

MAINE STATE LEGISLATURE

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121st MAINE LEGISLATURE

FIRST REGULAR SESSION-2003

Legislative Document

No. 132

S.P. 55

In Senate, January 21, 2003

An Act Requiring Disclosure of Prescription Drug Advertising and Promotional Expenses

Reference to the Committee on Health and Human Services suggested and ordered printed.

A handwritten signature in cursive script, reading 'Joy J. O'Brien'.

JOY J. O'BRIEN
Secretary of the Senate

Presented by Senator MAYO of Sagadahoc.

Cosponsored by Representative FISCHER of Presque Isle, Representative RICHARDSON of Brunswick and

Senators: SAWYER of Penobscot, TREAT of Kennebec, Representatives: BULL of Freeport, DUDLEY of Portland, LEMOINE of Old Orchard Beach, O'NEIL of Saco, WOODBURY of Yarmouth.

2
3 **Be it enacted by the People of the State of Maine as follows:**

4 **Sec. 1. 22 MRSA §2699** is enacted to read:

6 **§2699. Advertising and promotional expenses**

8 A manufacturer or labeler of prescription drugs dispensed in
10 this State that employs, directs or utilizes marketing
12 representatives in this State shall report the costs of
14 advertising and promotional expenses for prescription drugs in
16 this State as provided in this section. For the purposes of this
18 section, "manufacturer" and "labeler" have the same meanings as
20 provided in section 2697, subsection 1.

22 **1. Purposes.** Advertising and promotional expenses for
24 prescription drugs in this State must be reported to the Maine
26 Health Data Organization, established in chapter 1683, for the
28 purposes of assisting this State in its role as a purchaser of
30 prescription drugs and an administrator of prescription drug
32 programs, enabling this State to determine the scope of
34 prescription drug advertising and promotional expenses and their
36 effect on the cost, utilization and delivery of health care
38 services and furthering the role of this State as guardian of the
40 public interest.

42 **2. Manner of reporting.** By July 1st each year a
44 manufacturer or labeler of prescription drugs that directly or
46 indirectly distributes prescription drugs for dispensation to
48 residents of this State shall file an annual report with the
50 Maine Health Data Organization in the form and manner provided by
the organization. The report must be accompanied by payment of a
fee, as set by the organization in rule, to support the work of
the organization under this section.

3. Content of annual report by manufacturer or labeler.
The annual report filed under subsection 2 must include the
following information as it pertains to advertising and
promotional activities conducted within this State:

A. All expenses associated with advertising, marketing and
direct promotion of prescription drugs through radio,
television, magazines, newspapers, direct mail and telephone
communications as they pertain to residents of this State;

B. With regard to all persons and entities licensed to
provide health care in this State, including health care
professionals and persons employed by them in this State,
carriers licensed under Title 24 or Title 24-A, health plans
and benefits managers, pharmacies, hospitals, nursing
facilities, clinics and other entities licensed to provide

2 health care under this Title, the following information
3 provided in a form that provides the value, nature, purpose
4 and recipient of the expense:

5 (1) All expenses associated with educational or
6 informational programs, materials and seminars and
7 remuneration for promoting or participating in
8 educational or informational sessions, regardless of
9 whether the manufacturer or labeler provides the
10 educational or informational sessions or materials;

11 (2) All expenses associated with food, entertainment,
12 gifts valued at more than \$25 and anything provided to
13 a health care professional for less than market value;

14 (3) All expenses associated with trips and travel; and

15 (4) All expenses associated with product samples,
16 except for samples that will be distributed free of
17 charge to patients; and

18 C. The aggregate cost of all employees or contractors of
19 the manufacturer or labeler who directly or indirectly
20 engage in the advertising or promotional activities listed
21 in paragraphs A and B, including all forms of payment to
22 those employees. The cost reported under this paragraph
23 must reflect only that portion of payment to employees or
24 contractors that pertains to activities within this State or
25 to recipients of the advertising or promotional activities
26 who are residents of or are employed in this State.

27 **4. Exceptions.** The following advertising and promotional
28 expenses are not subject to the requirements of this section:

29 A. Expenses of \$25 or less;

30 B. Reasonable compensation and reimbursement for expenses
31 in connection with a bona fide clinical trial of a new
32 vaccine, therapy or treatment; and

33 C. Scholarships and reimbursement of expenses for attending
34 a significant educational, scientific or policy-making
35 conference or seminar of a national, regional or specialty
36 medical or other professional association if the recipient
37 of the scholarship is chosen by the association sponsoring
38 the conference or seminar.

39 **5. Maine Health Data Organization reports.** By November
40 30th each year the Maine Health Data Organization shall provide
41 an annual report, providing information in aggregate form, on
42

2 prescription drug advertising and promotional expenses to the
4 Legislature. By January 1, 2005 and every 2 years after that
6 date, the Maine Health Data Organization shall provide a report,
8 providing information in aggregate form, containing an analysis
10 of the data submitted to the organization, including the scope of
prescription drug advertising and promotional activities and
expenses and their effect on the cost, utilization and delivery
of health care services and any recommendations with regard to
advertising and promotional activities of prescription drug
manufacturers and labelers.

12 6. Confidentiality; public information. Information
14 submitted to the Maine Health Data Organization pursuant to this
16 section is confidential and is not a public record as defined in
18 Title 1, section 402, subsection 3. Data compiled in aggregate
20 form by the organization for the purposes of reporting required
by this section is a public record as defined in Title 1, section
402, subsection 3, as long as it does not reveal trade
information that is protected by state or federal law.

22 7. Penalty. A manufacturer or labeler that fails to
24 provide a report as required by this section commits a civil
violation for which a fine of \$1000 may be adjudged, plus costs
and attorney's fees.

26 8. Rulemaking. The Maine Health Data Organization shall
28 adopt rules to implement this section. Rules adopted pursuant to
30 this section are routine technical rules as defined in Title 5,
chapter 375, subchapter 2-A.

32 **Sec. 2. Effective date.** This Act takes effect January 1, 2004.

34 **SUMMARY**

36 This bill requires prescription drug manufacturers and
38 labelers whose drugs are dispensed to Maine residents to file
40 annual reports with the Maine Health Data Organization regarding
42 their expenses for advertising and promoting their drugs. The
44 bill requires the Maine Health Data Organization to file an
46 annual report regarding the information filed and a biennial
48 report that contains analysis of information and
recommendations. The bill continues the confidentiality of trade
information that is protected under state and federal law. The
bill provides for a fine of \$1,000 for failure to report as
required. The bill provides for rulemaking by the Maine Health
Data Organization and contains an effective date of January 1,
2004.