HOUSE OF REPRESENTATIVES
TWENTY-FOURTH LEGISLATURE, 2008
STATE OF HAWAII

H.B. NO. 2445 H.D. 1

A BILL FOR AN ACT

RELATING TO ADVERTISING BY MANUFACTURERS OF PRESCRIPTION DRUGS AND DISCLOSURE OF CLINICAL TRIALS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 328, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"**PART . PRESCRIPTION DRUG ADVERTISING**

§328-A Definitions. As used in this part, unless the context otherwise requires:

"Clinical trial" means a clinical investigation as defined by the 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 Food and Drug Administration as part of an application for a research or marketing permit.

"Manufacturer" includes:

(1) A manufacturer of prescription drugs or an affiliate of the manufacturer;

(2) A manufacturer of biological products or an affiliate of the manufacturer; or

(3) 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, 207.20 (1999).

"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.

§328-B Regulated advertisement requirement. Beginning October 15, 2010, 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 law.

§328-C Disclosure of clinical trials of prescription drugs. Beginning October 15, 2010, manufacturers shall post, with regard to those prescription drugs, 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, 2004:

(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; and

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

To satisfy the requirements of this section, the publicly accessible website and manner of posting shall be acceptable to the department.

§328-D Fees. Beginning April 1, 2011, each manufacturer that produce prescription drugs provided to Hawaii residents

through any state program shall pay a fee of $100 per calendar year to the department. Fees collected under this section shall be used to cover the cost of implementing this part, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under section 328-C and other relevant sites, assessing whether and the extent to which state residents have been harmed by the use of a particular drug, and undertaking the public education initiative under section 328-F. Revenues received under this section shall be deposited into the prescription drug advertising special fund established under section 328-E.

§328-E Prescription drug advertising special fund. (a) There is established in the state treasury a prescription drug advertising special fund, into which shall be deposited fees collected pursuant to section 328-D. The prescription drug advertising special fund shall be administered by the department of health.

(b) Moneys from the prescription drug advertising special fund shall be used by the department to implement this part.

§328-F Public education initiative. The department shall undertake a public education initiative to inform residents of the state about clinical trials and drug safety information.

§328-G Penalties. A violation of this part is a violation of section 480-2. Each day a manufacturer is in violation of this part is considered a separate violation.

§328-H Rulemaking. The department shall adopt rules, pursuant to chapter 91, to implement this part."

SECTION 2. The department of health shall submit a report to the legislature no later than twenty days before the convening of the regular session of 2010 regarding the department's compliance with this Act. The report shall describe the completeness and ease of public access to clinical trials information provided by the manufacturers, and make a recommendation concerning the need for further action or legislation.

SECTION 3. In codifying the new part added to chapter 328, Hawaii Revised Statutes, by section 1 of this Act, the revisor of statutes shall substitute appropriate section numbers for the letters used in designating the new sections in this Act.

SECTION 4. This Act shall take effect upon its approval.

Report Title:
Prescription Drugs; Clinical Trials; Disclosures; Special Fund

Description:
Requires prescription drug ads to meet federal standards, public disclosure of clinical trial information, and drug manufacturers to pay fees to department of health to fund a public education initiative on clinical trials and drug safety. Establishes special fund. (HB2445 HD1)