

By: Ellis

S.B. No. 151

A BILL TO BE ENTITLED

AN ACT

relating to the disclosure of certain expenditures by prescription drug manufacturers; imposing a penalty.

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 173 to read as follows:

CHAPTER 173. PRESCRIPTION DRUG MARKETING

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 173.001. 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) "Department" means the Department of State Health Services.

(3) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

(4) "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

1 wholesale drug distributor or a pharmacist.

2 (5) "Pharmaceutical representative" means a person
3 who is employed by or under contract to represent a pharmaceutical
4 manufacturing company and who engages in pharmaceutical detailing,
5 promotional activity, or other marketing of prescription drugs in
6 this state to a physician, hospital, nursing home, pharmacist,
7 health benefit plan administrator, or other person authorized to
8 prescribe or dispense prescription drugs. The term does not include
9 a wholesale prescription drug distributor or the distributor's
10 representative who promotes or otherwise markets the services of
11 the wholesale drug distributor in connection with a prescription
12 drug.

13 Sec. 173.002. RULES. The executive commissioner, in
14 consultation with the Texas State Board of Pharmacy, shall adopt
15 the rules necessary to implement this chapter.

16 [Sections 173.003–173.050 reserved for expansion]

17 SUBCHAPTER B. PHARMACEUTICAL MANUFACTURING COMPANIES

18 Sec. 173.051. ANNUAL REPORT. (a) A pharmaceutical
19 manufacturing company doing business in this state shall submit an
20 annual report to the department and the Texas State Board of
21 Pharmacy that discloses:

22 (1) the value, nature, and purpose of any gift, fee,
23 payment, subsidy, or other economic benefit received in connection
24 with detailing, promotional, or other marketing activities of the
25 company, directly or through its representatives, by a physician,
26 hospital, nursing home, pharmacist, pharmacy, health benefit plan
27 administrator, or other person authorized to prescribe or dispense

1 prescription drugs in this state; and

2 (2) the name and address of each gift recipient.

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

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

10 Sec. 173.052. CONFIDENTIALITY. (a) Information identified
11 as trade secret information under Section 173.051(b) is
12 confidential and exempt from disclosure under Chapter 552,
13 Government Code.

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

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

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

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

24 (4) a scholarship or other support for a medical
25 student, resident, or fellow to attend a significant educational,
26 scientific, or policy-making conference of a national, regional, or
27 specialty medical or other professional association if the

1 recipient of the scholarship or other support is selected by the
2 association.

3 (c) Except as provided by Subsection (a) or (b), information
4 provided in an annual report is public information.

5 Sec. 173.053. DEPARTMENT DISCLOSURE OF REPORT. (a) Except
6 as provided by Section 173.052, the department shall review and
7 make available to the public an annual report submitted under
8 Section 173.051.

9 (b) The department shall publish the annual report on the
10 department's website and shall make printed copies of the report
11 available on request.

12 Sec. 173.054. VIOLATION: INJUNCTION OR CIVIL PENALTY. (a)
13 The attorney general may bring an action:

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

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

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

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

24 SECTION 2. (a) The Texas State Board of Pharmacy shall
25 develop the form required by Section 173.051, Health and Safety
26 Code, as added by this Act, not later than October 1, 2009.

27 (b) Notwithstanding Section 173.051, Health and Safety

1 Code, as added by this Act, a pharmaceutical manufacturing company
2 is not required to submit the annual report required by that section
3 before June 30, 2010.

4 SECTION 3. This Act takes effect September 1, 2009.