

As Introduced

128th General Assembly
Regular Session
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H. B. No. 94

Representative Skindell

Cosponsors: Representatives Foley, Patten, Harris, Williams, S., Hagan,
Murray, Stewart, Domenick, Koziura

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A BILL

To amend section 3715.99 and to enact section 3715.93 1
of the Revised Code regarding prescription drug 2
marketing disclosures. 3

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

Section 1. That section 3715.99 be amended and section 4
3715.93 of the Revised Code be enacted to read as follows: 5

Sec. 3715.93. (A) As used in this section: 6

(1) "Detailing" means the marketing or promotion of dangerous 7
drugs by or on behalf of a manufacturer or labeler. 8

(2) "Labeler" means a person to whom both of the following 9
apply: 10

(a) The person receives dangerous drugs from a manufacturer 11
or wholesaler and repackages them for retail sale. 12

(b) The person has a labeler code from the United States food 13
and drug administration under 21 C.F.R. 207.20. 14

(3) "Marketer" means a person who, while employed by or under 15
contract to represent a manufacturer or labeler, engages in 16
pharmaceutical detailing or other marketing or promotion of 17

dangerous drugs. 18

(4) "Sample drug" has the same meaning as in section 2925.01 19
of the Revised Code. 20

(5) "Wholesaler" means a person who, on official written 21
orders other than prescriptions, supplies dangerous drugs that the 22
person has not manufactured, produced, or prepared personally and 23
includes a "wholesale distributor of dangerous drugs" as defined 24
in section 4729.01 of the Revised Code. 25

(B)(1) On or before the first day of January of each year, 26
each manufacturer and labeler that sells dangerous drugs shall 27
report to the director of health the name and address of the 28
individual responsible for the manufacturer's or labeler's 29
compliance with this section. 30

(2) On or before the first day of February of each year, each 31
manufacturer or labeler that sells dangerous drugs shall submit to 32
the director a report that discloses, except as provided in 33
division (E) of this section, the value, nature, and purpose of 34
any gift, fee, payment, subsidy, or other economic benefit 35
provided in connection with detailing, promotion, or other 36
marketing activities by the manufacturer or labeler, directly or 37
through a marketer, to any licensed health professional authorized 38
to prescribe drugs, hospital, nursing home, residential care 39
facility, adult care facility, pharmacist, or health benefit plan 40
administrator. The report shall cover the prior calendar year and 41
be made on a form and in a manner prescribed by the director in 42
rules adopted under this section. 43

(C) No manufacturer or labeler shall fail to make a 44
disclosure in the report required by division (B)(2) of this 45
section with respect to a particular licensed health professional 46
authorized to prescribe drugs, hospital, nursing home, residential 47
care facility, adult care facility, pharmacist, or health benefit 48

plan administrator that is provided a gift, fee, payment, subsidy, 49
or other economic benefit in connection with detailing, promotion, 50
or other marketing activities. 51

(D) On or before the first day of June of each year, the 52
director shall submit to the governor and members of the general 53
assembly a report summarizing the reports received in that year 54
under division (B)(2) of this section. 55

(E) All of the following are exempt from disclosure under 56
this section: 57

(1) Any gift, fee, payment, subsidy, or other economic 58
benefit the value of which does not exceed twenty-five dollars; 59

(2) Sample drugs that are given with the intent that they be 60
distributed to patients; 61

(3) The payment of reasonable compensation and reimbursement 62
of expenses in connection with a bona fide clinical trial 63
conducted in connection with a research study designed to answer 64
specific questions about vaccines, new therapies, or new ways of 65
using known treatments; 66

(4) Scholarships or other support for medical students, 67
residents, and fellows to attend bona fide educational, 68
scientific, or policy-making conferences of an established 69
professional association if the recipients of the scholarships or 70
other support are selected by the association. 71

(F) The director shall adopt rules in accordance with Chapter 72
119. of the Revised Code to do both of the following: 73

(1) Prescribe the form and manner in which each manufacturer 74
and labeler is to make the report required by division (B)(2) of 75
this section; 76

(2) Define the terms "bona fide clinical trial" and "bona 77
fide educational, scientific, or policy-making conference" for 78

purposes of divisions (E)(3) and (4) of this section. 79

(G) In addition to the penalty prescribed by section 3715.99 80
of the Revised Code, whoever violates division (C) of this section 81
may be subject to an action by the attorney general in the 82
Franklin county court of common pleas for injunctive relief. The 83
court may issue an injunction and also may award costs and 84
attorney's fees associated with the action. 85

Sec. 3715.99. (A) Whoever violates sections 3715.13 to 86
3715.19, or 3715.38 of the Revised Code is guilty of a minor 87
misdemeanor. 88

(B) Whoever violates section 3715.22, 3715.25, 3715.27, or 89
3715.34 of the Revised Code is guilty of a misdemeanor of the 90
fourth degree. 91

(C) Whoever violates section 3715.23 or 3715.36 of the 92
Revised Code is guilty of a misdemeanor of the second degree. 93

(D) Whoever violates section 3715.52 or 3715.65 of the 94
Revised Code is guilty of a misdemeanor of the fourth degree on a 95
first offense; on each subsequent offense, the person is guilty of 96
a misdemeanor of the second degree. 97

(E) Whoever violates section 3715.521 of the Revised Code is 98
guilty of a minor misdemeanor. A violation of that section occurs 99
on a daily basis, not according to the number of times per day 100
that an expired drug, baby food, or infant formula is sold, 101
offered for sale, or delivered at retail or to the consumer. Each 102
day of violation is a separate offense. 103

(F) Whoever violates division (C) of section 3715.93 of the 104
Revised Code shall be fined not more than ten thousand dollars. 105
Each violation is a separate offense. 106

Section 2. That existing section 3715.99 of the Revised Code 107
is hereby repealed. 108