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Opinion 06-019

Purchase of Prescription Drugs from Foreign Countries

QUESTIONS

1. If an individual purchases prescription drugs for personal use from a foreign country, would that individual be violating any state or federal law?

2. Would the state, individual, or entity violate any state or federal law if they set up and maintained a website that permitted individuals to order prescription drugs from other countries?

3. If the activity inquired about in question number 2 above were legal, would the state, individual, or entity be limited to FDA-approved drugs only?

4. If FDA approval is required, are you aware of a procedure in place to monitor FDA-approved drugs?

OPINIONS

1. The individual would likely be in violation of federal law. According to the United States Food and Drug Administration, virtually no imported prescription drugs are manufactured in foreign facilities inspected and approved by the FDA, labeled correctly, and dispensed with a valid prescription, as required by the Federal Food, Drug and Cosmetic Act.

2. "Causing" the sale of illegal prescription drugs from other countries through an internet service would also constitute a violation of federal law.

3-4. In light of our response to your second question, these questions are pretermitted.

ANALYSIS

1. The United States Food and Drug Administration (FDA), an arm of the U.S. Department of Health and Human Services (HHS), administers the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301, *et seq*. Currently, the only two types of prescription drugs that may be legally imported are those that are manufactured in foreign facilities inspected and approved by the FDA and those that are manufactured in the United States under FDA-approved conditions, subsequently sent abroad and then imported back into the United States by the manufacturer. HHS Task Force on Drug Importation, Report on Prescription Drug Importation,

Dept. of Health and Human Services at VIII (Dec. 2004).[1] The FDA has stated that virtually all drugs imported to the United States from Canada and other foreign countries violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a) and/or (d).[2] Letter dated August 25, 2003, to Gregory Gonot, Deputy Attorney General, State of California from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (available at http://www.fda.gov/opacom/gonot.html; last visited January 18, 2006). Additionally, 21 U.S.C. § 331(t) provides that anyone other than the original manufacturer who re-imports or causes the re-importation of FDA-approved drugs (in violation of 21 U.S.C. § 381(d)(1)) commits a prohibited act.

21 U.S.C. § 384(j) gives the Secretary of HHS discretion to grant individuals a waiver of the importation prohibition. Congress specified that, in enforcement against individuals who import prescription drugs, the Secretary should focus on cases in which the importation poses a significant threat to public health and should permit individuals to import prescription drugs where the drugs are clearly for personal use and do not appear to present an unreasonable risk to the individual. 21 U.S.C. § 384(j)(1). In particular, Congress mandated that the Secretary provide importation waivers to individuals who import drugs from Canadian sellers registered with the FDA. 21 U.S.C. § 384(j)(3). However, these importation provisions will not be effective unless the Secretary certifies that they will pose no additional risk to public health and safety. 21 U.S.C. § 384(l). No HHS Secretary has yet made the necessary certification.[3]

Therefore, we conclude that an individual who purchases prescription drugs for personal use from a foreign country would be in violation of federal law unless the drugs were manufactured in

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[1]The report may be viewed at http://www.hhs.gov/importtaskforce/Report1220.pdf (last visited January 18, 2006).

[2]S*ee also* 21 U.S.C. § 381(a).

[3]Despite the fact that the HHS Secretary has not yet made the necessary certification, the FDA currently has a personal use importation policy that permits it to exercise its enforcement discretion to allow individuals, under certain limited circumstances, to import otherwise illegal drugs. Under this policy, the FDA permits individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. The policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens. And the FDA warns that its personal use importation policy does not change the law, that it is "not . . . a license to persons to import or export illegal drugs into the United States," and that the FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated. Letter dated July 27, 2005, to Greg Abbott, Attorney General, State of Texas from Randall W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration (available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/abbott072705.html; last visited January 18, 2006).

The Food and Drug Administration's personal use importation policy may be viewed at its website (http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html; last visited January 18, 2006).

foreign facilities inspected and approved by the FDA, were labeled correctly, and were dispensed with a valid prescription.

2. As described above, virtually every importation of a prescription drug will violate federal law. Individuals or programs that "cause" illegal shipments also violate the FFDCA. 21 U.S.C. § 331. The FDA states that neither public nor private entities can avoid jurisdiction under the FFDCA by merely "facilitating" the sale of foreign drugs to individuals through a third-party internet service. Letter dated August 25, 2003, to Gregory Gonot, Deputy Attorney General, State of California from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, *supra*.

To date, court decisions have generally confirmed the FDA's above-described interpretation of federal law. In *United States v. Rx Depot, Inc.*, 290 F.Supp. 2d 1238 (N.D. Okla. 2003), the district court entered a preliminary injunction order to prevent RxDepot, Inc., from causing the importation of unapproved and misbranded drugs into the United States from Canada. Rx Depot was a domestic storefront pharmacy that assisted individuals in procuring prescription medications from pharmacies in Canada. Rx Depot accepted prescriptions from U.S. customers and transmitted them to a cooperating pharmacy in Canada. The Canadian pharmacy filled the prescriptions and shipped the prescription drugs directly to the U.S. citizens. The court held that, although Rx Depot never took possession of the imported drugs, its encouragement and facilitation of the illegal importation of drugs constituted the requisite "causing" under 21 U.S.C. § 331. *Id*. at 1247.

In *Vermont v. Leavitt*, 2005 WL 3529665 (D. Vt. 2005), the district court dismissed a lawsuit challenging the validity of the FDA's denial of the Vermont State Employee Medical Benefit Plan's proposal to establish a program for the individual importation of prescription drugs from Canada. The state employee plan sought authority to contract with providers to create a system under which its members could forward a prescription to a Canadian firm; the prescription would be re-written as a Canadian prescription, then forwarded to a licensed Canadian pharmacy to be filled, and the prescription medication would be sent by mail to the member in the United States. Citing *Rx Depot*, the court concluded, "[t]here is no question that Vermont's proposed program would violate the [FFDCA]." *Id.* at *6. The court explained that, "as Vermont's proposed plan would be highly likely to include drugs manufactured in the United States, it would lead to violations of [21 U.S.C. § 331(t)]." *Id.* In addition, the court explained that the plan would likely lead to violations of 21 U.S.C. § 331(a) because "[m]any Canadian drugs will have packaging and labeling that is not approved by the FDA" and "many Canadian drugs may not have been manufactured according to [good manufacturing practice] (even if these drugs are pharmacologically identical to drugs approved by the FDA)." *Id*. The court held that these violations of the FFDCA would occur regardless of whether the employee benefit plan or the members themselves imported the drugs. *Id.*

We therefore conclude that setting up and maintaining a website that permitted individuals to order prescription drugs from other countries would likely violate federal law.

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