



Toby Goodman
STATE REPRESENTATIVE
DISTRICT 93

RQ-0289-gc

P.O. Box 2910
Austin, Texas 78768-2910
512/463-0562
Fax: 512/475-1178

September 25, 2000

1600 E. Lamar Blvd.
Suite 115
Arlington, Texas 76011
817/460-8290
Fax: 817/861-2125

The Honorable John Cornyn
Attorney General of Texas
P.O. Box 12548
Austin, Texas 78711-2548

RECEIVED
OCT 03 2000
OPINIONS COMMITTEE

FILE # ML-41671-00
I.D. # 41671

RE: Request for Attorney General Opinion -- Does § 562.014 of the Occupations Code Require the Texas State Board of Pharmacy to Adopt a List of NTI Drugs?

Dear General Cornyn:

The 75th Legislature passed new Section 40(m) of the Pharmacy Act, which creates an exception to the general substitution law for refills of narrow therapeutic index ("NTI") drugs. Section 40(m), which has been codified as § 562.014 in the Occupations Code, requires that a prescription for an NTI 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 the 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 notifies the patient at the time the prescription is dispensed, and the prescribing physician within 72 hours. §562.014 (*Attachment 1*) reads as follows:

Except as provided by this subsection, drug product selection authorized in this section 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 establish, by rule, a list of narrow therapeutic index drugs that are subject to this subsection. 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. 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:

- (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 practitioner 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.
- (*Emphasis added*)

The Texas State Board of Pharmacy ("Board") recently adopted a rule, 22 TAC §309.3, in essence adopting no list. The rule states in pertinent part as follows:

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Chairman, Juvenile Justice and Family Issues
Civil Practices

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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, Occupations Code. The board has specified in § 309.7 of this title (relating to dispensing responsibilities) that pharmacist 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. (See Attachment 2.)

I respectfully request your opinion on whether the Board of Pharmacy has met the legislative mandate of § 562.014 of the Occupations Code to adopt a list of NTI drugs by its determination that no list is a list.

Sincerely,

Handwritten signature of Toby Goodman in black ink.

Toby Goodman, Chairman
Committee on Juvenile Justice and Family Issues

Enclosures