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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 largely has been around creating a new legal option for the import of prescription drugs into the United States at lower cost than the same drugs available domestically. This has raised concern from stakeholders about drug safety and the feasibility of such a program.

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. To get that 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.

Pre-market Approval

FDA's prescription drug approval requirements apply to all manufacturers that market drugs in the United States, regardless of whether the manufacturing facility is located domestically or in a foreign country. Thus, before a drug manufactured in a foreign country is imported into the United States for commercial use, it must be approved by FDA. To obtain approval, the manufacturer must submit a New Drug Application (NDA), or in the case of a generic drug, an abbreviated NDA (ANDA), which must include, among other things, information about the facility in which it was manufactured, a product description (e.g., chemical formulation), processing methods, manufacturing controls, and labeling. An active pharmaceutical ingredient (API) is defined as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug" (21 CFR §203.3(e)). An API may be imported into the United States if it is the subject of a valid NDA or investigational new drug application (IND) if it is to be used for laboratory research or clinical trials and meets other specified requirements.

Facility Inspection

Domestic facilities that engage in the "manufacture, preparation, propagation, compounding or processing" of a drug, and foreign facilities that engage in the "manufacture, preparation, propagation, compounding or processing" of a drug that is imported into the United States, whether an API or the finished form of the drug, must register with FDA (FFDCA Section 510) and are subject to FDA inspection. FDA conducts preapproval, surveillance, and for-cause

inspections. Preapproval inspections are part of the drug approval process, while surveillance inspections are conducted once a drug is on the market to assess compliance with manufacturing standards. For-cause inspections are to investigate, for example, complaints from the public about a drug or concerns about its quality. FDA is required to conduct surveillance inspections of both domestic and foreign establishments using a risk-based approach (FFDCA Section 510(h)).

Many prescription drugs that are sold in the United States are manufactured, at least in part, abroad. FDA estimates that in 2018, 88% of facilities making APIs and 63% of sites making finished drugs were located overseas. FDA has foreign offices around the world and the agency recognizes inspections conducted by certain foreign regulatory authorities within the European Union and relies upon their inspection data.

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

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) except 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 does not apply to those drugs that are manufactured outside of the United States and are authorized to be marketed in the United States and are labeled according to the relevant requirements in the FFDCA (i.e., drugs that are FDA-approved).

Reimportation. Current law also prohibits the *reimportation* of a U.S.-manufactured drug by anyone other than the manufacturer (FFDCA Section 801(d)(1)(A)). Reimportation by anyone other than the original manufacturer of a U.S.-manufactured drug 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. Thus far, no Secretary has ever given such approval.

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.

Prescription Drug Price and Importation

It is not clear how or if expanding legal drug importation would affect cost for U.S. consumers and payers. Several bills introduced in the 116th Congress would authorize both personal and commercial importation of unapproved prescription drugs, subject to specified requirements, from countries where they may be less expensive. In addition, in July 2019, HHS announced its “Safe Importation Action Plan.” This plan proposes to establish, relying on both Section 804 and Section 801(d) authorities, two pathways to allow for the importation of unapproved drugs into the country. The first pathway—through rulemaking—would propose to allow states, pharmacists, and wholesalers to submit to HHS for review and possible approval plans for demonstration projects to import certain Health Canada-approved drugs into the country. The second pathway—through guidance—would allow foreign-made versions of FDA-approved drugs to be imported into the United States under the existing approval for the FDA-approved version of the drug. This second pathway would depend on the manufacturer being able to successfully demonstrate that the foreign-made version is identical to the version approved for U.S. marketing. Generally, 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. Groups such as the American Medical Association (AMA) have expressed support for policies that would provide for importation or reimportation of lower-cost drugs for personal use in a way that ensures drug safety and integrity.

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