

SUBJECT: Restricting the substitution of transplant immunosuppressant drugs

COMMITTEE: Public Health — committee substitute recommended

VOTE: 9 ayes — Delisi, Laubenberg, Jackson, Cohen, Coleman, Gonzales,
S. King, Olivo, Truitt

0 nays

WITNESSES: For — (*Registered, but did not testify*: Dan Finch, Texas Medical Association; Carlos Higgins; Rita Littlefield, Texas Renal Coalition; Sister Michele O'Brien, Christus Santa Rosa; Laurie Reece, Texas Transplantation Society; Marolyn W. Stubblefield, National Kidney Foundation; Matthew T. Wall, Texas Hospital Association)

Against — (*Registered, but did not testify*: Bruce Lott, Generic Pharmaceutical Association; Karen Reagan, Texas Federation of Drug Stores; Susan Ross, Barr Labs; Brad Shields, Texas Society of Health System Pharmacists; Mark Vane, Gardere Wynne Sewell; Kristie Zamrazil, Texas Pharmacy Association)

On — Gay Dodson, Texas State Board of Pharmacy

BACKGROUND: Occupations Code, ch. 501 regulates health professions, including the licensing of pharmacies. Subch. A, ch. 562 sets forth prescription and substitution requirements. Secs. 562.008 - 562.013 allow a less expensive generically equivalent drug to be substituted for certain brand name drugs unless the physician certifies on the prescription form that a specific prescribed brand is medically necessary. Patients have the right to refuse the substitution.

Sec. 562.014 stipulates that drug selection authorization does not apply to refills of a prescription for a narrow therapeutic index of drugs. A prescription for a narrow therapeutic index drug may be refilled only by using the same drug by the same manufacturer that the pharmacist originally dispensed. If the drug is not in stock, the pharmacist may dispense a generically equivalent drug only if the pharmacist notifies the patient and the physician that a substitution has been made.

DIGEST:

CSHB 1443 would prohibit the interchange of an immunosuppressant drug or formulation of an immunosuppressant drug, brand or generic, for the treatment of a patient following a transplant without prior notification of and the signed, informed consent of the substitution from the prescribing physician.

Interchange would mean the substitution of one version of the same drug, including a generic version for the prescribed brand, a brand version for the prescribed generic version, or a generic version by one manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed drug or a different drug for the drug originally prescribed.

A pharmacist could secure the informed, written consent of the physician by telephone or electronically and would have to document the notification and consent as provided by the bill. The notification and consent would be considered a statement that the prescription was “brand medically necessary” and would be considered part of the prescription.

If the prescription were for an immunosuppressant drug prescribed for immunosuppressant therapy following a transplant, pharmacists would have to comply with the provisions of the bill.

The bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2007.

SUPPORTERS
SAY:

CSHB 1443 would provide additional patient protection for Texans who had undergone organ transplantation. It would not be designed to limit access to any drugs – generic or otherwise – and would aim to carry out the wishes of physicians in choosing the right medication for their patients. Several leading clinicians and organizations have done studies on the dangers to patients when immunosuppressant medications are substituted, including organ rejection or failure or serious life-threatening infections.

In 1999, the National Kidney Foundation (NKF) published a paper on the difference between generic and brand name drugs and the safe and effective use of generic immunosuppressant drugs in organ transplant recipients. Generic substitution is a key issue in transplantation because

transplant drugs are expensive and the consequences of poorly controlled immunosuppression are serious.

The Food and Drug Administration (FDA) considers generic medications to be equivalent to brand name medications only to a certain degree — called bioequivalence — which is acceptable for many medications. The NKF paper concluded that the bioequivalent criteria may be insufficient for critical-dose drugs and recommended that pharmacists notify the prescribing physician and patient whenever a critical-dose drug is dispensed in a different formulation and that substitution should not be made unless the physician has granted approval.

The bill would not impede the efficient delivery of patient care, but would guarantee safe and effective treatment. The successful treatment of transplant patients is determined by a team of specialists, including the doctor and the patient, and the proper medication is critical to the treatment and continued recovery of organ transplant patients. Claims that the bill would increase costs are overblown because the bill would allow interchanges, or substitutions of generic to generic, which current law does not address, brand-name to brand-name, brand-name to generic, and generic to brand-name. With only about 28,000 transplant patients in Texas over the last 20 years, the number of patients who would be affected by these provisions would not be large.

**OPPONENTS
SAY:**

Current law provides enough protection for transplant patients, and HB 1443 would be an unnecessary measure that would limit patient access to generic medication, increase costs to public programs, and possibly delay the delivery of patient care. Only generic drugs approved by the FDA as equivalent to brand-name drugs may be substituted, and practitioners and patients have the power to stop substitutions they do not want. Practitioners simply may write “brand medically necessary” on a prescription to prevent generic substitution in cases in which they want the brand-name drug or a generic drug by a specific manufacturer.

An FDA-approved, generically equivalent drug has undergone rigorous testing and can be expected to have the same clinical effect as the brand-name drug. A generic drug contains identical amounts of the same active ingredient as the brand-name product, and the degree of difference allowed by the FDA between a brand-name and a generic drug is the same degree of difference allowed between batches of brand-name drugs.

This bill would require pharmacists to obtain a signed, informed consent from the prescribing physician in order to substitute a drug when this could be avoided by the physician writing “brand necessary” on the prescription. The State Board of Pharmacy may sanction pharmacists who substitute drugs against the written direction on a prescription or consent of the patient.

The bill would prevent access to cost-effective care. Patients often request generic products to save on insurance co-pays, and many insurance companies will pay only for a generic product when it is available. Likewise, the cost to the state would rise every year because as Medicaid caseloads rise, as more patients were shifted to brand-name drugs, and as the costs of those drugs increases, cost to the state also would increase.

To date, no scientific evidence has been brought forth to prove there is a problem with generic immunosuppressant drugs. If there is a concern about these drugs, the Texas Board of Pharmacy has a process designed for designating drugs on a narrow therapeutic index or NTI list. Once a drug is on the NTI list, it is deemed so special that it cannot be substituted. If CSHB 1443 were enacted, it would circumvent this established process and would open the door for more drugs to be statutorily restricted by the Legislature.

The bill also is unclear about what would constitute “informed consent.” In normal circumstances, informed consent relates to the patient’s understanding of a medical treatment, but this bill would require a physician to give informed consent, when a written consent or documented verbal consent granted by the prescribing physician should be sufficient.

NOTES:

The original bill stipulated that a pharmacist could not dispense a immunosuppressant drug unless the drug was a specific formula and made by a specific manufacturer prescribed by the physician. The substitute added the procedures for a pharmacist to document the notification and consent of a physician regarding the substitution as well as that such notification and consent would be considered a statement that the prescription was “brand medically necessary.” The substitute also changed the effective date to upon passage or September 1, 2007.

According to the Legislative Budget Board, there could be a fiscal impact to the Medicaid program if a significant number of prescriptions for

immunosuppressive drugs following transplant that were previously filled as generic were filled as brand name. The cost to convert all generic prescriptions for drugs filled in the Medicaid program in fiscal 2006 to brand name prescriptions would be an estimated \$1.5 million in general revenue. If some of the drugs were for diagnoses unrelated to transplants, they still could be filled as generic, in which case the fiscal impact would not be as significant.

The companion bill, SB 625 by Janek, passed the Senate on April 12 on the Local and Uncontested Calendar and was reported favorably, without amendment, by the House Public Health Committee on April 23, making it eligible to be considered in lieu of HB 1443.