SB2533

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

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.

Introducer(s):
IGE

Current Referral:
HTH, WAM

LINDA LINGLE
GOVERNOR OF HAWAII

CHIYOME LEINAALA FUKINO, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O. Box 3378
HONOLULU, HAWAII 96801-3378

In reply, please refer to:
File:

Testimony of Chiyome Leinaala Fukino, M.D.
Director of Health

1:15 pm

Department's Position: The Department sympathizes with the purpose of this bill, but has concerns regarding this proposal, and therefore, respectfully opposes this bill.

Fiscal Implications: Implementation of this measure will require additional staff, which is not included or funded in the current executive supplemental budget request.

Purpose and Justification: This bill amends HRS Chapter 328 by introducing new language, which would ensure all drug advertisements (via television, radio, or internet) and printed material within the State are in compliance with State and Federal regulations regarding prescription drug misbranding. It also states that information regarding clinical trials of prescription drugs shall be posted on the publicly accessible internet website of the National Institutes of Health (NIH), and that each manufacturer of prescription drugs that are provided to Hawaii residents through any State program shall pay a fee of $1,000 to the Department. This fee will be used to fund a public education program about clinical trials and drug safety.

We appreciate the intent of the bill, which attempts to guard against false or misleading advertisement for prescription drugs and to provide information to the public regarding clinical trials. However, these areas are already currently addressed.

As stated in this measure, there is already State and Federal oversight on the misbranding of prescription drugs. If the Department has determined the advertisement of a drug product is misleading, the drug product would be deemed misbranded and subject to the Department's embargo powers. Products produced out-of-state are under the jurisdiction of FDA, as they are responsible for interstate commerce.

Public disclosure of information regarding clinical trials is already available on NIH and FDA's websites. The National Library of Medicine (part of NIH) maintains an interactive database that can help you locate clinical trials for serious illnesses (www.ClinicTrials.gov). This was developed as a result of the Food and Drug Modernization Act, which was passed into law in November 1997. Another pertinent website accessible on the FDA website is an industry-sponsored website called www.ClinicalStudyResults.org, which is a central, widely accessible, web-based repository for clinical study results presented in a standardized and reader-friendly format.

Clinical trials and drug safety are further covered by the Food and Drug Administration Amendments Act of 2007 (FDAAA), Title VIII – Clinical Trial Databases and Title IX – Enhanced Authorities Regarding Postmarket Safety of Drugs. The FDAAA adds many new provisions to the Federal Food, Drug and Cosmetic Act (FD&C Act), covering a wide range of food and drug safety laws. Title VIII of the FDAAA contains very detailed and lengthy requirements for the expansion of a clinical trial results database, administered and maintained by the NIH. It is clear that the elements proposed for Section HRS 328-C in SB 2533 would be more than satisfied by the requirements found in Title VIII of the FDAAA of 2007.

We are concerned that Title VIII may pre-empt States from establishing or to continue in effect any requirement for the registration of clinical trails or for the inclusion of information relating to the results of clinical trials in a database. We defer to the Attorney General on this question.

With respect to drug advertisements, Title IX of the FDAAA specifically strengthens current Federal misbranding regulations concerning direct-to-consumer advertisements.

The Department feels the thorough and complex amendments to the FD&C Act, plus current State misbranding laws appropriately address the items proposed in SB 2533. For these reasons, the Department recommends this measure be deferred.

Thank you for the opportunity to testify.

WRITTEN ONLY

TESTIMONY BY GEORGINA K. KAWAMURA
DIRECTOR, DEPARTMENT OF BUDGET AND FINANCE
STATE OF HAWAII
TO THE SENATE COMMITTEE ON HEALTH
ON
SENATE BILL NO. 2533

February 13, 2008

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

Senate Bill No. 2533 establishes a Prescription Drug Advertising Special Fund to be administered by the Department of Health for the collection of $1,000 in annual fees from each manufacturer of prescription drugs that are provided to Hawaii residents through any State program. The proposed fund would be used to finance a public education initiative on clinical trials and drug safety.

As a matter of general policy, this department does not support the creation of any special or revolving fund which does not meet the requirements of Section 37-52.3 of the Hawaii Revised Statutes. Special or revolving funds should: 1) reflect a clear nexus between the benefits sought and charges made upon the users or beneficiaries of the program; 2) provide an appropriate means of financing for the program or activity; and 3) demonstrate the capacity to be financially self-sustaining. It is difficult to determine whether the fund will be self-sustaining.

POLICY ADVISORY BOARD FOR ELDER AFFAIRS (PABEA)
NO.1 CAPITOL DISTRICT
150 SOUTH HOTEL STREET, SUITE 406
HONOLULU, HAWAII 96813

TO: SENATE-SGT-AT- ARMS

February 11, 2008
Fax 586-6659

FROM: Bruce McCullough
Legislative Committee, PABEA

FOR: Committee on Health
Senator David Y. Ige, Chair
Senator Carol Fukunaga, Vice Chair

RE: SB 2533 Relating to Advertising by Manufacturers of Prescription Drugs and Disclosure of Clinical Trials

DATE: February 13, 2008

TIME: 1:15 PM

PLACE: RM 016

I am offering testimony on behalf of PABEA, which is a State appointed Board tasked with advising the Executive Office on Aging (EOA). My testimony does not represent the views of the EOA, but of the board.

PABEA is in strong support of this proposed legislation.

This bill deals with an aspect of pharmaceutical research that highlights the growing trend of drugs being rushed to the market without adequate trials and/or lack of information provided to physicians.

The bill inserts definitions into existing state law that constitutes a "clinical trial", "drug manufacturer" and "regulated advertisement", addressing similar concerns on the mainland with a lack of specificity.

The bill contains language that establishes a boundary around state lines for this bill to take place and affects only the advertising of drugs and various marketing within the State.

The pharmaceutical industry vehemently opposes state regulation that imposes a requirement to disclose trial results due to the potential negative impact on sales caused by an adverse result. As demonstrated by the Vioxx drug problem, the pharmaceutical companies constantly downplay any sort of negative findings through aggressive marketing and skirting questions or concerns raised by physicians.

This bill will require the companies to fully disclose information and provide to the public for access and review, without impeding the company's ability to effectively market the drug.

HAWAII ALLIANCE FOR RETIRED AMERICANS (HARA)
AN AFFILIATE OF THE ALLIANCE FOR RETIRED AMERICANS
C/O AFSCME, 888 MILILANI STREET, SUITE 101
HONOLULU, HAWAII 96813

TO: SENATE-SGT-AT- ARMS

FEBRUARY 11, 2008
Fax 586-6659

FROM: Bruce McCullough
HARA Legislative Committee, Chair

FOR: COMMITTEE ON HEALTH
Senator David Y. Ige, Chair
Senator Carol Fukunaga, Vice Chair

RE: SB 2533 Relating to Advertising by Manufacturers of Prescription Drugs and Disclosure of Clinical Trials

DATE: February 13, 2008

TIME: 1:15 PM

PLACE: RM. 016

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February 11, 2008

TO: Chair David Y. Ige and Members of the Senate Committee on Health

FROM: Pharmaceutical Research and Manufacturers of America
(Norman H. Suzuki)

RE: **SB 2533** Relating to Advertising by Manufacturers of Prescription Drugs and Disclosure of Clinical Trials

Hearing Date: 2/13/08 at 1:15 p.m.

My name is Norman Suzuki. I am a representative of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which is a trade association of the country's leading research-based pharmaceutical and bio-technology companies, which are in the business of making medicines.

PhRMA respectfully **opposes** passage of **SB 2533** for the reasons set forth in the attached statement.

Thank you for considering this testimony.

Statement PhRMA

In Opposition to Hawaii Senate Bill 2533

February 11, 2008

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes Hawaii Senate Bill 2533 (SB 2533), which would, among other things, require the posting of all phases of clinical trials which could drive manufacturers out of Hawaii or disadvantage Hawaii residents with chronic or terminal illnesses who may be prevented from participating in cutting-edge clinical trials.

As drafted, SB 2533 would set restrictions on prescription drug advertising in Hawaii and require a manufacturer of prescription drugs to post certain information on all of its clinical trials on the National Institutes of Health's website or other public website. The clinical trial postings would require, among other things, the results of all phases of any clinical trial. The bill also imposes an industry specific annual "fee" on prescription drug manufacturers who provide drugs to residents through any state program to cover the cost of maintaining the clinical trial website, assessing whether and the extent to which the state's residents have been harmed by the use of a particular drug, and undertaking a public education initiative.

Clinical Trials

Currently, there are over 240 industry sponsored clinical trials recruiting or preparing to recruit patients in Hawaii. This bill could put those critical trials in jeopardy. As proposed, SB 2533 requires all clinical trials to be posted, Phases I through IV. It also requires posting of clinical trials even if and regardless of the reason the clinical trial was stopped. However, many clinical trials in their early stages contain proprietary information and the reason a clinical trial may have been stopped may be proprietary. Yet, this legislation would require the disclosure of what is considered trade secret information without any confidentiality protections.

It should also be noted that federal law already preempts a state from establishing clinical trial registries of the nature that SB 2533 proposes. The 2007 Federal Food, Drug, and Cosmetic Act (Title VIII, section 6, subsection "d") declares that:

> "...no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database."

Furthermore, in 2002, the pharmaceutical industry adopted the "PhRMA Principles for the Conduct of Clinical Trials and Communication of Clinical Trial Results" as a means to communicate results of clinical studies, regardless of their outcome. These principles were the foundation for establishing in 2004 a new database (www.clinicalstudyresults.org) which gives unprecedented access to clinical study information to physicians and patients. Through this database, the industry is beginning to post *results* of *all* clinical trials (both positive and negative, inclusive of mid-to-late stages) completed since October 2002 for drug products that are on the market.

Advertising Restrictions

Under SB 2533, manufacturers would be subject to federal and state violations for the same infractions. The bill would establish restrictions on prescription drug advertising "presented within the state". The term "presented within the state" potentially attempts to regulate interstate commerce for those advertisements broadcast from outside the state. The landmark U.S. Supreme Court decision, Central Hudson Gas & Electric Corp. v. Public Serv. Commission Of New York, established a four-part test to be applied by courts in determining the constitutionality of commercial speech restrictions.[1] Speech may be restricted only if: 1) it is inherently false or misleading; 2) there is "substantial" interest; 3) the restriction "advances the Government's interest"; and, 4) the restriction is no more extensive than necessary. Although Central Hudson provides the foundation for assessment of commercial speech restrictions under the First Amendment, the Court has been increasingly protective of commercial speech in the last decade and has been applying the four-part test with a rigor that approaches strict scrutiny.

Industry Specific Fee

SB 2533 would require pharmaceutical manufacturers who provide drugs to residents through any state program to cover the cost of maintaining the clinical trial website, assessing whether and the extent to which the state's residents have been harmed by the use of a particular drug, and undertaking a public education initiative. This fee represents an unjustified charge to merely provide a link on the state's Department of Health website to the existing, mandatory federal site and the voluntary pharmaceutical website. Furthermore, the Federal Food and Drug Administration already monitors whether individuals have been harmed by prescription drugs through the reporting of adverse events. It is not prudent for the state to expend its resources on a system that is already being carried out on a federal level.

It is for these reasons, we respectfully urge legislators to oppose Hawaii Senate Bill 2533.

[1] Central Hudson Gas & Elec. Corp. v. Public Serv. Commission, 447 U.S. 557 566 (1980).

TESTIMONY OF THE STATE ATTORNEY GENERAL
TWENTY-FOURTH LEGISLATURE, 2008

ON THE FOLLOWING MEASURE:
S.B. NO. 2533, RELATING TO ADVERTISING BY MANUFACTURERS OF PRESCRIPTION DRUGS AND DISCLOSURE OF CLINICAL TRIALS.

BEFORE THE:
SENATE COMMITTEE ON HEALTH

DATE: Wednesday, February 13, 2008 **TIME:** 1:15 PM
LOCATION: State Capitol, Room 016
Deliver to: Committee Clerk, Room 215, 1 copy

TESTIFIER(S): Mark J. Bennett, Attorney General
or Wade H. Hargrove III, Deputy Attorney General

Chair Ige and Members of the Committee:

The Attorney General has several concerns about the constitutionality of this bill. This bill would add a new part to chapter 328, Hawaii Revised Statutes, to require the disclosure of clinical trials by manufacturers of prescription drugs.

First, the Hawaii Constitution, in article III, section 14, provides that each law shall embody only one subject and that the subject must be expressed in the title of the law. The title of this bill expresses two distinct subjects: (1) advertising by manufacturers of prescription drugs, and (2) disclosure of clinical trials. Although it is possible that a court might conclude that these two subject matters are interrelated and thus "one subject," the plain reading of the title of this bill is inconsistent with a plain reading of article III, section 14 of the Hawaii Constitution and a court could find this law unconstitutional on that basis.

Second, in proposed section 328-C, which requires either the manufacturer or the labeler to post certain information about clinical trials for a prescription drug on a publicly available website, there is no requirement that the manufacturer or labeler have any specific contact with the State of Hawaii. Consequently,

this requirement may be challenged on constitutional due process grounds.

Third, it is unclear, in light again of due process concerns, whether a "labeler" (a term which remains undefined in the bill) can be given the legal burden of producing information to which it may not have any reasonable access. Section 328-C requires that either the manufacturer or the labeler must post on the website of the federal National Institutes of Health or its successor agency, or some other publicly available website, information concerning the clinical trials conducted by the manufacturer. Since the labeler was not involved in the development or implementation of these clinical trials, and could presumably access the information only as a third party, it is unreasonable to require the labeler to post this information (and, by extension, be accountable for it).

Finally, section 328-C appears to violate the supremacy clause of the United States Constitution because section 801(d)(1) of the federal Food and Drug Administration Amendments Act of 2007, which amends the Public Health Service Act (42 U.S.C. section 282) (the "Federal Act"), states, in part, that "upon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act, as added by this section, no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database." The National Institutes of Health website (clinicaltrials.gov) currently provides a registry and results data base for clinical trials pursuant to existing federal law, therefore, the information that this bill would require is already available and mandated by federal law. Furthermore, pursuant to section 801(a)(2) of the Federal Act, the "expansion of the registry and results data base" must be accomplished by federal rulemaking no later than September 27, 2010. Interestingly enough, proposed section 328-C would only go into effect on October 15, 2010, less

than one month after the federal expansion of the registry and results data base must have already taken place. Therefore, in addition to the information already federally required and available, the Federal Act requires that this information be expanded extensively before this provision of the bill would even take effect.

Because the federal preemption language appears designed to prevent the very registry requirements that this bill proposes and because the only other substantive section in this bill (section 328-B) is merely a restatement of the fact that all prescription drug manufactures must follow existing state and federal labeling laws (which goes without saying), we recommend that this bill be held.