LEGISLATURE OF NEBRASKA

ONE HUNDREDTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 675

Introduced by Lathrop, 12

Read first time January 17, 2007

Committee: Health and Human Services

A BILL

FOR AN ACT relating to pharmaceutical manufacturing companies; to require certain disclosures; to provide for enforcement; and to provide powers and duties.

Be it enacted by the people of the State of Nebraska,

Section 1. (1) For purposes of this section:

(a) Approved clinical trial means a clinical trial that has been approved by the United States Food and Drug Administration or has been approved by a duly constituted Institutional Review Board after reviewing and evaluating it in accordance with the human subject protection standards set forth in 21 C.F.R. Part 50 or 45 C.F.R. Part 46, as such parts existed on the effective date of this act, or an equivalent set of standards of another federal agency;

(b) Bona fide clinical trial means an approved clinical trial that constitutes research as that term is defined in 45 C.F.R. 46.102, as such section existed on the effective date of this act, when the results of the research can be published freely by the investigator and reasonably can be considered to be of interest to scientists or medical practitioners working in the particular field of inquiry;

(c) Clinical trial means any study assessing the safety or efficacy of drugs administered alone or in combination with other drugs or other therapies or any study assessing the relative safety or efficacy of drugs in comparison with other drugs or other therapies;

(d) Pharmaceutical manufacturing company means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of

natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. Pharmaceutical manufacturing company does not include a wholesale drug distributor or pharmacist licensed under the Uniform Licensing Law or the Wholesale Drug Distributor Licensing Act;

(e) Pharmaceutical marketer means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. Pharmaceutical marketer does not include a wholesale 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; and

(f) Unrestricted grant means any gift, payment, subsidy, or other economic benefit to an educational institution, professional association, health care facility, or governmental entity which does not impose any restrictions on the use of the grant, such as favorable treatment of a certain product or an ability of the marketer to control or influence the planning, content, or execution of the education activity.

(2)(a) Annually on or before December 1 of each year, every pharmaceutical manufacturing company shall disclose to the chief administrative officer for the Nebraska Health and Human Services System the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in Nebraska authorized to prescribe, dispense, or purchase prescription drugs in this state. Disclosure shall include the name of the recipient. Disclosure shall be made on a form and in a manner prescribed by the chief administrative officer and shall require pharmaceutical manufacturing companies to report the value, nature, and purpose of all gift expenditures according to specific categories. The chief administrative officer shall report annually on the disclosures made under this section to the Legislature and the Governor on or before April 1.

(b) Annually on October 1, each pharmaceutical manufacturing company shall also disclose to the chief administrative officer the name and address of the individual responsible for the company's compliance with this section or, if this information has been previously reported, any changes to the name or address of the individual responsible for the company's compliance with this section.

(3) The chief administrative officer shall keep confidential all trade secrets as defined in section 87-502. The disclosure form shall permit the company to identify any information that it claims is a trade secret. In the event that the chief administrative officer receives a request for any information designated as a trade secret, the chief administrative officer shall promptly notify the company of such request. Within thirty days after such notification, the company shall respond to the requester and the chief administrative officer by either consenting to the release of the requested information or by certifying in writing the reasons for its claim that the information is a trade secret. Any requester aggrieved by the company's response may apply to the district court of Lancaster County for a declaration that the company's claim of trade secret is invalid. The chief administrative officer shall not be made a party to the district court proceeding. Prior to and during the pendency of the district court proceeding, the chief administrative officer shall keep confidential the information that has been claimed as a trade secret, except that the chief administrative officer may provide the requested information to the court under seal.

(4) The following shall be exempt from disclosure under this section:

(a) Free samples of prescription drugs intended to be distributed to patients;

(b) The payment of reasonable compensation and

reimbursement of expenses in connection with bona fide clinical trials;

(c) Any gift, fee, payment, subsidy, or other economic benefit the value of which is less than twenty-five dollars;

(d) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policymaking 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;

(e) Unrestricted grants for continuing medical education programs; and

(f) Prescription drug rebates and discounts.

(5) The Attorney General may bring an action in the district court of Lancaster County for injunctive relief, costs, and attorney's fees and to impose on a pharmaceutical manufacturing company that fails to disclose as required by this section a civil penalty of no more than ten thousand dollars per violation. Each unlawful failure to disclose shall constitute a separate violation.