

Commerce 3/6

Senate File 268
Commerce
Rodgers, Chairman
Priebe
Bergman

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SENATE FILE 268

By REDMOND and GLUBA

Passed Senate, Date _____ Passed House, Date _____

Vote: Ayes _____ Nays _____ 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 is as shown in that compendium, however if a drug is
11 recognized in the United States Pharmacopoeia and the
12 Homeopathic Pharmacopoeia under different official titles
13 the established name is that appearing in the United States
14 Pharmacopoeia unless the drug is labeled and offered for sale
15 as a 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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