SB2506

LINDA LINGLE
GOVERNOR

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LAWRENCE M. REIFURTH
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TO THE SENATE COMMITTEE ON HEALTH

TWENTY-FIFTH STATE LEGISLATURE
REGULAR SESSION, 2010

Monday, February 8, 2010
2:45 p.m.

TESTIMONY ON SENATE BILL NO. 2506
RELATING TO MEDICAL GIFTS

WRITTEN ONLY

TO THE HONORABLE DAVID Y. IGE, CHAIR, AND MEMBERS OF THE COMMITTEE:

The Department of Commerce and Consumer Affairs (Department) appreciates the opportunity to express concerns regarding Senate Bill No. 2506, Relating to Medical Gifts. My name is Lawrence M. Reifurth, and I am the Department's Director. Among other things, Senate Bill No. 2506 proposes to:

(1) With enumerated exceptions, prohibit pharmaceutical and medical device manufacturers and wholesale distributors of medical devices from offering or giving any gift to a health care provider;

(2) Require pharmaceutical and medical device manufacturers to disclose to the Director of Commerce and Consumer Affairs (Director), the value,

nature, and purpose, and recipient information of any allowable expenditures or gifts;

(3) Authorize the Director to bring civil actions for injunctive relief, costs, and attorney's fees and impose on manufacturers that violate the prohibition on gifts a civil penalty of not more than $10,000 per violation ; and

(4) Require the Director to make disclosed data publicly available and searchable through an internet website.

In the interest of government efficiency, the Department suggests that the responsibilities that are being proposed to be place in the Department be placed with an agency that is already performing similar functions. We suggest placing the responsibilities with the State Ethics Commission (Commission).

The Department's core mission is to protect consumers from unfair business practices while "upholding fairness in the marketplace". Among other things, the Department licenses professions and vocations; investigates complaints against professional and vocational licensees; ensures that property and casualty insurance is neither excessive, inadequate, or unfairly discriminatory; and ensures that the State's financial institutions and insurance companies are solvent. This bill would cause the Department to stray from, and lose focus of, its core mission.

However, the Commission already has the responsibility of receiving public financial disclosure filings, gifts disclosure filings, and lobbying filings. The Commission also has enforcement authority for those laws. It would be more efficient for the

Commission to perform functions that are similar to those that it already performs than to have a Department build from the ground up, a system to handle those functions.

For the reasons enumerated above, the Department request that the bill be amended by replacing the Department with the Commission as the agency that will be responsible for the functions called for in the bill.

Thank you for the opportunity to express our concerns over the proposal.

From: mailinglist@capitol.hawaii.gov
Sent: Saturday, February 06, 2010 4:27 PM
To: HTHTestimony
Cc: Tlenzer@hawaii.rr.com
Subject: Testimony for SB2506 on 2/8/2010 2:45:00 PM

Testimony for HTH 2/8/2010 2:45:00 PM SB2506

Conference room: 016
Testifier position: support
Testifier will be present: No
Submitted by: Anthony Lenzer
Organization: Policy Advisory Board for Elder Affairs Legislative Committee
Address:
Phone: 261-2095
E-mail: Tlenzer@hawaii.rr.com
Submitted on: 2/6/2010

Comments:
My name is Anthony Lenzer. I am testifying on behalf of the policy advisory board for elder affairs (PABEA), an appointed board which advises the executive office on aging (EOA). My testimony does not represent the views of the EOA but of the board. PABEA supports Senate Bill 2506, which bans drug or device manufacturers or wholesale distributors of medical devices from offering gifts to healthcare providers except under certain specified conditions. The bill also requires disclosure of permissible gifts to the director of commerce and consumer affairs, and makes these disclosures publicly available. In addition, provides substantial fines for violation of the provisions of this bill.

As the bill indicates, health product manufacturers and distributors have often used gifts, honoraria, trips etc. to influence health care providers into using their products or services. When this happens, patients and consumers do not necessarily get the best or the least expensive products for their health dollars. Specific disclosure rules and regulations, such as those contained in this bill, should reduce the inappropriate offerings of gifts to physicians, hospitals and other healthcare providers. At the same time, the bill clearly indicates the legitimate ways in which such manufacturers and distributors can support those who provide health services to the public.

For these reasons, we strongly support and urge passage of Senate Bill 2506.

Thank you for the opportunity to submit this testimony.

February 5, 2010

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

FROM: Pharmaceutical Research and Manufacturers of America
(William L. Goo)

RE: **SB 2506** - Relating to Medical Gifts

Hearing Date: Monday, February 8, 2010 at 2:45 p.m.

My name is William L. Goo. I represent Pharmaceutical Research and Manufacturers of America (PhRMA).

PhRMA respectfully opposes passage of **SB 2506.** Attached is PhRMA's testimony in opposition.

Thank you for considering this testimony. It is respectfully requested that the Committee hold this measure.

Statement PhRMA

In Opposition to Senate Bill 2506

Position: PhRMA opposes Senate Bill 2506 as it unfairly singles out the pharmaceutical industry which is already policing itself and highly regulated by the Federal government. The proposed legislation requires pharmaceutical manufacturers to report marketing and advertising expenses associated with prescription drug marketing; institutes a ban on items of educational and economic value with limited exceptions; and requires pharmaceutical manufacturers to report economic benefits excepted from the ban in an annual report to the State.

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its members have a strong interest in benefiting patients by providing critical information and access to life-sustaining pharmaceuticals. The industry is committed to patient safety and ethical interactions with healthcare professionals. As part of those efforts, PhRMA issued its updated "Code" on interactions with healthcare providers in 2008 to reflect changes and developments since the Code was first issued.

Federal and PhRMA marketing guidelines make the proposed legislation unnecessary and duplicative of efforts already underway.

Pharmaceutical manufacturers are subject to criminal anti-kickback statutes and other criminal and civil provisions, enforced by the U.S. Department of Justice, that govern their relationships with healthcare providers, and the HHS Office of Inspector General (OIG) maintains detailed guidance for pharmaceutical companies designed to deter violations of these federal laws. These marketing guidelines prohibit *quid pro quos* between drug makers and healthcare professionals. Furthermore, the pharmaceutical industry issued a newly revised version of the Code which is part of an ongoing effort to ensure that pharmaceutical interactions with healthcare providers comply with the highest ethical standards. The Code is based on the principle that a healthcare professional's care of patients should be based solely on each patient's medical needs and the healthcare professional's medical knowledge and experience. The Code prohibits the distribution of non-educational items (pens, mugs, and other "reminder" items), provides detailed standards regarding the independence of continuing medical education (CME), and guidance for speaking and consulting arrangements with healthcare professionals.

SB 2506 threatens to violate federal laws protecting fair trade practices.

A trade secret is "any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others." *Restatement (Third) of Unfair Competition § 39 (1995)* This definition includes compilations of data, pricing, marketing techniques, and the identity and requirements of customers. SB 2506 does not indicate the extent of the state's liability and a manufacturer's recourse for the unauthorized disclosure of protected trade secrets.

Mandatory disclosure of marketing expenses represents unwarranted government interference in a competitive healthcare marketplace.

Mandated disclosure of such marketing expenses as defined by SB 2506 could give competitors proprietary information about each manufacturer's proprietary drug research and marketing practices. The potential result is a decrease in competition in the health care marketplace and an increase in long-term health care costs for Hawaii's residents.

Marketing efforts ultimately benefit patients by promoting competition and helping to improve patient access to prescription drugs.

Marketing increases competition by promoting access to information and choices available in the marketplace that, in turn, reduces prescription drug and other health costs. Pharmaceutical companies compete to discover and develop life-saving and life-enhancing new products, to bring them to market, and to win market share based on the product value.

For the reasons stated above, PhRMA respectfully opposes SB 2506.

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AdvaMed
Advanced Medical Technology Association

February 8, 2010

The Honorable David Y. Ige, Chair
Senate Health Committee
Hawaii Senate
Honohulu, HI 96813

Dear Senator Ige:

I want to let you know of the Advanced Medical Technology Association's (AdvaMed) opposition to Senate Bill 2506, relating to medical gifts. This legislation is unnecessary since this issue is being addressed by federal legislation, your bill will not provide any additional benefit to consumers, and will impose a regulatory burden on medical device manufacturers.

AdvaMed is the primary trade association for companies producing the medical technology that is transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallestmedical technology innovators and companies.

AdvaMed strongly supports ethical interactions between manufacturers and health care providers and we support appropriate disclosure of relationships between medical technology companies and physicians. That is why we have adopted an aggressive Code of Ethics (www.advamed.org) that bans noneducational gifts and provides companies guidance on appropriate interactions with health care professionals, including critically needed education and training on use of sophisticated technologies. As part of the most recent update, effective July 1, 2009, companies certifying adoption of the Code and implementation of an effective compliance program are listed on the association's website. Already, nearly 100 company CEOs have publicly certified the Code will apply within their companies.

Further, it will be much more beneficial for consumers and less burdensome and costly for manufacturers if disclosure of these relationships is done through a single national framework, as will occur with the passage of the federal Physician Payments Sunshine Act of 2009. Additional localized databases, collecting different information over different time periods will only bring greater confusion on the nature of relationships between companies and physicians.

For these reasons, we must oppose Senate Bill 2506. We would be glad to talk with you further about our concerns with this issue.

Sincerely,

Thomas E. Tremble

Thomas E. Tremble
Associate Vice President, State Government Relations

Prepared Testimony of the Marketing Research Association (MRA)

Delivered by Howard Fienberg, PLC (MRA Director of Government Affairs)

To the Senate Health Committee

For the February 8, 2010 hearing regarding S.B. 2506

Chairman Ige, Vice-Chairman Green, and members of the Health Committee, thank you for the honor of allowing me to submit testimony for today's hearing.

I must express the severe concern that this legislation, S.B. 2506, would inadvertently cripple survey and opinion research with health care providers in Hawaii.

My name is Howard Fienberg, and I am the Director of Government Affairs for the Marketing Research Association (MRA), the leading and largest association of the survey and opinion research profession[1]. MRA promotes, advocates and protects the integrity of the research profession and strives to improve research participation and quality.

S.B. 2506 would prohibit gifts from pharmaceutical and medical device manufacturers to health care providers. "Gifts" in this case, unfortunately, would include payments to health care providers for participation in marketing research studies sponsored by such manufacturers, even though such payments are made through independent survey and opinion research companies.

MRA understands and sympathizes with the sponsor's concerns about manufacturers pursuing influence with providers through gifts. But the only influence sought through research incentives is to influence a difficult to reach but highly important community to participate in research. The ban proposed by S.B. 2506 would effectively cease all marketing research with health care providers in Hawaii, whose participation is often tied to sizeable research incentives because of the high demands on and value of their time.

[1] The research profession is a multi-billion dollar worldwide industry, comprised of pollsters and government, public opinion, academic and goods and services researchers. Purchasers of opinion and survey research include the government (the world's largest purchaser), media, political campaigns, and commercial and non-profit entities.

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What is marketing research and what are marketing research incentives?

Though sometimes mistaken for it because of the term, marketing research is not marketing – it is a social science, involving surveys, focus groups, and studies. Most research studies are blinded, to protect the research from bias. The participants, and often the interviewers, are not informed who sponsored the study. More importantly, the sponsors do not know about or choose specific participants and are not given access to any participants' personally identifiable information. Research industry codes **forbid** researchers and their clients from marketing to research study participants.

We know, from experience in states like Maine and West Virginia, that reporting requirements drive manufacturers away from doing *any* research in states that require it. So even if you were to exclude research incentives from the ban in S.B. 2506, the reporting requirements for "allowed" payments would still cease marketing research with providers in Hawaii.

Health care costs

While Hawaii is understandably concerned about rising healthcare costs, marketing research is not part of the problem, it is part of the solution. Studies with providers are an integral part of the fight to control healthcare costs. More and better marketing research results in cost savings. It unveils potential flaws in drugs and devices before they pose a real risk to patients. Marketing research also helps focus scarce resources on effective and necessary drug and device development, technical support, education, and (sometimes) promotion.

Marketing research benefits patients and the public

Marketing research provides benefits far beyond just the information and analysis produced for the companies that purchase it.

- Adverse event reporting: Many pharmaceutical companies are now training third party researchers how to handle "adverse events" that may be reported in marketing research studies and how to correctly route them to the Food and Drug Administration. This ensures a fuller data set for regulators and the public at large, which leads to great safety and awareness.

- Simulations are safer: The best way that medical device manufacturers have to evaluate if health care providers are using their equipment correctly is a simulation – a form of marketing research. It allows a full test of equipment without actually cutting someone open.

- Ensuring patients get needed treatments: Marketing research studies with health care providers about their patients' compliance with treatment regimens help manufacturers

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determine what causes patients to avoid or cease treatment and how to encourage compliance -- which in turn promotes health and longer life.

- Checking adequacy of surgical training: A recent marketing research study discovered a need for much greater applied training for certain kinds of doctors.

- Improving acceptance and adoption of needed drugs and devices: Marketing research studies of how doctors will accept and adopt new drugs and medical devices are crucial to the development of new life-saving drugs and devices. If a drug or device has poor odds of acceptance or adoption, the manufacturer may not invest in producing it, but may learn from the research how to counteract those deficiencies with an improved product.

- Preventing medical errors: Marketing research helps assure comprehension of materials and differentiation of names among health care providers for drugs and devices, which helps prevent "medical errors".

- Role-playing yields results: A series of pharmaceutical and medical device manufacturing marketing research studies involving doctor-patient role playing can garner unexpected findings vital to more than just the studies' sponsors. For example, studies have discovered that physicians often don't describe all available options to patients even though they claim to do so in conventional research surveys.

- Eliminating side effects for patients: Pharmaceutical marketing research with doctors -- through in-depth interviews and focus groups -- led to the reformulation of a drug to deal with its side effects. The drug fights blindness, but resulted in burning red eyes for many users. Marketing research revealed that these side effects, which were not being perfectly reported, were keeping many patients from taking the drugs (on the required schedule, or sometimes at all). Reformulation removed the side effects, saved the drug, and saved many people's sight.

Amending S.B. 2506

I have submitted amendment language, should you be willing to amend S.B. 2506 to affirmatively exclude bona fide marketing research.

There is ample precedent for such exclusion. Only a few weeks ago, on January 20, the Minnesota Board of Pharmacy rescinded their long-standing ban on marketing research incentives, having determined that marketing research constitutes a "genuine research project." In April 2009, the Massachusetts Department of Public Health excluded incentives from their state's new reporting requirements. Finally, in late 2009, the U.S.

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Congress excluded incentives from the Physician Payments Sunshine Act, as part of both the House and Senate-passed healthcare reform bills.[2]

Conclusion

On behalf of MRA, the research profession, and the public, I strongly urge you to consider my suggestions or to work with me on other possible solutions. Thank you again for the opportunity to testify before your Committee. I look forward to talking with you and providing any further information you might require.

[2] Sec. 6002 of H.R. 3590, as passed by the U.S. Senate, and Sec. 1451 of H.R. 3962, as passed by the U.S. House.

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Amendment proposal for S.B. 2506

Submitted by the Marketing Research Association (MRA)

For the February 8, 2010 meeting of the Senate Judiciary Committee

Purpose: to exclude from the ban and reporting requirements in S.B. 2506 marketing research incentives from independent survey and opinion research companies for health care providers to participate in marketing research studies.

In § -1 Definitions, under the definition of "Allowable expenditures", insert:

"(8) Honoraria or payment made indirectly to a health care provider through a third party for participation in bona fide marketing research."

In § -1 Definitions, add a new definition:

" "*Bona fide marketing research*" means the collection and analysis of data regarding opinions, needs, awareness, knowledge, views and behaviors of a population, through the administration of surveys, interviews, focus groups, polls, observation, or other research methodologies, in which no sales, promotional or marketing efforts are involved and through which there is no attempt to influence a participant's attitudes or behavior."

In § -3 Disclosure of allowable expenditures and gifts by manufacturers of prescribed products, insert:

" (i) Disclosure under this section shall not apply to any honoraria or payment made indirectly to a health care provider through a third party for participation in bona fide marketing research."

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Larry Geller
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SB2506
HTH
Monday, February 8, 2010
2:45 p.m.
Room 016

COMMITTEE ON HEALTH
Senator David Y. Ige, Chair
Senator Josh Green, M.D., Vice Chair

February 2, 2010

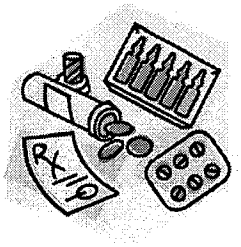
Re: SB2506—Relating to Medical Gifts

In Support—with Amendment

Dear Senator Ige, Senator Green, and members of the Committee:

This bill discourages unethical conduct as a result of payments or gifts. A doctor's decisions should be based on sound research unbiased by corporate compensation.

One clarification though—I hope the bill can make it clear that medical samples intended for patient use are not considered gifts. I personally am grateful when my doctor offers a handful of some little tubes of cream that will solve a skin problem (for example) without the need for me to fill a prescription or pay a co-pay. Of course, if it works and I need more of it, off to the pharmacy I go, since I know it works for me.



The availability of samples lets a doctor try something to see if it works at no expense to the patient.

Samples should be specifically excluded if the Committee agrees.

I urge the committee to pass this bill with the above clarification.

Larry Geller