

CLIENT ALERT

New Developments on Drug Reimportation

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By Amy Newman

Despite consistent opposition from the Bush administration, growing popular sentiment in the United States has repeatedly called on Congress and the relevant regulatory agencies to permit reimportation of drugs into the United States. Reimportation occurs when a drug is manufactured in the United States, exported out of the country, and then imported back into the United States. Under current law, the importation or reimportation of prescription drugs into the United States is prohibited except for importation by the original manufacturer. For purposes of this summary, the terms “reimportation” and “importation” are used interchangeably.

With the support of the domestic drug manufacturers, the Administration has consistently opposed such measures, citing health and safety concerns and lack of safeguards to ensure that drugs imported into the United States are safe and effective and that the “reimported” prescription drugs are not counterfeit. HHS recently released its Task Force Report on Prescription Drug Importation, which echoes these concerns, yet leaves the door open to development of solutions. Drug manufacturers, insurers, Congress, administrative agencies and states all are struggling with this issue in various ways. Addressed briefly below are developments on various fronts to watch in the upcoming months and year.

Enforcement

The Department of Health and Human Services (“HHS”), Food and Drug Administration (“FDA”), Drug Enforcement Agency (“DEA”) and U.S. Customs and Border Protection (“CBP”) are the primary agencies tasked with enforcing U.S. law in this arena. Enforcement by these agencies generally focuses on commercial transactions, rather than on individual consumers, due to the large volume of individual transactions. FDA’s policy is to allow individuals entering the U.S. to import up to a three-month supply of a drug if certain conditions are met. See FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importations. CBP follows FDA’s policy.

FDA inspects drugs at the border to ensure safety and efficacy and enforces the prohibition on reimportation. In addition to these inspection efforts, FDA repeatedly has sent warning letters to states initiating or planning to initiate programs to import prescription drugs from Canada or which pass law allowing the licensing of foreign pharmacies. In those letters, FDA has explained repeatedly that these programs violate federal law and that federal law, in any event, preempts any state law in this field.

CBP assists with enforcement by working in conjunction with FDA at the 355 points of entry into the U.S. While CBP periodically conducts “blitz” inspections, it currently does not inspect each entry. See fn. 3. However, upon finding unapproved drugs, CBP can seize the drugs.

Federal and State Legislation

In the last Congress, several bills were introduced with bi-partisan support to permit importation of prescription drugs into the U.S.; none was passed. In the first month of 2005, three bills with bi-partisan support have been introduced (H.R. 328, S. 184 and S. 239). It remains to be seen whether any of these have a chance of passage. However, Majority Leader Frist already has promised a hearing on S. 239 within the next 90 days.

Rhode Island is an example of state legislation seeking to ease reimportation. A recent Rhode Island law authorizes that state's Department of Health to license Canadian pharmacies to import prescription drugs into Rhode Island. FDA issued a detailed letter warning the Rhode Island Attorney General of the illegality of such imports and potential liability. It remains to be seen what next steps will be taken by Rhode Island and/or FDA. For a copy of FDA's letter.

Litigation

Both purchasers challenging the prohibition and regulatory agencies seeking enforcement of the laws have filed lawsuits in federal court. As more states, municipalities and other health care providers challenge FDA's authority to prohibit the importation or reimportation of prescription drugs, more lawsuits are likely to follow. Here are a couple of cases to watch:

- State of Vermont v. Thompson (D. Vt.) – suit against Secretary Thompson and HHS seeking declaratory and injunctive relief based on FDA's denial of the State of Vermont's citizen petition requesting that the Vermont State Employee Medical Benefit Plan be allowed to establish a program for the importation of prescription drugs from Canada
- United States v. Canada Care Drugs, Inc. (S.D.N.Y.) – FDA filed a civil complaint against Canada Care Drugs, Inc. (“Canada Care”) and certain individuals for the illegal importation of prescription drugs into the U.S.; this case is related to the case against Rx Depot, Inc., a formerly related company that entered into a consent decree with FDA on August 20, 2004. On December 16, 2004, the court granted a preliminary injunction against Canada Care.

A domestic producer may initiate an investigation at the U.S. International Trade Commission under 19 U.S.C. § 1337 (“Section 337”). Under Section 337, a domestic industry may file a complaint at the ITC against a foreign producer who imports into the United States infringing goods. Protection of intellectual property rights is a key issue of concern for U.S. drug manufacturers, who may sometime soon pursue this avenue.

In addition to general litigation to enforce intellectual property rights and Section 337, the United States is a party to the TRIPS Agreement among the members of the World Trade Organization (“WTO”). TRIPS Agreement member nations must maintain national laws to protect intellectual property rights. In addition, the U.S. has negotiated other intellectual property agreements with groups of and individual countries. Each agreement is different, but such considerations should be kept in mind when considering a drug importation program.

Trade agreements can contain restrictions on reimportation. For example, the recently signed U.S.-Australia Free Trade Agreement bans the export of pharmaceuticals if purchased under Australia's Pharmaceutical Benefits Scheme.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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