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Prescription Drug Importation

In the context of rising drug prices, commercial and personal importation of prescription drugs from other countries at lower prices is often a subject of discussion. Generally, the importation or reimportation of a prescription drug that does not meet Federal Food, Drug, and Cosmetic Act (FFDCA) requirements is prohibited, with certain limited exceptions. The recent policy debate has included options to modify or expand legal pathways and appropriate safety and quality requirements for personal and commercial prescription drug importation.

Prescription Drug Regulation

The Food and Drug Administration (FDA), under the 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.

Prescription Drug Importation

The FFDCA provides for the limited circumstances under which an unapproved drug, including foreign-made versions of FDA-approved drugs that have not been evaluated through the FDA process, may be imported into the United States. This section provides an overview of the general prohibition on importation of unapproved drugs, as well as the narrow exceptions under which it may be allowed.

Prohibited Importation

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) 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 in FFDCA Section 804. 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 *reimportation*—importing an exported U.S.-manufactured drug back into the United States—by anyone other than the manufacturer (FFDCA Section 801(d)(1)(A)), with two exceptions. Reimportation of a U.S.-manufactured drug may be authorized (1) if required for emergency medical care and (2) under FFDCA Section 804. Reimportation of a U.S.-manufactured drug by anyone other than the original manufacturer is generally illegal even if it meets all the requirements for approval under the FFDCA because it could have been mishandled or otherwise adulterated after export.

This provision was enacted in 1988 in an effort to ensure a "closed system" for 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.

Authorized Importation

FFDCA Section 804 (21 U.S.C. § 384). Section 804 was enacted in the early 2000s, during a period of high prescription drug inflation, by the Medicine Equity and Drug Safety Act (MEDS Act; P.L. 106-387) and subsequently amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173).The section provides the HHS Secretary authority to promulgate regulations to establish a drug importation program under which pharmacists and wholesalers may import certain 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. 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 in late 2020 (described 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 (under FFDCA Section 801(d)(1)(B)) is that the HHS Secretary may authorize the importation of an unapproved drug on the drug shortage list to help alleviate the shortage. This is generally done rarely, after other options (e.g., diverting manufacturing to another facility, working with a facility to address quality issues) are considered.

Personal Importation Policy. As outlined by FDA, the agency allows some personal importation of unapproved drugs on a case-by-case basis. 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 personal importation of drugs that are obviously for personal use, if such use does not appear to present an unreasonable risk to the individual. FDA has generally allowed individuals to bring into the United States a 90-day supply of an unapproved drug for personal use where (1) effective treatment is not available in the United States, (2) it is for the treatment of a serious medical condition, (3) the drug is not considered to present an unreasonable risk, and (4) there is no commercialization of the drug to U.S. residents. FDA's personal importation policy has normally not been intended as a way for consumers to bring lower-priced prescription drugs into the United States; rather, FDA intended this policy to allow individuals to gain access to 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 the program will adequately ensure the protection of public health and 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. Concurrent with publication of the SIP final rule, FDA 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. In contrast, the final rule creates a mechanism for importation by entities other than the drug manufacturer and does not require a manufacturer's authorization. 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, and in April 2025, Executive Order 14273 required FDA to "take steps to streamline and improve the Importation Program under section 804 of the Federal Food, Drug, and Cosmetic Act to make it easier for States to obtain approval without sacrificing safety or quality." FDA has published materials to support SIP sponsors on its website.

Issues for Consideration

Over the years, Congress has introduced legislation that would authorize both personal and commercial importation of unapproved prescription drugs, subject to specified requirements, from countries where they may be less expensive. Some stakeholders express support for policies allowing commercial and personal importation of lower-cost drugs in a way that ensures drug safety and integrity. Alternatively, proposals to expand drug importation have been opposed by some former FDA Commissioners and HHS Secretaries, as well as by the pharmaceutical industry, citing safety concerns.

Despite publication of the final regulation implementing Section 804 and final guidance as noted, it remains unclear to what extent these policies will be successfully implemented. To date, a few states have reportedly submitted SIP proposals to FDA, and only Florida has received authorization (in January 2024). Florida's authorization has been extended several times, most recently in November 2025. The authorization is time-limited, and Florida has several obligations, including, for example, adverse event monitoring, quarterly reporting to the FDA, and ensuring supply chain integrity. 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. For example, 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 shortage.

Amanda K. Sarata, Specialist in Health Policy

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