September 20, 2001

Charles E. Bell, M.D.
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Texas Department of Health
1100 West 49th Street
Austin, Texas 78756-3199

Opinion No. JC-0412

Re: Whether, in accordance with section 439.022 of the Health and Safety Code, the Texas Board of Health must adopt rules providing for a nursing home to recycle certain prescription drugs that are scheduled to be destroyed (RQ-0371-JC)

Dear Dr. Bell:

Under section 439.021 of the Health and Safety Code, a nursing home's "consulting pharmacist . . . may select, from a supply of drugs due" to be destroyed, certain drugs to ship to a foreign country. TEX. HEALTH & SAFETY CODE ANN. § 439.021(a) (Vernon 2001). Section 439.022 requires the Texas Board of Health (the "Board") to adopt rules "consistent with federal and state law" to implement this directive. *Id.* § 439.022(a). Assuming that "[f]ederal law seems to prohibit the recycling of prescription drugs except for physicians' samples,"[1] you ask, on behalf of the Board, whether the Board is "preempted by federal law from adopting rules" in accordance with section 439.022, except to the extent that the drugs involved are physician samples. Request Letter, note 1, at 1. The federal Food and Drug Administration's Department of Health and Human Services has informed us that sample and nonsample prescription drug products may be donated to foreign countries in certain limited circumstances.[2] We accordingly conclude that federal law does not preempt the Board's responsibility to adopt the required rules. The rules must comport with federal limitations on the class of prescription drugs that may be recycled, however. *See* TEX. HEALTH & SAFETY CODE ANN. § 439.022(a) (Vernon 2001) (requiring Board to adopt rules "consistent with federal and state law").

Chapter 439, subchapter C of the Health and Safety Code, which consists of sections 439.021 through 439.023, concerns preserving and distributing certain unused drugs. *See id.* §§ 439.021-

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[1]Letter from Charles E. Bell, M.D., Executive Deputy Commissioner, Texas Department of Health, to Honorable John Cornyn, Attorney General of Texas (Mar. 26, 2001) (on file with Opinion Committee) [hereinafter Request Letter].

[2]*See* Letter from Dennis E. Baker, Associate Commissioner for Regulatory Affairs, United States Department of Health and Human Services, Food and Drug Administration, to Charles E. Bell, M.D., Executive Deputy Commissioner, Texas Department of Health (July 5, 2001) (on file with Opinion Committee) [hereinafter FDA Letter].

.023. Section 439.021 authorizes a nursing home's consulting pharmacist to select certain unused drugs that would otherwise be destroyed to ship to a foreign country:

> (a) A consulting pharmacist of a nursing home may select, from a supply of drugs due for destruction, certain drugs to be used for shipment to a foreign country as provided by this subchapter.
>
> (b) The supply of drugs due for destruction are those drugs accumulated because of the death of a resident of the nursing home or because a physician has ordered the use of the drug to be discontinued.
>
> (c) Quarterly, before the drugs are destroyed, the consulting pharmacist may, in the pharmacist's professional judgment, select the drugs to be used under this subchapter and seal them in a box for shipment.
>
> (d) The consulting pharmacist shall account to the Texas Department of Health for all drugs selected for shipment under this subchapter.
>
> (e) This subchapter does not apply if the unused drug is a controlled substance as defined by Chapter 481 [of the Health and Safety Code] (Texas Controlled Substances Act).

Id. § 439.021. The Board is required to adopt rules that are consistent with state and federal law to implement the subchapter and to specify the foreign countries that may receive the drugs:

> (a) The . . . Board . . . shall adopt rules consistent with federal and state law to implement this subchapter, including rules relating to:
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> (1) the packaging and inventory of drugs for shipment;
>
> (2) the manner of shipment of the drugs from original shipment under this subchapter until the final destination; and
>
> (3) safeguards to ensure the proper handling of and accounting for all drugs shipped.
>
> (b) The . . . Board . . . by rule shall determine, in consultation with the United States Department of State and other appropriate federal agencies, the foreign countries to receive the drugs.

> (c) The salvaging of drugs under this subchapter is not subject to Chapter 431 (Texas Food, Drug and Cosmetic Act).

Id. § 439.022. The state Department of Health may contract with other entities, such as local governments and civic organizations, to implement the subchapter and may accept gifts, grants, and other funds to implement the subchapter. *See id.* § 439.023.

Although we have not located any current Board regulation regarding the recycling of drugs authorized by sections 439.021 and 439.022 of the Health and Safety Code, we have located regulations of other state agencies that appear to apply. A regulation adopted by the State Board of Pharmacy, for example, prohibits a licensed pharmacist to "accept any unused prescription or drug, in whole or part, after it has been dispensed or sold, for the purpose of re-dispensing or resale to any person." 22 TEX. ADMIN. CODE § 291.8(a) (2001) (Bd. of Pharmacy, Return of Prescription Drugs). Violations "shall be dealt with as a violation of pharmacy law." *Id.* § 291.8(b). A Department of Human Services regulation requires that medications of deceased nursing-home residents, medications that have expired, and discontinued medications "be disposed of according to federal and state laws or rules on a quarterly basis." 40 TEX. ADMIN. CODE § 19.1504(h) (2001) (Dep't of Human Services, Drug Security).

You suggest that federal law prohibits recycling drugs in accordance with section 439.021 except to the extent that the drugs to be recycled are physician samples. *See* Request Letter, *supra* note 1, at 1. You cite in particular FDA Compliance Policy Guide No. 7132.08, which, as you quote it, recommends that "sample drugs . . . be collected from [a] physician's office" and, before being shipped overseas, be sorted and screened by "the responsible collection agency . . . , under the supervision of a registered pharmacist or licensed physician . . . to eliminate all recalled, outdated and investigational drugs." *See id.* at 1-2 (quoting FDA Compliance Policy Guide No. 7132.08). You also cite sections 381(e) and 382(f) of title 21 of the United States Code. Taking these sections in reverse order, section 382(f) prohibits the export of an adulterated or misbranded drug. 21 U.S.C. § 382(f)(3) (1994 & Supp. V). Section 381(e) states that a drug intended for export is not adulterated or misbranded if it:

> (A) accords to the specification of the foreign purchaser;
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> (B) is not in conflict with the laws of the country to which it is intended for export;
>
> (C) is labeled on the outside of the shipping package that it is intended for export, and
>
> (D) is not sold or offered for sale in domestic commerce.

Id. § 381(e)(1). None of the federal statutes or materials you cite appear to prohibit the collection and shipment to a foreign country of a nursing home's unused prescription drugs.

Moreover, the federal Food and Drug Administration's Department of Health and Human Services (the FDA) indicates that federal law permits the practice with certain limitations. *See* FDA Letter, *supra* note 2, at 1. According to the FDA, prescription drug samples may be donated in accordance with 21 C.F.R. § 203.39, which requires that:

- samples be in their original packaging;
- samples be delivered in a sealed container;
- the recipient will prepare a donation record that includes the donor's identity; the manufacturer, brand name, quantity, and lot number of the sample; and the date the recipient receives the sample;
- a licensed practitioner or pharmacist will examine each sample unit prior to distribution to determine that the donation record accurately describes the drug sample and that the drug sample has not been recalled, is not outdated, or is not otherwise unsuitable for human use;
- unsuitable sample drugs be destroyed or returned to the supplier to be destroyed;
- the recipient will keep for at least three years complete and accurate records of drug sample donation, receipt, examination, inventory, dispensing, redistribution, destruction, and returns;
- the recipient annually inventories all drug samples, prepares a report of the inventory reconciling the results with the results of the most recent prior inventory, and investigates and reports to the FDA any inventory discrepancies;
- any theft or significant loss of drug samples will be reported to the FDA; and
- samples are appropriately stored.

See FDA Letter, *supra* note 2, at 1-2; *see also* 21 C.F.R. § 203.39 (2001). Prescription drugs that are not samples but that are in the original packaging also may be donated in accordance with FDA recommendations:

- The donor must verify that the requesting charity is legitimate.
- A physician or pharmacist must screen all of the donated drugs to eliminate recalled, outdated, or otherwise unsuitable drugs.
- Unsuitable drug products must be destroyed or returned to the supplier.
- Adequate inventory, accountability, and security systems must be in place to prevent loss, theft, or diversion of the donated drugs.
- Previously dispensed drugs may not be donated.
- Requirements of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. chapter 9 (§§ 301 - 397), and Wholesaler Licensing Guideline regulations, 21 C.F.R. part 205 must be met.

FDA Letter, *supra* note 2, at 2. Given that the FDA is authorized to adopt regulations to enforce the relevant federal drug laws, *see* 21 U.S.C. § 371(a) (1994 & Supp. V), we presume that the FDA has correctly interpreted those laws.

Although federal law limits the class of prescription drugs that can be collected and shipped to foreign countries, it does not preempt state law as you suggest. *See* Request Letter, *supra* note 1, at 1. State law is preempted only when Congress has expressed an intent to preempt; when state law stands as an obstacle to accomplishing and executing Congress' purposes and objectives; or when it is impossible to comply with both state and federal law. *See* U.S. CONST. art. VI, cl. 2; *Zachry-Dillingham v. Am. President Lines, Ltd.*, 739 S.W.2d 420, 422 (Tex. App.–San Antonio 1987, writ denied); Tex. Att'y Gen. Op. Nos. JC-0007 (1999) at 2; MW-463 (1982) at 3 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). We have not found any congressional expression of an intent to preempt the state's statute in this matter, nor have we found that the state law, when it is construed to incorporate the federal limitations, obstructs federal policy or makes it impossible to comply with federal law.

In accordance with the FDA's interpretation, we conclude that federal law permits, with certain limitations, the collection and shipment to foreign countries of prescription drugs that are no longer needed by nursing-home residents, where those drugs are samples or are in the original packaging. As section 439.022 of the Texas Health and Safety Code directs, therefore, the Board must adopt regulations that provide for the recycling of such drugs and distribution to foreign countries. TEX. HEALTH & SAFETY CODE ANN. § 439.022(a) (Vernon 2001). The regulations must comport with the FDA's interpretation of federal law, as well as with any other applicable state law. *See id.*

SUMMARY

As the federal Food and Drug Administration interprets applicable federal law, federal law permits, with certain limitations, the collection and shipment to foreign countries of unused prescription drugs that are no longer needed by nursing-home residents, where the drugs are samples or are in the original packaging. In accordance with section 439.022 of the Texas Health and Safety Code, the state Board of Health must adopt regulations that provide for the collecting of such drugs, sample and nonsample, and shipment to foreign countries. *See* Tex. HEALTH & SAFETY CODE ANN. § 439.022(a) (Vernon 2001). The regulations must comport with federal law, as well as with any other applicable state law. *See id.*

Yours very truly,

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