February 12, 2001

The Honorable Toby Goodman
Chair, Committee on Juvenile Justice
and Family Issues
Texas House of Representatives
P.O. Box 2910
Austin, Texas 78768-2910

Opinion No. JC-0341

Re: Whether a Texas State Board of Pharmacy rule specifying that no drugs shall be included on a list of narrow therapeutic index drugs is consistent with section 562.014 of the Texas Occupations Code, which requires the Board, by rule, to "establish a list of narrow therapeutic index drugs" (RQ-0289-JC)

Dear Representative Goodman:

Section 562.014 of the Texas Occupations Code provides that the general statutory provisions authorizing a pharmacist to substitute a generically equivalent drug for a prescribed drug do not apply to the refill of a prescription for a "narrow therapeutic index drug" and charges the Texas State Board of Pharmacy to "establish a list of narrow therapeutic index drugs." TEX. OCC. CODE ANN. § 562.014 (Vernon 2001). You ask whether a Texas State Board of Pharmacy rule specifying that no drugs shall be included on a list of narrow therapeutic index drugs, *see* 22 T.A.C. § 309.3(d)(2) (2000) (Tex. State Bd. of Pharm., Prescription Drug Orders), is consistent with section 562.014.[1] We conclude that the rule is consistent with section 562.014.

Title 3, subtitle J of the Texas Occupations Code, the Texas Pharmacy Act, TEX. OCC. CODE ANN. chs. 551-566 (Vernon 2001), regulates the practice of pharmacy in this state. The Texas State Board of Pharmacy (the "Board") is charged with administering and enforcing the Act, *see id.* chs. 552, 554, including regulating the delivery and distribution of prescription drugs, *id.* § 554.005(a)(1), and is authorized to adopt rules consistent with subtitle J, *see id.* § 554.051(a).

Chapter 562, subchapter A, governs the authority of a pharmacist to dispense prescribed drugs and to substitute generically equivalent products. Under subchapter A, a "generically equivalent" drug means a drug that is pharmaceutically (*i.e.*, chemically) and therapeutically equivalent to the drug prescribed. *See id.* § 562.001(1); *see also id.* § 562.001(2) ("'Pharma-

[1]*See* Letter from Honorable Toby Goodman, Chair, Committee on Juvenile Justice and Family Issues, to Honorable John Cornyn, Texas Attorney General (Sept. 25, 2000) (on file with Opinion Committee) [hereinafter Request Letter].

ceutically equivalent' means drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendial or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium."); *id.* § 562.001(3) ("'Therapeutically equivalent' means pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity."). If the physician's signature on the prescription form does not indicate that the prescription must be dispensed as written, the pharmacist may select a generically equivalent drug. *See id.* § 562.008. A pharmacist who selects a generically equivalent drug must inform the patient of the substitution and of his or her right to refuse the substitution or must display a sign providing notice regarding substitutions. *See id.* § 562.009. Subchapter A specifically provides that it is the legislature's intent "to save consumers money by allowing the substitution of lower-priced generically equivalent drug products for certain brand name drug products." *Id.* § 562.002.

You ask about a rule adopted under section 562.014 of the Occupations Code, which limits the authority of a pharmacist to refill a prescription using a generically equivalent drug as a substitute for the drug originally prescribed, if that drug is a "narrow therapeutic index drug." Section 562.014 states as follows:

> Except as provided by this section, drug selection as authorized by this subchapter does not apply to the refill of a prescription for a narrow therapeutic index drug. The board, in consultation with the Texas State Board of Medical Examiners, shall by rule establish a list of narrow therapeutic index drugs to which this subsection applies. A prescription for a narrow therapeutic index drug may be refilled only by using the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless otherwise agreed to by the prescribing physician. If a pharmacist does not have the same drug product by the same manufacturer in stock to refill the prescription, the pharmacist may dispense a drug product that is generically equivalent if the pharmacist, before dispensing the generically equivalent drug product, notifies:
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> (1) the patient, at the time the prescription is dispensed, that a substitution of the prescribed drug product has been made; and
>
> (2) the prescribing physician of the drug product substitution by telephone, facsimile, or mail, at the earliest reasonable time, but not later than 72 hours after dispensing the prescription.

Id. § 562.014.

The term "narrow therapeutic index drug" is not defined in the Texas Pharmacy Act or elsewhere in the laws of this state. A Federal Food and Drug Administration regulation indicates that a "narrow therapeutic index drug" is one that

> exhibit[s] a narrow therapeutic ratio, e.g., there is less than a 2-fold difference in median lethal dose . . . and median effective dose . . . values, or [has] less than a 2-fold difference in the minimum toxic concentrations and minimum effective concentrations in the blood, and safe and effective use of the drug product[] requires careful dosage titration and patient monitoring.

21 C.F.R. § 320.33(c) (2000). A brief from the Texas State Board of Medical Examiners explains that narrow therapeutic index drugs "are those medications where very small changes in the dosage level could cause toxic results in patients."[2]

Pursuant to section 562.014, the Board has adopted the following rule as a subpart to section 309.3 of title 22 of the Texas Administrative Code:

> (d) Refills.
>
> (1) Original substitution instructions. Refills shall follow the original substitution instructions unless otherwise indicated by the practitioner or practitioner's agent.
>
> (2) Narrow therapeutic index drugs.
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> (A) *The board, in consultation with the Texas State Board of Medical Examiners, has determined that no drugs shall be included on a list of narrow therapeutic index drugs* as defined in § 562.013 [sic], Occupations Code. The board has specified in § 309.7 of this title (relating to dispensing responsibilities) that pharmacist[s] shall use as a basis for determining generic equivalency, Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication.
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> (i) Pharmacists may only substitute products that are rated therapeutically equivalent in the Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements.

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[2]Brief from Ms. Michele L. Shackelford, General Counsel, Texas State Board of Medical Examiners, to Ms. Susan D. Gusky, Chair, Opinion Committee 1-2 (Nov. 16, 2000) (on file with Opinion Committee).

> (ii) Practitioners may prohibit substitution either by signing on the "Dispense as Written" line of a written prescription drug order or by clearly indicating on an oral prescription drug order that the brand name product must be dispensed.
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> (B) The board shall reconsider the contents of the list if the Federal Food and Drug Administration determines a new equivalence classification which indicates that certain drug products are equivalent but special notification to the patient and practitioner is required when substituting these products.

22 T.A.C. § 309.3(d) (2000) (emphasis added); *see also id.* § 309.7(b) ("Pharmacists shall utilize as a basis for the determination of generic equivalency as defined in the Act, . . . Approved Drug Products With Therapeutic Equivalence Evaluations and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication.").

In short, the Board has determined that there are no "narrow therapeutic index drugs" for which special rules should apply with respect to the use of generic substitutions in refills. As a result, the same rules that apply to the use of generic substitutions in the filling of an original prescription and refills generally apply to refills for narrow therapeutic index drugs. As with original prescriptions and all other refills, *see id.* §§ 309.3-.4, .7, pharmacists may substitute only products that are rated therapeutically equivalent in the Federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, *see id.* § 309.3(d)(2)(i), and practitioners may prohibit substitution either by signing on the "Dispense as Written" line of a written prescription drug order or by clearly indicating on an oral prescription drug order that the brand name product must be dispensed, *see id.* § 309.3(d)(2)(ii).

You ask whether the Board "has met the legislative mandate of § 562.014 of the Occupations Code to adopt a list of NIT drugs by its determination that no list is a list." Request Letter, *supra* note 1, at 2. We conclude that the Board's rule on narrow therapeutic index drugs satisfies the legislature's mandate and is therefore valid.

Your query suggests that the Board's determination that there are no therapeutic index drugs for which special refill rules should apply conflicts with section 562.014. In reviewing the rule, we are guided by the maxim that "an agency can adopt only such rules as are authorized by and consistent with its statutory authority." *Railroad Comm'n v. Arco Oil & Gas Co.*, 876 S.W.2d 473, 481 (Tex. App.–Austin 1994, writ denied). The critical factor in determining whether an administrative agency has exceeded its rule-making authority is whether the rule's provisions are in harmony with the general objectives of the statute involved. *Edgewood Indep. Sch. Dist. v. Meno*, 917 S.W.2d 717, 750 (Tex. 1995); *Railroad Comm'n v. Lone Star Gas Co.*, 844 S.W.2d 679, 685 (Tex. 1992). A court will uphold an agency rule if it is reasonable.

The Board's rule is not in conflict with section 562.014. Again, section 562.014 provides that, "[e]xcept as provided by this section, drug selection as authorized by this subchapter does not apply to the refill of a prescription for a narrow therapeutic index drug. The board, in consultation with the Texas State Board of Medical Examiners, shall by rule establish a list of narrow therapeutic index drugs to which this subsection applies." TEX. OCC. CODE ANN. § 562.014 (Vernon 2001). Section 562.014 imposes a mandatory duty on the Board to consult with the Board of Medical Examiners and to enact a rule, *see* TEX. GOV'T CODE ANN. § 311.016(2) (Vernon 1998) ("'Shall' imposes a duty."), which it has done. On its face, however, section 562.014 does not dictate the substance of the rule or necessarily preclude the Board from determining that there are no narrow therapeutic index drugs to which special refill rules should apply. Rather, the legislature has delegated the authority to develop a list of narrow therapeutic index drugs to the Board, and specified that it do so in consultation with the Board of Medical Examiners. In enacting this provision, the legislature intended the Board, using its expertise and the expertise of the Board of Medical Examiners, to exercise judgment and discretion in selecting drugs the refill of which should be subject to special treatment. We do not believe it is inconsistent with this delegation of authority for the Board to determine that there are no narrow therapeutic index drugs to which special refill rules should apply.

Furthermore, we believe that the rule is in harmony with the general objectives of section 562.014. The purpose of section 562.014 appears to be to protect patients from adverse health consequences from the substitution of generic drugs. It is clear from the face of the rule that the Board has determined that use of the Federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations and physicians' option to prohibit the use of generic substitutions adequately protect patients. *See* 22 T.A.C. § 309.3(d)(2)(i), (ii) (2000) (Tex. State Bd. of Pharm., Prescription Drug Orders). In addition, we note that the purpose of subchapter A is to encourage the use of generic drugs "to save consumers money." TEX. OCC. CODE ANN. § 562.002 (Vernon 2001). The Board rule is in harmony with the general objectives of section 562.014 and the overall purpose of subchapter A.

As to whether the rule is reasonable, we defer, as we believe a court would, to the Board and the State Board of Medical Examiners' expertise in making judgments in this highly technical area. *See generally State v. Public Util. Comm'n of Tex.*, 883 S.W.2d 190, 197 (Tex. 1994) ("When an administrative agency is created to centralize expertise in a certain regulatory area, it is to be given a large degree of latitude in the methods it uses to accomplish its regulatory function.").

In sum, the Board's rule is consistent with section 562.014 and is in harmony with both the general objectives of that statute and of subchapter A. We believe that a court would determine that the rule is reasonable. We conclude that the rule is a valid exercise of the Board's authority.

S U M M A R Y

A Texas State Board of Pharmacy rule, 22 T.A.C. § 309.3(d)(2) (2000) (Tex. State Bd. of Pharm., Prescription Drug Orders), which specifies that no drugs shall be included on a list of narrow therapeutic index drugs to which special refill rules should apply, is consistent with section 562.014 of the Texas Pharmacy Act, TEX. OCC. CODE ANN. § 562.014 (Vernon 2001).

Yours very truly,

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