FEB 13 1975

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HOUSE FILE 200

STATE GOVERNMENT, Pass pen 5/9/7

By PATCHETT, MONROE and KRAUSE

House File 200
State Government
Patchett, Chairman
Monroe
Drake

House File 200
State Government
Patchett, Chair
Monroe
Drake

Passed House, Date 2-26-76 (p. 705) Passed Senate, Date _____

Vote: Ayes 84 Nays 4 Vote: Ayes _____ Nays _____

Approved _____

A BILL FOR

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, and clarifying the right of a wholesale drug salesman to possess prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

S.F. _____ H.F. 200

Section 1. Section two hundred three A point two (203A.2), Code 1975, is amended by adding the following new subsections:

NEW SUBSECTION. The "established name" of a prescription drug is:

a. The applicable official name designated pursuant to section three hundred fifty-eight (358) of the federal Act; or

b. If there is no applicable official name and the drug is recognized in an official compendium, then its official title in that compendium, however if a drug is recognized in the United States Pharmacopoeia and the Homeopathic Pharmacopoeia under different official titles the established name is that appearing in the United States Pharmacopoeia unless the drug is labeled and offered for sale as a homeopathic drug, in which case the official title listed in the Homeopathic Pharmacopoeia shall be the established name; or

c. If neither paragraph a nor paragraph b apply, the common or usual name of the drug.

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.

NEW SUBSECTION. "Bioequivalent" and "bioequivalence" are terms which, when applied to two or more chemically equivalent drug products, indicate that all of the products are equal in bioavailability.

NEW SUBSECTION. "Bioavailability" is a term used to indicate both the relative amount of an administered drug that reaches the general circulation and the rate at which this occurs.

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

NEW SUBSECTION. "Packer" or "distributor" means a person who repackages or otherwise changes the container, wrapper or labeling of any drug or cosmetic 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. 2. 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, 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 five (5) of this Act shall be deemed in compliance with clause "a" of this subsection.

Sec. 3. Chapter two hundred three A (203A), Code 1975, is amended by adding sections four (4) through seven (7) of this Act.

Sec. 4. NEW SECTION. STATEMENT OF PURPOSE. The enactment of sections five (5) through seven (7) of this Act is an exercise by the general assembly of its power to protect the health, safety and welfare of the citizens of this state, by:

1. Enabling consumers to rely upon chemically equivalent drug products certified interchangeable by the board to produce, within an acceptable degree of tolerance, equivalent therapeutic effects when lawfully administered or prescribed and dispensed; and

2. Seeking to make it feasible for the state to require that, where any drug lawfully prescribed for an individual entitled to any form of public assistance is to be paid for wholly or partially by public funds and is available as two

or more drug products certified interchangeable by the board, the lowest priced available drug product shall be dispensed.

Sec. 5. NEW SECTION. INFORMATION FILED AND DISTRIBUTED. Any prescription drug, as defined in section one hundred fifty-five point three (155.3), subsection ten (10), of the Code is misbranded unless there has been filed with the board by the manufacturer, packer or distributor of the drug, and included in all advertisements and other descriptive matter concerning the drug issued or caused to be issued by the manufacturer, packer or distributor, a statement which is accurate with respect to the drug setting forth:

1. The established name of the drug, which in advertisements and other descriptive matter shall be printed in a type size at least half as large as that used for the proprietary name of the drug product.

2. The name and place of business of the actual manufacturer of the finished dosage form of the drug and the name and place of business of the packer or distributor of the drug.

3. Additional information relating to side effects, contraindications and effectiveness as may be required by rules adopted by the board. The information required by the board under this subsection shall be no less extensive than that required by section five hundred two (502), subsection n, of the federal Act.

4. In addition to the information made available pursuant to subsection three (3) of this section, such information concerning the bioequivalence of any drug product with any other chemically identical drug product as the board shall require in order to implement section six (6) of this Act.

Sec. 6. NEW SECTION. LIST OF CHEMICAL EQUIVALENTS--CERTIFICATION OF INTERCHANGEABILITY. The board shall as expeditiously as possible prepare and thereafter update as necessary a list of all groups of two or more chemically equivalent prescription drug products which to its knowledge

are administered or dispensed in this state, and shall assign each group to one of the two following classifications:

1. Those for which bioequivalence is not considered essential to safe and effective therapeutic use. The board shall certify as interchangeable any drug products constituting a group classified under this subsection.

2. Those for which bioequivalence is considered essential to safe and effective therapeutic use. The board shall certify as interchangeable any two or more drug products included in a group classified under this subsection when satisfied, on the basis of information submitted to the board as required by section five (5), subsection four (4), of this Act, that the drug products are bioequivalent.

Sec. 7. NEW SECTION. INFORMATION TO BE DISSEMINATED. The board shall adopt rules requiring that all pharmacists and all practitioners authorized by law to prescribe drugs shall receive all of the information filed with the board pursuant to section five (5) of this Act, either from the board or from the manufacturers, packers or distributors, as is deemed most appropriate and feasible.

Sec. 8. Section one hundred fifty-five point twenty-six (155.26), Code 1975, is amended to read as follows:

155.26 POSSESSION OF PRESCRIPTION DRUGS. Any person found in possession of a drug or medicine limited by law to dispensation by a prescription, unless such drug or medicine was so lawfully dispensed, shall be deemed guilty of violating the provisions of this section, and upon conviction thereof, shall be fined not more than one thousand dollars or be imprisoned in the county jail for not more than one year, or both. This section shall not apply to a licensed pharmacy, wholesale salesman, licensed wholesaler, physician, veterinarian, dentist, podiatrist or nurse acting under the direction of a physician or the board of pharmacy examiners, its officers, agents, inspectors, and representatives, nor to a common carrier or messenger when transporting such drug

or medicine in the same unbroken package in which the drug or medicine was delivered to him for transportation.

Sec. 9. The board of pharmacy examiners shall not later than January 15, 1976 and January 15, 1977 submit reports to the president of the senate and the speaker of the house, for transmission to the appropriate standing committees of the senate and house, stating what progress has been made and what problems, if any, have been encountered in implementing sections five (5) and six (6) of this Act.

Sec. 10. The operation of section five (5) of this Act, with reference to any prescription drug being administered, prescribed, dispensed or lawfully offered for sale in this state on the effective date of this Act, is suspended until the required information has been filed with the board of pharmacy examiners or until March 1, 1976, whichever date occurs earlier with respect to each individual prescription drug.

EXPLANATION

This bill requires the Board of Pharmacy Examiners to obtain information regarding all prescription drugs lawfully available for distribution in Iowa which are chemically identical, and which of the chemically identical drug products may safely be considered "bioequivalent". This term refers to equality of amount and rate of absorption into the bloodstream. Not all drug products which are chemically equivalent are bioequivalent, and in some cases drug products chemically equivalent but not bioequivalent should not be substituted for each other in filling a prescription.

Under this bill, the Board of Pharmacy Examiners must first determine which chemically equivalent drug products may be interchanged without regard to bioequivalence. The Board must also determine, where bioequivalence is important, which groups of chemically identical drug products have been demonstrated to be bioequivalent and may therefore be safely interchanged. This information must be distributed to pharmacists

and doctors so that they and their customers may take into consideration the relative prices of interchangeable drug products when a prescription is filled.

H-5197

Amend House File 200 as follows:

1. By striking all after the enacting clause and inserting in lieu thereof the following:

"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 a substantial 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 person purchasing the prescription by selecting a drug product generically equivalent to but of equal or lesser cost than the one prescribed for dispensing and sale to the person.

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; or

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

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 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 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."

2. Amend the title by striking from line 4 the words "state, and" and by striking all of lines 5 and 6, and inserting in lieu thereof the word "state."

H-5197 FILED - Adopted BY COMMITTEE ON STATE GOVERNMENT Amended by 5315, 5318
FEBRUARY 11, 1976 2/26 MONROE of Des Moines, Chair and 5365
Vote 45 46 (p. 704)

HOUSE FILE 200

H-5315

Amend the Committee on State Government amendment, H-5197, to House File 200 as follows:

1. Page 2, line 38, by striking the word "person" and inserting in lieu thereof the words "patient or the patient's adult representative who is".

2. Page 2, line 40, by striking the words "equal or".

3. Page 2, line 41, by striking the word "person" and inserting in lieu thereof the word "patient".

4. Page 2, by inserting after line 41 the words "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."

H-5315 FILED - adopted 2/26 BY CUSACK of Scott
FEBRUARY 23, 1976 (p. 693) DRAKE of Muscatine
EGENES of Story
BYERLY of Polk

HOUSE FILE 200

H-5318

Amend the Committee on State Government amendment, H-5197, to House File 200, page 4, by inserting after line 1 the following section:

"Sec. ___. Section twenty-five A point fourteen (25A.14), Code 1975, is amended by adding the following new subsection:

NEW SUBSECTION. In the event of a substitution, pursuant to section four (4) of this Act, or any unauthorized substitution by a pharmacist of a different drug product than that prescribed by a physician, the state of Iowa shall not be liable for any injury as the result of such substitution under this chapter or other act of the general assembly."

H-5318 FILED - adopted 2/26 BY DRAKE of Muscatine
FEBRUARY 24, 1976 (p. 693) HARVEY of Scott
DOYLE of Woodbury
VARLEY of Adair
WYCKOFF of Benton

H-5351

Amend the Committee on State Government amendment H-5197 to House File 200 as follows:

1. Page 2, by inserting after line 41 the following: "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 in the economic interest of the person purchasing the prescription by selecting a drug product generically equivalent to and of 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."

H-5351 FILED - 5365 substituted FEBRUARY 26, 1976

BY GILLOON of Dubuque
DYRLAND of Clayton
HORN of Linn
TAUKE of Dubuque
JOCHUM of Dubuque
HINES of Story
HUSAK of Tama

H-5365

Amend the Committee on State Government amendment H-5197 to House File 200 as follows:

1. Page 2, by inserting after line 41 the following: "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.

H-5365 FILED - Substituted for 5351 and adopted 2/26 (p. 704) 45-40 FEBRUARY 26, 1976

BY GILLOON of Dubuque

Sen. Hr House File 200
Human Resources
Gluba, Chairperson
Plymat
Miller of Des Moines

4 Pages per 5439 4/2

HOUSE FILE 200

By PATCHETT, MONROE and KRAUSE

(As Amended and Passed by the House)

Passed House, Date 4-7-76 (1213) Passed Senate, Date 4-7-76 (1213)
Vote: Ayes 46 Nays 0 Vote: Ayes 46 Nays 0
Approved 5-7-76

Re-passed House for Senate amendment
4-15-76 (1968)
89-3

A BILL FOR

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:

House Amendments

S.F. _____ H.F. 206

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 a substantial 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 non-equivalent 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 bioavilability 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 bio-availability 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; or

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

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 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 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.

Sec. 8. Section twenty-five A point fourteen (25A.14), Code 1975, is amended by adding the following new subsection:

NEW SUBSECTION. In the event of a substitution, pursuant to section four (4) of this Act, or any unauthorized substitution by a pharmacist of a different drug product than that prescribed by a physician, the state of Iowa shall not be liable for any injury as the result of such substitution under this chapter or other act of the general assembly.

S-5439

Amend House File 200, as amended, passed and reprinted by the House, as follows:

1. Page 3, by striking lines 18 through 35, and page 4, by striking line 1.

2. Page 4, by inserting after line 10 the following:

"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 on the prescription presented by the patient or the patient's representative, or reduced to writing by the pharmacist pursuant to section one hundred fifty-five point thirty-three (155.33), subsection two (2) of the Code."

3. Page 5, by striking lines 23 through 31.

S-5439 FILED - Withdrawn 4/7 (1209)
APRIL 2, 1976

BY COMMITTEE ON HUMAN RESOURCES
WILLIAM E. GLUBA, Chairperson

S-5462

Amend House File 200, as amended, passed and reprinted by the House, as follows:

1. Page 4, by inserting after line 10, the following:

"3. A prescriber shall not be civilly liable for any personal injury or wrongful death arising out of any substitution of a drug or drug product selection by a pharmacist as permitted by this Act."

S-5462 FILED - Lost 4/7 (1212)
APRIL 6, 1976

BY LOWELL L. JUNKINS

S-5468

Amend the Junkins amendment, S-5462 to House File 200 as amended, passed and reprinted by the House as follows:

1. Page 1, lines 6 and 7 by striking the words "arising out of any", and inserting in lieu thereof the words "specifically caused by".

S-5468 FILED - adopted 4/7 (1211)
APRIL 6, 1976

BY LOWELL L. JUNKINS

S-5470

Amend House File 200 as amended, passed, and reprinted by the House, as follows:

1. Page 4, line 8, by inserting after the word "dispensed" the words ", unless the substitution is one required by subsection one (1), unnumbered paragraph two (2), of this section".

S-5470 FILED - adopted 4/7 (1211)
APRIL 6, 1976

BY JOAN ORR
EUGENE M. HILL
WILLIAM D. PALMER

S-5469

Amend House File 200 as amended, passed and reprinted by the House as follows:

1. Page 4, line 27 by inserting after the words "manufacturer, and" the words "if different, the name and place ."

2. Page 5, line 13 by inserting before the words "the name" the words "if different,".

S-5469 FILED - Adopted 4/7 (1212)
APRIL 6, 1976

BY RICHARD J. NORPEL, SR.

S-5466

Amend House File 200 as amended, passed and reprinted by the House as follows:

1. Page 2, by striking lines 4 through 27 and inserting in lieu thereof the following:

"NEW SECTION. EQUIVALENT DRUG PRODUCT LIST. The board shall be responsible for the distribution of an Equivalent Drug Product List. Such a list shall be limited to those chemically identical drug products determined and published by final regulation of the federal Department of Health, Education and Welfare, Food and Drug Administration to be therapeutically equivalent and interchangeable. The board shall mail a copy of the equivalent drug product list to each pharmacy registered with it and to 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 equivalent drug product list as determined by the federal Food and Drug Administration. Notifications of such additions or deletions shall be made promptly to each pharmacist registered with the board and to each physician, dentist, podiatrist and veterinarian licensed to practice in this state."

S-5466 FILED - Lost 4/7 14-32 p. 1210
APRIL 6, 1976

BY LOWELL L. JUNKINS
RICHARD J. NORPEL, SR.
LOUIS CULVER

SENATE AMENDMENT TO HOUSE FILE 200

H-6242

Amend House File 200 as amended, passed and reprinted by the House as follows:

1. Page 2, line 7, by striking the words "a substantial" and inserting in lieu thereof the words "an actual".

2. Page 4, line 8, by inserting after the word "dispensed" the words ", unless the substitution is one required by subsection one (1), unnumbered paragraph two (2), of this section".

3. Page 4, by inserting after line 10 the following:

"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.".

4. Page 4, line 27 by inserting after the words "manufacturer, and" the words "if different, the name and place".

2. Page 5, line 13 by inserting before the words "the name" the words "if different,".

5. Page 5, by striking lines 23 through 31.

H-6242 FILED
RECEIVED FROM SENATE
APRIL 9, 1976

House concurred 4/15 (1968)

S-5457

Amend House File 200 as amended, passed, and reprinted by the House, page 2, line 7, by striking the word "substantial".

S-5457 FILED - Ruled out of order with adoption of 5457
APRIL 6, 1976

BY STEVE SOVERN

S-5459

Amend the Committee on State Government amendment S-5439 to House File 200 as amended, passed and reprinted by the House, as follows:

1. Line 4, by inserting after the figure "1" the words "and inserting in lieu thereof the following:

Upon presentation of a prescription which is to be purchased wholly or partially from public funds authorized under chapters two hundred forty-nine A (249A), two hundred fifty-two (252), two hundred fifty-three (253), or two hundred fifty-five (255) of the Code, the pharmacist shall exercise his or her professional judgment by dispensing a drug product of the same generic name and demonstrated bioavailability but of a lesser cost than the one prescribed, if the pharmacy has in stock one or more such drug products and the substitution would not be contrary to subsection two (2), paragraphs a or c of this section.

2. Page 4, line 8, by inserting after the word "dispensed" the words ", unless the substitution is one required by subsection one (1), unnumbered paragraph two (2), of this section"."

2. By renumbering succeeding sections of the amendment in accordance with this amendment to the amendment.

S-5459 FILED - Ruled out of order upon withdrawal of 5439 4/7
APRIL 6, 1976

BY JOAN ORR
EUGENE M. HILL
WILLIAM D. PALMER

S-5463

Amend House File 200 as amended, passed and reprinted by the House as follows:

1. Page 4, after line 10 by inserting the following:

"d. The pharmacist does not inform the physician of the fact of substitution and the drug product dispensed within 72 hours from the time substitution is made.".

S-5463 FILED - Lost 4/7 (12-11)
APRIL 6, 1976

BY RICHARD J. NORPEL, SR.

S-5461

Amend House File 200, as amended, passed and reprinted by the House, as follows:

1. Page 3, by striking lines 18 through 35, and page 4, by striking line 1. S-5461A

2. Page 4, by inserting after line 10 the following: S-5461B

"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 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 (155.53), subsection two (2) of the Code."

3. Page 5, by striking lines 23 through 31. S-5461C

S-5461 FILED A- Lost 4/6 (1179)
APRIL 6, 1976 B- Adopted as amended by 5464 & 5465 4/7 (1209) C- Adopted 4/7 (1209)
BY WILLIAM E. GLUBA

S-5464

Amend the Gluba amendment S-5461, to House File 200, as amended, passed and reprinted by the House as follows:

1. Page 1, line 15, by striking the figure "(155.53)" and inserting in lieu thereof the figure "(155.33)".

S-5464 FILED - Adopted 4/7 (1209)
APRIL 6, 1976
BY WILLIAM E. GLUBA

S-5465

Amend the Gluba amendment S-5461 to House File 200, as amended, passed and reprinted by the House as follows:

1. Page 1, line 11, by inserting after the word "fact" the words "and the name of the manufacturer of the selected drug".

S-5465 FILED - Adopted 4/7 (1208)
APRIL 6, 1976
BY RICHARD R. RAMSEY

S-5467

Amend House File 200 as amended, passed, and reprinted by the House, page 2, line 7, by striking the words "a substantial" and inserting in lieu thereof the words "an actual".

S-5467 FILED - Adopted 4/7 (1210)
APRIL 6, 1976
BY STEVE SOVERN

HOUSE FILE 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.

DALE M. COCHRAN
Speaker of the House

ARTHUR A. NEU
President of the Senate

I hereby certify that this bill originated in the House and is known as House File 200, Sixty-sixth General Assembly.

DAVID L. WRAY
Chief Clerk of the House

Approved _____, 1976

ROBERT D. RAY
Governor