

STATE OF OKLAHOMA

2nd Session of the 50th Legislature (2006)

HOUSE BILL 2914

By: Morgan (Danny)

AS INTRODUCED

An Act relating to public health and safety; creating requirements for prescription drug advertising; defining terms; requiring promulgation of certain rules; providing certain immunity; providing penalty; providing for a fee; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-1412.1 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. As used in this section, "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.

B. The State Department of Health shall promulgate 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.

C. 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 State Department of Health pursuant to subsection B of this section.

D. 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 State Department of Health, 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:

1. The name of the entity that conducted or is conducting the clinical trial;
2. A summary of the purpose of the clinical trial;
3. The dates during which the trial has taken place;
4. Information concerning the results of the clinical trial, including potential or actual adverse effects of the drug; and
5. Any other information determined by the Department to be relevant.

The provisions of this subsection shall apply to clinical trials commenced on or after November 1, 2006.

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

F. A violation of this section is a violation of the Oklahoma Consumer Protection Act, for which remedy shall be determined in accordance with Section 761.1 of Title 15 of the Oklahoma Statutes. Each day a manufacturer is in violation of this section is considered a separate violation.

G. The State Department of Health shall maintain a database of clinical trial information provided pursuant to this section and, to the extent permissible under federal law, shall provide access to the public to that information through an Internet website. The Department may adopt rules to implement the purposes of this section.

H. For each prescription drug advertised in a television broadcast, radio broadcast, or printed material that originates in this state, the manufacturer of the drug shall pay a fee to the State Department of Health of not to exceed Five Hundred Dollars (\$500.00), as determined by rule of the Department, to offset the cost of implementing and maintaining a clinical trial database.

SECTION 2. This act shall become effective November 1, 2006.

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