CHAPTER 1116

PRESCRIPTION DRUGS

H. F. 200

AN ACT relating to the labeling of prescription drugs, requiring that certain information regarding prescription drugs be made available to the board of pharmacy examiners and to pharmacists and practitioners in this state.

Be It Enacted by the General Assembly of the State of Iowa:

SECTION 1. Section one hundred fifty-five point three (155.3), Code 1975, is amended by adding the following new subsections:

NEW SUBSECTION. "Demonstrated bioavailability" is a term used to refer to the rate and extent of absorption of a drug or drug ingredient from a specified dosage form, as reflected by the time-concentration curve of the drug or drug ingredient in the systemic circulation.

NEW SUBSECTION. "Manufacturer" means a person who prepares, compounds, processes or fabricates any prescription drug.

NEW SUBSECTION. "Packer" or "distributor" means a person who repackages or otherwise changes the container, wrapper or labeling of any prescription drug in furtherance of the distribution of the drug, but does not include a retailer who repackages a prescription drug at the time of sale to its ultimate consumer.

NEW SUBSECTION. "Brand name" or "trade name" means the registered trademark name given to a drug product or ingredient by its manufacturer, labeler or distributor.

NEW SUBSECTION. "Generic name" means the official title of a drug or drug ingredient published in an official compendium as defined in section two hundred three A point two (203A.2), subsection six (6), of the Code.

NEW SUBSECTION. The "finished dosage form" of a prescription drug is that form of the drug which is or is intended to be dispensed or administered to the patient, and which requires no further manufacturing or processing other than packaging, reconstituting and labeling.

SEC. 2. Section one hundred fifty-five point thirteen (155.13), subsection six (6), Code 1975, is amended to read as follows:

6. Substitution of a drug, *or* substance, ~~or~~ ~~brand~~ other than the drug, *or* substance ~~or~~ ~~brand~~ ordered in the prescription of a physician, dentist, podiatrist or veterinarian licensed by law.

SEC. 3. Chapter one hundred fifty-five (155), Code 1975, is amended by adding the following new section:

NEW SECTION. **Nonequivalent drug or drug product list.** The board shall be responsible for designating drugs or drug products which, because of the lack of demonstrated bioavailability, would pose an actual threat to the health, safety, and welfare of the people of Iowa if such drugs or drug products were subject to dispensing under the provisions of section four (4) of this Act. Within one hundred eighty days after the effective date of this Act, the board shall cause to be issued a list of those drugs or drug products which have been demonstrated as being nonequivalent and are not interchangeable as determined by the federal food and drug administration. The board shall mail a copy of the nonequivalent drug or drug product list to each pharmacy registered with it and each physician, dentist, podiatrist and veterinarian licensed to practice in this state. Thereafter, the board shall from time to time make additions to or deletions from the nonequivalent drug or drug product list as determined by the federal food and drug administration. Notification of such additions or deletions shall be made promptly to each pharmacist registered with the board and each physician, dentist, podiatrist and veterinarian licensed to practice in this state.

SEC. 4. Chapter one hundred fifty-five (155), Code 1975, is amended by adding the following new section:

NEW SECTION. **Product selection by pharmacist-restrictions.**

1. If a physician, dentist, podiatrist or veterinarian prescribes, either in writing or orally, a drug by its brand or trade name and does not specifically state that only that designated brand or trade name drug product is to be dispensed, and if the pharmacy to which the prescription is presented or communicated has in stock one or more other drug products with the same generic name and demonstrated bioavailability as the one prescribed, the pharmacist may exercise his or her professional judgment in the economic interest of the patient or the patient's adult representative who is purchasing the prescription by selecting a drug product generically equivalent to but of lesser cost than the one prescribed for dispensing and sale to the patient. If the pharmacist does so, he or she shall inform the patient or the patient's adult representative of the savings which the patient will obtain as a result of substitution and pass on to the patient or the patient's representative the full difference in actual acquisition costs between the drug prescribed and the drug substituted.

If the cost of the prescription or any part thereof shall be paid by expenditure of public funds authorized under chapters two hundred thirty-nine (239), two hundred forty-nine (249), two hundred forty-nine A (249A), two hundred fifty-two (252), two hundred fifty-three (253), two hundred fifty-four (254), or two hundred fifty-five (255) of the Code of Iowa, the pharmacist shall exercise his or her professional judgment by selecting a drug product of the same generic name and demonstrated bioavailability but of a lesser cost than the one prescribed for dispensing and sale to the person unless the physician, dentist, or podiatrist specifically states that only that designated brand or trade name drug product is to be dispensed. Under no circumstances shall a pharmacy to which the prescription is presented or communicated be required to substitute a drug of the same generic name and demonstrated bioavailability but of lesser cost unless the pharmacy has in stock one or more other such drug products.

2. The pharmacist shall not dispense a generically equivalent drug product under this section if:

a. The prescriber indicates that no drug product selection shall be made; or

b. The person presenting the prescription indicates that only the specific drug product prescribed is to be dispensed, unless the substitution is one required by subsection one (1), unnumbered paragraph two (2), of this section; or

c. The drug product to be dispensed is listed in the nonequivalent drug product list.

3. If substitution of a generically equivalent drug product for the designated brand or trade name drug product prescribed is made under this section, the pharmacist making the substitution shall note that fact and the name of the manufacturer of the selected drug on the prescription presented by the patient or the patient's representative, or the substitution shall be reduced to writing by the pharmacist pursuant to section one hundred fifty-five point thirty-three (155.33), subsection two (2) of the Code.

SEC. 5. Section two hundred three A point two (203A.2), Code 1975, is amended by adding the following new subsections:

NEW SUBSECTION. "Manufacturer" means a person who prepares, compounds, processes or fabricates any prescription drug.

NEW SUBSECTION. "Packer" or "distributor" means a person who repackages or otherwise changes the container, wrapper or labeling of any prescription drug in furtherance of the distribution of the drug or cosmetic, but does not include a retailer who repackages a drug or cosmetic at the time of sale to its ultimate consumer.

SEC. 6. Section two hundred three A point ten (203A.10), subsection two (2), Code 1975, is amended to read as follows:

2. If in package form unless it bears a label containing (a) the name and place of business of the manufacturer, *and if different, the name and place of the* packer, or distributor; and (b) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under clause "a" of this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the board. *Any drug subject to and in compliance with section seven (7) of this Act shall be deemed in compliance with clause "a" of this subsection.*

SEC. 7. Chapter two hundred three A (203A), Code 1975, is amended by adding the following new section:

NEW SECTION. **Information filed and placed on labels.** Any prescription drug, as defined in section one hundred fifty-five point three (155.3), subsection ten (10) of the Code, is misbranded unless:

1. The label sets forth:

a. The generic name of the drug, which shall be printed in a type size at least half as large as that used for the brand or trade name of the drug product; and

b. The name and place of business of the actual manufacturer of the finished dosage form of the drug and if different, the name and place of business of the packer or distributor of the drug.

2. There has been filed with the board by the manufacturer packer or distributor of the drug a statement which is accurate with respect to the drug setting forth the information required by subsection one (1) of this section together with all additional information relating to demonstrated bioavailability, side effects, contraindications and effectiveness as may be required by rules of the board.

Approved May 7, 1976

CHAPTER 1117

PRESCRIPTION DRUGS AND CONTROLLED SUBSTANCES

H. F. 1464

AN ACT relating to regulation of prescription drugs and controlled substances by the board of pharmacy examiners.

Be It Enacted by the General Assembly of the State of Iowa:

SECTION 1. Section one hundred fifty-five point three (155.3), subsection five (5), Code 1975, is amended to read as follows:

5. The term "wholesaler" shall mean any person operating or maintaining, *either within or outside this state,* a manufacturing plant, wholesale distribution center, wholesale business or any other business in which prescription drugs, medicinal chemicals, medicines or poisons, are sold, manufactured, compounded, dispensed, stocked, exposed or offered for sale at wholesale *in this state.* The term "wholesaler" shall not include those wholesalers who sell only the products defined in subsection 7. Nothing contained in this subsection shall in any way affect the exemptions provided in section 155.25.

SEC. 2. Section one hundred fifty-five point twelve (155.12), unnumbered paragraph two (2), Code 1975, is amended to read as follows: