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TO THE HOUSE COMMITTEE ON HEALTH

TWENTY-FOURTH STATE LEGISLATURE
REGULAR SESSION, 2008

Friday, February 1, 2008
8 a.m.

TESTIMONY ON HOUSE BILL NO. 2445 – RELATING TO ADVERTISING BY MANUFACTURERS OF PRESCRIPTION DRUGS AND DISCLOSURE OF CLINICAL TRIALS.

TO THE HONORABLE JOSH GREEN, CHAIR, AND MEMBERS OF THE COMMITTEE:

The Department of Commerce and Consumer Affairs ("Department") appreciates the opportunity to testify in opposition to House Bill No. 2445, Relating to Advertising by Manufacturers of Prescription Drugs and Disclosure of Clinical Trials. My name is Stephen Levins, and I am the Executive Director of the Department's Office of Consumer Protection.

House Bill No. 2445, among other things, seeks to require the public disclosure of clinical trials of prescription drugs. Violation of its provisions would constitute an

unfair or deceptive trade practice pursuant to section 480-2 of the Hawaii Revised Statutes.

This measure appears to be based, in large part, on a law recently passed in the State of Maine. While many of its provisions are laudable, passage of this bill would be fruitless since the United States Congress has now preempted the states from enacting such legislation. Specifically, "The Food and Drug Administration Act of 2007" states 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." See, Section 801 (d) of the Food & Drug Administration Act of 2007.

In view of the recent change to federal law, it is not appropriate for the Legislature to impose the disclosure requirements contemplated by House Bill No. 2445 at this time.

Thank you for this opportunity to testify on House Bill No. 2445. I will be happy to answer any questions that the members of the Committee may have.

WRITTEN ONLY

TESTIMONY BY GEORGINA K. KAWAMURA
DIRECTOR, DEPARTMENT OF BUDGET AND FINANCE
STATE OF HAWAII
TO THE HOUSE COMMITTEES ON HEALTH AND
HUMAN SERVICES AND HOUSING
ON
HOUSE BILL NO. 2445

February 1, 2008

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

House Bill No. 2445 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.

LINDA LINGLE
GOVERNOR OF HAWAII

CHIYOME LEINAALA FUKINO, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
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In reply, please refer to:
File:

House Committee on Health

House Committee on Human Services & Housing

HB No. 2445, RELATING TO ADVERTISING BY MANUFACTURERS OF PRESCRIPTION DRUGS AND DISCLOSURE OF CLINICAL TRAILS

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

February 1, 2008
8:00am

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 biennium 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.

The FDA website has a tremendous amount of information that has been developed for and easily accessible to the general public. Readers are able to get answers to basic questions: What are clinical trials? Why should I volunteer? What are my rights as a participant? (Informed consent regulations), etc.

For these reasons, the Department recommends this measure be deferred.

Thank you for the opportunity to testify.

January 30, 2008

TO: Chair Josh Green, M.D. and Members of the House Committee on Health

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

RE: **HB 2445** Relating to Advertising by Manufacturers of Prescription Drugs and Disclosure of Clinical Trials

Hearing Date: 2/1/08 at 8:00 a.m.

My name is Norman Suzuki. I am a representative of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which is an organization comprised 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 **HB 2445** for the reasons set forth in the attached statement.

Thank you for considering this testimony.

Statement PhRMA

In Opposition to Hawaii House Bill 2445

January 30, 2008

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes Hawaii House Bill 2445 (HB 2445), 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, HB 2445 would set restrictions on prescription drug advertising in the state 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.

Advertising Restrictions

Under HB 2445, 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.

Clinical Trials

This bill requires all clinical trials to be posted, Phases I through IV. The bill 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.

Currently, there are **247** industry sponsored clinical trials recruiting or preparing to recruit patients in Hawaii. This bill could put those critical trials in jeopardy.

Section 113 of the Food and Drug Modernization Act of 1997 (FDAMA) requires the Secretary of Health and Human Services (HHS), acting through the Director of the National Institutes of Health (NIH), to "establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions...." 42 U.S. C. §282(j)(1)(A). Following passage of FDAMA, this data bank –

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

known as the Clinical Trials Data Bank – was established by the NIH National Library of Medicine (NLM) and implemented in a phased approach over the course of several years. PhRMA strongly supports the Data Bank as an important resource for physicians and patients seeking information about ongoing clinical trials for serious or life-threatening diseases and conditions, such as cancer. While a clinical trial should not be viewed as a treatment option, such trials nevertheless can provide access to promising new therapies for seriously ill patients with few other options. Ultimately, a successful and robust clinical trial enterprise in the U.S. leads to new cures for all patients.

PhRMA has worked closely with NIH and the FDA over the past several years to establish and implement the Data Bank. For instance, PhRMA established a Task Force on Section 113 that provided significant comments and feedback to the FDA and NLM during the implementation period on a number of issues associated with the Data Bank, including technical issues regarding the web-based interface for posting clinical trial information. PhRMA's efforts have been directed at ensuring that the Data Bank functions as seamlessly as possible so that patients and physicians have access to all relevant information about ongoing clinical trials.

In keeping with their commitment to transparency in the area of clinical trials, PhRMA member companies support the registration of new and ongoing clinical trials. In this regard, information about ongoing clinical trials – beyond what is required by law – has been made available by pharmaceutical companies and posted to the government's existing clinical trial registry (www.clinicaltrials.gov). Under current law, pharmaceutical manufacturers are required to provide information to www.clinicaltrials.gov on clinical trials that deal with serious or life-threatening diseases and conditions. Doctors and patients now have unprecedented access to information about current and ongoing clinical trials and studies. To facilitate access to this important information we encourage Hawaii to provide links to these websites on the appropriate state agency web pages.

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.

Industry Specific Fee

HB 2445 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.

For these reasons, we respectfully urge legislators to oppose Hawaii House Bill 2445.

May Mizuno

From: sandymccul@aol.com
Sent: Wednesday, January 30, 2008 6:23 PM
To: HLTtestimony
Subject: Relating to prescription drugs clinical trials and advertisement

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

FROM: Bruce McCullough
Legislative Committee Chair, HARA
FOR: Committee on Health
Josh Green, Chair; John Mizuno, Vice Chair
DATE: February 1, 2008; Time 8:00 AM; Place RM 329

We are submitting testimony on behalf of the Hawaii Alliance for Retired Americans (HARA). HARA represents over 17,000 retirees, organizations and individuals. HARA is a member of the Alliance for Retired Americans (ARA), a national advocate for seniors and retirees with three million members.

HARA 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 an/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 it to the public for access and review, without impending the company's ability to effective market the drug.

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