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TEXAS STATE BOARD OF PHARMACY

FILE # ML-44250-05
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June 23, 2005

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NO. 7106 4575 1292 5699 3948

RQ-0355-GA

The Honorable Greg Abbott
Attorney General of the State of Texas
Opinion Committee
Office of the Attorney General
P.O. Box 12548
Austin, Texas 78701-2548

Re: Request for Opinion

Dear General Abbott:

This letter is a request for an opinion as to whether federal law preempts §§ 36 – 43 of S.B. 410 of the 79th Texas Legislature and, therefore, precludes the implementation of S.B. 410 by the Texas State Board of Pharmacy (Board). The Board also requests an opinion on the related question whether it is a violation of federal law for the Board to authorize and promote the importation of pharmaceuticals from Canada. This request is made in my capacity as Executive Director/Secretary of the Board and head of the agency on behalf of the Board.

Background

S.B. 410, as enacted by the Texas Legislature and signed by Governor Perry on June 18, 2005, requires the Texas State Board of Pharmacy to inspect and authorize Canadian pharmacies to import prescription medications into the State of Texas. The law requires that the Board designate from one to ten Canadian pharmacies as having passed inspection, and thus allow the pharmacies to ship prescription drugs into Texas. The Board is also mandated to provide information on these pharmacies on its website to facilitate ordering of drugs by Texas residents.

This process is not equivalent to licensure; however, the procedure proscribed by the Legislature would be equivalent to the Board condoning, if not promoting, these Canadian pharmacies shipping prescription drugs into Texas. The law also requires the Board to implement emergency rules to carry out the implementation of this legislation by October 1, 2005.

Exhibits

I have attached, as Exhibit 1, a brief that summarizes the legal issues regarding this opinion request. Also attached is a letter from the U.S. Food and Drug Administration, which was sent to Governor Rick Perry and addresses concerns held by the FDA (Exhibit 2). The FDA has issued similar letters to other states attempting to import foreign drugs, which can be accessed at www.fda.gov. I am also attaching a letter from the National Association of Boards of Pharmacy (Exhibit 3), which was sent to Governor Perry and outlines the position of this professional organization representing all state boards of pharmacy.

I respectfully request your opinion on these issues for the benefit of the Board. Please contact me with any additional questions.

Sincerely,

Gay Dodson, R.Ph.
Executive Director/Secretary

GD/ka

Enclosures
c: Board Members

TEXAS STATE BOARD OF PHARMACY

Brief in Support of Request for Opinion Regarding Implementation of S.B. 410

QUESTIONS: Does federal law preempt §§ 36 – 43 of S.B. 410 of the 79th Texas Legislature and, therefore, preclude the implementation of S.B. 410 by the Texas State Board of Pharmacy? Is it a violation of federal law for the Board to authorize and promote the importation of pharmaceuticals from Canada?

DISCUSSION:

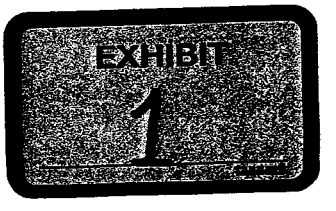
The discussion below addresses the implications for the implementation of S.B. 410 of the 79th Legislature. Section I summarizes S.B. 410, including the legislative findings, the substantive provisions, and the potential conflicts with other state law. Section II describes the position of the U.S. Food and Drug Administration on the importation of foreign drugs, with specific focus on the Personal Importation policy and on the stance that FDA has taken with states allowing such importation. The preemption of state law by the Federal Food, Drug, and Cosmetic Act and by international trade law is addressed in Section III.

I. S.B. 410, §§ 36 – 43, IMPORTATION OF PRESCRIPTION DRUGS FROM CANADA

A. Legislative Findings

The provisions of S.B. 410 relating to importation of prescription drugs from Canada begin in section 36 with legislative findings that:

- Prescription drugs are expensive, and can be purchased at much lower costs in Canada;
- Scams are prevalent that make it difficult for Texas consumers to know how and where to purchase safe and effective prescription drugs at affordable prices;
- The Regulatory Procedures Manual of the FDA "authorizes agency personnel to allow the importation of products regulated by that agency



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when the quantity and purpose are clearly for personal use and the product does not present an unreasonable risk to the user";[1] and

- Other (unnamed) states and municipalities provide Internet websites and other methods to allow their residents to safely purchase prescription drugs from Canada.

B. Summary of Substantive Provisions

1. Section 37 of S.B. 410 amends the Occupations Code to require the Texas Board of Pharmacy to designate "at least one and not more than 10 Canadian pharmacies ... as having passed inspection by the board for shipping, mailing, or delivering to this state a prescription dispensed under a prescription drug order to a resident in this state." Sec. 37 (to be codified at Tex. Occ. Code Ann. § 554.016). The Board is also required to "establish and maintain a website to provide information necessary to enable residents of this state to conveniently order prescription drugs from Canadian pharmacies designated by the board as having passed inspection to dispense prescription drugs to residents in this state...."[2]

2. Section 38 governs inspections of designated Canadian pharmacies. It requires the Board, at least annually, to conduct random inspections of such pharmacies, and allows the Board to establish the standards and procedures for such inspections by rule, "notwithstanding the requirements of this chapter." The Board may enter into an agreement with another state for the other state to perform inspections other than the initial inspection. (To be codified at Tex. Occ. Code Ann. § 556.0555).

3. Section 39 prohibits Canadian pharmacies, other than those designated by the Board, from shipping, mailing, or delivering into Texas a prescription drug dispensed under a prescription to a Texas resident. (To be codified at Tex. Occ. Code Ann. § 560.001).

4. Section 40 includes the qualification requirements for designated Canadian pharmacies. They include:

   a. Meeting Texas licensing standards;
   b. Evidence of a Canadian pharmacy license, registration or permit;
   c. An affidavit by the pharmacist-in-charge that he/she has read and understands the Texas laws and rules; and

[1] *See* Section II, below, for a discussion of the FDA's statements.

[2] The Board website must include a statement that the Board is not liable for any act or omission of the designated Canadian pharmacies.

d. Evidence that the pharmacy meets the standards established by Board rules to ensure customer safety in dispensing, storing, packing, shipping, and delivering prescriptions.

A representative of the Board is required to visit a pharmacy and review compliance with these requirements before the pharmacy may be designated. (To be codified at Tex. Occ. Code Ann. § 560.0525).

5. Section 41 requires designated Canadian pharmacies to designate a pharmacist-in-charge and to be under the continuous on-site supervision of a pharmacist. (To be codified at Tex. Occ. Code Ann. § 562.101(f)).

6. Section 42 allows a Texas pharmacy to order a prescription from a designated Canadian pharmacy for a consumer, with the knowledge and clear consent of the consumer. (To be codified at Tex. Occ. Code Ann § 562.111).

7. Section 43 adds Subchapter E, entitled "Practice by Canadian Pharmacy," to Chapter 562 of the Occupations Code. It contains both "Additional Practice Requirements" (section 562.201), and "Limitations on Practice" (section 562.202).

a. Requirements – may only:

i. dispense prescriptions from practitioners licensed in the U.S.;
ii. dispense a prescription approved by Canada's Therapeutic Products Directorate for sale to Canadians;
iii. dispense a drug "in the original, unopened manufacturer's packaging whenever possible"; and
iv. dispense drugs prescribed for long-term use.

b. Limitations – may not:

i. Dispense a "prescription drug for which there is not an equivalent drug approved by" the FDA for sale in the U.S.;
ii. Dispense a drug that cannot be safely shipped;
iii. Dispense in one order a prescription that exceeds a 3 month supply or the amount ordered by the practitioner;
iv. Fill a prescription that the consumer indicates is the consumer's first prescription for that drug;
v. Dispense certain listed types of drugs, such as controlled substances, infused drugs, intravenously injected drugs, and drugs that are inhaled during surgery.

c. Designated pharmacies are also required to provide periodic complaint reports to the Board (to be codified at Tex. Occ. Code Ann. § 562.203), and to maintain a guaranteed price list (to be codified at Tex. Occ. Code Ann. § 562.204).

C. Potential Conflicts with Other State Law

1. Under the Texas Pharmacy Act, the Board is required to "cooperate with other ... federal agencies in the enforcement of any law relating to the practice of pharmacy or any drug or any drug-related law." Tex. Occ. Code Ann. § 554.001(a)(2). The FDA has consistently taken the position that "a U.S. pharmacy or other business virtually always violates U.S. law by importing or causing the importation of [drugs from Canadian pharmacies]." *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Ok. 2003)(granting injunction to prevent importation of Canadian drugs). It has sent letters to other states warning that state statutes allowing the importation of prescription drugs from Canada violate federal law and are preempted. Therefore, implementation of the S.B. 410 would be contrary to the directive that the Board "cooperated with federal agencies in the enforcement of drug-related law."

2. Board members are required to take an official oath of office by which they swear or affirm that they will "preserve, protect and defend the Constitution and laws of the United States and of this State" to the best of their ability. Tex. Const. art. XVI, § 1. Therefore, the implementation by the Board of a provision of Texas law that is in violation of federal law would be contrary to the oath taken by its members. If S.B. 410 violates the Federal Food, Drug, and Cosmetic Act, then the Board members would be violating the oath of office by implementing the measures to allow importation of Canadian drugs.

II. FDA AUTHORITIES AND POSITION

A. Regulatory Procedures Manual Cited in Texas Legislative Findings Does Not Authorize Personal Importation.

Chapter 9 of the FDA Regulatory Procedures Manual includes a subchapter entitled "Coverage of Personal Importations." As noted above, the findings in support of S.B. 410 refer to language from this subchapter. The Manual states that, in order "to gain the greatest degree of public protection with allocated resources" the "FDA has focused its enforcement resources more on products that are shipped commercially, including small shipments solicited by mail-order promotions, and less on those products that are personally carried, shipped by a personal non-commercial

representative of a consignee, or shipped from [a] foreign medical facility where a person has undergone treatment."

The "General Guidance" portion of the subchapter provides:

> The statements in this chapter are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person. FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should <u>not</u> be interpreted as a license to individuals to bring in such shipments.

The Guidance goes on to say, with regard to drugs;

> In deciding whether to exercise discretion to allow personal shipments of drugs or devices, the FDA personnel may consider a more permissive policy in the following situations:
>
> 1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or
>
> 2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than a 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

Clearly, despite the "findings" attached to S.B. 410, the policy "is not a license for individuals to import unapproved, and therefore illegal, drugs for personal use into the

United States."[3] In fact, "[b]ecause the policy does not apply to medications that are already available in the U.S., even if sold under the same name, only a very few drug products available from foreign sources, especially Canada and Mexico, meet the personal importation criteria" of the policy. *Id.*

B. Other FDA Statements Regarding Imporation of Drugs Indicate Personal Imporation is Not Legal

There are several other documents on the FDA website regarding importation of drugs that make clear the Guidance discussed above is not an authorization by the FDA for importing prescription drugs from Canada for personal use:

1. FDA Position on Foreign Drug Imports

Under this heading, the FDA has posted on its website (www.fda.gov) a copy of its February 12, 2003, letter to an attorney in New Orleans who represents sponsors and/or administrators of employer-sponsored health plans that wanted to allow coverage for importation of prescriptions. The letter states that the FDA is "very concerned" about such a scenario. It discusses the Regulatory Procedures Manual provisions relied on in S.B. 410, noting that "the policy simply describes the agency's enforcement priorities" and "does not change the law." The letter also states that while the FDA has not often prosecuted those importing illegal drugs into the U.S. from Canada, it reserves the right to do so.

The letter lays out the general legal framework for the FDA's conclusion that "it is extremely unlikely" that any drug imported from Canada would meet all of the requirements of the Federal Food, Drug, and Cosmetic Act (the Act). With regard to drugs manufactured in the U.S., it is a violation of the Act for anyone other than the U.S. manufacturer to re-import the drug. 21 U.S.C. § 381(d)(1). Importation of drugs manufactured outside of the U.S. violates the Act unless the drugs are FDA-approved and meet all labeling requirements. 21 U.S.C. §§ 331, 353(b)(1), 355.

2. Traveler Alert Regarding Importation of Prescription Medicines/Drugs

The FDA has also posted on its website a Traveler Alert regarding importation of drugs. It begins by explaining that the Act prohibits interstate shipment (which includes importation) of unapproved new drugs, which are "any drugs, including foreign-made versions of U.S. approved drugs, that have not received FDA approval...." The Alert then describes the Regulatory

[3] *See* Sept. 25, 2002 testimony of William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, FDA, at Senate Committee on Aging hearing titled "Buyer Beward: Public Health Concerns of Counterfeit Medicine."

Procedures Manual guidance on personal importations, but cautions that the guidance is not "a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S." and that even "if all of the factors noted in the guidance are present, the drugs remain illegal and the FDA may decide that such drugs should be refused entry or seized."

3. Information on Importation of Drugs Prepared by the Division of Import Operations and Policy, FDA

This position statement posted on the FDA website reiterates the Act's prohibition against importation of unapproved new drugs, whether for personal use or otherwise. "Unapproved new drugs" are defined as "any drugs, including foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval." The statement also addresses the Regulations Procedure Manual guidance, which is described as setting forth the agency's enforcement priorities. The statement repeats that the guidance is not binding and does not confer any rights, privileges or benefits. It also emphasizes that "the intent of the personal use importation guidance is to save FDA resources and to generally permit, through the exercise of enforcement discretion, medical treatments sought by individuals that are not otherwise available in the United States." "[F]oreign-made chemical versions of drugs available in the U.S. are not intended to be covered by the policy." Importation of a heart medication from Mexico, simply because it is cheaper than buying the medication in the U.S., is given as an example of conduct that is not covered by the guidance.

C. Case Law

The FDA's assertion that its enforcement focus has been commercial operations is validated by *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003), in which the FDA was granted an injunction against companies involved in procuring prescription drugs from Canada for U.S. patients. The court found that the defendants violated federal law by introducing into interstate commerce unapproved new drugs and by causing the reimportation of U.S. manufactured drugs.

D. June 17, 2005 Letter from FDA to Governor of Texas

On June 17, 2005, the FDA wrote to Governor Rick Perry regarding S.B. 410. The letter expresses FDA's concern about potential safety risks raised by this legislation. It also explains that such importation would violate the Federal Food, Drug, and Cosmetic Act (Act) "in virtually every instance," and that federal law "preempts conflicting state or local legislation that would legalize the importation of certain drugs from Canada in contravention of the" Act.

1. How Importation Violates Federal Law

The letter explains that 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 referred to as "American goods returned." Importing a drug in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

It also points out that the Act prohibits importing any drug (regardless of where manufactured) that is not approved by the FDA and/or does not comply with federal labeling requirements. 21 U.S.C. §§ 331.(a),(d); 352, 353, 355. According to the letter:

> 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 may also be misbranded because it may lack certain information that is required under [labeling requirements of the Act] 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)).

Therefore, to ensure compliance with the Act, a person could only import prescription drugs that are manufactured outside of the U.S., are FDA-approved, and comply with their FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, appearance, and labeling requirements.

2. Why the FDA believes Federal Law Preempts State Importation Statutes

The letter lays out the three ways federal law may preempt state law: (1) when Congress expresses a clear intent to do so; (2) when it is clear, despite the absence of express preemptive language, that Congress intended, by legislating comprehensively, to "occupy the field"; or (3) when compliance with both state and federal law is impossible, or when state law stands as an obstacle to

accomplishment and execution of the full purposes and objectives of Congress.[4] It then goes on to say federal law preempts in this area because "Congress set forth a comprehensive importation scheme ... that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce." According to the letter:

> 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. Licensure of Canadian pharmacies by the state of Texas would be inconsistent with the plain objectives of the [Act] if such licensure authorized those Canadian pharmacies to ship into the United States drugs that violate the provisions of the [Act].

III. PREEMPTION

As noted by the FDA in its letter to Governor Perry, 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. If a state law conflicts with federal law, it is preempted and has no effect. *Maryland v. Louisiana*, 451 U.S. 725, 747 (1981); *Am. Cyanamid Co. v. Geye*, 79 S.W. 3d 21, 23 (Tex. 2002).

In determining whether a federal statute preempts state law, Texas courts are "bound to give effect to the will of Congress," *Worthy v. Collagen Corp.* 967, S.W.2d 360, 367 (Tex. 1998), and must follow guidelines established by the United States Supreme Court in determining congressional intent. The Texas Supreme Court has summarized those guidelines as follows:

> A state law is preempted and "without effect" if it conflicts with federal law. A federal law may expressly preempt state law. Additionally, preemption may be implied if the scope of the statute indicates that Congress intended federal law to

[4] Case law defines three ways that a federal statute may preempt a state law. *See Great Dane Trailers, Inc. v. Estate of Wells*, 52 S.W.3d 737, 743 (Tex. 2001). First, "[a] federal law may expressly preempt state law." *Id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)). Second, "federal law or regulations may impliedly preempt state law or regulations if the statute's scope indicates that Congress intended federal law or regulations to occupy the field exclusively." *Id.* (citing *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). Finally, state law is also impliedly preempted if it actually conflicts with federal law or regulations, because "(1) it is impossible for a private party to comply with both state and federal requirements; or (2) state law obstructs accomplishing and executing Congress' full purposes and objectives." *Id.*

occupy the field exclusively or when state law actually conflicts with federal law. A state law presents an actual conflict with federal law when "'it is impossible for a private party to comply with both state and federal requirements' or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes or objectives of Congress.'"

Hyundai Motor Co. v. Alvarado, 974 S.W.2d 1, 4 (Tex. 1998) (citations omitted).

A. Federal Food, Drug and Cosmetic Act Preemption

The FDA argues that implied preemption applies to importation statutes such as S.B. 410 because: (1) Congress intended to occupy the field exclusively; and (2) state laws allowing importation of prescription drugs from Canada actually conflict with federal law because they stand as an obstacle to accomplishment and execution of the purposes and objectives of the Federal Food, Drug and Cosmetic Act. Congress may not have intended to legislate comprehensively so as to occupy the field (*i.e.*, Congress left some room for the states to supplement federal law). Nonetheless, the importation provisions of S.B. 410 present an actual conflict with Federal Food, Drug and Cosmetic Act, by allowing importation of non-FDA approved drugs (*see* section 43 of the bill, requiring only an "equivalent" to an FDA-approved drug).

B. International Trade Law Preemption

In addition to conflicting with the Federal Food, Drug and Cosmetic Act, the provisions of S.B. 410 may be inconsistent with U.S. obligations under federal trade agreements, potentially exposing the U.S. to trade retaliation. Allowing Canadian pharmacies to obtain a designation to do business in Texas while not granting equal treatment to pharmacies in other foreign countries would likely cause the U.S. to run afoul of the WTO General Agreement on Trade in Services (GATS) and the North American Free Trade Agreement (NAFTA). The GATS includes a broad most-favored nation obligation, Article II:1, which requires that each WTO Member must accord "immediately and unconditionally" to services and service suppliers of any other WTO Member "treatment no less favorable than that it accords to like services and service providers of any other country." The GATS also bans discriminatory recognition of foreign licensing in Article VII:3. Likewise, Chapter 12 of NAFTA, on cross-border trade in services, in Article 1203, requires each NAFTA country to accord to service providers of any other NAFTA country treatment no less favorable than it accords, in like circumstances, to service providers of any other country. Implementing the Canadian pharmacy provisions of S.B. 410 could trigger trade agreement complaints and retaliation against U.S. exports by Mexico and other countries.

These conflicts with U.S. trade obligations provide yet another basis for a court to find the new state laws preempted. In the field of importation, the "power of Congress is exclusive and absolute." *The James J. Hill v. Retzlaff*, 65 F. Supp. 265, 269 (D.C. Md. 1946) (dismissing complaint seeking injunction against enforcement of FDA

order requiring that 40,000 bushels of Canadian wheat be exported or destroyed under Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 381).

C. Recent Case Law

The United States Supreme Court's willingness to uphold Congress' plenary commerce power in the face of conflicting state law is demonstrated in the medical marijuana opinion recently issued. *Gonzales v. Raich*, 125 S. Ct. 2195 (2005). Although the opinion deals with a constitutional challenge to enforcement of the federal Controlled Substances Act, rather than a preemption claim, it is nonetheless instructive. California is one of at least nine states that authorize the use of marijuana for medical purposes. Two California residents, whose local growth and use of marijuana for medical purposes was authorized by state law, challenged the federal Controlled Substances Act (CSA), which makes such use illegal, arguing that its enforcement against them violated the Commerce Clause, the Due Process Clause, and the Ninth and Tenth Amendments to the Constitution. The Court held that the CSA was a valid exercise of federal power to regulate interstate markets for medicinal substances, even to the extent that the act governs portions of those markets that are supplied with drugs produced and consumed legally. *Id.* at 2201. The opinion points out that "limiting the activity to marijuana possession and cultivation 'in accordance with state law' cannot serve to place respondents' activities beyond congressional reach." *Id.* at 2212.

> The Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail It is beyond peradventure that federal power over commerce is "superior to that of the States to provide for the welfare or necessities of their inhabitants" however legitimate or dire those necessities may be. ...[S]tate action cannot circumscribe Congress' plenary commerce power.

Id.

This case demonstrates the willingness of the nation's highest court to give deference to Congress' commerce power in the face of conflicting laws in numerous states. *Cf.* S.B. 410, § 36, above (finding that other states allow purchase of prescription drugs from Canada).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

June 17, 2005

The Honorable Rick Perry
Office of the Governor
State Insurance Building
1100 San Jacinto
Austin, Texas 78701

Dear Governor Perry:

I write in response to the recent bill passed by the Texas legislature authorizing the Texas State Board of Pharmacy to license Canadian pharmacies to import prescription medications into the State of Texas. It is my understanding that if this bill became law, regulations would be promulgated by the Texas State Board of Pharmacy no later than September 1, 2005. I wanted to bring to your attention some of FDA's safety and legal concerns with the proposed law.

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 appear 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.

In addition, we note several other specific safety concerns related to the proposed law. First, it does not provide for a recall of imported products that are recalled in Canada but not in the U.S. It has been our experience in the past that products recalled in Canada may not be recalled in the U.S., since they were made in different manufacturing facilities or to different specifications. With the proposed law lacking a provision to notify Texas patients if there are health alerts and recalls of the medicines exported from Canada, patients are put at an unnecessary risk. Also, with some recalled medications patients may need replacement medicines very quickly.

We also note that the proposed law does not require that products have adequate labeling to ensure safe use. In the absence of appropriate labeling, physicians and consumers are unlikely to know the identity of all the inactive ingredients in a Canadian drug without consulting the Canadian Physicians Desk Reference, which is not generally available in the U.S. This could frustrate efforts to prevent allergic reactions. In addition, patients may not get the FDA-approved medication guide or risk management plan for those drugs with serious or significant side effects.

Moreover, under the proposed law, physicians, pharmacists and patients would be unable to judge properly whether products are truly substitutable. Some consumers' health may be at risk, since some medications that are safe and effective only in a narrow therapeutic range, such as anti-seizure medications, may be replaced with foreign versions whose therapeutic equivalence to U.S. versions that are not substitutable or whose therapeutic equivalence to U.S. versions is unknown to American health care providers.

The proposed Texas law creates no mechanism to ensure compliance by Canadian pharmacies, other than a threat of cancellation of pharmacy licenses by the Texas Board of Pharmacy. Thus, if a Canadian pharmacy, whose cross border shipments are not regulated in Canada, knowingly decides to profit by shipping to Texas ineffective look-alike drugs originating from dubious sources, it would apparently face no criminal liability and could profit until its fraud is detected. Moreover, the proposed state inspection program extends only to Canadian pharmacies, and not to wholesalers and repackagers. U.S. wholesalers and repackagers are subject to regulatory oversight by both federal and state authorities to prevent unsafe or fake drugs from reaching U.S. consumers.

The proposed Texas law also seems to sanction the importation of foreign drugs in blister-proof packages and manufacturer containers that are not childproof. This violation of federal law could put young children at risk. It would also allow U.S. pharmacists to order medications from Canada for their patients with their patients' consent. This provision invites Texas pharmacists to violate federal law and may expose them to increased tort liability.

It is also unclear whether Canadian pharmacies exporting drugs to Texas would abide by federal laws protecting privacy. A Canadian pharmacy dispensing drugs into the U.S. would have to collect and maintain records on patients' medical history, current medications, allergies, and U.S. physician's name, address, and telephone number-private information protected in the U.S. by the Health Insurance Portability and Accountability Act (HIPAA). In the event of abuse of such information in Canada, the only recourse would be for the Texas Board of Pharmacy to terminate the pharmacists' license to import.

Many of these safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit 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 an entity or person were to import prescription drugs into the State of Texas from Canada, that importation would violate the FFDCA in virtually every instance. This is true even if the proposed Texas legislation purports to legalize the conduct under state law. Furthermore, the drug importation scheme 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(d), and/or (a). *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, 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 ("The following acts and the causing thereof are hereby prohibited...").

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. 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 allows consumers to import 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 that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens. (Foreign versions are often what Canadian pharmacies offer 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.

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 held 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. To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad. *See United States v. Rx Depot, Inc.*, 290 F.Supp.2d 1238 (N.D. Okla. 2003). 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. Nevertheless, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

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 absence 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 same subject"; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." *Hillsborough County v. Automated Medical Laboratories, Inc.,* 471 U.S. 707, 713 (1895) *quoting Rice v. Santa Fe Elevator Corp.,* 331 US 218, 230 (1947).

In the instant matter, 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. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as part of the federal Prescription Drug Marketing Act. PL. 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]large 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 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. 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 the 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 new initiatives to accelerate approval of innovative medical procedures and drug therapies, 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 the generic drugs sold elsewhere in the industrialized world. Also, the Medicare prescription drug discount card provides 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

Footnote

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

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Via Facsimile
512.463.1849

June 14, 2005

The Honorable Rick Perry
Office of the Governor
State of Texas
P. O. Box 12428
Austin, TX 78711

Dear Governor Perry:

I am contacting you on behalf of the National Association of Boards of Pharmacy (NABP) to express our serious concerns with SB 410 and respectfully request that you not sign the legislation into law. NABP is the professional organization that represents state boards of pharmacy in all regions of the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, two states in Australia, New Zealand, and South Africa.

NABP shares the concerns of the Food and Drug Administration (FDA) that the legislation will jeopardize patient safety and clearly violates federal law. I have enclosed testimony which NABP presented to the Committee on Government Reform, U.S. House of Representatives Internet Pharmacy Consumer Protection Act on March 18, 2004 that outlines our concerns with the operation and licensure of illegally operating foreign pharmacies.

NABP is also concerned that should the State of Texas proceed with the licensing of pharmacies engaged in illegal activities (as outlined by the FDA), the credibility of Texas' licensing procedures and decisions may be called into question by the other states. Specifically, any pharmacy located in Texas that engages in the practice of pharmacy in other states and is licensed in that other jurisdiction may be challenged and the licensure deemed null and void in the other jurisdiction.

EXHIBIT 3

I again respectfully request your consideration in this matter. If I can be of further assistance or you need to speak to me directly, please do not hesitate to contact me.

Cordially,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

CC/mwg
Enclosure

cc: Gay Dodson, Executive Director, Texas State Board of Pharmacy
Thomas J. McGinnis, Director of Pharmacy Affairs, Office of Policy, FDA

Testimony of
Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary
National Association of Boards of Pharmacy

Testimony before Committee on Government Reform
United States House of Representatives
Internet Pharmacy Consumer Protection Act

March 18, 2004

Mr. Chairman and Members of the Committee:

I am honored to be here today and discuss with you how to curb the illegal sale of prescription drugs over the Internet, particularly those sales which result without a valid prescription.

The National Association of Boards of Pharmacy (NABP), which I represent, was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, three Australian States, New Zealand, and South Africa. Our purpose is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

The Internet and Its Impact on the Practice of Pharmacy

The Internet is a remarkable medium that offers seemingly limitless opportunities for improving how we live and how medications can be dispensed to patients. The legitimate Internet pharmacies serving patients in the US are providing valuable and innovative services to their patients. It is unfortunate that the benefits of these legitimate pharmacies are often overshadowed by the activities of rogue sites whose concerns do not rest with the best interest of the patient or compliance with state and federal laws.

NABP's involvement with the distribution and dispensing of medications from pharmacies utilizing the Internet began in 1997. At that time NABP began to develop the Verified Internet Pharmacy Practice Sites (VIPPS) program, an innovative initiative to inform consumers of legal and safe Internet pharmacies. From the first awarding of a VIPPS certificate in 1999 to the present time, NABP has monitored the activities of Internet sites distributing and dispensing medications. We have observed firsthand the birth, evolution, and revolution of an industry that holds promise for growing populations of patients but, if allowed to proceed along the present course, will remove the Food and Drug Administration's (FDA) drug approval system and the dispensing of medications for chronic diseases out from the US to the country, territory, or back room with the

lowest prescription drug prices, regardless of the standards or safeguards in place in those other countries or territories.

NABP works with the state boards of pharmacy, the FDA and state legislatures to develop regulatory strategies that manage this emerging practice area and provide consumers with the information needed to distinguish legitimate Internet pharmacies from rogue or illegal sites. Our efforts have helped millions of consumers and resulted in the closing of rogue and illegal sites and the prosecution of pharmacists and prescribers involved with those sites. The data we have compiled and collect daily concerning the rogue sites and their operations serves as a useful source of information for other Congressional Committees, federal and state agencies, and consumer outreach programs.

Scope of Internet Sites

In late 1997, NABP and state and federal regulators made the startling observation that Web sites were appearing on the Internet and offering prescription medications to consumers without a valid prescription in direct violation of state and federal laws and regulations. At first, it appeared that such activity was an aberration or the misguided actions of uninformed entrepreneurs who viewed the distribution of medications via the Internet in the same light of opportunity as books and compact discs. However, subsequent research into this emerging area of e-commerce indicated otherwise. NABP detected a clear pattern of lawlessness and disregard for the legal safeguards in place for the practices of pharmacy and medicine.

The numbers of Web sites grew steadily in 1998 and soon were present in all areas of the Web. Data compiled by NABP, the FDA and other state and federal agencies presented a growing area of concern and potential compromise of the US medication distribution system and public health protections. In 1999, a coordinated effort between state agencies (state boards of pharmacy and medicine) and the FDA, and the introduction of NABP's Verified Internet Pharmacy Practice Sites Program (VIPPS) increased consumer awareness about the dangers of rogue or illegal sites, and helped to close a number of rogue and illegal sites. Those efforts were making significant progress in ceasing the operations of the rogue sites when the September 11 attack occurred and provided an unfortunate opportunity for the rogue sites to re-emerge and play on the fears of a shocked nation by offering prescription drugs and products to counter bio-terrorism attacks. The number of sites on the Internet operating outside of the law increased dramatically at this time. Fortunately, the threat of an anthrax attack dissipated in the early months of 2003 and subsequently, the number of sites offering antidotes and prophylactic therapies began to diminish.

In early 2003, NABP again detected a major shift in activity on the Internet. At this time, there appeared to be an unprecedented increase in the number of Internet Web sites offering American consumers lower priced medications from Canada and other foreign sources. Sites involved in this illegal activity jammed the Internet, deluged consumers with advertisements and solicitations at every turn and click, and aggressively lobbied

senior citizen groups and other special interest groups for Congressional support to protect their activities. NABP spoke out at the time, and continues to speak out, against these sites and their illegal activities. NABP has commented extensively on the need to close these sites and end their illegal operations. Working with the states and the FDA, NABP has documented incidences of patient harm from Internet sites and pharmacies operating in Canada and other parts of the world. The illegal distribution of drugs from foreign-based Web sites must be a major concern of any effort to regulate Internet sites. Although not the primary focus of the proposed legislation before the Committee today, such rogue sites must not be ignored.

The VIPPS Program

In early 1999, working with federal and state regulators, consumers, and the legitimate Internet pharmacy industry, NABP developed the Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program fashioned traditional regulation and consumer empowerment into a thorough and successful verification and authentication system. The VIPPS process developed by NABP encompasses compliance with state and federal laws governing the practice of pharmacy and the direct verification of licensure of the Internet pharmacy with all states where licensure or registration is required. VIPPS certifies, through on-site inspections and the meticulous analysis of the site's operations and submitted written information, compliance with a 19-point criteria review. The VIPPS criteria include verification of valid licensure in all of the US states with additional criteria that concentrate on the distinctions of Internet practice such as the transmission of prescription information and patient data, confidentiality of patient records, and quality improvement and monitoring of prescription processing and patient interactions.

The VIPPS program was implemented with wide consumer acceptance and support. Information about the VIPPS program has appeared on national and local news media programs and consumer information specials. The exposure included programming on CNN, ABC World News Tonight, NPR Radio, NBC News, CBS News, and Fox Special Report. Articles, stories and consumer advice recommending the VIPPS program have also appeared throughout the print media in local newspapers across the country as well as in Time, Newsweek, the Ladies Home Journal, Consumer Reports, USA Today, Wall Street Journal, New York Times, Washington Post, and other national publications. NABP estimates that more than 10 million consumers have heard, watched, or read about the VIPPS program. Government agencies such as the Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services also reference and recommend that consumers refer to the VIPPS program. Professional organizations such as the Federation of State Medical Boards (FSMB), American Pharmaceutical Association (APhA), and the American Medical Association (AMA) have also referenced and recommended consumers to the VIPPS program to consumers.

In November 2003, NABP and the National Association of Pharmacy Regulatory Authorities (NAPRA) expanded the VIPPS program to include legitimate, legal, and safe pharmacies duly registered in the various provinces. The VIPPS Canada program mirrors NABP's VIPPS program in the US and will identify for Canadian patients legal and safe Internet pharmacies accredited by a credible and valid system with standards that focus on the protection of the public health and patient safety. Presently, those Canadian pharmacies which ship prescription drugs into the US in direct violation of state and federal laws would not qualify for VIPPS certification.

NABP and NAPRA are also in discussions to develop a regulatory framework that regulates the inter-border practice of pharmacy and dispensing of medications to patients in the US and Canada. The framework would provide similar protections as those afforded US patients who utilize pharmacies engaged in the interstate practice of pharmacy and dispensing of medications. The framework will coordinate the regulatory efforts and resources of Canadian provinces and US state boards of pharmacy.

Regulatory Challenges by Practicing Pharmacy Across State Lines

The Internet changed pharmacy practice in a revolutionary manner by allowing for the electronic transmission of prescriptions and patient data, enhanced access to health care information and treatment, improved communications among health care practitioners, and distant care treatment occurring in real time. These advances have also brought new challenges to practitioners and regulators; challenges that question traditional enforcement provisions. For state boards of pharmacy the regulation of US-based sites, although exigent is not impossible. The physical presence of a building (pharmacy or wholesale operation) or person (pharmacist or prescriber) in a state or US territory provides state regulators with the information and access needed to identify these entities and successfully prosecute them. In fact, the combined regulatory actions of states and the FDA have resulted in the disciplining of practitioners, the closing of sites, the restriction of sites from operating in certain states, and multi-million dollar fines.

NABP believes and is on record noting that the state boards of pharmacy and other state regulatory agencies, working with the FDA and other federal agencies, can be effective in monitoring and regulating US-based sites offering prescription medications over the Internet. All states have in place laws and regulations governing the practice of pharmacy. These laws and regulations ensure that the provision of pharmaceuticals and pharmacist care meet accepted standards of practice and protect the public from harm. The various practice acts and regulations also establish the criteria for licensing pharmacists and pharmacies, operating a pharmacy to dispense medications to patients, and disciplining those pharmacists and pharmacies who violate state laws and regulations and endanger the health and safety of the citizens of the states.

The states have determined that Internet sites offering prescription medications are engaged in the practice of pharmacy and therefore must abide by the same laws and rules that presently apply to traditional brick and mortar pharmacies. Internet pharmacies, although unique in their structure and environment, essentially represent the operations of non-resident or mail order pharmacies. The basic construction of these systems involves the receipt of prescription orders from patients who do not physically deliver the prescription orders to the pharmacy and the delivery of prescription medications to patients who reside in locations different than where the pharmacy is located. All activities between these beginning and end points involve the practice of pharmacy and require adherence to present state laws and regulations. Additional regulations enacted in these states to specifically address Internet pharmacies have more specifically identified Internet practice and defined a valid patient-prescriber relationship.

All but a handful of states require that non-resident or out of state pharmacies license or register with them and comply with their applicable laws and statutes. These laws and regulations have been in place for almost 20 years, effectively protecting the citizens of the states and fostering cooperation among the states. What the various laws and regulations governing the practice of pharmacy and Internet sites have restricted is the operation of illegal sites seeking to bypass the regulatory system. State laws and regulations recognize the advantages of the Internet and allow for the practice of telemedicine and telepharmacy. Specific provisions of the majority of state laws and regulations allow for the electronic transmission of prescriptions, shared data bases, electronic patient profiles, and other advantages offered through the Internet and other electronic means. These laws and regulations transfer existing and accepted standards for patient care from traditional activities to the new, non-traditional activities of the Internet.

Review of H.R. 3880

Posting of Practice and Licensure Information

The required posting of information by Internet sites, outlined by H.R. 3880, is an important component of identifying and eliminating rogue and illegal sites from the Internet. NABP is concerned that simply mandating the posting of information, without independent and credible verification of the information, could provide an avenue for rogue site operators to exploit the law and mislead consumers under the guise of complying with the mandated posting requirements. NABP's VIPPS Program provides and validates directly with the appropriate state licensing jurisdiction all of the information H.R. 3880 proposes to require as well as the actual license number in the various states, contact information for the state agency holding the license, indication if the pharmacy has any disciplinary actions against the license, services offered by the Internet pharmacy, and corporate information The VIPPS Program information is identified through the VIPPS Seal and security protected links to NABP's Web site. NABP's VIPPS program also provides consumers with the opportunity to report any problems encountered with the site or the operation of any suspicious site they may have encountered while utilizing the Internet through a consumer awareness and reporting service.

Our experience in determining the true origin of rogue and illegal Web sites indicates that such operations deliberately conceal identifying information or fabricate information to provide the appearance of legitimacy to the site and affiliated persons. It is NABP's position that without this verification and validation of information, rogue sites will post fraudulent information to mislead and confuse the public without any regard for the possible penalties or actions for engaging in such conduct.

Although H.R. 3880 affords the Secretary of Health and Human Services the option of recognizing programs such as the VIPPS to implement the proposed revisions of Section 503B of the Federal Food, Drug, and Cosmetic Act, absent the mandating of a valid and credible certification process, it is highly unlikely that this will occur. Again, if Internet sites are simply required to post information to assist consumers in distinguishing legal Internet sites from rogue and illegal sites without any independent verification of that information, rogue operators will post fraudulent information in complete disregard for the law.

Defining a Bonafide Medical Relationship

NABP applauds the sponsors of H.R. 3880 for addressing one of the most problematic areas of Internet practice, the patient-prescriber relationship. NABP is alarmed by the number of Internet sites that purport to establish a bonafide patient-prescriber relationship through the use of cyberspace consultations or medical questionnaires. In NABP's opinion, the use of a questionnaire or cyberspace consultation as the sole basis for establishing a patient-prescriber relationship does not meet the standards of medical practice and violates state and federal laws defining a bonafide patient-prescriber relationship. The proposed revisions of H.R. 3880 which define a "Qualifying Medical Relationship" will close a regulatory loophole exploited by rogue and illegal Internet sites. Requiring at least one in-person medical evaluation of the patient will help to eliminate the dangerous practices of rogue and illegal Internet sites by establishing a legitimate patient-prescriber relationship. Equally as important, the proposed requirement of an in-person medical evaluation will not adversely impact the practices of telemedicine and telepharmacy. Conversely, the proposed requirement will further qualify the practice parameters of telepharmacy and telemedicine and eliminate those Internet sites which are concerned with exploiting consumers and cannot provide an acceptable medical evaluation because doing so would reduce their profit margin and expose their activities as fraudulent and dangerous.

Nationwide Injunctive Relief

NABP also strongly supports the provisions of H.R. 3880 which allow states to bring civil action forth to enjoin the practices of illegal Internet sites and obtain nationwide injunctions against their operations. NABP's experiences indicate that the operators of illegal and rogue sites are extremely knowledgeable about existing state and federal laws and will relocate their operations to those states or areas where their activities are not specifically prohibited and may in fact fall within a regulatory "gray area." Within this "safety net" the rogue or illegal site will operate in defiance of state and federal law and

without any desire to comply with existing laws and regulations if there appears to be even a scintilla of ambiguity in the law. Nationwide injunctive relief will cease these practices and allow states to work together to close regulatory loopholes and eliminate safe havens within the US for illegal and rogue sites.

Interactive Computer Service Advertising

NABP and state boards of pharmacy believe that Internet Service Providers (ISPs), advertising services, and search engines play a direct and abetting role in the activities of illegal and rogue Internet sites. The inclusion of advertising from these sites on legitimate Internet sites misinforms consumers that such sites are legitimate and safe and have been qualified in some way by the ISP, search engine, or advertising service that accepts and transmits their advertisements or services. States are beginning to take action against such entities for aiding and abetting in the violation of state and federal laws.

NABP requests that the provisions of H.R. 3880, which hold harmless interactive computer services or advertising services be reconsidered, and that these entities be required to assume responsibility for their acceptance of funding and services from illegal and rogue sites which threaten the public health and safety.

Conclusions

NABP appreciates the opportunity to share its comments with the Committee. We are hopeful that the proposed bill can be revised to address the concerns noted by NABP. NABP is anxious to assist the sponsors and supporters of H.R. 3880 in achieving the stated objectives and ultimately in ensuring that consumers can safely use the Internet to obtain prescription medications. Thank you.