

STATE OF TENNESSEE

OFFICE OF THE
ATTORNEY GENERAL
PO BOX 20207
NASHVILLE, TENNESSEE 37202

October 13, 2003

Opinion No. 03-135

Unlicensed Sale and Distribution of Prescription Veterinary Drugs

QUESTIONS

1. Is the unlicensed sale and distribution of drugs that can only be dispensed pursuant to a prescription from a licensed veterinarian a violation of either the Veterinary Practice Act or the Pharmacy Practice Act?
2. What penalties can be imposed upon a person or entity that is not licensed by the Board of Pharmacy for selling and/or distributing drugs that can only be dispensed pursuant to a prescription from a licensed veterinarian?
3. Under current law, what jurisdiction does either the Board of Veterinary Medical Examiners or the Board of Pharmacy have over a person or entity that is not licensed by the Board of Pharmacy for selling and/or distributing drugs that can only be dispensed pursuant to a prescription from a licensed veterinarian?

OPINIONS

1. The sale or distribution of drugs which are required to be dispensed pursuant to a prescription from a licensed veterinarian by an unlicensed person or entity violates the Tennessee Veterinary Practice Act if such sale or distribution occurs either within the scope of practice of veterinary medicine, or with respect to any person, corporation or similar organization required to be licensed, permitted or authorized by the Board of Veterinary Medical Examiners. Further, the unlicensed sale or distribution of prescription veterinary drugs is a violation of the Pharmacy Practice Act and also constitutes a criminal offense.
2. Both criminal and civil penalties may be imposed upon an unlicensed person or entity for selling or distributing prescription veterinary drugs.
3. The Board of Veterinary Medical Examiners has jurisdiction over an unlicensed person or entity that is selling or distributing prescription veterinary drugs, provided that such sale or distribution occurs either within the scope of practice of veterinary medicine, or with respect to any person, corporation or similar organization required to be licensed, permitted or authorized by the Board of Veterinary Medical Examiners. In addition, the Board of Pharmacy has

jurisdiction over an unlicensed person or entity that is selling or distributing prescription veterinary drugs without a license.

ANALYSIS

(1)

The instant request arises out of the following fact situation. Legend drugs, in this instance veterinary prescription drugs which only can be sold and distributed with a prescription from a veterinarian licensed in Tennessee, are being “drop shipped” to locations in Tennessee from out-of-state distributors. The drugs then are sold in Tennessee without a prescription by entities or persons who are licensed neither by the Board of Pharmacy nor the Board of Veterinary Medical Examiners. Specifically, the request relates a concern voiced by a veterinarian who discovered that one of his clients had obtained the drug Domosedan, an animal sedative, without a veterinarian’s prescription.

a. Board of Veterinary Medical Examiners.

One of the purposes of the Tennessee Veterinary Practice Act of 1967, Tenn. Code Ann. §§ 63-12-101, *et seq.* (“Veterinary Practice Act”), is to protect the public from unauthorized practitioners. Tenn. Code Ann. § 63-12-102. The Veterinary Practice Act contains a veterinarian license requirement:

Any person wishing to practice veterinary medicine in this state shall obtain a license from the board. It is unlawful for such person to practice veterinary medicine as defined herein unless the person obtains a license, and if the person so practices the person shall be considered to have violated the provisions of this chapter.

Tenn. Code Ann. § 63-12-112(a).¹

The Veterinary Practice Act defines the “practice of veterinary medicine,” in pertinent part, as meaning to:

(A) Diagnose, prescribe or administer any drug, medicine, biologic, appliance, application or treatment of whatever nature for the cure, prevention or relief of any wound, fracture, bodily injury or disease of animals;

¹The Veterinary Practice Act also requires licensing of veterinary technicians, Tenn. Code Ann. § 63-12-135, and further requires that any person who owns or operates any veterinary facility, or any other premises where a licensed veterinarian practices or where the practice of veterinary medicine occurs, first must apply for and secure a premises permit from the Board of Veterinary Medical Examiners. Tenn. Code Ann. §§ 63-12-139, 63-12-140.

* * * *

(D) Represent oneself as engaged in the practice of veterinary medicine in any of its branches;

(E) Offer, undertake or hold oneself out to be able to diagnose, treat, operate or prescribe for any animal disease, pain, injury, deformity or physical condition;

(F) Use any words, letters or titles in such connection or under such circumstances as to induce the belief that the person using them is engaged in the practice of veterinary medicine; such use shall be prima facie evidence of the intention to represent oneself as engaged in the practice of veterinary medicine;

* * * *

Tenn. Code Ann. § 63-12-103(10)(A),(D)(E) and (F).²

Among the powers of the Board of Veterinary Medical Examiners, enumerated in Tenn. Code Ann. § 63-12-106, is the power to adopt reasonable rules governing the practice of veterinary medicine “as are necessary to enable it to carry out and make effective the purpose and intent of this chapter.” Tenn. Code Ann. § 63-12-106(1). Further, Tenn. Code Ann. § 53-11-301 provides that

[t]he board of pharmacy and the appropriate occupational or professional licensing board governing persons who may legally dispense controlled substances may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this state.

Both Tenn. Comp. R. & Reg. 1730-1-.21(contained in the General Rules Governing Veterinarians), as well as Tenn. Comp. R. & Reg. 1730-2-.05 (contained in the General Rules Governing Veterinary Facilities) regulate “prescribing, dispensing, or otherwise distributing pharmaceuticals.” Each requires that all veterinarians who dispense pharmaceuticals comply with all federal regulations for the dispensing of controlled substances, and dispense all non-controlled drugs in an appropriate container with specified labeling. Each also prohibits the distribution of prescription veterinary drugs by persons who are not licensed veterinarians:

Distribution of veterinary prescription drugs to laymen may occur

²The Board of Veterinary Medical Examiners has by rule further defined the scope of practice of veterinary medicine, in pertinent part, as meaning “to diagnose, treat, correct, change, relieve, or prevent animal disease, deformity, defect, injury, or other physical or mental conditions; *including the prescription or administration of any drug, medicine, biologic, apparatus, application, anesthetic, or other therapeutic or diagnostic substance or technique....* or to render advice or recommendation with regard to any of the above.” Tenn. Comp. R. & Reg. 1730-1-.02(1) (emphasis added).

only on the prescription or other order of a licensed veterinarian. The prescriptions must be issued in the course of his or her professional practice, with a veterinarian-client-patient relationship existing.

Tenn. Comp. R. & Reg. 1730-1-.21(2)(a).

Distribution of veterinary prescription drugs to laymen shall occur only on the prescription of a licensed Veterinarian or on the order of another licensed Veterinarian. The prescriptions shall be issued in the course of his or her professional practice, with a veterinarian-client-patient relationship existing.

Tenn. Comp. R. & Reg. 1730-2-.05(1)(d).

Thus, the Board of Veterinary Medical Examiners has by rule interpreted the prescribing, dispensing, or otherwise distributing veterinary prescription drugs to laymen as falling exclusively within the professional province of licensed veterinarians.

The above rules should be interpreted in light of the statutory definition and regulatory scope of the practice of veterinary medicine. Thus, for example, if an unlicensed person merely sells or distributes a veterinary prescription drug for a purpose other than the treatment of an animal; without representing himself as engaged in the practice of veterinary medicine; without using any words, letters or titles as to induce the belief that he is practicing veterinary medicine; without holding himself out as diagnosing, treating or prescribing for an animal; and is not a person, corporation or similar organization³ required to be licensed, permitted or authorized by the Board of Veterinary Medical Examiners, then such sale or distribution would fall outside the scope of the Board's authority. If, on the other hand, an unlicensed person's or entity's sale or distribution of prescription veterinary drugs either falls within the definition of the "practice of veterinary medicine," or occurs "with respect to any person required to be licensed, permitted or authorized" by the Board, Tenn. Code Ann. § 63-1-134, then such act violates the Veterinary Practice Act.

The Board of Veterinary Medical Examiners may seek injunctive relief against an unlicensed violator under Tenn. Code Ann. § 63-12-132:

Enjoining violations. - In addition to the penalties herein provided, the board may institute legal proceedings to enjoin the violation of the provisions of this chapter or rules of the board in any court of competent jurisdiction, and such court may grant a temporary or

³The Board of Veterinary Medical Examiners has authority, after proper hearing, to discipline "any person, corporation, or other similar organization, public or private, for-profit or not-for profit" for violation of the Veterinary Practice Act or any of the Board's rules. Tenn. Code Ann. § 63-12-128(a).

permanent injunction restraining the violation thereof.

Criminal penalties also may be imposed under the Veterinary Practice Act for unlicensed practice. Tenn. Code Ann. § 63-12-119 provides:

Penalty for unlicensed practice. - Any person who practices or attempts to practice veterinary medicine in this state and makes a charge therefor, without having complied with the provisions of this chapter, commits a Class B misdemeanor for each instance of such practice.

b. Pharmacy Board.

The Tennessee Pharmacy Practice Act of 1996 (“Pharmacy Practice Act”) is found in Tenn. Code Ann. § 63-10-401 *et seq.* The purpose of this act is to “define and regulate the practice of pharmacy to protect the health, safety and welfare of the people of Tennessee.” Tenn. Code Ann. § 63-10-403(a). Regulation is governed by the Board of Pharmacy. Among the Board of Pharmacy’s duties are those of enforcing Tennessee laws pertaining to the “practice of pharmacy, the manufacture, distribution or sale of drugs, and the medication use process including: compounding, selection, preparation/production, dispensing/distribution, patient administration, education and monitoring of drugs, devices, chemicals or poisons.” Tenn. Code Ann. § 63-10-504(a). *See also* Tenn. Code Ann. § 53-11-301.

The term “drug” is defined in Tenn. Code Ann. § 63-10-404(14), which says,

“Drug” means any of the following:

- (A) Articles recognized as drugs or drug products in any official compendium or supplement thereto;
- (B) Articles, other than food, intended to affect the structure or function of the body of humans or other animals;
- (C) Articles, including radioactive substances, intended for use in the diagnosis, cure mitigation, treatment or prevention of disease in humans or other animals; or
- (D) Articles intended for use as a component of any articles specified in this subdivision.

The term “prescription drug” is defined in Tenn. Code Ann. § 63-10-404(33), which says,

“Prescription drug” means a drug which under federal law is required to be labeled with either of the following statements:

- (A) “Caution: Federal law prohibits dispensing without a prescription”;
- (B) “Caution: Federal law restricts this drug to use by, or on the order

of, a **licensed veterinarian**”; or

(C) A drug which is required by any applicable federal or state law or regulation to be dispensed only pursuant to a prescription order or is restricted to use by prescribers.

(emphasis added). These definitions must be read in conjunction with Tenn. Code Ann. § 63-10-504(a), which declares that the Board of Pharmacy has the duty “to enforce all the laws of the state now or hereinafter enacted which pertain to the practice of pharmacy, the manufacture, distribution, or sale of drugs, and the medication use process

Thus, it is clear that the unlicensed sale or distribution of prescription veterinary drugs is a violation of the Pharmacy Practice Act.

(2)

The next question relates to the penalties that can be imposed on an unlicensed person or entity for selling or distributing prescription veterinary drugs. In the first place, such acts constitute criminal offenses.

a. State Criminal Offenses.

The Tennessee Drug Control Act of 1989 (“Drug Control Act”) is found in Tenn. Code Ann. §§ 39-17-401 *et seq.*, 53-11-301 *et seq.*, and 53-11-401 *et seq.* Tenn. Code Ann. § 39-17-401 *et seq.* addresses criminal offenses against the public health, safety and welfare with respect to unlawful distribution of controlled substances as defined in the statute. Tenn. Code Ann. § 53-11-301 *et seq.* provides for the regulation of the manufacture, distribution and dispensing of controlled substances in Tennessee. Tenn. Code Ann. § 53-11-401 *et seq.* provides additional criminal penalties and methods of enforcement for violations of the Drug Control Act.

The term “controlled substance” means “a drug, substance, or immediate precursor in Schedules I through VI of §§ 39-17-403 - 39-17-415 inclusive.” Tenn. Code Ann. § 39-17-402(4). The referenced schedules classify particular drugs based on their potential for abuse, in accordance with the factors listed in Tenn. Code Ann. § 39-17-403. Controlled substances include both legal (available by prescription) and illegal drugs. If prescription veterinary drugs are among those listed in the Drug Control Act, then their unlawful distribution would be a violation of this act, which would be a criminal offense, a felony.

There are several criminal offenses listed in the Drug Control Act that may be relevant to the issue of unlawful sale or distribution of prescription veterinary medicine. For example, it is a criminal offense to knowingly manufacture, deliver or sell a controlled substance. Tenn. Code Ann. § 39-17-417(1)-(3). It is also a criminal offense to knowingly “possess a controlled substance with intent to manufacture, deliver or sell such controlled substance.” Tenn. Code Ann. § 39-17-417(4). Third, it is a criminal offense for a person to “knowingly possess or casually exchange a controlled

substance unless the substance was obtained directly from, or pursuant to, a valid prescription . . .” Tenn. Code Ann. § 39-17-418(a).

In the alternative, the veterinary drugs referred to may be legend drugs whose unlawful distribution would be governed by Tenn. Code Ann. § 53-10-101 *et seq.* A “legend drug” is “any item which federal law prohibits dispensing without a prescription from a licensed doctor, dentist, optometrist or veterinarian.” Tenn. Code Ann. § 53-10-101(a). A drug may be both a legend drug and a controlled substance, but to be both, it must be available only by prescription and also must be listed in one of the schedules found in Tenn. Code Ann. §§ 39-17-403 to -415. If not listed in one of the referenced schedules, then its only designation would be as a legend drug.

It is unlawful to possess, sell, barter or give away legend drugs without a valid prescription from “a duly licensed physician, certified physician assistant, [lawfully authorized] nurse . . . , a dentist, a [lawfully authorized] optometrist . . . , or a veterinarian” Tenn. Code Ann. § 53-10-104(a). It is also unlawful for an unauthorized person to possess a legend drug without a valid prescription from “a duly licensed physician, certified physician assistant, dentist, [authorized] optometrist . . . , or veterinarian and having been dispensed by a pharmacy duly licensed and registered in [Tennessee]” unless that person is a “resident of another state and had the prescription . . . filled by a duly licensed and registered pharmacist of such other state.” Tenn. Code Ann. § 53-10-105(a). Thus, since prescription veterinary drugs are legend drugs under Tennessee law, then their unlawful distribution would be a violation of these Code provisions, which would also be a criminal offense, a misdemeanor. Tenn. Code Ann. § 53-10-108.

Criminal penalties may be imposed for violations of the Drug Control Act and also for violations of Tenn. Code Ann. § 53-10-101 *et seq.* Specific penalties under the Drug Control Act are listed in Tenn. Code Ann. §§ 39-17-417, 39-17-418, 53-11-401, and 53-11-402. These penalties range from prosecution for commission of a Class A Felony to a Class E Felony, depending on the particular violation.⁴

Tenn. Code Ann. § 53-11-403 makes it clear that criminal penalties imposed under the Drug Control Act are “in addition to, and not in lieu of any civil or administrative penalty or sanction otherwise authorized by law.” The purpose of the language of this Code section is to allow for the civil sanction of forfeiture where applicable under Tenn. Code Ann. §§ 53-11-201 *et seq.* and

⁴Authorized terms of imprisonment and fines for felonies and misdemeanors are found in Tenn. Code Ann. § 40-35-111. Conviction for commission of a Class A Felony may result in imprisonment for between fifteen and sixty years and a fine of up to \$50,000. Tenn. Code Ann. § 40-35-111(b)(1). Conviction for commission of a Class B Felony may result in imprisonment for between eight and thirty years and a fine of up to \$25,000. Tenn. Code Ann. § 40-35-111(b)(2). Conviction for commission of a Class C Felony may result in imprisonment for between three and fifteen years and a fine of up to \$10,000. Tenn. Code Ann. § 40-35-111(b)(3). Conviction for commission of a Class D Felony may result in imprisonment for between two and twelve years and a fine of up to \$5,000. Tenn. Code Ann. § 40-35-111(b)(4). Conviction for commission of a Class E Felony may result in imprisonment for between one and six years and a fine of up to \$3,000. Tenn. Code Ann. § 40-35-111(b)(5).

53-11-451. *Stuart v. State Department of Safety*, 963 S.W.2d 28, 33 (Tenn. 1998). Thus, another potential penalty is the civil penalty of forfeiture if the drugs are narcotics or controlled substances and the provisions of the forfeiture statutes are met. Tenn. Code Ann. §§ 53-11-201 *et seq.* and 53-11-451.

The penalty for violation of the laws dealing with legend drugs is found in Tenn. Code Ann. § 53-10-108. This section provides that “[a]ny person, firm or corporation possessing, selling, bartering or giving away any drug in violation of this part or violating any other provision of this part commits a Class C misdemeanor.⁵

b. Federal Criminal Offenses.

In addition, federal law forbids dispensing certain veterinary drugs without a lawful written or oral order of a licensed veterinarian in the course of the veterinarian’s professional practice. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 353(f)(1). Generally, a drug is deemed “misbranded” unless its labeling bears “adequate directions for use.” 21 U.S.C. § 352(f)(1). However, under 21 C.F.R. § 201.105, a drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of or collateral measures necessary for its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence, for which “adequate directions for use” cannot be prepared, is exempt from 21 U.S.C. § 352(f)(1) if all of the conditions specified in the regulation are met. These conditions include that:

(a) The drug is:

- (1)(i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of drugs that are to be used only by or on the prescription or other order of a licensed veterinarian; or
 - (ii) In the possession of a retail, hospital, or clinic pharmacy, or other person authorized under State law to dispense veterinary prescription drugs, who is regularly and lawfully engaged in dispensing drugs that are to be used only by or on the prescription or other order of a licensed veterinarian; or
 - (iii) In the possession of a licensed veterinarian for use in the course of his professional practice; and
- (2) To be dispensed in accordance with section 503(f) of the act.⁶

21 C.F.R. § 201.105(a). Moreover, the conditions also reference a number of specific labeling requirements, including the statement “Caution: Federal law restricts this drug to use by or on the

⁵Conviction for commission of a Class C Misdemeanor may result in imprisonment for not more than thirty days or a fine not to exceed \$50.00, or both. Tenn. Code Ann. §40-35-111(e)(3).

⁶This section of the Act is codified at 21 U.S.C. § 353(f).

order of a licensed veterinarian,” as well as

adequate information for its use . . . under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented

21 C.F.R. § 201.105(b) and (c)(1). Hence, an animal drug described in 21 C.F.R. § 201.105 which either is not used only on the “prescription or other order” of a veterinarian, or which does not bear the required cautionary and instructional labeling, or which is not otherwise exempt, does not comply with the regulation and is “misbranded.” In particular, 21 U.S.C. § 360b(a)(5) sets forth the parameters under which an approved “new animal drug” may be used, including restriction of its use or intended use to by, or on the lawful written or oral order of, a licensed veterinarian within the context of a veterinarian-client-patient relationship, as well as compliance with applicable regulations that establish the conditions for the use or intended use of the drug in animals.⁷ Any new animal drug is deemed unsafe unless so approved, and such drug, its labeling, and its use conform to such approved application. *See United States v. 9/1 KG. Containers, More or Less, of an Article of Drug for Veterinary Use*, 854 F.2d 173 (7th Cir. 1988). The FDA approved labeling of such new animal drug renders it subject to 21 C.F.R. § 201.105, and failure to distribute such drug in accordance with its labeling, mandating a veterinarian’s order, may revoke the drug’s exemption and render it misbranded under 21 C.F.R. § 201.105. *See United States v. Colahan*, 811 F.2d 287, 290-93 (6th Cir. 1987).

Distribution of misbranded animal drugs may be enjoined. 21 U.S.C. § 332. In affirming judgment for the United States enjoining distribution of misbranded animal drugs, the court in *Colahan* wrote:

A requirement that unsafe animal drugs be sold only on the direct order of a veterinarian in order to insure that the veterinarian actually supervises their use does not significantly contribute to the problems defendants predict but does protect the farmers, the animals, and the public that consumes the food products of the livestock against potential harm from improper use or sale of these unsafe drugs.

Id. at 294.

Moreover, distribution of such misbranded drugs is a criminal offense which, unless it falls within an enumerated exception, is punishable by a fine of not more than \$1,000 and imprisonment

⁷The particular drug which your request mentions, Domosedan (Detomidine hydrochloride injection) is considered a “new animal drug” under federal law. 21 C.F.R. § 522.536.

for not more than one year, or both. 21 U.S.C. §333(a)(1). Further, if a person commits a second violation, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years, or fined not more than \$10,000, or both. 21 U.S.C. §333(a)(2).

The Food, Drug and Cosmetic Act also authorizes government seizure and condemnation of such drugs. 21 U.S.C. § 334.

Also, distribution of misbranded veterinary drugs, coupled with harm to the user, may result in civil liability. *See Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908 (5th Cir. 1987).

c. State Law Penalties.

In addition to the criminal penalties under state and federal law discussed above, significant civil penalties may be imposed under the statutes and rules pertaining to the Board of Veterinary Medical Examiners and the Pharmacy Board. These are discussed in greater detail in Section 3.

(3)

The final question addresses the jurisdiction of the Board of Veterinary Medical Examiners and the Board of Pharmacy over those who sell or distribute prescription veterinary drugs without a license. Consistent with the answer to Question 1 above, the respective boards have jurisdiction when such acts are offenses under the respective acts.

a. Board of Veterinary Medical Examiners

The Board of Veterinary Medical Examiners, as part of its enforcement powers, may conduct investigations of all alleged violations, and to that end, may employ investigators, counsel and clerical assistance, or any other necessary personnel. Tenn. Code Ann. § 63-12-129. As mentioned previously, the Board has authority, after proper hearing, to enter an order to discipline “any person, corporation, or other similar organization, public or private, for-profit or not-for-profit” for violation of any provision of the Veterinary Practice Act or of the Board’s rules. Tenn. Code Ann. § 63-12-128(a). Since an unlicensed person or entity has no license, certificate or premises permit which the Board of Veterinary Medical Examiners might discipline, there remains only one possible sanction for unlicensed practice which the Board may impose directly under the Veterinary Practice Act, namely, civil penalties.

Civil penalties may be imposed against unlicensed persons or entities under the Veterinary Practice Act. Tenn. Code Ann. § 63-1-134, referred to previously, provides in pertinent part that

[w]ith respect to any person required to be licensed, permitted or authorized by any board, commission or agency attached to the division of health related boards, each respective board,

commission or agency may assess a civil penalty against such person in an amount not to exceed one thousand dollars (\$1,000) for each separate violation of a statute, rule or order pertaining to such board, commission or agency. Each day of continued violation constitutes a separate violation.

Tenn. Code Ann. § 63-1-134(a).

Thus, we believe that Tenn. Code Ann. § 63-1-134(a) permits the Board of Veterinary Medical Examiners to assess civil penalties against an unlicensed person or entity that sells or distributes prescription veterinary drugs, provided that such sale or distribution occurs either within the scope of practice of veterinary medicine, or with respect to any person, corporation or similar organization required to be licensed, permitted or authorized by the Board.

In addition, costs of prosecution “against the licensee or other person,” including investigatory costs where appropriate, are allowable under Tenn. Code Ann. § 63-12-143.

b. Pharmacy Board.

The Pharmacy Practice Act was enacted to “define and regulate the practice of pharmacy to protect the health, safety and welfare of the people of Tennessee.” Tenn. Code Ann. § 63-10-403. Under the terms of this act, the Board of Pharmacy is “authorized to petition any circuit or chancery court, having jurisdiction of any person who is practicing pharmacy in Tennessee without a valid license or who has violated any of the provisions of parts 4-6 of this chapter or the rules of the board, to enjoin such person from continuing to practice within this state.” Tenn. Code Ann. § 63-10-504(f)(4). Any violation of the Pharmacy Practice Act, “unless otherwise specified by law, shall be classified as a Class C misdemeanor.” Tenn. Code Ann. § 63-10-408.

As discussed above, the powers of the Board of Pharmacy reach the selling and distributing by any means of controlled substances in Tennessee. Tenn. Code Ann. § 63-10-504(a) gives the Board of Pharmacy the duty to

enforce all the laws of the state now or hereinafter enacted which pertain to the practice of pharmacy, the manufacture, distribution or sale of drugs, and the medication use process including compounding, selection, preparation/production, dispensing/distribution, patient administration, education and monitoring of drugs, devices, chemicals or poisons.

The Board’s means of enforcement, however, are limited. Tenn. Code Ann. § 53-10-103 gives the Board of Pharmacy the power to make rules and regulations for enforcement of the laws under its jurisdiction. In addition, Tenn. Code Ann. § 63-10-504 accords the Board powers to make rules, to subpoena witnesses, and to seek to enjoin those practicing pharmacy without a license. *See also*

Tenn. Code Ann. § 53-11-301.

The Pharmacy Board has express authority to impose civil penalties upon those engaging in the activities which it is authorized to license. Since those activities include the “distribution or sale of drugs,” Tenn. Code Ann. § 63-10-504(a), it can reach persons who sell drugs without otherwise holding themselves out as a pharmacist. Tenn. Code Ann. § 56-1-308 provides,

With respect to any person required to be licensed, permitted, or authorized by any board, commission or agency attached to the division of regulatory boards, each respective board, commission or agency may assess a civil penalty against such person in an amount not to exceed one thousand dollars (\$1,000) for each separate violation of a statute, rule or order pertaining to such board, commission or agency. Each day of continued violation constitutes a separate violation.

(b) Each board, commission or agency shall by rule establish a schedule designating the minimum and maximum civil penalties, which may be assessed under this section.

In accordance with this section, the Board has promulgated Tenn. Comp. R. & Regs. 1140-8-01, concerning the assessment of civil penalties. Consistent with this authority, the Board may impose civil penalties on those who sell or distribute prescription veterinary drugs without a license.

PAUL G. SUMMERS
Attorney General and Reporter

MICHAEL E. MOORE
Solicitor General

CHARLES L. LEWIS
Deputy Attorney General

SARA E. SEDGWICK
Assistant Attorney General

Requested by:

The Honorable Glen Casada
State Representative
209 War Memorial Building
Nashville, Tennessee 37243-0163