ACT 122 H.B. NO. 2057-82

A Bill for an Act Relating to Drugs.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Chapter 328, Hawaii Revised Statutes, is amended as follows:

1. By adding a new section to part I to be appropriately designated and to read as follows:

"§328- **Principal labeler responsibility under recall of drug.** Whenever the manufacturer of a drug voluntarily recalls the drug or the federal Food and Drug Administration or a court orders the recall of a drug, the principal labeler of the drug shall remove the drug from all pharmacies, prescriber offices, and health care facilities."

2. Section 328-2 is amended by adding a new definition of "principal labeler" to be appropriately inserted and to read as follows:

""Principal labeler" means the manufacturer, packer, or distributor whose name is on the package which contains the finished drug and is distributed to the dispenser. If more than one name is on the package, the principal labeler shall be the manufacturer, packer, or distributor whose name is on the package and who had possession of the package immediately before the dispenser of the drug."

3. Section 328-91 is amended by adding a new definition to be appropriately inserted and to read as follows:

""Agent" means a person under the direct supervision of a dispenser, acting in the dispenser's presence."

4. Section 328-92 is amended by amending subsections (a) and (b) to read as follows:

"(a) A dispenser or his authorized agent [filling a prescription for a drug product prescribed by its trade or brand name] shall:

(1) Offer to the consumer substitutable and lower cost equivalent drug products from the formulary, adopted pursuant to section 328-96;

(2) Inform the consumer of the retail price difference between the brand name drug product and the substitutable drug product; and

(3) Inform the consumer on his or her right to refuse substitution.

The dispenser shall substitute if the consumer consents, [and] the prescriber does

not prohibit substitution under subsection (b), and the price of the substitute equivalent drug product is less than the price of the prescribed drug product. The dispenser shall not substitute if the consumer refuses.

(b) [The] In filling initial or original prescriptions, the dispenser shall not substitute an equivalent drug product if the prescriber, and only the prescriber, handwrites "do not substitute" on the written prescription. The dispenser shall not substitute an equivalent drug product if the prescription is ordered orally [,] unless the oral prescription is a refill of a prior written prescription for which selection of an equivalent drug product was permitted. The designation of "do not substitute" and the physician's signature shall not be preprinted or stamped on the prescription.] and the prescriber or authorized employee of the prescriber orally orders "do not substitute".

In refilling prior written prescriptions, the dispenser shall not substitute an equivalent drug product if the oral prescription is a refill of a prior written prescription for which selection of an equivalent drug product was not permitted; provided that if the prior written prescription permitted the selection of an equivalent drug product, such substitution may be allowed. However, the dispenser shall not substitute an equivalent drug product if a refill of a prescription is ordered orally and the prescriber or authorized employee of the prescriber orally orders "do not substitute".

The designation of "do not substitute" and the physician's signature shall not be preprinted or stamped on the prescription."

5. Section 328-93 is amended to read as follows:

"[[]§328-93[]] **Prescription label.** Every dispenser shall indicate on the label affixed to the immediate container in which the drug product is sold or dispensed the name and strength of the drug product and [its manufacturer] the name or commonly accepted abbreviation of the principal labeler, and the statement "Substituted for (Brand name of drug product prescribed)" unless the prescriber specifically states otherwise. The dispenser shall record on the prescription form the brand name or the name or commonly accepted abbreviation of the [manufacturer] principal labeler of the drug product dispensed."

6. Section 328-96 is amended by amending subsection (a) to read as follows:

"(a) The board shall adopt rules, pursuant to chapter 91, for the establishment and maintenance of a state drug formulary of equivalent drug products, and to effectuate the purpose of this part. The formulary shall list all drug products that the Commissioner of Food and Drugs, United States Food and Drug Administration, has approved as safe and effective, and has determined to be therapeutically equivalent. [The formulary shall also list all drug products that (1) were not subject to premarketing approval for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act; (2) are manufactured by firms meeting the requirements of that Act; (3) are subject to pharmacopoeial standards adequate to assure product quality; and (4) have been determined by the Commissioner of Food and Drugs to meet any other requirements necessary to assure therapeutic equivalence.] The formulary may list additional drug products that are determined by the board to meet requirements adequate to assure product quality and therapeutic equivalence. The formulary may delete approved drugs upon a finding that product quality or therapeutic equivalency or bioequivalency, as appropriate, is not adequately

assured."

7. Section 328-96 is amended by amending subsection (c) to read as follows:

"(c) The department of health shall provide for distribution of the formulary and revisions to all dispensers and prescribers licensed and practicing in this State and to other appropriate individuals. The department of health may establish fees to be charged to persons who receive the formulary and revisions. The amounts of the fees charged for the formulary and revisions shall be approximately the same as the costs of producing and distributing the formulary and revisions."

SECTION 2. Statutory material to be repealed is bracketed. New material is underscored.[1]

SECTION 3. This Act shall take effect upon its approval.

(Approved May 26, 1982.)

Note

1. Edited pursuant to HRS §23G-16.5.