L.D. 1618

DATE: 6/7/05 (Filing No. H-661)

HEALTH AND HUMAN SERVICES

Majority

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STATE OF MAINE
HOUSE OF REPRESENTATIVES
122ND LEGISLATURE
FIRST SPECIAL SESSION

COMMITTEE AMENDMENT "A" to H.P. 1141, L.D. 1618, Bill, "An Act Regarding Advertising by Drug Manufacturers"

Amend the bill by striking out everything after the enacting clause and before the summary and inserting in its place the following:

'**Sec. 1. 22 MRSA c. 605** is enacted to read:

CHAPTER 605

PRESCRIPTION DRUG ADVERTISING

§2700-A. Prohibitions and required disclosures

1. Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any trial to test the safety or efficacy of a drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.

B. "Manufacturer of prescription drugs" or "manufacturer" means a manufacturer of prescription drugs or biological products or an affiliate of the manufacturer or a labeler that receives prescription drugs or biological products from a manufacturer or wholesaler and repackages those drugs or

biological products for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 2027.20 (1999).

C. "Regulated advertisement" means the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is:

(1) Broadcast on television or radio from a station that is physically located in the State;

(2) Broadcast over the Internet from a location in the State; or

(3) Printed in magazines or newspapers that are printed, distributed or sold in the State.

2. Regulated advertisement requirement. Beginning October 15, 2005, a manufacturer may not present or cause to be presented in the State a regulated advertisement, unless that advertisement meets the requirements concerning misbranded drugs and devices and prescription drug advertising of federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202 and state rules.

3. Prior disclosure of clinical trials of prescription drugs. Beginning October 15, 2005, a manufacturer may not present or cause to be presented a regulated advertisement in this State, unless, with regard to the prescription drug that is the subject of the regulated advertisement, the manufacturer has posted on the publicly accessible Internet website of the federal National Institutes of Health or its successor agency or another publicly accessible website the following information concerning any clinical trial that the manufacturer conducted or sponsored on or after October 15, 2002:

A. The name of the entity that conducted or is conducting the clinical trial;

B. A summary of the purpose of the clinical trial;

C. The dates during which the trial has taken place; and

D. Information concerning the results of the clinical trial, including potential or actual adverse effects of the drug.

In order to satisfy the requirements of this subsection, the publicly accessible website and manner of posting must be acceptable to the department.

4. Fees. Beginning April 1, 2006, each manufacturer of prescription drugs that are provided to Maine residents through the MaineCare program under section 3174-G or the elderly low-cost drug program under section 254 shall pay a fee of $1,000 per calendar year to the department. Fees collected under this subsection must be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subsection 3 and other relevant sites, assessing whether and the extent to which Maine residents have been harmed by the use of a particular drug and undertaking the public education initiative under subsection 5. Revenues received under this subsection must be deposited into an Other Special Revenue Funds account to be used for the purposes of this subsection.

5. Public education initiative. The department shall undertake a public education initiative to inform residents of the State about clinical trials and drug safety information.

6. Penalties. A violation of this section is a violation of the Maine Unfair Trade Practices Act. Each day a manufacturer is in violation of this chapter is considered a separate violation.

7. Rulemaking. The department may adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. Report. By January 15, 2007, the Department of Health and Human Services shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters regarding compliance with the Maine Revised Statutes, Title 22, section 2700-A, the completeness and ease of public access to information provided by the drug manufacturers and the need for further action or legislation.'

SUMMARY

This amendment is the majority report of the committee. The amendment replaces the bill. It:

1. Defines "clinical trial," "manufacturer of prescription drugs" and "regulated advertisement";

2. Requires drug manufacturers to disclose clinical trial information regarding drugs that are advertised in the State;

3. Requires manufacturers to pay fees that will be used to support overseeing the implementation of the new prescription drug advertising laws, including maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information, assessing harm from drugs to Maine residents and undertaking a public education initiative;

4. Provides penalties under the Maine Unfair Trade Practices Act for failure to comply;

5. Directs the Department of Health and Human Services to adopt rules to implement the provisions; and

6. Directs the Department of Health and Human Services to report by January 15, 2007 on compliance with the provisions, the completeness of and ease of public access to information provided by drug manufacturers and the need for further action or legislation to the joint standing committee of the Legislature having jurisdiction over health and human services matters.

FISCAL NOTE REQUIRED
(See attached)

Approved: 06/03/05 mac

122nd MAINE LEGISLATURE

LD 1618 **LR 0487(02)**

An Act Regarding Advertising by Drug Manufacturers

Fiscal Note for Bill as Amended by Committee Amendment "A"
Committee: Health and Human Services
Fiscal Note Required: Yes
Majority Report

Fiscal Note

Undetermined current biennium revenue increase - Other Special Revenue Funds
Undetermined current biennium cost increase - Other Special Revenue Funds
Minor cost increase - General Fund
Minor revenue increase - General Fund

Correctional and Judicial Impact Statements

Establishes new violations of the Maine Unfair Trade Practices Act.

The collection of additional fines may increase General Fund revenue by minor amounts.

Fiscal Detail and Notes

Assumes additional costs to the Department of Human Services to implement the provisions of the bill would be funded with fees on certain manufacturers of prescription drugs. The amount of fees that will be generated cannot be determined at this time.

Any additional costs to the Department of the Attorney General can be absorbed utilizing existing budgeted resources.