HOUSE OF REPRESENTATIVES
TWENTY-THIRD LEGISLATURE, 2006
STATE OF HAWAII

H.B. NO. 1869 H.D. 1 S.D. 1

A BILL FOR AN ACT

RELATING TO ADVERTISING BY DRUG MANUFACTURERS 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 any pharmaceutical, pharmacokinetic, or other study of the safety or efficacy of a pharmaceutical drug, whether or not completed in full, including but not limited to:

(1) A clinical investigation that involves any trial to test the safety or efficacy of a pharmaceutical drug 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 any application for a research or marketing permit or for any other type of application, permit, procedure, or

requirement of the Food and Drug Administration, including but not limited to an Abbreviated New Drug Application, an Investigational New Drug Application, a New Drug Application, non-confidential additions to the Drug Master File, Postmarketing Adverse Events Recording, or compliance with the electronic or paper Common Technical Document; and

(2) Any pharmacological study subsequent to initial approval for sale by the Food and Drug Administration, including studies assessing potential off-label applications, new therapies, new ways of using known treatments and comparative drug trials assessing the efficacy or safety of a drug compared to other therapies.

"Department" means the department of health.

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

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

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

(2) Printed in magazines or newspapers that originated in the State.

§328-B Regulated advertisement requirement. Beginning October 15, 2007, 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. (a) Beginning October 15, 2007, a manufacturer or labeler of prescription drugs 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 in Hawaii on or after July 1, 2006:

(1) The names of all participating organizations and funding sources of the clinical trial, including the name and contact information, including institutional affiliation, of all sponsors, co-sponsors, and administrators, including the name of the principal investigators and study centers of the clinical trial;

(2) A summary of the purpose of the clinical trial, including the name of the drug being tested and its active ingredients, overall design of the study including the statistical method to be employed, status/phase type of trial, and the medical condition or conditions being studied and outcomes that were evaluated;

(3) The dates during which the trial has taken place;

(4) Information concerning the results and outcomes of the clinical trial, which shall include, but not be limited to: potential or actual adverse effects of the drug including the frequency, severity, and nature of adverse events for any trial participant and numbers of participants who discontinued participation in the trial and the reasons for such discontinuance; and

(5) Any other information necessary to assure complete information about the safety of prescription drugs taken by residents of the State included in regulations adopted pursuant to subsection (1) of this section.

(b) To satisfy the requirements of this section, the publicly accessible website and manner of posting shall be acceptable to the department if it is a free, non-subscription website that clearly indicates the location and instructions for downloading the files or information submitted pursuant to this section.

(c) Disclosure of clinical trials pursuant to this section shall include trials that the manufacturer, or an entity on its behalf, initiated but terminated prior to completion. For such trials, the manufacturer shall include an explanation for the termination of the trial, including but not limited to potential or actual adverse effects of the drug including frequency, severity, and nature of adverse effects for any trial participant and numbers of participants who discontinued participation in the trial and the reasons for discontinuance.

(d) A manufacturer shall post the information required by this section in accordance with the following:

(1) For a drug that has been approved by the Food and Drug Administration, within ninety days after the completion or termination of the clinical trial or within ninety days after the effective date of this Act, whichever is later; and

(2) In the case of a clinical trial performed prior to approval for sale by the Food and Drug Administration, or within sixty days after the date of approval for sale by the Food and Drug Administration, or within ninety days after the effective date of this Act, whichever is later.

§328-D Penalties. A violation of this part is a violation of chapter 481A, the Uniform Deceptive Trade Practice Act. Each day a manufacturer is in violation of this part is considered a separate violation. Each clinical trial registration or clinical trial results disclosure that does not fully comply with the requirements of this Act shall be treated as a separate violation.

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

SECTION 2. The department of health shall report to the legislature no later than twenty days before the convening of

the regular session of 2007 regarding compliance with this Act, the completeness and ease of public access to information provided by the drug manufacturers, and 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 on July 1, 2050.

HB1869.SD1

Report Title:
Prescription Drug Advertising; Clinical Trials; Disclosures

Description:
Requires prescription drug ads to meet federal standards and public disclosure of clinical trial information. (SD1)