., Florida, Colorado), FDA has not authorized any SIPs, and at least one lawsuit has been filed challenging the final rule. While the final guidance provides an option for drug manufacturers to import certain drugs, it is unclear if manufacturers are interested in importing drugs intended for foreign markets. Further, other countries may be reluctant to support U.S. importation policies, as it may affect their domestic supply of drugs. In November 2020, the Canadian government announced that certain drugs intended for the Canadian market may not be sold outside of Canada if such sale would cause or worsen a drug shortage.

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