HOUSE OF REPRESENTATIVES
TWENTY-THIRD LEGISLATURE, 2006
STATE OF HAWAII

H.B. NO. 1875

A BILL FOR AN ACT

RELATING TO ETHICAL MARKETING OF PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that prescription drug spending is the fastest growing component of health care spending in the United States. Drug manufacturers' one-on-one marketing to doctors, called "detailing", is resulting in doctors prescribing the most expensive medications, even when less expensive drugs are as effective or safer. Drug companies spend more than $16,000,000 a year on detailing of products to doctors. Gifts from prescription drug detailers to doctors play a major role in persuading doctors to change the drugs that they prescribe. More than eighty-four per cent of physicians indicate their prescribing has been influenced by lobbying from pharmaceutical companies.

The purpose of this Act is to lower prescription drug costs for individuals, businesses, and the State and to protect the health of Hawaii residents by deterring the practice of unethical gift giving by drug manufacturers.

SECTION 2. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"CHAPTER

ETHICAL MARKETING OF PRESCRIPTION DRUGS

§ -1 Definitions. For the purposes of this part, unless the context requires otherwise:

"Director" means the director of health or the director's designee.

"Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the Food and Drug Administration under 21 C.F.R. 207.20 (1999).

"Manufacturer" means a manufacturer of prescription drugs as defined in 42 U.S.C. section 132996r-8(k)(5), including a subsidiary or affiliate of a manufacturer.

"Pharmaceutical manufacturing company" means any entity that is engaged in the:

(1) Production, preparation, propagation, compounding, conversion, or processing of prescription drugs either directly or indirectly by extraction from substances

of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Packaging, repackaging, labeling, relabeling, or distribution of prescription drugs.

The term does not include a wholesale drug distributor or a licensed pharmacist.

"Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this State to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. 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.

§ -2 Disclosure of marketing practices. (a) Not later than October 1 of each year, every manufacturer and labeler who sells prescription drugs in the State shall disclose to the

director the name and address of the individual responsible for the company's compliance with this section.

(b) Not later than January 1 of each year, every manufacturer and labeler that sells prescription drugs in the State shall disclose to the director the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit in excess of $25 that is provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in the State authorized to prescribe, dispense, or purchase prescription drugs in this State. Disclosure shall cover the prior period of July 1 to June 30. Disclosure shall be made on a form and in a manner prescribed by the director.

(c) Not later than March 1 of each year, the director shall submit a report to the governor and the legislature on the disclosures made pursuant to this section.

(d) The following shall be exempt from disclosure:

(1) Any gift, fee, payment, subsidy, or other economic benefit the value of which is less than $25;

(2) Free samples of prescription drugs to be distributed to patients;

(3) Payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials. For the purposes of this section, "clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments; and

(4) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

§ **-3 Administration and enforcement.** (a) This chapter shall be enforced by the director, who shall adopt rules under chapter 91 necessary to implement this chapter and to administer compliance.

(b) The director may bring an action in court for injunctive relief, costs, and attorney's fees and to impose upon

a pharmaceutical manufacturing company that fails to make the required disclosures a civil penalty of up to $10,000 per violation. Each unlawful disclosure shall constitute a separate violation."

SECTION 3. The initial disclosure required pursuant to this Act shall be made before January 1, 2008, for the twelve-month period ending June 30, 2007.

SECTION 4. This Act shall take effect on July 1, 2006.

INTRODUCED BY: _____

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HB 1875

Report Title:
Physicians; Drug Detailing; Disclosure

Description:
Establishes ethical prescription drug marketing law. Requires annual disclosure of gifts worth more than $25 from pharmaceutical companies or their representatives to physicians and health care providers who issue prescriptions.