

FEB 13 1975

Reprinted 3/3/76

HOUSE FILE 200

STATE GOVERNMENT, *Pass per 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

1 An Act relating to the labeling of prescription drugs, requir-
2 ing that certain information regarding prescription drugs
3 be made available to the board of pharmacy examiners and
4 to pharmacists and practitioners in this state, and
5 clarifying the right of a wholesale drug salesman to
6 possess prescription drugs.

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

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

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

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

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

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

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

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

29 NEW SUBSECTION. "Bioavailability" is a term used to indi-
30 cate both the relative amount of an administered drug that
31 reaches the general circulation and the rate at which this
32 occurs.

33 NEW SUBSECTION. "Manufacturer" means a person who pre-
34 pares, compounds, propagates, processes or fabricates any
35 drug or cosmetic.

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

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

9 2. If in package form unless it bears a label contain-
10 ing (a) the name and place of business of the manufacturer,
11 packer, or distributor; and (b) an accurate statement of the
12 quantity of the contents in terms of weight, measure, or
13 numerical count; provided, that under clause "a" of this
14 subsection reasonable variations shall be permitted, and
15 exemptions as to small packages shall be established, by
16 regulations prescribed by the board. Any drug subject to
17 and in compliance with section five (5) of this Act shall
18 be deemed in compliance with clause "a" of this subsection.

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

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

27 1. Enabling consumers to rely upon chemically equivalent
28 drug products certified interchangeable by the board to pro-
29 duce, within an acceptable degree of tolerance, equivalent
30 therapeutic effects when lawfully administered or prescribed
31 and dispensed; and

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

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

3 Sec. 5. NEW SECTION. INFORMATION FILED AND DISTRIBUTED.

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

12 1. The established name of the drug, which in advertise-
13 ments and other descriptive matter shall be printed in a type
14 size at least half as large as that used for the proprietary
15 name of the drug product.

16 2. The name and place of business of the actual manu-
17 facturer of the finished dosage form of the drug and the name
18 and place of business of the packer or distributor of the
19 drug.

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

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

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

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

3 1. Those for which bioequivalence is not considered essen-
4 tial to safe and effective therapeutic use. The board shall
5 certify as interchangeable any drug products constituting
6 a group classified under this subsection.

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

14 Sec. 7. NEW SECTION. INFORMATION TO BE DISSEMINATED.

15 The board shall adopt rules requiring that all pharmacists
16 and all practitioners authorized by law to prescribe drugs
17 shall receive all of the information filed with the board
18 pursuant to section five (5) of this Act, either from the
19 board or from the manufacturers, packers or distributors,
20 as is deemed most appropriate and feasible.

21 Sec. 8. Section one hundred fifty-five point twenty-six
22 (155.26), Code 1975, is amended to read as follows:

23 155.26 POSSESSION OF PRESCRIPTION DRUGS. Any person found
24 in possession of a drug or medicine limited by law to
25 dispensation by a prescription, unless such drug or medicine
26 was so lawfully dispensed, shall be deemed guilty of violating
27 the provisions of this section, and upon conviction thereof,
28 shall be fined not more than one thousand dollars or be
29 imprisoned in the county jail for not more than one year,
30 or both. This section shall not apply to a licensed pharmacy,
31 wholesale salesman, licensed wholesaler, physician,
32 veterinarian, dentist, podiatrist or nurse acting under the
33 direction of a physician or the board of pharmacy examiners,
34 its officers, agents, inspectors, and representatives, nor
35 to a common carrier or messenger when transporting such drug

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

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

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

18 EXPLANATION

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

29 Under this bill, the Board of Pharmacy Examiners must first
30 determine which chemically equivalent drug products may be
31 interchanged without regard to bioequivalence. The Board
32 must also determine, where bioequivalence is important, which
33 groups of chemically identical drug products have been demon-
34 strated to be bioequivalent and may therefore be safely inter-
35 changed. This information must be distributed to pharmacists

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

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H-5197

1 Amend House File 200 as follows:

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

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

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

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

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

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

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

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

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

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

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

48 NEW SECTION. NONEQUIVALENT DRUG OR DRUG PRODUCT
49 LIST. The board shall be responsible for designating
50 drugs or drug products which, because of the lack

1 of demonstrated bioavailability, would pose a
2 substantial threat to the health, safety, and welfare
3 of the people of Iowa if such drugs or drug products
4 were subject to dispensing under the provisions of
5 section four (4) of this Act. Within one hundred
6 eighty days after the effective date of this Act,
7 the board shall cause to be issued a list of those
8 drugs or drug products which have been demonstrated
9 as being nonequivalent and are not interchangeable
10 as determined by the federal food and drug admin-
11 istration. The board shall mail a copy of the
12 nonequivalent drug or drug product list to each
13 pharmacy registered with it and each physician,
14 dentist, podiatrist and veterinarian licensed to
15 practice in this state. Thereafter, the board shall
16 from time to time make additions to or deletions from
17 the nonequivalent drug or drug product list as
18 determined by the federal food and drug administration.
19 Notification of such additions or deletions shall
20 be made promptly to each pharmacist registered with
21 the board and each physician, dentist, podiatrist
22 and veterinarian licensed to practice in this state.

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

26 NEW SECTION. PRODUCT SELECTION BY PHARMACIST--
27 RESTRICTIONS.

28 1. If a physician, dentist, podiatrist or
29 veterinarian prescribes, either in writing or orally,
30 a drug by its brand or trade name and does not
31 specifically state that only that designated brand
32 or trade name drug product is to be dispensed, and
33 if the pharmacy to which the prescription is presented
34 or communicated has in stock one or more other drug
35 products with the same generic name and demonstrated
36 bioavailability as the one prescribed, the pharmacist
37 may exercise his or her professional judgment in the
38 economic interest of the person purchasing the pre-
39 scription by selecting a drug product generically
40 equivalent to but of equal or lesser cost than the
41 one prescribed for dispensing and sale to the person.

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

- 44 a. The prescriber indicates that no drug product
45 selection shall be made; or
46 b. The person presenting the prescription indicates
47 that only the specific drug product prescribed is
48 to be dispensed; or
49 c. The drug product to be dispensed is listed
50 in the nonequivalent drug product list.

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

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

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

14 Sec. 6. Section two hundred three A point ten
15 (203A.10), subsection two (2), Code 1975, is amended
16 to read as follows:

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

29 Sec. 7. Chapter two hundred three A (203A), Code
30 1975, is amended by adding the following new section:

31 NEW SECTION. INFORMATION FILED AND PLACED ON
32 LABELS. Any prescription drug, as defined in section
33 one hundred fifty-five point three (155.3), subsection
34 ten (10) of the Code, is misbranded unless:

35 1. The label sets forth:

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

40 b. The name and place of business of the actual
41 manufacturer of the finished dosage form of the drug
42 and the name and place of business of the packer or
43 distributor of the drug.

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

Page 4

1 as may be required by rules of the board."

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

HOUSE FILE 200

H-5315

- 1 Amend the Committee on State Government amend-
- 2 ment, H-5197, to House File 200 as follows:
- 3 1. Page 2, line 38, by striking the word "person"
- 4 and inserting in lieu thereof the words "patient or
- 5 the patient's adult representative who is".
- 6 2. Page 2, line 40, by striking the words "equal
- 7 or".
- 8 3. Page 2, line 41, by striking the word "person"
- 9 and inserting in lieu thereof the word "patient".
- 10 4. Page 2, by inserting after line 41 the words
- 11 "If the pharmacist does so, he or she shall inform
- 12 the patient or the patient's adult representative
- 13 of the savings which the patient will obtain as a
- 14 result of substitution and pass on to the patient
- 15 or the patient's representative the full difference
- 16 in actual acquisition costs between the drug prescribed
- 17 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

- 1 Amend the Committee on State Government amend-
- 2 ment, H-5197, to House File 200, page 4, by inserting
- 3 after line 1 the following section:
- 4 "Sec. ____ . Section twenty-five A point fourteen
- 5 (25A.14), Code 1975, is amended by adding the follow-
- 6 ing new subsection:
- 7 NEW SUBSECTION. In the event of a substitution,
- 8 pursuant to section four (4) of this Act, or any
- 9 unauthorized substitution by a pharmacist of a
- 10 different drug product than that prescribed by a
- 11 physician, the state of Iowa shall not be liable for
- 12 any injury as the result of such substitution under
- 13 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

1 Amend the Committee on State Government amendment
2 H-5197 to House File 200 as follows:
3 1. Page 2, by inserting after line 41 the
4 following: "If the cost of the prescription or any
5 part thereof shall be paid by expenditure of public
6 funds authorized under chapters two hundred thirty-
7 nine (239), two hundred forty-nine (249), two
8 hundred forty-nine A (249A), two hundred fifty-two
9 (252), two hundred fifty-three (253), two hundred
10 fifty-four (254), or two hundred fifty-five (255)
11 of the Code of Iowa, the pharmacist shall exercise
12 his or her professional judgment in the economic
13 interest of the person purchasing the prescription
14 by selecting a drug product generically equivalent
15 to and of demonstrated bioavailability but of a
16 lesser cost than the one prescribed for dispensing
17 and sale to the person, unless the physician,
18 dentist, or podiatrist specifically states that
19 only that designated brand or trade name drug product
20 is to be dispensed."

H-5351 FILED - 5365 substituted BY GILLOON of Dubuque
FEBRUARY 26, 1976 DYRLAND of Clayton
HORN of Linn
TAUKE of Dubuque
JOCHUM of Dubuque
HINES of Story
HUSAK of Tama

H-5365

1 Amend the Committee on State Government amendment
2 H-5197 to House File 200 as follows:
3 1. Page 2, by inserting after line 41 the
4 following: "If the cost of the prescription or any
5 part thereof shall be paid by expenditure of public
6 funds authorized under chapters two hundred thirty-
7 nine (239), two hundred forty-nine (249), two
8 hundred forty-nine A (249A), two hundred fifty-two
9 (252), two hundred fifty-three (253), two hundred
10 fifty-four (254), or two hundred fifty-five (255)
11 of the Code of Iowa, the pharmacist shall exercise
12 his or her professional judgment by selecting a
13 drug product of the same generic name and
14 demonstrated bioavailability but of a lesser cost
15 than the one prescribed for dispensing and sale to
16 the person unless the physician, dentist, or
17 podiatrist specifically states that only that
18 designated brand or trade name drug product is to
19 be dispensed. Under no circumstances shall a
20 pharmacy to which the prescription is presented or
21 communicated be required to substitute a drug of the
22 same generic name and demonstrated bioavailability
23 but of lesser cost unless the pharmacy has in stock
24 one or more other such drug products.

H-5365 FILED - Substituted for BY GILLOON of Dubuque
FEBRUARY 26, 1976 5351 and
Adopted 2/26 (p. 704)
45-40

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 per Senate amendment
4-15-76 (1968)
89-3*

A BILL FOR

1 An Act relating to the labeling of prescription drugs, requir-
2 ing that certain information regarding prescription drugs
3 be made available to the board of pharmacy examiners and
4 to pharmacists and practitioners in this state.

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

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House Amendments _____

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

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

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

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

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

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

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

30 Sec. 2. Section one hundred fifty-five point thirteen
31 (155.13), subsection six (6), Code 1975, is amended to
32 read as follows:

33 6. Substitution of a drug, or substance, ~~or brand~~
34 other than the drug, or substance ~~or brand~~ ordered in
35 the prescription of a physician, dentist, podiatrist or

1 veterinarian licensed by law.

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

4 NEW SECTION. NONEQUIVALENT DRUG OR DRUG PRODUCT LIST.

5 The board shall be responsible for designating drugs
6 or drug products which, because of the lack of
7 demonstrated bioavailability, would pose a substantial
8 threat to the health, safety, and welfare of the people
9 of Iowa if such drugs or drug products were subject to
10 dispensing under the provisions of section four (4) of
11 this Act. Within one hundred eighty days after the
12 effective date of this Act, the board shall cause to
13 be issued a list of those drugs or drug products which
14 have been demonstrated as being nonequivalent and are
15 not interchangeable as determined by the federal food
16 and drug administration. The board shall mail a copy
17 of the nonequivalent drug or drug product list to each
18 pharmacy registered with it and each physician, dentist,
19 podiatrist and veterinarian licensed to practice in
20 this state. Thereafter, the board shall from time to
21 time make additions to or deletions from the non-
22 equivalent drug or drug product list as determined by
23 the federal food and drug administration. Notification
24 of such additions or deletions shall be made promptly
25 to each pharmacist registered with the board and each
26 physician, dentist, podiatrist and veterinarian licensed
27 to practice in this state.

28 Sec. 4. Chapter one hundred fifty-five (155), Code
29 1975, is amended by adding the following new section:

30 NEW SECTION. PRODUCT SELECTION BY PHARMACIST--
31 RESTRICTIONS.

32 1. If a physician, dentist, podiatrist or veterinarian
33 prescribes, either in writing or orally, a drug by its
34 brand or trade name and does not specifically state that
35 only that designated brand or trade name drug product is

1 to be dispensed, and if the pharmacy to which the
 2 prescription is presented or communicated has in stock
 3 one or more other drug products with the same generic
 4 name and demonstrated bioavailability as the one
 5 prescribed, the pharmacist may exercise his or her
 6 professional judgment in the economic interest of the
 7 patient or the patient's adult representative who is
 8 purchasing the prescription by selecting a drug product
 9 generically equivalent to but of lesser cost than the
 10 one prescribed for dispensing and sale to the patient.
 11 If the pharmacist does so, he or she shall inform the
 12 patient or the patient's adult representative of
 13 the savings which the patient will obtain as a result
 14 of substitution and pass on to the patient or the
 15 patient's representative the full difference in actual
 16 acquisition costs between the drug prescribed and the
 17 drug substituted.

18 If the cost of the prescription or any part thereof
 19 shall be paid by expenditure of public funds authorized
 20 under chapters two hundred thirty-nine (239), two hundred
 21 forty-nine (249), two hundred forty-nine A (249A), two
 22 hundred fifty-two (252), two hundred fifty-three (253),
 23 two hundred fifty-four (254), or two hundred fifty-five
 24 (255) of the Code of Iowa, the pharmacist shall exercise
 25 his or her professional judgment by selecting a drug
 26 product of the same generic name and demonstrated bio-
 27 availability but of a lesser cost than the one
 28 prescribed for dispensing and sale to the person unless
 29 the physician, dentist, or podiatrist specifically states
 30 that only that designated brand or trade name drug product
 31 is to be dispensed. Under no circumstances shall a
 32 pharmacy to which the prescription is presented or
 33 communicated be required to substitute a drug of the
 34 same generic name and demonstrated bioavailability but
 35 of lesser cost unless the pharmacy has in stock one or

1 more other such drug products.

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

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

6 b. The person presenting the prescription indicates
7 that only the specific drug product prescribed is to
8 be dispensed; or

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

11 Sec. 5. Section two hundred three A point two
12 (203A.2), Code 1975, is amended by adding the following
13 new subsections:

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

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

23 Sec. 6. Section two hundred three A point ten
24 (203A.10), subsection two (2), Code 1975, is amended to
25 read as follows:

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

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

3 NEW SECTION. INFORMATION FILED AND PLACED ON LABELS.

4 Any prescription drug, as defined in section one hundred
5 fifty-five point three (155.3), subsection ten (10) of
6 the Code, is misbranded unless:

7 1. The label sets forth:

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

11 b. The name and place of business of the actual
12 manufacturer of the finished dosage form of the drug
13 and the name and place of business of the packer or
14 distributor of the drug.

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

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

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

S-5439

- 1 Amend House File 200, as amended, passed and re-
- 2 printed by the House, as follows:
- 3 1. Page 3, by striking lines 18 through 35, and
- 4 page 4, by striking line 1.
- 5 2. Page 4, by inserting after line 10 the
- 6 following:
- 7 "3. If substitution of a generically equivalent
- 8 drug product for the designated brand or trade name
- 9 drug product prescribed is made under this section,
- 10 the pharmacist making the substitution shall note
- 11 that fact on the prescription presented by the patient
- 12 or the patient's representative, or reduced to writing
- 13 by the pharmacist pursuant to section one hundred
- 14 fifty-five point thirty-three (155.33), subsection
- 15 two (2) of the Code."
- 16 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

- 1 Amend House File 200, as amended, passed and
- 2 reprinted by the House, as follows:
- 3 1. Page 4, by inserting after line 10, the
- 4 following:
- 5 "3. A prescriber shall not be civilly liable
- 6 for any personal injury or wrongful death arising
- 7 out of any substitution of a drug or drug product
- 8 selection by a pharmacist as permitted by this
- 9 Act."

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

BY LOWELL L. JUNKINS

S-5468

- 1 Amend the Junkins amendment, S-5462 to House
- 2 File 200 as amended, passed and reprinted by the House
- 3 as follows:
- 4 1. Page 1, lines 6 and 7 by striking the words
- 5 "arising out of any", and inserting in lieu thereof
- 6 the words "specifically caused by".

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

BY LOWELL L. JUNKINS

S-5470

- 1 Amend House File 200 as amended, passed, and
- 2 reprinted by the House, as follows:
- 3 1. Page 4, line 8, by inserting after the word
- 4 "dispensed" the words ", unless the substitution is
- 5 one required by subsection one (1), unnumbered
- 6 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

1 Amend House File 200 as amended, passed and
2 reprinted by the House as follows:
3 1. Page 4, line 27 by inserting after the
4 words "manufacturer, and" the words "if different,
5 the name and place ."
6 2. Page 5, line 13 by inserting before the words
7 "the name" the words "if different,".

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

BY RICHARD J. NORPEL, SR.

S-5466

1 Amend House File 200 as amended, passed and
2 reprinted by the House as follows:
3 1. Page 2, by striking lines 4 through 27 and
4 inserting in lieu thereof the following:
5 "NEW SECTION. EQUIVALENT DRUG PRODUCT LIST.
6 The board shall be responsible for the distribution
7 of an Equivalent Drug Product List. Such a list shall
8 be limited to those chemically identical drug products
9 determined and published by final regulation of the
10 federal Department of Health, Education and Welfare,
11 Food and Drug Administration to be therapeutically
12 equivalent and interchangeable. The board shall
13 mail a copy of the equivalent drug product list to
14 each pharmacy registered with it and to each physician,
15 dentist, podiatrist and veterinarian licensed to
16 practice in this state. Thereafter, the board shall
17 from time to time make additions to or deletions from
18 the equivalent drug product list as determined by the
19 federal Food and Drug Administration. Notifications
20 of such additions or deletions shall be made promptly
21 to each pharmacist registered with the board and to
22 each physician, dentist, podiatrist and veterinarian
23 licensed to practice in this state."

S-5466 FILED - *Last 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

1 Amend House File 200 as amended, passed and re-
2 printed by the House as follows:

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

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

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

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

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

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

28 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

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

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

BY STEVE SOVERN

S-5459

- 1 Amend the Committee on State Government amendment
- 2 S-5439 to House File 200 as amended, passed and
- 3 reprinted by the House, as follows:
- 4 1. Line 4, by inserting after the figure "1" the
- 5 words "and inserting in lieu thereof the following:
- 6 Upon presentation of a prescription which is to
- 7 be purchased wholly or partially from public funds
- 8 authorized under chapters two hundred forty-nine A
- 9 (249A), two hundred fifty-two (252), two hundred
- 10 fifty-three (253), or two hundred fifty-five (255)
- 11 of the Code, the pharmacist shall exercise his or
- 12 her professional judgment by dispensing a drug product
- 13 of the same generic name and demonstrated
- 14 bioavailability but of a lesser cost than the one
- 15 prescribed, if the pharmacy has in stock one or more
- 16 such drug products and the substitution would not
- 17 be contrary to subsection two (2), paragraphs a or
- 18 c of this section.
- 19 2. Page 4, line 8, by inserting after the word
- 20 "dispensed" the words ", unless the substitution is
- 21 one required by subsection one (1), unnumbered
- 22 paragraph two (2), of this section."
- 23 2. By renumbering succeeding sections of the
- 24 amendment in accordance with this amendment to the
- 25 amendment.

S-5459 FILED - *ruled out of order upon* BY JOAN ORR
APRIL 6, 1976 *withdrawal of 5439 4/7* EUGENE M. HILL
WILLIAM D. PALMER

S-5463

- 1 Amend House File 200 as amended, passed and
- 2 reprinted by the House as follows:
- 3 1. Page 4, after line 10 by inserting the
- 4 following:
- 5 "d. The pharmacist does not inform the physician
- 6 of the fact of substitution and the drug product
- 7 dispensed within 72 hours from the time substitution
- 8 is made."

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

BY RICHARD J. NORPEL, SR.

S-5461

1 Amend House File 200, as amended, passed and re-
2 printed by the House, as follows:

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

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

7 "3. If substitution of a generically equivalent
8 drug product for the designated brand or trade name
9 drug product prescribed is made under this section,
10 the pharmacist making the substitution shall note
11 that fact on the prescription presented by the patient
12 or the patient's representative, or the substitution
13 shall be reduced to writing by the pharmacist pursuant
14 to section one hundred fifty-five point thirty-three
15 (155.53), subsection two (2) of the Code."

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

S-5461 FILED *A-Last 4/6 (1177)*
APRIL 6, 1976 *B-Adopted as amended by 5464-5465 4/7 (1209)* BY WILLIAM E. GLUBA
C-Adopted 4/7 (1209)

S-5464

1 Amend the Gluba amendment S-5461, to House File
2 200, as amended, passed and reprinted by the House
3 as follows:

4 1. Page 1, line 15, by striking the figure
5 "(155.53)" and inserting in lieu thereof the figure
6 "(155.33)".

S-5464 FILED - *Adopted 4/7 (1209)*
APRIL 6, 1976

BY WILLIAM E. GLUBA

S-5465

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

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

S-5465 FILED - *Adopted 4/7 (1208)*
APRIL 6, 1976

BY RICHARD R. RAMSEY

S-5467

1 Amend House File 200 as amended, passed, and
2 reprinted by the House, page 2, line 7, by striking
3 the words "a substantial" and inserting in lieu thereof
4 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