Texas AG Opinion Says Texas May Not Import Prescription Drugs from Canada

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Texas Senate Bill 4101 ("S.B. 410") was enacted by the 79th Texas Legislature and signed into law by Governor Rick Perry on June 18, 2005. Legislative findings set forth in Section 36 of the Bill concluded that:

(1) prescription drugs are expensive to the point that some residents of this state have been forced to choose between purchasing prescription drugs and paying for other essentials, such as groceries or rent;
(2) prescription drugs can be purchased at much lower costs in Canada;
(3) scams offering low-cost prescription drugs are prevalent on the Internet and in spam e-mail, and these practices make it difficult for consumers in this state to determine how and where to purchase safe and effective prescription drugs at affordable prices;
(4) the Regulatory Procedures Manual of the United States Food and Drug Administration authorizes agency personnel to allow the importation of products regulated by that agency when the quantity and purpose are clearly for personal use and the product does not present an unreasonable risk to the user; and
(5) other states and municipalities provide Internet websites and other methods to allow residents of those states or municipalities to safely purchase prescription drugs from Canada.2

Based on these findings the Legislature directed the Texas State Board of Pharmacy ("Board") to inspect, designate and authorize at least one and not more than 10 Canadian pharmacies to import prescription drugs into the State of Texas.3 The Board was also directed to establish an Internet website "to provide information necessary to enable residents of this state to conveniently order prescription drugs from Canadian pharmacies designated by the board ...."4 S.B. 410l also required that any Canadian pharmacy designated by the Board must "(1) compile and maintain a current price list for prescription drugs provided to residents in this state; and (2) guarantee those prices for not less than 30 days from the date the list is effective."5

On June 17, 2005, Dr. Randall W. Lutter, Acting Associate Commissioner for Policy and Planning with the U.S. Food and Drug Administration ("FDA") wrote to Governor Perry

2 Id. § 36.
3 Id. § 37.
4 Id. Interestingly, the law required the Board to include a disclaimer stating that the "the board is not liable for any act or omission of a Canadian pharmacy designated as having passed inspection to dispense prescription drugs to residents in this state." Id.
5 Id. § 43.
expressing the FDA’s position that “[t]he licensure of Canadian pharmacies by the [Board] will not only result in violations of federal law, it may put citizens at risk.”

The FDA letter raised several safety concerns with the proposed law. First, the FDA noted that drugs obtained from foreign sources may be of unknown origin and quality. Also, the law does not provide a mechanism for the recall of imported products that are recalled in Canada but not in the United States, a situation that sometimes happens because Canadian facilities may manufacture drugs to different specifications. The FDA also noted that Canadian drugs may be labeled differently than their U.S. counterparts. For example, inactive ingredients in Canadian drugs may be found only by consulting the Canadian Physicians Desk Reference (“PDR”), and the Canadian PDR may not be readily available to physicians in the U.S. Such “inactive” ingredients may cause allergic reactions in some individuals. The FDA also expressed concern that the Texas law could sanction importation of drugs in containers that are not childproof, placing children at greater risk. Finally, the letter questioned whether Canadian pharmacies would comply with the U.S. Health Insurance Portability and Accountability Act privacy rules.

The FDA letter outlined the legal framework and noted that several provisions of the U.S. Food Drug and Cosmetic Act (“FDCA”) would be violated by the importation of prescription drugs from Canada to the United States. Under the FDCA, imported drugs are considered to be “unapproved new drugs.” Such drugs may be labeled incorrectly from the perspective of U.S. law. Further, the FDCA provides that no person (other than the original manufacturer) may re-import into the United States drugs that were originally manufactured in the U.S. and sent abroad. In light of these provisions, the FDA letter concluded that “virtually every shipment would violate the [FDCA].” The FDA letter also noted that the Board could be in violation of the FDCA because “individuals or programs that cause illegal shipments also violate the [FDCA]” and that violations of the FDCA may result in serious civil and criminal liability. Finally, the FDA letter discussed federal preemption of state law and argued that the FDCA preempts contrary provisions of state law, concluding that “[l]icensure of Canadian pharmacies by the state of Texas would be inconsistent with the plain objectives of the [FDCA].

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7 Id. at 1.
8 Id.
9 Id.
10 Id.
11 Id. at 2.
12 Id.
13 Id. at 3, citing 21 U.S.C. § 355.
16 Id.
18 Id. at 4 (citing various statutory and case law).
On June 23, 2005, the Executive Director/Secretary of the Board sought an opinion from the Texas Attorney General’s office asking whether federal law preempts the implementation of S.B. 410 by the Board and whether the Board would violate federal law by authorizing and promoting the importation of prescription drugs from Canada. On December 21, 2005, the Texas Attorney General issued Opinion No. GA-0384 (“AG Opinion”), which states that Sections 36-43 of S.B. 410 “directly conflict with [the federal FDCA].”

The AG Opinion notes that Congress sought to allow some importation of drugs from Canada by passing the Medicine Equity and Drug Safety Act of 2000. However, that law provides that its importation provisions are not effective unless and until the U.S. Secretary of Health and Human Services (“HHS”) confirms that adequate safety can be maintained, and no Secretary of HHS has been willing to provide such assurances. After discussing S.B. 410 and the FDA letter to Governor Perry, the AG Opinion addresses the preemption doctrine, noting that although Article VI of the U.S. Constitution provides that “the Laws of the United States…shall be the supreme Law of the Land…,” the starting point is nonetheless that Congress does not intend to displace state law unless such intent is clear in the relevant federal law. Because the FDCA does not expressly address preemption, according to the AG Opinion, the analysis next turns to whether “compliance with both federal and state law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full objectives of Congress.”

The AG Opinion cites a September 2005 opinion of the Federal District Court of Vermont, holding that a Vermont program allowing for importation of Canadian drugs (similar to the Texas program) would violate the FDCA. The AG Opinion also cites Attorney General Opinions in Tennessee and Maryland that concluded that importation of drugs from foreign nations is illegal absent a waiver from the HHS secretary, which has not been forthcoming. The AG Opinion concluded that there is a direct conflict between the provisions of S.B. 410 and federal law and that federal law therefore preempts the provisions of S.B. 410.

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19 Id. at 6.
24 Id. at 3-4.
25 Id. at 4.
28 Id.
The Texas Supreme Court has held that “the FDA is in a unique position to determine the scope of preemption because of its role in the creation of preemptive federal requirements”\textsuperscript{29} so the FDA’s position is entitled to deference. The AG Opinion also concludes that S.B. 410 could place the Board in the position of violating federal law by “facilitating” illegal importation of prescription drugs into Texas.\textsuperscript{30}

Efforts by the Texas Legislature and similar efforts in other states to reduce prescription drug costs by allowing importation of Canadian drugs may be laudable, but the law seems clear. Unless and until the Secretary of HHS confirms that adequate safety can be maintained, such efforts are legally doomed to failure.

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\textsuperscript{29} Id., citing Worthy v. Collagen Corp., 967 S.W.2d 360, 375 (Tex. 1998).