Drugs

Texas: Attorney General Greg Abbott

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Rockville MD 20857

July 27, 2005

The Honorable Greg Abbott
Attorney General of the State of Texas
Office of the Attorney General
P.O. Box 12548
Austin , Texas 78701 -25481

RE: RQ-0355-GA

Dear Honorable Greg Abbott:

I am writing in response to your June 30 request for opinions as to whether provisions of the recently enacted Texas Senate Bill 410, which permits the State Board of Pharmacy to authorize Canadian pharmacies to import prescription drugs, are preempted by federal law. As you know, on June 17, 2005 , we sent a letter to Governor Perry regarding our concerns with Texas Senate Bill 410. We now take this opportunity to raise these concerns with you as well.

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appea to be the same as U.S. approved prescription drugs have been of unknown origin and quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same as products approved by FDA. These safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit both the types of drugs that may be imported into the United States and who may import them. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. Accordingly if a person within the State of Texas were to import prescription drugs into the State of Texas from Canada , it would violate the FFDCA in virtually every instance. Furthermore, the drug importation program set forth by Congress preempts conflicting state or local legislation that would legalize the importation of certain drugs from Canada in contravention of the FFDCA.

General Legal Framework

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada .[1]

First, virtually all prescription drugs imported for personal use into the United States from Canada violate the FFDCA because they are unapproved new drugs (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). See also 21 U.S.C. § 381(a).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, packaging location, container/closure system and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured or packaged by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus is unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 353(b) but is not required in the foreign country, or it may be labeled in a language other than English (see 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any person that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with their FDA approvals in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, packaging location, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all applicable U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" provision in 21 U.S.C. § 381(d)(1).

Practically speaking, it is extremely unlikely that all of the applicable legal requirements will be met if Canadian pharmacies ship drugs into Texas . Consequently, virtually every shipment would violate the FFDCA. Moreover, individuals or programs that "cause" illegal shipments also violate the FFDCA. 21 U.S.C. § 331.

FDA's Personal Importation Policy

There has been some confusion about whether FDA's personal importation policy changes the law with respect to personal imports of pharmaceuticals. To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad. As a matter of enforcement discretion, FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into the United States for their own personal use. Instead, FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs.

The personal importation policy is used to guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA does not stop the importation of otherwise illegal drugs. Under this policy, 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. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product is also expected to provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. See FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importations.

However, this policy is not intended to allow importation of foreign versions of drugs when such drugs are being "commercialized" to U.S. citizens. (Foreign versions are often what Canadian pharmacies offe to sell to U.S. consumers.) Moreover, the policy simply describes the agency's enforcement priorities. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States . While FDA currently has no plans to alter this policy, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

Potential Liability

There are many sources of civil and criminal liability for parties who violate the FFDCA. A court can

enjoin violations of the FFDCA under 21 U.S.C. § 332. A person who violates the FFDCA can also be hel criminally liable under 21 U.S.C. § 333. A violation of 21 U.S.C. §§ 331(a), (d), or (t) may be prosecuted as a strict liability misdemeanor offense. See United States v. Dotterweich, 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). Any such violation that is committed with intent to defraud or mislead or after a prior conviction for violating the FFDCA may be prosecuted as a felony under 21 U.S.C. § 333(a)(2). Separately, it is also a felony to knowingly import a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1). See 21 U.S.C. § 333(b)(1)(A). In addition, those who can be found civilly and criminally liable include all who cause a prohibited act under the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited")

Federal Preemption

Federal preemption of state law is grounded in the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Cause states that: "This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

The Supreme Court has held that, under the Supremacy Clause, the enforcement of a state regulation may be pre-empted by federal law in several circumstances: first, when Congress, in enacting a federal statute, has expressed a clear intent to preempt state law; second, when it is clear, despite the absenc of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law; and finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Capital Cities Cable, Inc. v. Crisp, 467 US 691, 698-99 (1984) (quotation marks and citations omitted); see also English v. General Electric Co., 496 US 72, 78-79 (1990); Association of Int'l Auto Mfrs., Inc. v. Abrams, 84 F.3d 602, 607 (2nd Cir. 1996).

Courts have thus held that federal law preempts state law when, inter alia, Congress has intended to occupy a field of regulation comprehensively (termed "field preemption"). See English v. General Electric Co., 496 US at 78-79; Choate v. Champion Home Builders Co., 222 F.3d 788, 792 (10th Cir. 2000).

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the States to supplement it"; 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the sam subject"; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." Hillsborough Country v. Automated Medical Laboratories, Inc., 471 U.S. 707, 713 (1985) quoting Rice v. Santa Fe Elevator Corp., 331 US 218, 230 (1947).

In the instant matter, Congress set forth a comprehensive importation plan in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as par of the federal Prescription Drug Marketing Act. P.L. 100-293 (April 22, 1988). In enacting the law, Congress cited the explicit goal of limiting the flow of drugs into the United States from abroad. In section 2 of the bill, Congress found, "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." Id. Clearly, Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goa of controlling the types of drugs that could be legally imported into the United States . The federal plan is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated. By definition, the plan cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports. Licensure of Canadian pharmacies by the State of Texas would be inconsistent with the plain objectives of the FFDCA if such licensure authorized those Canadian pharmacies to ship into the United States drugs that violate the provisions of the FFDCA.

Conclusion

I hope that the preceding discussion is helpful to you. The licensure of Canadian pharmacies by the Texas State Board of Pharmacy will not only result in violations of federal law, it may put citizens at risk. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality and origin. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. Accordingly, the FFDCA strictly limits the types of prescription drugs that may be imported into th United States . Any state law that legalizes imports in contravention of the FFDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FFDCA would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.

We are aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs in the United States without opening our borders to the potential dangers of foreign unapproved pharmaceuticals. These steps include changes to our regulations to reduce litigation that has been shown to delay unnecessarily access to more affordable generic drugs and proposals to increase agency resources for the review and approval of generic drugs -- products that are often far less expensive than brand name products in the U.S., and generally less expensive than generic drugs sold elsewhere in the industrialized world. Also, the Medicare prescription drug discount card and soon to be implemented prescription drug benefit provide millions of America 's seniors with discounts and coverage for their prescription medicines.

If you need additional information, please feel free to contact me.

Sincerely,

Randall W. Lutter, Ph.D.
Acting Associate Commissioner for Policy
and Planning

[1]We will limit our discussion to drugs imported from Canada because the Texas law is so limited. The legal analysis is the same for drugs imported from any foreign country.

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