ACT 187 S.B. NO. 2134-80

A Bill for an Act Relating to Food, Drugs, and Cosmetics.

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

SECTION 1. Chapter 328, Hawaii Revised Statutes, is amended by adding a

new part to be appropriately designated and to read as follows:

"PART . DRUG PRODUCT SELECTION

Sec. 328- Definitions. As used in this part:

(1) "Bioequivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability, as defined by the Federal Food and Drug Administration.

(2) "Board" means the drug product selection board.

(3) "Dispenser" means a person authorized to dispense drugs in the State.

(4) "Equivalent drug product" means a drug product with the same established name, active ingredient strength, quantity, and dosage form as the drug product identified in the prescription, and listed as therapeutically equivalent in the current state drug formulary.

(5) "Established name" has the meaning given in section 502(e) (3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 352(e) (3)).

(6) "Prescriber" means a person licensed by the State to prescribe drug products.

Sec. 328- Drug product selection. (a) A dispenser 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- ;

(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 shall not substitute if the consumer refuses.

(b) 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 a 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.

(c) The dispenser shall not substitute an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.

(d) Enforcement. Any wilful violation of this part shall be a misdemeanor. The county prosecutors and the attorney general may bring action upon complaint by an aggrieved person or upon their motion in the name of the State against any person to enjoin any violation of this part.

Sec. 328- 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 unless the prescriber specifically states otherwise. The dispenser shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

Sec. 328- Prescription record. Each dispenser shall maintain a record of any substitution of a generically equivalent drug product for a prescribed brand name drug product as provided in this part.

Sec. 328- Establishment of drug product selection board. (a) There is established a drug product selection board composed of one representative from the department of health, one representative from either the University of Hawaii school of medicine or the University of Hawaii school of public health, two physicians, and two pharmacists; to be appointed by the governor with the advice and consent of the senate, pursuant to section 26-34. The board shall designate the chairman from its duly appointed membership. A seventh member shall be the director of health or his designated representative.

(b) The drug product selection board shall be placed, for administrative purposes only, within the department of health.

(c) The members of the drug product selection board shall serve without compensation, but shall be reimbursed for expenses, including travel expenses, incurred in the performance of their duties.

Sec. 328- Drug formulary. (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.

(b) The board shall provide for revision of the formulary as necessary but not less than annually. The formulary shall be adopted by the board no later than January 1, 1981.

(c) The department of health shall provide for distribution of the formulary and revisions to all dispensers and prescribers licensed in this State and to other appropriate individuals.

(d) The department of health shall provide for public education regarding the provisions of this part and shall monitor the effects of this part.

Sec. 328- Posting requirements. Every pharmacy shall prominently display, in clear and unobstructed public view, a sign in block letters which shall read: "HAWAII LAW REQUIRES THAT LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG PRODUCTS BE OFFERED TO THE CONSUMER. CONSULT YOUR PHYSICIAN AND PHARMACIST CONCERNING THE AVAILABILITY OF THE LEAST EXPENSIVE DRUG PRODUCT FOR YOUR USE." The letters must be at least one inch in height.

Sec. 328- Dispenser liability. A dispenser who selects an equivalent drug product pursuant to this part assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

Sec. 328- Exceptions. Out-of-state prescriptions filled pursuant to section 330-7 shall be exempt from this part."

SECTION 2. Section 328-6, Hawaii Revised Statutes, is amended to read as follows:

"**Sec. 328-6 Prohibited acts.** The following acts and the causing thereof within the State by any person are prohibited:

(1) The manufacture, sale, delivery, holding, or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
(2) The adulteration or misbranding of any food, drug, device, or cosmetic;
(3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;
(4) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 328-11, 328-12, or 328-17;
(5) The dissemination of any false advertisement;
(6) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by sections 328-22, 328-23 to 328-27, or to permit access to or copying of any record as authorized by section 328-23;
(7) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the State from whom he received in good faith the food, drug, device, or cosmetic;
(8) The removal or disposal of a detained or embargoed article in violation of sections 328-25 to 328-27;
(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if the act is done while the article is held for sale and results in the article being adulterated or misbranded;
(10) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under this part or the Federal Act;
(11) The using, on the labeling of any drug or in any advertisement relating to the drug, of any representation or suggestion that an application with respect to the drug is effective under section 328-17, or that the drug complies with the provisions of such section;
(12) The using by any person to his own advantage, or revealing other than to the department of health or to the courts when relevant in any judicial proceeding under this part, any information acquired under authority of section 328-11, 328-12, 328-17, or 328-23, concerning any method or process

which as a trade secret is entitled to protection;

(13) In the case of a prescription drug distributed or offered for sale in this State, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer the drug who makes written request for information as to the drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the Federal Act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this part;

(14)(A) Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or

(B) Selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by [clause] subparagraph (A) hereof; or

(C) Making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device, or container thereof;

(15) [Dispensing] Except as provided in part dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without express permission in each case of the person ordering or prescribing;

(16) The distribution in commerce of a consumer commodity as defined in this part, if such commodity is contained in a package, or if there is affixed to that commodity a label, which does not conform to the provisions of this part and of regulations promulgated under authority of this part; provided that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons (1) are engaged in the packaging or labeling of such commodities, or (2) prescribe or specify by any means the manner in which such commodities are packaged or labeled;

(17) The selling or dispensing in restaurants, soda fountains, drive-ins, lunch wagons, or similar public eating establishments of imitation milk and imitation milk products in place of fresh milk and fresh milk products respectively; of liquid or dry products which simulate cream but do not comply with content requirements for cream in place of cream; of non-dairy frozen desserts which do not comply with content requirements for dairy frozen desserts in place of dairy frozen desserts; and of any other imitation food or

one made in semblance of a genuine food in place of such genuine food, unless the consumer is notified by either proper labeling or conspicuous posted signs or conspicuous notices on menu cards and advertisements informing of such substitution, to include but not limited to the substitution of imitation milk in milk shake and malted milk drinks;

[[](18) []] Wilfully and falsely representing or using any devices, substances, methods, or treatment as effective in the diagnosis, cure, mitigation, treatment, or alleviation of cancer. The provisions of this paragraph shall not apply to any person who depends exclusively upon prayer for healing in accordance with teachings of a bona fide religious sect, denomination, or organization, nor to a practitioner thereof."

SECTION 3. Statutory material to be repealed is bracketed. New material is underscored.

SECTION 4. This Act shall take effect upon its approval.

(Approved May 30, 1980.)