Session of 2008

HOUSE BILL No. 2914

By Committee on Federal and State Affairs

2-15

AN ACT concerning pharmaceutical manufacturing companies; relating to disclosure of gifts, payments and other economic benefits; amending K.S.A. 46-253, 46-254, 46-289, 46-290, 46-291 and 46-292 and K.S.A. 2007 Supp. 46-288 and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

New Section 1. Sections 1 through 7, and amendments thereto, shall be known and may be cited as the pharmaceutical manufacturing company disclosure act.

New Sec. 2. As used in this act:

(a) "Act" means the pharmaceutical manufacturing company disclosure act.

(b) "Approved clinical trial" means a clinical trial that has been approved by the United States food and drug administration (FDA) or has been approved by a duly constituted institutional review board (IRB) after reviewing and evaluating it in accordance with the human subject protection standards set forth in 21 C.F.R. Part 50, 45 C.F.R. Part 46 or an equivalent set of standards of another federal agency.

(c) "Bona fide clinical trial" means an approved clinical trial that constitutes "research" as that term is defined in 45 C.F.R. §46.102 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.

(d) "Clinical trial" means any study assessing the safety or efficacy of drugs administered alone or in combination with other drugs or other therapies, or assessing the relative safety or efficacy of drugs in comparison with other drugs or other therapies.

(e) "Commission" means the governmental ethics commission created in K.S.A. 25-4119a, and amendments thereto.

(f) "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.

The term does not include a wholesale drug distributor or such distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.

(g) "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 in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs. The term does not include a wholesale drug distributor or pharmacist licensed under K.S.A. 65-1625 et seq., and amendments thereto.

(h) "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 educational activity.

New Sec. 3. (a) Annually, every pharmaceutical manufacturing company doing business in Kansas shall register with the secretary of state by completing and signing a registration form prescribed and provided by the commission. Such registration shall show the name and address of the pharmaceutical manufacturing company and the name and address of its pharmaceutical marketers in Kansas.

(b) On or after October 1 in any year, a pharmaceutical manufacturing company may register under this section for the succeeding year. Such registration shall expire annually on December 31, of the year such pharmaceutical manufacturing company is registered. In any calendar year, before engaging 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 manufacturing companies to which this section applies shall register or renew their registrations as provided in this section. Every pharmaceutical manufacturing company shall pay a registration fee to the secretary of state of an amount set by the secretary of state not to exceed $100 for such company and $35 for each of its pharmaceutical marketers. The secretary of state shall remit all moneys received under this section to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon the receipt of each remittance, the state treasurer shall deposit the entire amount in the state treasury to the credit of the governmental ethics commission fee fund.

(c) Any person who has been registered as a pharmaceutical marketer

by a pharmaceutical manufacturing company may file with the secretary of state, upon termination of such person's activities, a statement terminating such person's registration as a pharmaceutical marketer. Such statement shall be on a form prescribed by the commission and shall state the name and address of such marketer, the name and address of the pharmaceutical manufacturing company such person was registered under and the date of termination of the pharmaceutical marketer's marketing activities.

(d) No pharmaceutical manufacturing company which has failed or refused to pay a civil penalty imposed pursuant to section 6, and amendments thereto, shall be authorized or permitted to register as a pharmaceutical manufacturing company in accordance with this section until such penalty has been paid.

New Sec. 4. The secretary of state shall maintain alphabetical listings of all pharmaceutical manufacturing companies and their pharmaceutical marketers. Such listing shall be supplemented by indices alphabetically listing the pharmaceutical marketers and relevant information as to each marketer. All registration papers and reports made under sections 3 and 5, and amendments thereto, shall be open to public inspection at all reasonable times. The listings and supplemental indices provided for by this section shall be maintained current at all times and from time to time each year shall be printed, published and distributed by the secretary of state.

New Sec. 5. (a) Annually, on or before December 1, every registered pharmaceutical manufacturing company shall file a disclosure report with the secretary of state disclosing 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 pharmaceutical manufacturing company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator or any person in Kansas authorized to prescribe, dispense or purchase prescription drugs in this state.

(b) The disclosure report required under subsection (a) shall include the name of the recipient and shall be made on a form and in a manner prescribed by the secretary of state. In such disclosure report pharmaceutical manufacturing companies shall report the value, nature and purpose of all gift expenditures according to specific categories. Annually, on or before March 1, the secretary of state shall report to the legislature and governor the disclosures made under this section.

(c) Annually, on or before October 1, each pharmaceutical manufacturing company subject to the provisions of the pharmaceutical manufacturing company disclosure act shall disclose to the secretary of state, the name and address of the individual responsible for the company's com-

pliance with the provisions of this act, 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 the provisions of this act.

(d) The following shall be exempt from disclosure:

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

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

(3) any gift, fee, payment, subsidy or other economic benefit with a value of less than $25;

(4) scholarship or other support for medical students, residents and fellows 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; and

(5) prescription drug rebates and discounts.

(e) Disclosure of grants for continuing medical education programs shall be limited to the value, nature and purpose of the grant and the name of the grantee. It shall not include disclosure of the individual participants in such programs.

New Sec. 6. (a) The commission shall send a notice by registered or certified mail to any pharmaceutical manufacturing company failing to register or to file any report or statement as required by section 3 or 5, and amendments thereto, within the time period prescribed therefor. The notice shall state that the required registration, report or statement has not been filed with the office of secretary of state. The notice also shall state that such pharmaceutical manufacturing company has five days from the date of receipt of such notice to comply with the registration and reporting requirements before a civil penalty is imposed for each day that the required documents remain unfiled. If such pharmaceutical manufacturing company fails to comply within such period, such pharmaceutical manufacturing company shall pay to the state a civil penalty of $10 per day for each day that such pharmaceutical manufacturing company remains unregistered or that such report or statement remains unfiled, except that no such civil penalty shall exceed $300. The commission may waive, for good cause, payment of any civil penalty imposed under this section.

(b) Whenever the commission determines that any report or statement filed by a pharmaceutical manufacturing company as required by section 3 or 5, and amendments thereto, is incorrect, incomplete or fails to provide the information required by such section, the commission shall notify such pharmaceutical manufacturing company by registered or certified mail, specifying the deficiency. The notice shall state that the phar-

maceutical manufacturing company has 30 days from the date of the receipt of such notice to file an amended report correcting such deficiency before a civil penalty is imposed and the registration of such pharmaceutical manufacturing company and its pharmaceutical marketers is revoked. A copy of such notice shall be sent to the office of the secretary of state. If such pharmaceutical manufacturing company fails to file an amended report within the time specified, such pharmaceutical manufacturing company shall pay to the commission a civil penalty of $10 per day for each day that such pharmaceutical manufacturing company fails to file such report or statement except that no such civil penalty shall exceed $300. On the 31st day following the receipt of such notice, the registration of any pharmaceutical manufacturing company and its pharmaceutical marketers failing to file such amended report shall be revoked.

(c) Civil penalties provided for by this section shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount in the state treasury to the credit of the governmental ethics commission fee fund.

(d) (1) Except as provided in subsection (d)(2), if a pharmaceutical manufacturing company fails to pay a civil penalty provided for by this section, it shall be the duty of the commission to bring an action to recover such civil penalty in the district court of the county where such company's primary place of business is located or headquartered or where one of its pharmaceutical marketers resides.

(2) If a pharmaceutical manufacturing company required to file under section 3, and amendments thereto, fails to pay a civil penalty provided for by this section, it shall be the duty of the commission to bring an action to recover such civil penalty in the district court of Shawnee County, Kansas.

(e) Notices sent under this section are part of the public record.

New Sec. 7. The commission is hereby authorized to administer the provisions of sections 1 through 6, and amendments thereto, and to exercise the authority and powers granted to it under the provisions of the state governmental ethics law in administering the provisions of the pharmaceutical manufacturing company disclosure act.

Sec. 8. K.S.A. 46-253 is hereby amended to read as follows: 46-253. "Commission" as used in ~~K.S.A. 46-215 to 46-280, inclusive, 46-248a and K.S.A. 46-237a, and amendments thereto,~~ *the state governmental ethics law and the pharmaceutical manufacturing company disclosure act* means the governmental ethics commission. The commission may adopt rules and regulations for the administration of the provisions of ~~K.S.A. 46-215 to 46-280, 46-248a and K.S.A. 46-237a, and amendments thereto~~ *the state governmental ethics law and the pharmaceutical manufacturing company*

disclosure act. Any rules and regulations adopted by the Kansas commission on governmental standards and conduct shall continue in force and effect and shall be deemed to be the rules and regulations of the commission until revised, amended, repealed or nullified pursuant to law. All rules and regulations of the commission shall be subject to the provisions of article 4 of chapter 77 of Kansas Statutes Annotated.

Sec. 9. K.S.A. 46-254 is hereby amended to read as follows: 46-254. The commission upon its own initiative may, and upon the request of any individual to which ~~this act applies~~ *the state governmental ethics law and the pharmaceutical manufacturing company disclosure act apply*, shall render an opinion in writing on questions concerning the interpretation of ~~this act~~ *the state governmental ethics law or the pharmaceutical manufacturing company disclosure act*. Any person who acts in accordance with the provisions of such an opinion, shall be presumed to have complied with the provisions of this act. A copy of every opinion rendered by the commission shall be filed with the secretary of state, and any opinion so filed shall be open to public inspection. The secretary of state shall publish all opinions rendered under this section monthly and each such publication shall be cumulative. Copies of each opinion shall be filed with the secretary of the senate and the chief clerk of the house on the same date as the same are filed with the secretary of state. The secretary of state shall cause adequate copies of all filings under this section to be supplied to the state library.

Sec. 10. K.S.A. 2007 Supp. 46-288 is hereby amended to read as follows: 46-288. The commission, in addition to any other penalty prescribed under ~~K.S.A. 46-215 through 46-286, and amendments thereto,~~ *the state governmental ethics law or the pharmaceutical manufacturing company disclosure act,* may assess a civil fine, after proper notice and an opportunity to be heard, against any person for a violation pursuant to ~~K.S.A. 46-215 through 46-286, and amendments thereto,~~ *the state governmental ethics law, or the pharmaceutical manufacturing company disclosure act* in an amount not to exceed $5,000 for the first violation, not to exceed $10,000 for the second violation and not to exceed $15,000 for the third violation and for each subsequent violation. All fines assessed and collected under this section shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount in the state treasury to the credit of the governmental ethics commission fee fund.

Sec. 11. K.S.A. 46-289 is hereby amended to read as follows: 46-289. (a) If the commission determines after notice and opportunity for a hearing that any person has engaged or is engaging in any act or practice constituting a violation of any provision of ~~K.S.A. 46-215 through 46-286,~~

~~and amendments thereto,~~ *the state governmental ethics law or the pharmaceutical manufacturing company disclosure act* or any rule and regulation or order ~~hereunder~~ *thereunder*, the commission by order may require that such person *or pharmaceutical manufacturing company* cease and desist from the unlawful act or practice and take such affirmative action as in the judgment of the commission will carry out the purposes of ~~K.S.A. 46-215 through 46-286, and amendments thereto,~~ *the state governmental ethics law or the pharmaceutical manufacturing company disclosure act, as the case may be*.

(b) If the commission makes written findings of fact that the public interest will be irreparably harmed by delay in issuing an order under subsection (a), the commission may issue an emergency temporary cease and desist order. Such order, even when not an order within the meaning of K.S.A. 77-502 and amendments thereto, shall be subject to the same procedures as an emergency order issued under K.S.A. 77-536 and amendments thereto. Upon the entry of such an order, the commission shall promptly notify the person *or pharmaceutical manufacturing company* subject to the order that it has been entered, of the reasons therefor and that upon written request the matter will be set for a hearing which shall be conducted in accordance with the provisions of the Kansas administrative procedure act. If no hearing is requested and none is ordered by the commission, the order will remain in effect until it is modified or vacated by the commission. If a hearing is requested or ordered, the commission, after notice of and opportunity for hearing to the person *or pharmaceutical manufacturing company* subject to the order, shall by written findings of fact and conclusions of law vacate, modify or make permanent the order. Any such order shall be enforceable in any court of competent jurisdiction.

Sec. 12. K.S.A. 46-290 is hereby amended to read as follows: 46-290. Whenever it appears to the commission that any person *or pharmaceutical manufacturing company* has engaged in any act or practice constituting a violation of any provision of ~~K.S.A. 46-215 through 46-286, and amendments thereto,~~ *the state governmental ethics law or the pharmaceutical manufacturing company disclosure act* or any rule and regulation or order ~~hereunder~~ *thereunder*, the commission may bring an action in any court of competent jurisdiction to enjoin the acts or practices and to enforce compliance with ~~K.S.A. 46-215 through 46-286, and amendments thereto,~~ *the state governmental ethics law or the pharmaceutical manufacturing company disclosure act* or any rule and regulation or order ~~hereunder~~ *thereunder*. Upon a proper showing, a permanent or temporary injunction, restraining order, restitution, writ of mandamus or other equitable relief shall be granted.

Sec. 13. K.S.A. 46-291 is hereby amended to read as follows: 46-291.

The commission may enter into a consent decree with any person who has violated any provision of ~~K.S.A. 46-215 through 46-286, and amendments thereto,~~ *the state governmental ethics law or the pharmaceutical manufacturing company disclosure act*.

Sec. 14. K.S.A. 46-292 is hereby amended to read as follows: 46-292. Any person *or pharmaceutical manufacturing company* aggrieved by any order of the commission pursuant to ~~this act~~ *the state governmental ethics law or the pharmaceutical manufacturing company disclosure act* may appeal such order in accordance with the provisions of the act for judicial review and civil enforcement of agency actions.

Sec. 15. K.S.A. 46-253, 46-254, 46-289, 46-290, 46-291 and 46-292 and K.S.A. 2007 Supp. 46-288 are hereby repealed.

Sec. 16. This act shall take effect and be in force from and after its publication in the statute book.