122nd MAINE LEGISLATURE

FIRST SPECIAL SESSION-2005

Legislative Document **No. 1618**

H.P. 1141 House of Representatives, May 3, 2005

An Act Regarding Advertising by Drug Manufacturers

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

Millicent M. MacFarland

MILLICENT M. MacFARLAND
Clerk

Presented by Representative LERMAN of Augusta.
Cosponsored by Representative CAMPBELL of Newfield and
Representatives: BRAUTIGAM of Falmouth, BURNS of Berwick, GROSE of Woolwich, MILLER of Somerville, PINGREE of North Haven, Senators: BRENNAN of Cumberland, MAYO of Sagadahoc.

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

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, "clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any experiment to test the safety or efficacy of a drug or biological product with one or more human subjects and 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.

2. Adoption of federal law and regulations by reference. The department shall adopt rules to incorporate by reference federal statutes and regulations in 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202 and may adopt amendments to those statutes and regulations that are not inconsistent with those statutes and regulations. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

3. Misbranding and certain advertising prohibited. A manufacturer may not present or cause to be presented an advertisement for a prescription drug in a television broadcast, radio broadcast or printed material that originates in this State, unless that advertisement meets the requirements of federal laws and regulations concerning misbranded drugs and devices and prescription drug advertising as adopted by reference by rule of the department pursuant to subsection 2.

4. Disclosure of clinical trials. A manufacturer may not present or cause to be presented an advertisement for a prescription drug in a television broadcast, radio broadcast or printed material that originates in this State, unless the manufacturer has disclosed to the department, on a form provided by the department, the following information concerning any clinical trial of the prescription drug that the manufacturer has conducted or sponsored or is in the process of conducting or sponsoring:

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;

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

E. Any other information determined by the commissioner to be relevant.

This subsection applies to clinical trials commenced on or after October 15, 2005.

5. Immunity. Notwithstanding any other provision of law to the contrary, a person who is required or authorized by the commissioner to report, receive or disclose information pursuant to this chapter is immune from liability for reporting, receiving or disclosing that information in accordance with the provisions of this chapter or any rule adopted pursuant to this chapter.

6. Penalties. A violation of this chapter is a violation of the Maine Unfair Trade Practices Act, for which a fine of not more than $10,000 may be adjudged. Each day a manufacturer is in violation of this chapter is considered a separate violation.

7. Fee. For each prescription drug advertised in a television broadcast, radio broadcast or printed material that originates in this State, the drug's manufacturer shall pay a fee to the department, determined by the department by rule and not to exceed $500, to offset the cost of implementing and maintaining a clinical trial database. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. Commissioner of Health and Human Services to provide access to clinical trial information. The Commissioner of Health and Human Services shall maintain a database of clinical trial information provided pursuant to the Maine Revised Statutes, Title 22, section 2700-A and to the extent permissible under federal law shall provide access to the public to that information through an Internet website. The commissioner may adopt rules to implement the purposes of this section. Any rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

SUMMARY

This bill requires the Department of Health and Human Services to adopt rules incorporating by reference federal laws

and regulations concerning misbranded drugs and devices and prescription drug advertising. The bill also requires drug manufacturers to provide information concerning clinical trials of prescription drugs advertised in the State, provides immunity for disclosure of that information, directs the department to maintain this information on an Internet website and enables the department to collect a fee from manufacturers to support a clinical trial database. The bill makes violations of these requirements violations of the Maine Unfair Trade Practices Act, which are subject to a fine of not more than $10,000.