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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 first 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.

Facility Inspection

Facilities that engage in the "manufacture, preparation, propagation, compounding or processing" of a drug, whether an API or the finished form of the drug, must register with FDA, to be inspected by the agency prior to approval. 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 patients and health care professionals about a product or concerns about product quality. FFDCA Section 510(h) requires FDA to conduct surveillance inspections of both domestic and foreign establishments using a risk-based approach.

Many prescription drugs that are sold in the United States are manufactured, at least in part, abroad. According to a December 2016 U.S. Government Accountability Office (GAO) report, FDA estimates that more than 40% of finished drugs and 80% of APIs are produced overseas. FDA has foreign offices around the world and according to a December 2016 GAO report, FDA has increased the number of foreign drug inspections conducted each year since 2009. FDA also recognizes inspections conducted by certain foreign regulatory authorities within the European Union and relies upon their inspection data.

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. FFDCA Section 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 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).

Reimportion. In addition, current law 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 Health and Human Services (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. So far, because of concerns over safety, 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 (i.e., 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 the statutory basis for the FDA waiver authority outlined in the PIP guidance.

FDA has chosen to relatively leniently enforce the current prohibition, and has generally allowed individuals to bring into the United States a small amount (i.e., 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. This FDA policy requires those individuals to affirm in writing that the drugs are for their own use and to provide their physician's contact information. 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 115th Congress would authorize importation of prescription drugs, subject to specified requirements, from countries where they may be less expensive. 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. In particular, the former Commissioners wrote in a March 2017 letter to Congress that "drugs purchased from foreign countries may be substandard, unsafe, adulterated, or fake" and "FDA lacks the resources needed to oversee a major importation program." Other stakeholders have proposed allowing for drug importation in limited circumstances, for example, if a manufacturer raises the price of an older, off-patent medication. Groups such as the American Medical Association (AMA) and the Association of American Retired Persons (AARP) 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. In July 2018, FDA announced that it was establishing a working group to explore the feasibility of drug importation from other countries in the case of a price increase for a sole source off-patent, off-exclusivity drug.

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