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Opinion No. 05-083

Senate Bill 1989/House Bill 1870 — Consistent with federal law?

QUESTION

Would enactment of Senate Bill 1989/House Bill 1870 cause the State of Tennessee to be in violation of federal law?

OPINION

Yes, according to the United States Food and Drug Administration. Since the FDA is the agency charged with administering and enforcing the federal laws governing prescription drugs, its interpretation of those statutes is entitled to great deference.

ANALYSIS

If it becomes law, Senate Bill 1989 (and its equivalent, House Bill 1870) will enact the "Prescription Medicine Fair Pricing Act of 2005." Section 2 of the proposed legislation directs the Commissioner of Finance and Administration to enter into discussions with the member states of the I-SaveRx prescription drug program, with representatives of companies that import Canadian and other international prescription drugs to the United States, or with others in order to establish by January 1, 2006 a memorandum of understanding allowing all Tennessee residents to purchase prescription drugs through the I-SaveRx program or any other similar program. Alternatively, the Commissioner shall establish by January 1, 2006, a new Tennessee international prescription drug cost savings program for Tennessee residents.

Section 3 of the bill adds a new statutory provision, Tenn. Code Ann. § 56-7-2607. The new provision broadly requires any health insurance policy or contract that provides prescription drug coverage to offer and make available coverage for prescription drugs purchased in Canada, Ireland or the United Kingdom and used in Canada, Ireland or the United Kingdom or reimported legally, or purchased through any state-operated international prescription drug cost savings program, on the same benefit terms and conditions as prescription drugs purchased in this country. However, this requirement does not apply to short-term travel policies, certain short-term nonrenewable policies, accident only policies, limited or specific disease policies, and contracts designed for issuance to persons eligible for coverage under Medicare or state or governmental plans including the TennCare program.

The I-SaveRx program referred to in SB 1989 is a state-sponsored program intended to help residents buy cheaper prescription drugs from Canada and Europe. It was developed by the State of Illinois and launched in October 2004. Wisconsin, Missouri, Kansas and Vermont also participate. According to information obtained from the I-SaveRx website (http://www.i-saverx.net/)(last visited May 12, 2005), I-SaveRx works through a Canada-based clearinghouse administered by CanaRx Services Inc., an Ontario pharmaceutical benefits manager ("PBM"). To enroll in the program, consumers must mail or have their doctor fax a detailed health-profile form and a signed prescription to the clearinghouse, which checks for possible interactions with drugs the patient already takes. If the prescription passes the interaction test, it is turned over to a network doctor licensed in the selected country. That doctor reviews and rewrites the prescription for a local network pharmacy or wholesaler in Canada, Ireland or the United Kingdom, which does a final safety check to comply with local laws before dispensing the medication. I-SaveRx inspects and approves all pharmacies participating in the program.

The United States Food and Drug Administration (FDA) administers the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301, *et seq.* In a series of letters, the FDA has recently advised a number of states and others that importation of prescription drugs from foreign countries, and "facilitating" such importation, violates the FFDCA.[1] According to the FDA:

> First, 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).
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> 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, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured 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 it is considered to be unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may

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[1] *See, e.g.*, Letter dated January 28, 2005 to Patrick Lynch, Attorney General of Rhode Island from William K. Hubbard, Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration ("Hubbard")(available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/lynch012805.html) (last visited May 10, 2005); Letter dated February 23, 2004 to Tim Pawlenty, Governor of Minnesota from Hubbard (available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html) (last visited May 10, 2005); Letter dated August 25, 2003 to Gregory Gonot, Deputy Attorney General, State of California from Hubbard (available at http://www.fda.gov/opacom/gonot.html) (last visited May 10, 2005); Letter dated June 3, 2004 to Rod Blagojevich, Governor of Illinois from Lester M. Crawford, Acting Commissioner, FDA (available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/GovB63.pdf) (last visited May 10, 2005).

> lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) 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)).
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> Second, . . . 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. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).
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> . . .
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> Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county, or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited. . ."). Thus, neither the public nor private entities mentioned in [California's] letter can avoid jurisdiction under the FFDCA by merely "facilitating" the sale of Canadian drugs to California citizens 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, U.S. Food and Drug Administration, *supra* at fn. 1.

The FDA's letters also take the position that state laws that contravene the provisions of the FFDCA by authorizing the importation of prescription drugs are preempted by federal law. *See, e.g., id.* Moreover, they warn that there are many sources of civil and criminal liability for parties who violate the FFDCA, including those who cause a prohibited act under the FFDCA. *See, e.g., id.*

Since the FDA is the agency charged with administering and enforcing the federal laws governing prescription drugs, its interpretation of those statutes is entitled to great deference.[2] *See*

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[2]We note that the Maryland Attorney General's Office has recently reviewed the FDA's legal positions and issued written advice stating:

> . . . a letter from me concluding that the FDA misinterprets its own law would be of little use in the event that the FDA were to decide to bring an enforcement action against the State or one of its political subdivisions for facilitating the importation of prescription drugs. Having reviewed the matter, however, I find that I agree with their conclusions. The only court that I am aware of to look at these issues, in the context of a company that had storefronts in the United States for Canadian

Udall v. Tallman, 380 U.S. 1, 85 S.Ct. 792, 801, 13 L.Ed.2d 616 (1965).

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> pharmacies, has also upheld the position of the FDA. *United States v. RxDepot, Inc.*, 290 F.Supp.2d 1238 (N.D. Okla. 2003), *stay denied, United States v. RxDepot, Inc.*, [297 F.Supp.2d 1306] (N.D. Okla. Nov. 12, 2003).

Letter dated January 28, 2004 to the Honorable Kunar P. Barve from Kathryn M. Rowe, Assistant Attorney General, State of Maryland (available at http://www.oag.state.md.us/Opinions/Advice2004/BarveJan28.pdf) (last visited May 12, 2005). Moreover, the Kansas Attorney General has very recently issued an opinion concerning Kansas' involvement in the I-SaveRx program. It concludes, *inter alia*:

> . . . Whether a court would find that the State of Kansas' involvement in the I-SaveRx program would likewise amount to a responsible share in furtherance of acts prohibited under 21 U.S.C. § 331 is difficult, if not impossible, to predict. However, based on the statements made by the FDA and the court's decision in *Rx Depot, Inc.*, we believe that at best Kansas' involvement comes perilously close to causing violations of the FFDCA and at worst does cause such violations.

Kan. Atty. Gen. Op. No. 2005-11 (March 30, 2005) (available at http://www.kscourts.org/ksag/opinions/2005/2005-011.htm) (last visited May 10, 2005).