As Introduced

130th General Assembly
Regular Session **S. B. No. 91**
2013-2014

Senator Skindell

Cosponsor: Senator Tavares

A B I L L

To amend section 3715.99 and to enact section 3715.93 of the Revised Code regarding prescription drug marketing disclosures.

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

Section 1. That section 3715.99 be amended and section 3715.93 of the Revised Code be enacted to read as follows:

Sec. 3715.93. (A) As used in this section:

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

(2) On or before the first day of February of each year, each manufacturer or labeler that sells dangerous drugs shall submit to the director a report that discloses, except as provided in division (E) of this section, 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 benefit plan administrator. The report shall cover the prior calendar year and be made on a form and in a manner prescribed by the director in rules adopted under this section. When submitting the report, the manufacturer or labeler shall pay a fee in an amount and in a manner prescribed by the director in rules adopted under this section.

(C) No manufacturer or labeler shall fail to make a disclosure in the report required by division (B)(2) of this section with respect to a particular licensed health professional authorized to prescribe drugs, hospital, nursing home, residential

care facility, adult care facility, pharmacist, or health benefit plan administrator that is provided a gift, fee, payment, subsidy, or other economic benefit in connection with detailing, promotion, or other marketing activities.

(D) On or before the first day of June of each year, the director shall submit a report to the governor and, in accordance with section 101.68 of the Revised Code, the general assembly. The report shall summarize the reports received in that year under division (B)(2) of 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) Scholarships 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 recipients of the scholarships or other support are selected by the association.

(F) The director shall adopt rules in accordance with Chapter 119. of the Revised Code to do all of the following:

(1) Prescribe the form and manner in which each manufacturer and labeler is to make the report required by division (B)(2) of this section;

(2) Prescribe the amount and manner in which each manufacturer and labeler is to pay the fee required by division (B)(2) of this section;

(3) 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 this section.

(G) In addition to the penalty prescribed by section 3715.99 of the Revised Code, whoever violates division (C) of this section 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 3715.93 of the Revised Code shall be fined not more than ten thousand dollars. Each violation is a separate offense.

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