As Introduced

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Representative Skindell

Cosponsors: Representatives Stewart, D., Foley, Koziura, Ujvagi, Strahorn, Lundy, Hagan, R., Bolon, Brady, Beatty

A B I L L

To amend section 3715.99 and to enact sections 3715.88, 3715.89, and 3715.90 of the Revised Code to require manufacturers and labelers of dangerous drugs to disclose to the Director of Health the value, nature, and purpose of certain gifts, fees, payments, subsidies, and other economic benefits they provide in connection with pharmaceutical detailing, marketing, or promotion.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That section 3715.99 be amended and sections 3715.88, 3715.89, and 3715.90 of the Revised Code be enacted to read as follows:

Sec. 3715.88. (A) As used in this section and section 3715.89 of the Revised Code:

(1) "Detailing" means the marketing or promotion of dangerous drugs by or on behalf of a manufacturer or labeler.

(2) "Labeler" means a person to whom both of the following apply:

(a) The person receives dangerous drugs from a manufacturer or wholesaler and repackages them for retail sale.

(b) The person has a labeler code from the United States food and drug administration under 21 C.F.R. 207.20.

(3) "Marketer" means a person who, while employed by or under contract to represent a manufacturer or labeler, engages in pharmaceutical detailing or other marketing or promotion of dangerous drugs.

(4) "Sample drug" has the same meaning as in section 2925.01 of the Revised Code.

(5) "Wholesaler" means a person who, on official written orders other than prescriptions, supplies dangerous drugs that the person has not manufactured, produced, or prepared personally and includes a "wholesale distributor of dangerous drugs" as defined in section 4729.01 of the Revised Code.

(B) On or before the first day of January of each year, each manufacturer and labeler that sells dangerous drugs shall disclose to the director of health the name and address of the individual responsible for the manufacturer's or labeler's compliance with this section.

(C) Subject to division (E) of this section, no manufacturer or labeler that sells dangerous drugs shall fail, on or before the first day of February of each year, to disclose to the director the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotion, or other marketing activities by the manufacturer or labeler, directly or through a marketer, to any licensed health professional authorized to prescribe drugs, hospital, nursing home, residential care facility, adult care facility, pharmacist, or health plan administrator. Disclosure shall cover the prior calendar year and be made on a form and in a manner prescribed by

the director in rules adopted under section 3715.89 of the Revised Code. No manufacturer or labeler shall fail to comply with this division.

(D) On or before the first day of June of each year, the director shall submit to the governor and members of the general assembly a report summarizing the disclosures made in that year under this section.

(E) All of the following are exempt from disclosure under this section:

(1) Any gift, fee, payment, subsidy, or other economic benefit the value of which does not exceed twenty-five dollars;

(2) Sample drugs that are given with the intent that they be distributed to patients;

(3) The payment of reasonable compensation and reimbursement of expenses in connection with a bona fide 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;

(4) Scholarship or other support for medical students, residents, and fellows to attend bona fide educational, scientific, or policy-making conferences of an established professional association if the recipient of the scholarship or other support is selected by the association.

Sec. 3715.89. The director of health shall adopt rules under Chapter 119. of the Revised Code to do both of the following:

(A) Prescribe the form and manner in which each manufacturer and labeler is to make the disclosures required by division (C) of section 3715.88 of the Revised Code;

(B) Define the terms "bona fide clinical trial" and "bona fide educational, scientific, or policy-making conference" for

purposes of divisions (E)(3) and (4) of section 3715.88 of the Revised Code.

Sec. 3715.90. In addition to the penalty prescribed by section 3715.99 of the Revised Code, whoever violates section 3715.88 of the Revised Code may be subject to an action by the attorney general in the Franklin county court of common pleas for injunctive relief. The court may issue an injunction and also may award costs and attorney's fees associated with the action.

Sec. 3715.99. (A) Whoever violates sections 3715.13 to 3715.19, or 3715.38 of the Revised Code is guilty of a minor misdemeanor.

(B) Whoever violates section 3715.22, 3715.25, 3715.27, or 3715.34 of the Revised Code is guilty of a misdemeanor of the fourth degree.

(C) Whoever violates section 3715.23 or 3715.36 of the Revised Code is guilty of a misdemeanor of the second degree.

(D) Whoever violates section 3715.52 or 3715.65 of the Revised Code is guilty of a misdemeanor of the fourth degree on a first offense; on each subsequent offense, the person is guilty of a misdemeanor of the second degree.

(E) Whoever violates section 3715.521 of the Revised Code is guilty of a minor misdemeanor. A violation of that section occurs on a daily basis, not according to the number of times per day that an expired drug, baby food, or infant formula is sold, offered for sale, or delivered at retail or to the consumer. Each day of violation is a separate offense.

(F) Whoever violates division (C) of section 3715.88 of the Revised Code shall be fined not more than ten thousand dollars per violation. Each unlawful failure to disclose under that section constitutes a separate violation.

Section 2. That existing section 3715.99 of the Revised Code is hereby repealed.