

JAN 19 2007

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:

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

4 **"PART . PRESCRIPTION DRUG ADVERTISING**

5 **§328-A Definitions.** As used in this part, unless the
6 context otherwise requires:

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

14 "Department" means the department of health.

15 "Manufacturer of prescription drugs" or "manufacturer"
16 means a manufacturer of prescription drugs or biological
17 products or an affiliate of the manufacturer or a labeler that



1 receives prescription drugs or biological products from a
2 manufacturer or wholesaler and repackages those drugs or
3 biological products for later retail sale and that has a labeler
4 code from the federal Food and Drug Administration under 21 Code
5 of Federal Regulations, 207.20 (1999).

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

- 10 (1) Broadcast on television or radio from a station that
11 is physically located in the State;
- 12 (2) Broadcast over the Internet from a location in the
13 State; or
- 14 (3) Printed in magazines or newspapers that are printed,
15 distributed, or sold in the State.

16 **§328-B Regulated advertisement requirement.** Beginning
17 October 15, 2009, a manufacturer may not present or cause to be
18 presented in the State a regulated advertisement, unless that
19 advertisement meets the requirements concerning misbranded drugs
20 and devices and prescription drug advertising of federal law and
21 regulations under 21 United States Code, Sections 331 and 352(n)
22 and 21 Code of Federal Regulations, Part 202 and state law.



1 **§328-C Disclosure of clinical trials of prescription**
2 **drugs.** Beginning October 15, 2009, a manufacturer or labeler of
3 prescription drugs shall post, with regard to those prescription
4 drugs, on the publicly accessible internet website of the
5 federal National Institutes of Health or its successor agency or
6 another publicly accessible website, the following information
7 concerning any clinical trial that the manufacturer conducted or
8 sponsored on or after October 15, 2004:

- 9 (1) The name of the entity that conducted or is conducting
10 the clinical trial;
- 11 (2) A summary of the purpose of the clinical trial;
- 12 (3) The dates during which the trial has taken place; and
- 13 (4) Information concerning the results of the clinical
14 trial, including potential or actual adverse effects
15 of the drug.

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

19 **§328-D Fees.** Beginning April 1, 2010, each manufacturer
20 of prescription drugs that are provided to Hawaii residents
21 through any state program shall pay a fee of \$1,000 per calendar
22 year to the department. Fees collected under this section shall



1 be used to cover the cost of implementing this part, including
2 but not limited to maintaining links to publicly accessible
3 websites to which manufacturers are posting clinical trial
4 information under section 328-C and other relevant sites,
5 assessing whether and the extent to which state residents have
6 been harmed by the use of a particular drug, and undertaking the
7 public education initiative under section 328-F. Revenues
8 received under this section shall be deposited into the
9 prescription drug advertising special fund established under
10 section 328-E.

11 **§328-E Prescription drug advertising special fund.** (a)
12 There is established in the state treasury a prescription drug
13 advertising special fund, into which shall be deposited fees
14 collected pursuant to section 328-D. The prescription drug
15 advertising special fund shall be administered by the department
16 of health.

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

19 **§328-F Public education initiative.** The department shall
20 undertake a public education initiative to inform residents of
21 the State about clinical trials and drug safety information.



1 §328-G Penalties. A violation of this part is a violation
2 of section 480-2. Each day a manufacturer is in violation of
3 this part is considered a separate violation.

4 §328-H Rulemaking. The department shall adopt rules,
5 pursuant to chapter 91, to implement this part."

6 SECTION 2. The department of health shall submit a report
7 to the legislature no later than twenty days before the
8 convening of the regular session of 2009 regarding the
9 department's compliance with this Act. The report shall
10 describe the completeness and ease of public access to clinical
11 trials information provided by the manufacturers of prescription
12 drugs, and make a recommendation concerning the need for further
13 action or legislation.

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

18 SECTION 4. This Act shall take effect upon its approval.
19

INTRODUCED BY:

David Y. Lee

Carol Fukunaga

Therese Chun Oshiro

Wm. Sakuma Jr.

[Handwritten signatures: John M. Waihele, Rose H. Baker, and others]



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.

