



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

December 21, 2005

Ms. Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-3943

Opinion No. GA-0384

Re: Whether federal law preempts a portion of Senate Bill 410, enacted during the regular session of the Seventy-ninth Legislature, that purports to authorize the importation of Canadian pharmaceuticals into Texas, and to require the State Board of Pharmacy to assist in such importation (RQ-0355-GA)

Dear Ms. Dodson:

You ask whether federal law preempts a portion of Senate Bill 410, recently enacted during the regular session of the Seventy-ninth Legislature.¹ See Act of May 29, 2005, 79th Leg., R.S., ch. 1345, §§ 36-43, 2005 Tex. Gen. Laws 4194, 4205-06 (effective March 1, 2006). Senate Bill 410 purports to authorize the importation of Canadian pharmaceuticals into this state, and to require the State Board of Pharmacy to assist in such importation.

I. Background

A. Federal Law

1. History of Prescription Drug Regulation

Nearly one hundred years ago, the United States Congress adopted the Food and Drug Act of 1906, “a broad prohibition against the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). Thereafter, Congress adopted the Food, Drug, and Cosmetic Act of 1938 and subsequent amendments in 1962, “requiring that the U.S. Food and Drug Administration approve each new drug as safe and effective before marketing and authorizing FDA to oversee the production of drugs, whether manufactured in a U.S. facility or imported from abroad.”²

¹Letter from Ms. Gay Dodson, R.Ph., Executive Director/Secretary, Texas State Board of Pharmacy, to Honorable Greg Abbott, Attorney General of Texas (June 23, 2005) (on file with Opinion Committee, *also available at* <http://www.oag.state.tx.us>).

²HHS TASK FORCE ON DRUG IMPORTATION, REPORT ON PRESCRIPTION DRUG IMPORTATION, DEP’T OF HEALTH & HUMAN SERVICES at VII (Dec. 2004), *available at* <http://www.hhs.gov/importtaskforce/Report1220.pdf> (last visited (continued...))

In 1987, Congress adopted the Prescription Drug Marketing Act, which “strengthened oversight of domestic wholesalers” and prohibited “anyone except a drug’s manufacturer from importing into the U.S. a prescription drug that was originally manufactured in the U.S. and then sent abroad.”³ Amendments to this statute were enacted in 1993. Prescription Drug Amendments of 1992, Pub. L. No. 102-353, 106 Stat. 941 (codified as amended in 21 U.S.C. sections 331, 333, 353, 381). In 2000, Congress adopted the Medicine Equity and Drug Safety Act (“MEDS”), to address and regulate the importation of drugs. Medicine Equity and Drug Safety Act of 2000, Pub. L. No. 106-387, 114 Stat. 1549, 1549A-35 (codified as amended in scattered sections of 21 U.S.C.). This statute was in turn replaced in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”). Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21 U.S.C.). *See* 21 U.S.C.A. § 384 (1999 & Supp. 2005).

2. *Present State of Federal Law*

The present version of the Federal Food, Drug, and Cosmetic Act (the “FFDCA”), codified at chapter 9 of title 21 of the United States Code, *see generally* 21 U.S.C. § 301 (2000 & Supp. 2003), establishes the Food and Drug Administration (the “FDA”) in the United States Department of Health and Human Services (the “HHS”). The FDA is responsible for protecting the public health by insuring that “drugs are safe and effective.” *See id.* § 393(b)(2)(B). The drug distribution system as it exists today under the FFDCA is basically a “closed system.”⁴ The only two kinds of prescription drugs that may be legally imported are those manufactured in foreign facilities inspected and approved by the FDA and those manufactured in the United States under FDA approved conditions and subsequently sent abroad and then imported back into the United States by the manufacturer.⁵ Importation of prescription drugs that are manufactured outside the United States violates the FFDCA unless the drugs have been approved by the FDA and covered either under an “approved application” for new drugs or under an “investigational new drug” exemption. *See id.* § 381; 21 C.F.R. § 314.410 (2005). The FFDCA prohibits the interstate shipment of unapproved new drugs. *See* 21 U.S.C.A. § 355(a) (1999 & Supp. 2005); 21 U.S.C. § 331(d) (2000 & Supp. 2003). Anyone other than the original manufacturer who re-imports or causes the re-importation of FDA-approved drugs in violation of section 381(d)(1) commits a prohibited act under section 331(t).

In the MEDS Act of 2000, Congress opened the drug distribution system by permitting pharmacists and wholesalers to import prescription drugs into the United States. Medicine Equity and Drug Safety Act of 2000, Pub. L. No. 106-387, 114 Stat. 1549, 1549A-36 (codified as amended in section 21 U.S.C. § 384). The MEDS Act was a response to Congressional findings that the cost

²(...continued)
Oct. 24, 2005) [hereinafter Task Force Report].

³*Id.* at VII-VIII.

⁴*Id.* at VIII.

⁵*Id.*

of prescription drugs was continuing to rise, that life-saving prescription drugs are available in other countries at lower costs, and that many Americans travel to other countries to purchase prescription drugs at lower costs. *Id.* § 745(b)(1)-(4). Its successor, the MMA of 2003, provides that the Secretary of Health and Human Services must promulgate regulations allowing pharmacists and wholesalers to import prescription drugs. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21 U.S.C.). This statute, however, permits the importation of prescription drugs only from Canada. 21 U.S.C.A. § 384(b) (1999 & Supp. 2005). The statute also gives the Secretary of HHS discretion to grant waivers of the importation prohibition with regard to individuals. *Id.* § 384(j). 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 seem to present an unreasonable risk to the individual. *Id.* § 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. *Id.* § 384(j)(3).

On the other hand, section 384 of the FFDCa states that the importation provision will not be effective unless the HHS Secretary finds that adequate safety can be maintained. *Id.* § 384(l). Shortly after the enactment of the MEDS Act, predecessor to the MMA, then-HHS Secretary Donna Shalala notified President Clinton that she could not provide the necessary certification. *See* DONNA U. VOGT & BLANCHARD RANDALL IV, DOMESTIC SOCIAL POLICY DIVISION, CONGRESSIONAL RESEARCH SERVICE, CRS REPORT FOR CONGRESS, THE PRESCRIPTION DRUG IMPORT PROVISIONS OF THE FY2001 AGRICULTURE APPROPRIATIONS ACT, P.L. 106-387, Order Code RS20750 (Jan. 10, 2001) (citing letter from Secretary Shalala of Health and Human Services, to President William J. Clinton, December 26, 2000, *available at* <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS20750.pdf>) (last visited Oct. 26, 2005). Subsequently, then-HHS Secretary Tommy Thompson sent a similar letter, concluding that “the provisions in the MEDS Act will pose a greater public health risk than we face today and a loss of confidence by Americans in the safety of our drug supply, and that “[i]nsufficient information exists for me to demonstrate that implementation of the law will result in significant reduction in the cost of drug products to the American consumer.” Letter from Tommy G. Thompson, Secretary, United States Department of Health and Human Services, to Honorable James Jeffords, United States Senator (July 9, 2001), *available at* <http://www.fda.gov/oc/po/thompson/medsact.html> (last visited Oct. 24, 2005). At the present time, no HHS Secretary has made the necessary certification and, as a result, Congress has by delegation elected not to permit such unrestricted importation.⁶ Finally, the FFDCa makes it unlawful not only

⁶One provision of the MMA directed the HHS Secretary to conduct a study on drug importation. The Secretary appointed a Task Force, which issued its report in December 2004. The report explained that “[n]early five million shipments, comprising about 12 million prescription drug products with a value of approximately \$700 million, entered the U.S. from Canada alone in 2003, via internet sales and travel to Canada by American consumers.” Task Force Report, *supra* note 2, at IX. The report further estimated “that an equivalent amount of prescription drugs are currently coming in from the rest of the world, mostly through the mail and courier services.” *Id.* On the basis of inspections of these shipments, the report found, during the period of summer 2003, 88% of the shipments violated federal law, and 85% of those did so because “they appeared to be unapproved drugs,” because they were improperly labeled, contained inadequate instructions, were improperly packaged, were controlled substances, were previously removed from the U.S.

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to import, but to “cause the importation of prohibited medications.” 21 U.S.C. § 331(t) (2000 & Supp. 2003).

B. Senate Bill 410

The Seventy-ninth Texas Legislature, finding that the price of prescription drugs has become burdensome and that prescription drugs can be purchased in Canada at much lower costs, enacted Senate Bill 410, which amends various chapters of the Texas Occupations Code. *See* Act of May 29, 2005, 79th Leg., R.S., ch. 1345, § 36(1)-(2), 2005 Tex. Gen. Laws 4194, 4205. The legislature also found that scams and frauds relating to the offering of low-cost prescription drugs were prevalent on internet sites, making it difficult for consumers to determine how and where to purchase safe, effective, and affordable prescription drugs. *Id.* § 36(3). Senate Bill 410 thus requires the Texas State Board of Pharmacy (the “Board”) to designate at least one and not more than ten Canadian pharmacies as having passed inspection by the Board for shipping, mailing, or delivering to Texas residents prescriptions dispensed under a prescription drug order. *Id.* § 37. The statute also provides that the Board must establish and maintain an internet site which provides information

⁶(...continued)

market, were “foreign versions” of FDA-approved drugs, or were drugs that require specific screening, monitoring, dosing, or management. *Id.* at 13-14. The Task Force concluded as follows:

- (1) The current system of drug regulation in the U.S. has been very effective in protecting public safety, but is facing new threats. It should be modified only with great care to insure continued high standards of safety and effectiveness of the U.S. drug supply;
- (2) There are significant risks associated with the way individuals are currently importing drugs;
- (3) It would be extraordinarily difficult and costly for “personal” importation to be implemented in a way that insures the safety and effectiveness of the imported drugs;
- (4) Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities;
- (5) The public expectation that most imported drugs are less expensive than American drugs is not generally true;
- (6) Legalized importation will likely adversely affect the future development of new drugs for American consumers;
- (7) The effects of legalized importation on intellectual property rights are uncertain but likely to be significant; and
- (8) Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

Id. at XII-XIII.

necessary to enable Texas residents to order prescription drugs from the designated Canadian pharmacies. *Id.* The site must include a disclaimer that the Board is not liable for any act or omission of a Canadian pharmacy so designated on the Board's internet site. Not only can Texas residents use the site to order prescription drugs from Canada, but Texas pharmacies may also order consumers' prescription drugs from the designated Canadian pharmacies. *Id.* § 42, at 4206. The statute prohibits Canadian pharmacies not designated by the Board from shipping, mailing, or delivering prescription drugs to Texas residents. *Id.* § 39, at 4205.

Senate Bill 410 requires that the Board annually inspect the designated Canadian pharmacies to insure compliance with the "safety standards and other requirements of this subtitle and board rules." *Id.* § 38. The Board is given the discretion to establish the standards and procedures for inspection. *Id.* In order to pass an inspection, a Canadian pharmacy must meet Texas licensing standards. *Id.* § 40, at 4206. In addition to satisfying the requirements of chapter 560 of the Occupations Code, Canadian pharmacies must submit: (1) evidence of licensure or of good standing issued by Canadian authorities; (2) the name and address of the pharmacy's owner and pharmacist-in-charge; (3) evidence of ability to provide records of prescription drug orders from Texas residents within 72 hours of a request from the Board; (4) an affidavit that the pharmacist-in-charge has read and understood this subtitle and the rules adopted under it; (5) evidence that the pharmacy meets the Board's standards to insure customer safety; and (6) evidence that the pharmacy's employees have been licensed by the appropriate Canadian authority. *Id.* Section 40 of Senate Bill 410 also requires that a Board representative visit the Canadian pharmacy to review the pharmacy's compliance with the requirements and standards of this subtitle. *Id.* In addition, the designated Canadian pharmacies must be constantly supervised by a pharmacist licensed by the licensing agency of Canada or the Canadian province. *Id.* § 41.

The designated Canadian pharmacies must also fulfill additional practice requirements, and are subject to additional limitations. A pharmacy may dispense to Texas residents only the following: (1) prescriptions under the order of a practitioner licensed in the United States; (2) drugs approved by Canada's Therapeutic Products Directorate for sale to Canadian residents; (3) prescription drugs in the original, unopened manufacturer's packaging whenever possible; and (4) drugs prescribed for long term use. *Id.* § 43. A designated pharmacy may not dispense to Texas residents the following: (1) prescription drugs for which there is not an equivalent drug approved by the FDA for sale in the United States; (2) prescription drugs that cannot be safely shipped by mail, common carrier, or delivery service; (3) a prescription drug quantity that exceeds either a three-month supply or the amount ordered by the practitioner; (4) the first prescription for the drug for that particular resident; (5) a substance designated as a controlled substance under chapter 481 of the Health and Safety Code; (6) a biological product under 42 U.S.C. § 262; (7) an infused drug; (8) an intravenously injected drug; or (9) a drug inhaled during surgery. *Id.*

C. The FDA's Position

In a letter sent to Governor Rick Perry, Mr. Randall W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning of the U. S. Food and Drug Administration, specifically set forth the FDA's position regarding Senate Bill 410. Dr. Lutter first raised a number of safety concerns about the provisions of the Texas statute: (1) inability of the FDA to "provide

adequate assurance to the American public that the drug products delivered to consumers in the United States are the same as products approved by FDA”; (2) failure of the Texas statute to provide for a recall of imported products that are recalled in Canada but not in the United States; (3) failure of the Texas statute to require that imported prescription drugs “have adequate labeling to ensure safe use”; (4) inability of physicians, pharmacists and patients to “judge properly whether products are truly substitutable”; (5) failure of the statute to create a “mechanism to ensure compliance by Canadian pharmacies, other than a threat of cancellation of pharmacy licensees by the Texas Board of Pharmacy”; (6) the statute’s apparent “sanction . . . of foreign drugs in blister-proof packages and manufacturer containers that are not childproof”; and (7) lack of clarity in the Texas statute as to “whether Canadian pharmacies exporting drugs to Texas would abide by federal laws protecting privacy.”⁷

In addition to these safety concerns, Dr. Lutter also raised legal concerns about potential conflict between Senate Bill 410 and federal law: (1) “virtually all prescription drugs imported for personal use into the United States from Canada violate the FDCA because they are unapproved new drugs, labeled incorrectly, or dispensed without a valid prescription”; (2) “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”; (3) “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”; (4) the foreign version of the drug “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”; and (5) “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 . . . even if the drug at issue were to comply in all other respects with the FDCA.” FDA Letter, *supra* note 7, at 2-3. Dr. Lutter’s letter to Governor Perry concludes that “[t]he 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.” *Id.* at 5.

II. The Preemption Doctrine

Article VI of the United States Constitution provides that “the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. CONST. art. VI, cl. 2. As the United States Supreme Court declared in *Hillsborough County, Florida v. Automated Med. Labs.*, 471 U.S. 707, 712 (1985), “[i]t is a familiar and well-established principle that the Supremacy Clause . . . invalidates state laws that ‘interfere with, or are contrary to,’ federal law (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824)). Courts begin preemption analysis “with the basic assumption that Congress did not intend to displace state law.” *Md. v. La.*, 451 U.S. 725, 746 (1981). Any understanding of the scope of a preemption statute “must rest primarily on ‘a fair understanding of congressional purpose.’”

⁷Letter from Randall W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning, U. S. Food and Drug Administration, to Honorable Rick Perry, Governor of Texas at 1-2 (June 17, 2005), available at <http://www.fda.gov/oc/opacom/hottopics/importdrugs/perry061705.html> (last visited Dec. 20, 2005) [hereinafter FDA Letter].

Lohr, 518 U.S. at 485-86 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530 n.27 (1992)). In determining whether a federal law preempts state law, Texas courts are required to give effect to the will of Congress. *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 367 (Tex. 1998).

“Under the Supremacy Clause, federal law may supersede state law in several different ways.” *Hillsborough*, 471 U.S. at 713. Express preemption occurs when Congress expresses a clear intent to preempt state law using clear preemptive language. *Id.* In addition to express preemption, there are at least two kinds of implied preemption. The first is generally known as “field preemption.” As the Supreme Court declared in *Hillsborough*:

In the absence of express pre-emptive language, Congress’ intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress “left no room” for supplementary state regulation. . . . Pre-emption of a whole field will also be inferred where the field is one in which “the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.”

Id. (citations omitted). The second kind of implied preemption, known as “conflict preemption,” “arises when ‘compliance with both federal and state regulations is a physical impossibility,’” *id.*, (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)), “or when state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Id.* at 713 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 66-67 (1941)).⁸

III. Analysis

A. Federal Preemption

1. *Express Preemption*

Express preemption is not applicable to the situation you pose, “because there is no provision in the [F]FDCA or its regulations⁹ regarding prescription drugs which purport to preempt state law.” See *Cartwright v. Pfizer*, 369 F. Supp. 2d 876, 884-85 (E.D. Tex. 2005).

⁸The categories of preemption are not “rigidly distinct. Indeed, field pre-emption may be understood as a species of conflict pre-emption: A state law that falls within a pre-empted field conflicts with Congress’ intent (either express or plainly implied) to exclude state regulation.” *English v. General Elec. Co.*, 496 U.S. 72, 79 n.5 (1990).

⁹It is well established that “state laws can be pre-empted by federal regulations as well as by federal statutes.” *Hillsborough*, 471 U.S. at 713.

2. *Conflict Preemption*

As we have noted, conflict preemption arises when 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. *See Paul*, 373 U.S. at 142-43; *Hines*, 312 U.S. at 66-67.

In September 2005, the Federal District Court of Vermont considered a suit by the Vermont Agency of Administration in response to an FDA denial of a request to permit Vermont to “establish a program for the orderly importation of prescription medications” from Canada. *State of Vt. & Vt. Agency of Admin. v. Leavitt*, No. 2:04-CV-206, slip op. at 3 (U.S.D.C. Vt. Sept. 19, 2005). The court dismissed the suit for failure to state a claim and held, *inter alia*, that (1) the FFDCA “creates a ‘closed’ system in which the FDA regulates the manufacture, marketing and labeling of drugs sold in the United States,” *id.* at 10; (2) Vermont’s plan will “‘cause[]’ its members to import drugs in violation of 21 U.S.C. § 381(d)(1),” *id.* at 13; (3) “there is no question that Vermont’s proposed program” would violate the FFDCA, *id.*; and (4) “Vermont’s citizen petition asked the FDA to approve a program that was, and remains, illegal.” *Id.* at 26.

Likewise, in an opinion of the Attorney General of Tennessee, dated May 16, 2005, that official concluded that the participation of the State of Tennessee with other states in the I-SaveRx prescription drug program would contravene federal law, primarily because “the FDA is the agency charged with administering and enforcing the federal laws governing prescription drugs [and thus] its interpretation of those statutes is entitled to great deference.” Tenn. Att’y Gen. Op. No. 05-083 (2005) at 1. Similarly, a letter from the Office of the Attorney General of Maryland has held that “importation of prescription drugs from foreign sources, and thus the facilitation of such importation, is currently illegal, whether performed by the State or a political subdivision thereof.”¹⁰

Congress has granted to the HHS Secretary authority to determine whether to waive restrictions on the individual importation of prescription drugs from foreign nations. The Secretary has not granted such a waiver. As a consequence, there appears to be a direct conflict between those provisions of Senate Bill 410 that allow an individual to import prescription drugs from abroad and section 384(l) of the FFDCA, which permits the importation of such drugs only after the HHS Secretary makes the certification required by that section of the statute. Thus, those provisions of Senate Bill 410 that permit individual importation would necessarily conflict with federal law.

3. *Field Preemption*

Because we have concluded that the relevant provisions of Senate Bill 410 are conflict-preempted, we need not address the subject of field preemption.

¹⁰Letter from Kathryn M. Rowe, Assistant Attorney General, State of Maryland, to Honorable Kumar P. Barve, Maryland State Delegate (Jan. 28, 2004) (on file with Opinion Committee) (attached to Brief from Locke, Liddell & Sapp, LLP).

B. Deference to the FDA's Position

In his letter to Governor Perry, Dr. Lutter unequivocally expressed the FDA's belief that the relevant portions of Senate Bill 410 are preempted by federal law and, hence, unconstitutional under the Supremacy Clause:

Congress set forth a comprehensive importation scheme in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce Clearly, Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goal of controlling the types of drugs that could be legally imported into the United States. The federal scheme 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 scheme 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.

FDA Letter, *supra* note 7, at 4. Thus, Dr. Lutter concludes that “[a]ny state law that legalizes imports in contravention of the FFDCA would be preempted by federal law.” *Id.* at 5.

As the United States Supreme Court said in *Medtronic, Inc. v. Lohr*, when discussing FDA regulations regarding the marketing of medical devices, “Congress has given the FDA a unique role in determining the scope” of a statute’s preemptive effect. *Lohr*, 518 U.S. at 495-96. The Court continued:

Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [Medical Device Amendments to the FFDCA, 21 U.S.C. § 371(a)], the agency is uniquely qualified to determine whether a particular form of state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress” . . . , and, therefore, whether it should be pre-empted.

Id. at 496 (citation omitted). In *Geier v. American Honda Motor Co., Inc.*, the Court, in alluding to the authority of the Federal Department of Transportation (“DOT”) under the National Traffic and Motor Vehicle Safety Act, stated the following:

Congress has delegated to DOT authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have

a thorough understanding of its own regulation and its objectives and is “uniquely qualified” to comprehend the likely impact of state requirements.

Geier, 529 U.S. 861, 883 (2000) (citation omitted). Congress likewise has committed to the FDA and the HHS Secretary the authority to implement the FFDCCA; the subject matter is technical; the relevant history and background are complex and extensive; and the agency is likely to have a thorough understanding of its own regulation and its objectives and is thus “uniquely qualified” to comprehend the likely impact of state requirements. Finally, the Texas Supreme Court has itself recognized that “a majority of the Supreme Court [of the United States believes] 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.” *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 375 (Tex. 1998).

C. Whether Senate Bill 410 Would Require the Texas State Board of Pharmacy to Violate Federal Law

You also ask whether Senate Bill 410 would require the Board to contravene federal law by facilitating the importation of prohibited medications. Senate Bill 410, as we have observed, requires the Board to designate at least one and not more than ten Canadian pharmacies as having passed inspection by the Board for shipping, mailing, or delivering to Texas residents prescriptions dispensed under a prescription drug order. Act of May 29, 2005, 79th Leg., R.S., ch. 1345, § 37, 2005 Tex. Gen. Laws 4194, 4205. The statute also directs the Board to establish and maintain an internet site that provides information necessary to enable Texas residents to order prescription drugs from the designated Canadian pharmacies. *Id.* Moreover, Canadian pharmacies not designated by the Board may not ship, mail or deliver prescription drugs to Texas residents. *Id.* § 39, at 4205. In addition, the Board must annually inspect the designated Canadian pharmacies to insure compliance with safety requirements and other Board rules. *Id.* § 38. Finally, a Board representative must visit the Canadian pharmacy to review the pharmacy’s compliance with the requirements and standards of this subtitle. *Id.* § 41, at 4206.

Section 331(t) of the FFDCCA makes it an offense not only to import, but to “cause” the importation of prohibited medications. In *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003), the court upheld the granting of an injunction brought by the FDA to prohibit a company incorporated in Nevada and doing business in Oklahoma from securing prescription drugs from Canada for American customers. The court found that the defendant, *Rx Depot*, “assists individuals in procuring prescription medications from pharmacies in Canada.” *Id.* at 1240. The court held that the facilitation of such imports contravenes federal law. Likewise, if the Board “designates” Canadian pharmacies, promotes them via its website, and expressly declares on that website that Texas residents may import from those pharmacies, but no others, prescription drugs whose importation is prohibited by federal law, we believe that a court would find that the Board would be “facilitating,” and thus “causing,” the prohibited importation of prescription drugs into Texas.

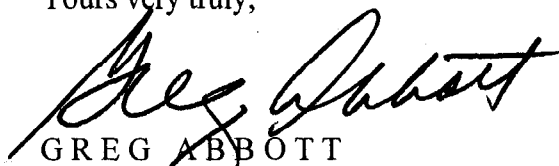
IV. Conclusion

Sections 36 through 43 of Senate Bill 410, enacted during the Seventy-ninth regular session of the Texas Legislature, directly conflict with federal law, namely, the FFDCA, chapter 9 of title 21, United States Code, and specifically, sections 381 and 384 thereof. Furthermore, as we have noted, the FFDCA makes it an offense not only to import, but to “cause” the importation of prohibited medications. *See* 21 U.S.C. § 331 (2000 & Supp. 2003). By “designating” certain Canadian pharmacies, promoting them on its website, and expressly permitting Texas consumers to import prescription drugs that cannot be imported under federal law, the Texas State Board of Pharmacy would violate the FFDCA, as would Texas consumers and those Texas pharmacies that take part in such transactions.

S U M M A R Y

Sections 36 through 43 of Senate Bill 410, enacted during the Seventy-ninth regular session of the Texas Legislature, directly conflict with federal law, namely the Federal Food, Drug, and Cosmetic Act, chapter 9 of title 21 of the United States Code (the "FFDCA"), and specifically sections 381 and 384 thereof. The FFDCA makes it an offense not only to import, but to "cause" the importation of prohibited medications. *See* 21 U.S.C. § 331 (2000 & Supp. 2003). By "designating" certain Canadian pharmacies, promoting them on its website, and expressly permitting Texas consumers to import prescription drugs that cannot be imported under federal law, the Texas State Board of Pharmacy would violate the Federal Food, Drug, and Cosmetic Act, as will Texas consumers and those Texas pharmacies that take part in such transactions.

Yours very truly,


GREG ABBOTT
Attorney General of Texas

BARRY R. MCBEE
First Assistant Attorney General

NANCY S. FULLER
Chair, Opinion Committee

Rick Gilpin
Assistant Attorney General, Opinion Committee