By: Deshotel H.B. No. 2046

A BILL TO BE ENTITLED

AN ACT

relating to a prescription drug cost control education program and disclosure of certain expenditures by prescription drug manufacturers.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle H, Title 2, Health and Safety Code, is amended by adding Chapter 168 to read as follows:

CHAPTER 168. PRESCRIPTION DRUGS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 168.001. DEFINITIONS. In this chapter:

(1) "Clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.

(2) "Pharmaceutical manufacturing company" means a person that produces, prepares, propagates, compounds, converts, or processes prescription drugs, either directly or indirectly, by extraction from substances of natural origin, by chemical synthesis, or by a combination of extraction and chemical synthesis, or packages, repackages, labels, relabels, or distributes prescription drugs. The term does not include a wholesale drug distributor or a pharmacist.

(3) "Pharmaceutical representative" means a person who is employed by or under contract to represent a pharmaceutical

manufacturing company, and who engages in pharmaceutical detailing, promotional activity, or other marketing of prescription drugs in this state to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or other person authorized to prescribe or dispense prescription drugs. The term does not include a wholesale prescription drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.

Sec. 168.002. RULES. The board, in consultation with the Texas State Board of Pharmacy, shall adopt the rules necessary to implement this chapter.

[Sections 168.003–168.050 reserved for expansion]

SUBCHAPTER B. PHARMACEUTICAL MANUFACTURING COMPANIES

Sec. 168.051. ANNUAL REPORT. (a) A pharmaceutical manufacturing company doing business in this state shall submit an annual report to the department and the Texas State Board of Pharmacy that discloses the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit received in connection with detailing, promotional, or other marketing activities of the company, directly or through its representatives, by a physician, hospital, nursing home, pharmacist, pharmacy, health benefit plan administrator, or other person authorized to prescribe or dispense prescription drugs in this state.

(b) The annual report must be on the form and submitted in the manner prescribed by the Texas State Board of Pharmacy. The form must allow a company to identify trade secret information.

(c) A pharmaceutical manufacturing company annually shall disclose to the Texas State Board of Pharmacy and to the department the name and address of the individual responsible for the company's compliance with this section.

Sec. 168.052. CONFIDENTIALITY. (a) Information identified as trade secret information under Section 168.051(b) is confidential and exempt from disclosure under Chapter 552, Government Code.

(b) Information relating to the following economic benefits is confidential and exempt from disclosure under Chapter 552, Government Code:

(1) free samples of prescription drugs intended for distribution to patients;

(2) payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials;

(3) a gift, payment, fee, subsidy, or other economic benefit valued at less than $25; and

(4) a scholarship or other support for a medical student, resident, or fellow to attend a significant educational, scientific, or policy-making conference of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(c) Except as provided by Subsection (a) or (b), information provided in an annual report is public information and available for inspection on request.

Sec. 168.053. DEPARTMENT DISCLOSURE OF REPORT. Except as provided by Section 168.052, the department shall review and make available to the public on request an annual report submitted under Section 168.051.

Sec. 168.054. VIOLATION: INJUNCTION OR CIVIL PENALTY. (a) The attorney general may bring an action:

(1) for injunctive relief to compel a person to file an annual report required under this subchapter; and

(2) to impose a civil penalty of not more than $10,000 for a failure to file an annual report required under this subchapter.

(b) The court may award to the attorney general reasonable court costs and attorney's fees in connection with an action brought under Subsection (a).

(c) Each failure to file an annual report constitutes a separate violation.

[Sections 168.055–168.100 reserved for expansion]

SUBCHAPTER C. PRESCRIPTION DRUG COST CONTROL EDUCATION PROGRAM

Sec. 168.101. ESTABLISHMENT. (a) The department shall establish, promote, and maintain a prescription drug cost control education program that:

(1) provides independent information and education on the therapeutic and cost-effective use of prescription drugs; and

(2) does not compromise the quality of care of physicians, pharmacists, and health care providers authorized to prescribe or dispense prescription drugs.

(b) The department shall develop and provide independent

informational materials related to:

(1) the therapeutic and cost-effective use of prescription drugs by patients;

(2) the fiscal impact of prescribing expensive and nationally advertised drugs; and

(3) the relative costs and benefits of a variety of prescription drugs, with an emphasis on:

(A) substituting generic prescription drugs for brand name prescription drugs when available and appropriate;

(B) prescribing established, less costly drugs instead of newer, more expensive prescription drugs when available and appropriate;

(C) prescribing lower dosages of prescription drugs when available and appropriate; and

(D) providing information about potentially harmful drug combinations, drug recalls, and drug studies.

Sec. 168.102. IMPLEMENTATION. The department shall:

(1) provide sufficient staff to implement the program;

(2) provide appropriate training for program staff;

(3) identify the appropriate persons to carry out the program;

(4) base the program on the most up-to-date information and findings; and

(5) identify and, when appropriate, replicate or use successful prescription drug cost control education programs and obtain related materials and services from organizations with appropriate expertise and knowledge of therapeutic and

cost-effective use of prescription drugs without compromising the quality of care.

Sec. 168.103. PROFESSIONAL EDUCATION. The department shall use the following strategies to educate physicians and health professionals and training community service providers on the most up-to-date and accurate scientific and medical information concerning the therapeutic and cost-effective use of prescription drugs without compromising quality:

(1) identify and obtain education materials for the professional that translates the latest scientific and medical information into clinical applications;

(2) raise awareness among physicians and health and human services professionals as to the importance of prescribing a cost-effective prescription drug without sacrificing quality of care; and

(3) conduct a statewide conference on therapeutic and cost-effective use of prescription drugs without compromising quality of care at appropriate intervals.

Sec. 168.104. GRANTS AND GIFTS. The department may accept grants of money, services, or property from the federal government, a foundation, organization, medical school, or other person to implement this subchapter.

SECTION 2. (a) The Texas State Board of Pharmacy shall develop the form required by Section 168.051, Health and Safety Code, as added by this Act, not later than October 1, 2003.

(b) The Texas Board of Health shall adopt the rules required and establish the education program required by Chapter 168, Health

and Safety Code, as added by this Act, not later than March 1, 2004.

(c) Notwithstanding Section 168.051, Health and Safety Code, as added by this Act, a pharmaceutical manufacturing company is not required to submit the annual report required by that section before June 30, 2004.

SECTION 3. This Act takes effect September 1, 2003.