HB12

HD2

Measure Title:
RELATING TO PRESCRIPTION DRUG COST CONTAINMENT AND AFFORDABLE ACCESS.

Report Title:
Prescription Drug Cost Containment; Disclosure of Gifts

Description:
Requires drug manufacturers to disclose economic benefits of $25 or more provided to persons who prescribe, dispense, or purchase prescription drugs. Provides for subsequent annual disclosures. (HB12 HD2)

Companion:
SB816

Introducer(s):
TAKUMI, BELATTI, BERG, LEE, LUKE, MORITA, NISHIMOTO, SAIKI, TAKAI, THIELEN, Rhoads, Wakai

Current Referral:
HTH, CPH/JDL

OFFICE OF INFORMATION PRACTICES

STATE OF HAWAII
NO. 1 CAPITOL DISTRICT BUILDING
250 SOUTH HOTEL STREET, SUITE 107
HONOLULU, HAWAII 96813
TELEPHONE: 808-586-1400 FAX: 808-586-1412
EMAIL: oip@hawaii.gov

To: Senate Committee on Health

From: Paul T. Tsukiyama, Director

Date: Friday, March 14, 2008, 1:15 p.m.
State Capitol, Room 016

Re: Testimony on H.B. 12, H.D.2
Relating to Prescription Drug Cost Containment and Affordable Access.

Thank you for the opportunity to submit testimony on H.B. 12, H.D. 2. The Office of Information Practices ("OIP") takes no position on the substance of this bill, but makes the following recommendation.

The bill seeks to add a provision at page 2, lines 10-13, which states as follows:

> (c) The board of pharmacy and the attorney general shall keep confidential all trade secret information. The disclosure form prescribed by the board of pharmacy shall permit the company to identify any information that is a trade secret.

OIP recommends that the second sentence be deleted. The sentence is unnecessary to allow an agency to allow a private company to identify what it believes to be a trade secret, which is what some agencies routinely do without such a statutory provision. However, the sentence, as written, appears to create a presumption that the company is allowed to determine what will be protected as a "trade secret."

This is contrary to the agency's responsibilities imposed under chapter 92F, HRS, the Uniform Information Practices Act (Modified), which places the burden on the agency to establish justification for nondisclosure. See Haw. Rev. Stat. § 92F-15 (1993). Thus, under the UIPA, it is the agency that must make the determination that information constitutes a "trade secret" in order to withhold that information. See Haw. Rev. Stat. § 92F-13(4) (1993) (UIPA does not require disclosure of government records which are protected from disclosure pursuant to state or federal law).

Accordingly, to avoid any ambiguity as to the agency's responsibility to make the final determination as to what constitutes a "trade secret," consistent with the UIPA and other confidentiality statutes protecting "trade secrets," OIP recommends that the second sentence of proposed subsection (c) be deleted.

Thank you for the opportunity to testify.

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

MARCH 12, 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: HB12, HD2 Relating to Prescription Drug Cost Containment & Affordable Access

DATE: Friday, March 14, 2008

TIME: 1:15 PM

PLACE: RM. 016 (I will testify in person)

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 is modeled after a Vermont law which was enacted on June 13,2003.

The bill will deter pharmaceutical representatives from unduly influencing the individuals who are responsible for prescribing, dispensing and purchasing prescription drugs.

The cost containment part of the original bill has been removed. This was a very important part of the bill and we would hope that somehow it could be reinstated to this piece of legislation.

March 13, 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: **HB 12, HD 2** Relating to Prescription Drug Cost Containment and Affordable Access

Hearing Date: 3/14/08 at 1:15 p.m.

My name is Norman Suzuki. I am a representative of the Pharmaceutical Research and Manufacturers of America ("PhRMA").

WE RESPECTFULLY OPPOSE PASSAGE OF HB 12, HD 2

WHAT THE BILL DOES:

HB 12, HD 2 requires every manufacturer selling prescription drugs in the State of Hawaii to file an annual disclosure for all items of economic benefit of $25 or more provided to a physician, hospital, nursing home or other provider of health services. The bill requires each company to select someone to be responsible for the accuracy of the disclosure report. Each violation will be subject to a civil penalty of up to $10,000.

LIMITS INFORMATION WHICH BENEFITS PATIENTS:

When a physician, clinic or hospital or other provider receives charts, graphs, medical literature, physical models, visual aids or any type of information which cost $25 or more, a disclosure must be made by the manufacturer. These items are intended to benefit the patient as well as the provider who obtains the information. Such disclosure requirements may be too onerous to comply with. At conventions for medical providers, often literature or other handouts are made available. If this bill becomes law, it will result in a loss to patients as well as doctors and hospitals. Calculating what materials may exceed $25 and having to account and take liability for disclosure may discourage the dissemination of worthwhile information.

REQUIRES TRADE INFORMATION DISCLOSURE:

The bill attempts to indicate that trade secret information will be held confidential, but there is no provision to insure confidentiality or place restrictions on the use of the information

collected. Free samples of drugs, which are given to physicians for needy patients, are excluded from this bill. Most of the promotional and advertising costs of pharmaceutical companies represent the value of free samples passed out to physicians or directly to patients through the various company pharmaceutical assistance plans. To place restrictions on the use of literature or other aids which may accompany the samples appears counterproductive.

IMPACT ON INNOVATION:

Marketing efforts increase competition among pharmaceutical companies by promoting access to information and the choices available in the marketplace. Pharmaceutical companies compete to discover and develop life-saving and life-enhancing new products. Government interference in the marketplace by requirements of disclosure and the attendant major liability for non-disclosure reduces the incentive of pharmaceutical companies to engage in research or development which lead to valuable medicines that may become available in the future. Many smaller companies which may rely on direct marketing to physicians or other providers may not be able to comply or compete.

FEDERAL AND PhRMA GUIDELINES ARE ALREADY IN PLACE:

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, including the *Food, Drug and Cosmetic Act*, the *Federal Anti-Kickback Statute, Prescription Drug Marketing Act*, the *Federal Trade Commission Act*, and the *False Claims Act.* Furthermore, the Federal Health and Human Services Office of Inspection 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 has issued its own voluntary guidelines, *The PhRMA Code for Interactions with Healthcare Professionals* (the "PhRMA Code"), related to communications with healthcare practitioners.

ADDITIONAL COST AND EXPENSE MAY INCREASE PRICES.

Requiring an additional layer of reporting and monitoring, given the presence of both the PhRMA Code and OIG guidance, and existing legal sanctions for unlawful behavior will result in additional compliance costs to the industry. Such compliance will result in increased cost of the product and is counterproductive to the goal of reducing drug costs to consumers. Such legislation that would require substantial oversight would also increase the financial and administrative resource burdens of the State.

Thank you for the opportunity to testify.

HDMA
Healthcare Distribution
Management Association

TESTIMONY IN SUPPORT (WITH SUGGESTED AMENDMENT) ON H.B. 12

SENATE COMMITTEE ON HEALTH

MARCH 14 AT 1:15

The Healthcare Distribution Management Association (HDMA) represents the nation's primary, full-service healthcare distributors and are responsible for ensuring that billions of units of medication are safely delivered to 144,000 retail pharmacies, hospitals, nursing homes, clinics and other provider sites in the most efficient manner possible. In light of the fact that three major healthcare distributors operate significant facilities in the state of Hawaii, we would like to comment on H.B. 12.

HDMA supports the ultimate goal of H.B. 12, that would require drug manfacturers to disclose to the board of pharmacy any economic benefits of $25 or greater to persons who prescribe or purchase prescription drugs. This legislation would ensure that those individuals who are responsible for the prescribing or purchase of prescription drugs do so based on the best interests of the patient rather than as a result of undue influence by pharmaceutical manufacturers.

The current language of H.B. 12 clearly exempts wholesale distributors from the definition of "pharmaceutical marketers" in recognition of the fact that wholesale distributors carry products from all manufacturers and have no vested interest in promoting the products of one manufacturer over another. We respectfully ask that the same exemption language also be included under the definition of "pharmaceutical manufacturing company

The sponsor of H.B. 12, Representative Takumi, is in agreement that wholesale distributors are NOT the intended target of this legislation and is in support of the addition of the following language under the definition of "pharmaceutical manufacturing company"

> "THE TERM DOES NOT INCLUDE A WHOLESALE DRUG DISTRIBUTOR OR THE DISTRIBUTOR'S REPRESENTATIVE WHO PROMOTES OR OTHERWISE MARKETS THE SERVICES OF THE WHOLESALE DRUG DISTRIBUTOR IN CONNECTION WITH A PRESCRIPTION DRUG."

If you have any questions or concerns about the information in this letter, please do not hesitate to contact me at (301) 885-0231 or at spilch@hdmanet.org

Sincerely,

Susan Pilch
Associate Director, State Government Affairs

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The Twenty-Fourth Legislature
Regular Session of 2008

THE SENATE
Committee on Health
Senator David Y. Ige, Chair
Senator Carol Fukunaga, Vice Chair

State Capitol, Conference Room 016
Friday, March 14, 2008; 1:15 p.m.

STATEMENT OF THE ILWU LOCAL 142 ON H.B. 12, HD2 RELATING TO PRESCRIPTION DRUG COST CONTAINMENT AND AFFORDABLE ACCESS

The ILWU Local 142 supports H.B. 12, HD2, which requires drug manufacturers to disclose economic benefits of $25 or more provided to persons who prescribe, dispense, or purchase prescription drugs.

Drug manufacturers have used their huge financial resources to influence those who prescribe, dispense, or purchase prescription drugs. While some may argue that this is the "free market" at work, medications that individuals need to survive or stay healthy should not be subject to biased judgment by those who should be objective and fair. Right or wrong, consumers are influenced by slick advertising on television, magazines, etc. Right or wrong, providers are influenced by drug salesmen who ply them with "free" samples and gifts. Disclosure will help to keep providers accountable.

The ILWU endorses this effort to require full disclosure and urges passage of H.B. 12, HD2. Thank you for the opportunity to provide testimony on this matter.

The Twenty-Fourth Legislature
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THE SENATE
Committee on Health
Senator David Y. Ige, Chair
Senator Carol Fukunaga, Vice Chair

State Capitol, Conference Room 016
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Genentech

IN BUSINESS FOR LIFE

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March 13, 2008

Hon. Roy Takumi
Representative, District 36
Hawaii State Capitol
415 South Beretania Street
Honolulu, HI 96813

RE: OPPOSE - HB 12, Marketing Disclosure Legislation

Dear Rep. Takumi,

On behalf of Genentech, Inc., I am writing to respectfully oppose your HB 12, which would require the disclosure of certain marketing activity.

Certainly transparency is important. However, this bill does not accomplish its intended purpose. It will not reduce drug costs, and if anything, may increase costs as companies struggle to comply.

Doctors do not prescribe drugs in response to drug company marketing activities. In today's world of managed care, doctors do not have the final word on decisions to prescribe or administer drugs, especially for patients with life-threatening, seriously debilitating, or chronic conditions. Rather, health plans lay out the drug coverage rules under which doctors seek prior authorization for the use of the most costly drugs. Disclosing "gifts" to doctors will not change that system.

HB 12 ignores the scientific expertise of our sales force. Our sales force, a large proportion of whom are Doctors of Pharmacy and oncology nurses, have extensive educational backgrounds in biological sciences. They provide valuable assistance to doctors working to understand who the right patients are -- and who the wrong patients are -- for the medications being contemplated to treat serious and complicated diseases like cancer.

Hawaii is currently competing with other states and countries to build a biotech and life sciences industry that could help invigorate the economies of the islands. As you know, the State of Hawaii has committed funding over many years to invest in the businesses and infrastructure to encourage the growth in the high technology industries, such as biotech and the life sciences. Unfortunately, HB 12 would mark Hawaii as hostile to the very industry you hope to attract.

Requiring pharmaceutical disclosure of marketing information would represent unwarranted interference that could decrease competition. It is important to note that no other industry in Hawaii is required to disclose marketing efforts. This bill would unnecessarily add to compliance costs while duplicating voluntary guidelines already established by the industry. It may also potentially violate federal trade secret laws because confidential marketing information would have to be disclosed. Certainly this issue is not best addressed at the state level. As you can imagine, complying with 50 different marketing disclosure laws in 50 different ways would require an inordinate amount of time and resources on the part of life sciences companies like Genentech.

Hawaii's economic future is grounded in attracting and retaining jobs in high technology fields, like biotechnology. With increasing national and international competition, we urge you and your colleagues to reconsider this legislation that would discourage private investment in Hawaii's biotech and life sciences industry.

Considered the founder of the biotechnology industry, Genentech has been delivering on the promise of biotechnology for 30 years, using human genetic information to discover, develop, manufacture and commercialize biotherapeutics that address significant unmet medical needs. Genentech is dedicated to ensuring no patient is denied one of our medications because of their economic circumstances. We are also committed to disclosing clinical trial data and other key information about our FDA approved products to ensure that doctors have all the information they need in order to make the best decisions for their patients.

Please do not hesitate to contact us with any questions or concerns you may have. Thank you for your consideration in this regard.

Respectfully,

Steve Hansen
State Government Affairs

CC: Senator David Ige, Chair of the Senate Health Committee
Senator Rosalyn H. Baker
Senator Ron Menor
Senator Paul Whalen
Linda Smith, Senior Policy Advisor to Gov. Lingle