



## **121st MAINE LEGISLATURE**

## FIRST REGULAR SESSION-2003

**Legislative Document** 

No. 1256

H.P. 930

House of Representatives, March 6, 2003

An Act To Prohibit Unethical Drug Marketing Practices

Reference to the Committee on Business, Research and Economic Development suggested and ordered printed.

Millicent M. Mac Jarland

MILLICENT M. MacFARLAND Clerk

Presented by Representative FAIRCLOTH of Bangor. Cosponsored by Senator BRENNAN of Cumberland and Representatives: DUDLEY of Portland, McNEIL of Rockland, MILLS of Cornville, O'NEIL of Saco, PINGREE of North Haven, RICHARDSON of Brunswick, SIMPSON of Auburn, Senator: MAYO of Sagadahoc.

| Be it enacted by the People of the State of Maine as follows:   |            |
|---|------------|
| Sec. 1. 24 MRSA c. 21, sub-c. 11 is enacted to read:  |            |
| SUBCHAPTER 11   |            |
| ACCEPTANCE OF GIFTS OR OTHER INDUCEMENTS BY<br>HEALTH CARE PRACTITIONERS AND HEALTH CARE PROVIDERS                        |            |
| <u>S2991. Definitions</u>   |            |
|   |            |
| As used in this subchapter, unless the context otherwi<br>indicates, the following terms have the following meanings.     | <u>.se</u> |
| 1. Drug distributor. "Drug distributor" means a pers  | on         |
| that purchases prescription drugs from one or more dr   | ug         |
| manufacturers or that sells or distributes prescription drugs   |            |
| a health care practitioner or health care provider or th  |            |
| purchases, sells or distributes prescription drugs to a pers  |            |
| that purchases, sells or distributes prescription drug<br>Manufacturing drugs or directly providing health care through t |            |
| use of drugs does not render a person a drug distributor.   |            |
|   |            |
| 2. Drug manufacturer. "Drug manufacturer" means a pers  | on         |
| engaged in the production of prescription drugs and includes  | <u>a</u>   |
| subsidiary or affiliate of a manufacturer.  |            |
| 3. Labeler. "Labeler" means a person that receiv  | 700        |
| rescription drugs from a manufacturer or wholesaler a   |            |
| epackages those drugs for later retail sale and that has  |            |
| abeler code from the United States Department of Health a   |            |
| Iuman Services, Food and Drug Administration under 21 Code  |            |
| Federal Regulations, 207.20 (2002).   |            |
|   |            |
| 4. Sales representative. "Sales representative" means a   |            |
| person who represents a prescription drug manufacturer, dr<br>distributor or labeler in marketing or promoting t          |            |
| prescription, purchase or sale of drugs.  | .ne        |
| <u></u>   |            |
| 2992. Interference in patient relationship prohibited   |            |
| <u>A drug manufacturer, drug distributor or labeler may r</u>   |            |
| interfere or attempt to interfere in the relationship between   | <u>a</u>   |
| nealth care practitioner or health care provider and a patient.   |            |
| 1. Nonmonetary gifts and other inducements; exception   | ns.        |
| The offer of any nonmonetary gift or other nonmonetary inducement   |            |
| by a drug manufacturer or drug distributor to or for the benef  |            |
| of a health care practitioner or health care provider that  |            |
| intended to or reasonably may influence the prescription  | or         |
|   |            |

| 2   | dispensing practices of that health care practitioner or health<br>care provider constitutes an attempt to interfere in the   |
|-----|---|
| 4   | relationship between that health care practitioner or health care<br>provider and its patients. This subsection does not apply to a<br>gift:  |
| 6   | 3   |
|     | A. Of not more than \$100 in market value if it is related  |
| 8   | to the health care practitioner's or health care provider's work or primarily entails a benefit to patients;  |
| 10  |   |
| 12  | <u>B. Supporting medical research or education, including</u><br><u>textbooks, meals of not more than \$50 in value and other</u><br><u>gifts if they serve a genuine educational function;</u> |
| 14  |   |
| 16  | C. Providing scientific and educational information;  |
| -•  | D. In exchange for consulting services by the health care   |
| 18  | practitioner or health care provider of approximately equal value; or   |
| 20  |   |
|     | E. Consisting of drug samples intended for free   |
| 22  | distribution to consumers or for personal use.  |
| 24  | 2. Gift of money; exceptions. The offer of any gift of  |
| 26  | money by a drug manufacturer or drug distributor to or for the<br>benefit of a health care practitioner or health care provider   |
| 20  | that is intended to or reasonably may influence the prescription  |
| 28  | or dispensing practices of that health care practitioner or   |
|     | health care provider constitutes an attempt to interfere in the   |
| 30  | relationship between the health care practitioner or health care  |
|     | provider and a patient. This subsection does not apply to:  |
| 32  |   |
| 34  | A. A subsidy to attend a continuing medical education<br>program or other scientific, educational or professional<br>meeting if the program or meeting is not conducted,                        |
| 36  | sponsored or underwritten by the person making the subsidy;   |
|     |   |
| 38  | B. Money given in exchange for consulting services of   |
|     | approximately equal value; or   |
| 40  |   |
| 4.2 | C. A scholarship or educational funds for attendance at an  |
| 42  | <u>event or institution if the recipient of the scholarship or funds is selected by the event or institution.</u>   |
| 44  | <u>runds is selected by the event of institution.</u>   |
|     | <u>§2993. Attempts to interfere</u>   |
| 46  |   |
|     | The promotion to a health care practitioner or health care  |
| 48  | <u>provider by a drug manufacturer, drug distributor or labeler,</u>  |
|     | directly or indirectly through the subsidy, sponsorship or  |
| 50  | underwriting of speakers or programs, of any drug for a use not   |

...

-

-

.

approved by the United States Department of Health and Human 2 Services, Food and Drug Administration constitutes an attempt to interfere in the relationship between that health care practitioner or health care provider and a patient. 4

6 §2994. Lack of influence not a defense

8 Lack of influence over or a failure to influence a health care practitioner's or health care provider's prescribing or dispensing practices is not a defense to a claim of attempted 10 interference in the relationship between a health care 12 practitioner or health care provider and a patient.

14 §2995. Acts of sales representatives are acts of their employers

16 Any act prohibited by this subchapter that is committed by a sales representative employed by a drug manufacturer, drug 18 distributor or labeler is deemed the act of that drug manufacturer, drug distributor or labeler for purposes of 20 liability and determining penalties under this subchapter.

- 22 §2996. Penalties
- 1. Unfair trade practice. A violation of this subchapter 24 is also a violation of the Maine Unfair Trade Practices Act.

2. Fines. Each violation of this subchapter constitutes a separate civil violation for which a fine of not less than \$1,000 28 may be adjudged.

30

34

26

3. Enforcement action. A person or class of persons may commence an action on behalf of the State for penalties under 32 this section and is entitled to retain 10% of the fines assessed,

- plus reasonable costs and attorney's fees.
- 36

## SUMMARY

38

This bill restricts the offer of gifts and other inducements by a drug manufacturer or drug distributor to a health care 40 practitioner or health care provider.