

1 H BILL NO. 286
 2 INTRODUCED BY PLINER James Kessler Cooney

3
 4 A BILL FOR AN ACT ENTITLED: "AN ACT TO BE CALLED THE
 5 MONTANA DRUG PRODUCT SELECTION ACT, ALLOWING FOR PRODUCT
 6 SELECTION OF CERTAIN PRESCRIBED DRUGS; AMENDING SECTIONS
 7 27-703 AND 66-1523, R.C.M. 1947."
 8

9 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

10 Section 1. Short title. This act may be cited as the
 11 "Montana Drug Product Selection Act".

12 Section 2. Definitions. As used in this act the
 13 following definitions apply:

14 (1) "Bioavailability" means the extent and rate of
 15 absorption from a dosage form as reflected by the
 16 time-concentration curve of the administered drug in the
 17 systemic circulation.

18 (2) "Bioequivalent" means a chemical equivalent which,
 19 when administered to the same individual in the same dosage
 20 regimen, will result in comparable bioavailability.

21 (3) "Brand name" means the proprietary or the
 22 registered trademark name given to a drug product by its
 23 manufacturer, labeler, or distributor and placed upon the
 24 drug, its container, label, or wrapping at the time of
 25 packaging.

1 (4) "Chemical equivalent" means drug products that
 2 contain the same amounts of the same therapeutically active
 3 ingredients in the same dosage forms and that meet present
 4 compendium standards.

5 (5) "Drug product" means a dosage form containing one
 6 or more active therapeutic ingredients along with other
 7 substances included during the manufacturing process.

8 (6) "Generic name" means the chemical or established
 9 name of a drug product or drug ingredients published in the
 10 latest edition of the official United States Pharmacopoeia
 11 or official Homeopathic Pharmacopoeia of the United States.

12 (7) "Present compendium standard" means the official
 13 standard for drug excipients and drug products listed in the
 14 latest revision of the United States Pharmacopoeia and the
 15 National Formulary.

16 (8) "Prescriber" means a practitioner licensed under
 17 the professional laws of the state to administer medicine
 18 and drugs.

19 (9) "Product selection" means to dispense without the
 20 prescriber's express authorization a different drug product
 21 in place of the drug product prescribed.

22 (10) "Therapeutically equivalent" means those chemical
 23 equivalents which, when administered in the same dosage
 24 regimen, will provide essentially the same therapeutic
 25 effect as measured by the control of a symptom or a disease

1 and/or toxicity.

2 Section 3. Product selection permitted. (1) Except as
3 limited by subsection (2) of this section and unless
4 instructed otherwise by the purchaser, the pharmacist who
5 receives a written or oral prescription for a specific drug
6 product by brand or proprietary name may select an equally
7 priced or less expensive drug product with the same generic
8 name, the same strength, quantity, dose, and dosage form as
9 the prescribed drug which is, in the pharmacist's
10 professional opinion, therapeutically equivalent.

11 (2) If, in the professional opinion of the prescriber,
12 it is medically necessary for his patient that an equivalent
13 drug product not be selected, the prescriber may so indicate
14 by certifying in his own handwriting that in his
15 professional judgment the specific brand name drug product
16 is medically necessary for that particular patient. An
17 example of an acceptable certification would be the notation
18 "medically necessary" or words of similar meaning on the
19 face of a written prescription. In no case may a facsimile
20 of the handwritten signature be preprinted to indicate
21 "medically necessary". In the case of a prescription
22 transmitted orally, the prescriber must expressly indicate
23 to the pharmacist that the brand name drug product
24 prescribed is medically necessary.

25 Section 4. Notice to purchaser. (1) A pharmacist who

1 selects a drug product as provided in [section 3] shall
2 notify the person presenting the prescription of the product
3 selection, together with the existence and amount of the
4 retail price difference between the brand name drug product
5 and the drug product substituted for it and shall inform the
6 person presenting the prescription that he may refuse the
7 product selection as provided in [section 3].

8 (2) Each pharmacy shall display in a prominent place
9 that is in clear and unobstructed public view, at or near
10 the place where prescriptions are dispensed, a sign stating,
11 "This pharmacy may be able to select a less expensive drug
12 product which is therapeutically equivalent to the one
13 prescribed by your physician unless you or your physician
14 request otherwise." The printing on the sign shall be in
15 block letters not less than 1 inch in height.

16 Section 5. Product selection when no increased cost.

17 (1) A pharmacist may select a drug product under [section
18 3] only when there will be a savings or no increased cost to
19 the purchaser.

20 (2) A pharmacist selecting a less expensive drug
21 product must pass on to the purchaser the full amount of the
22 savings realized by the product selection. In no event may
23 the pharmacist charge a different professional fee for
24 dispensing a different drug product than the drug product
25 originally prescribed.

1 (3) If the prescriber prescribes a drug product by its
2 generic name, the pharmacist must, consistent with
3 reasonable judgment, dispense the lowest retail priced,
4 therapeutically equivalent brand which is in stock.

5 Section 6. Records required and labeling. (1) Each
6 pharmacist shall maintain a record of any product selection
7 of a generically equivalent drug product for a prescribed
8 brand name drug product as provided for in this act.

9 (2) Except as provided in subsection (3) of this
10 section, when a pharmacist dispenses a selected drug product
11 as authorized, he must label the prescription container with
12 the name of the dispensed drug product. If the dispensed
13 drug product does not have a brand name, the prescription
14 label must indicate the generic name of the drug product
15 dispensed along with the name of the drug product's
16 manufacturer.

17 (3) Unless the prescriber writes "do not label" or
18 words of similar meaning on the prescription or so
19 designates in an oral transmission of the prescription, a
20 prescription dispensed by a pharmacist must bear upon the
21 label the name of the medication in the container.

22 Section 7. Product selection not practice of medicine.
23 The selection of a drug product by a registered pharmacist
24 under the provisions of this act does not constitute the
25 practice of medicine.

1 Section 8. When product selection evidence of
2 negligence. (1) A pharmacist making a product selection
3 under the provisions of this act assumes no greater
4 responsibility for selecting the dispensed drug product than
5 he would incur in filling a prescription for a drug product
6 prescribed by a generic name.

7 (2) In no event when a pharmacist selects a drug
8 product will the prescriber be liable in an action for loss,
9 damage, injury, or death to a person caused by the use of
10 the selected drug product unless the original drug product
11 was incorrectly prescribed.

12 Section 9. Rule making authorized. The board of
13 pharmacists may adopt, amend, or repeal rules necessary for
14 the implementation, continuation, and enforcement of this
15 act in accordance with the Montana Administrative Procedure
16 Act.

17 Section 10. Section 27-703, R.C.M. 1987, is amended to
18 read as follows:

19 "27-703. Prohibited acts enumerated. The following
20 acts and the causing thereof within the state of Montana are
21 hereby prohibited:

22 ~~(a)~~ (1) The manufacture, sale or delivery, holding or
23 offering for sale of any food, drug, device, or cosmetic
24 that is adulterated or misbranded.

25 ~~(b)~~ (2) The adulteration or misbranding of any food,

1 drug, device, or cosmetic.

2 ~~(c)~~ (3) The receipt in commerce of any food, drug,
3 device, or cosmetic that is adulterated or misbranded, and
4 the delivery or proffered delivery thereof for pay or
5 otherwise.

6 ~~(d)~~ (4) The sale, delivery for sale, holding for sale,
7 or offering for sale of any article in violation of ~~section~~
8 27-712 or 27-717.

9 ~~(e)~~ (5) The dissemination of any false advertisement.

10 ~~(f)~~ (6) The refusal to permit entry or inspection or to
11 permit the taking of a sample, as authorized by ~~section~~
12 27-722.

13 ~~(g)~~ (7) The giving of a guaranty or undertaking which
14 guaranty or undertaking is false, except by a person who
15 relied on a guaranty or undertaking to the same ~~effect~~
16 ~~(effect)~~ signed by, and containing the name and address of
17 the person residing in the state of Montana from whom he
18 received in good faith the food, drug, device, or cosmetic.

19 ~~(h)~~ (8) The removal or disposal of a detained or
20 embargoed article in violation of ~~section~~ 27-706.

21 ~~(i)~~ (9) The alteration, mutilation, destruction,
22 obliteration, or removal of the whole or any part of the
23 labeling of, or the doing of any other act with respect to a
24 food, drug, device, or cosmetic, if such act is done while
25 such article is held for sale and results in such article

1 being adulterated or misbranded.

2 ~~(j)~~ (10) Forging, counterfeiting, simulating, or falsely
3 representing, or, without proper authority, using any mark,
4 stamp, tag, label, or other identification device authorized
5 or required by regulations promulgated under the provisions
6 of this act or of the ~~Federal Act~~ federal act.

7 ~~(k)~~ (11) The using, on the labeling of any drug or in
8 any advertisement relating to such drug, of any
9 representation or suggestion that an application with
10 respect to such drug is effective under ~~section~~ 27-717, or
11 that such drug complies with the provisions of such section.

12 ~~(l)~~ (12) In the case of a prescription drug distributed
13 or offered for sale in this state, the failure of the
14 manufacturer, packer, or distributor thereof to maintain for
15 transmittal, or to transmit, to any practitioner licensed by
16 applicable law to administer such drug who makes written
17 request for information as to such drug, true and correct
18 copies of all printed matter which is required to be
19 included in any package in which that drug is distributed or
20 sold, or such other printed matter as is approved under the
21 ~~Federal Act~~ federal act. Nothing in this paragraph shall be
22 construed to exempt any person from any labeling requirement
23 imposed by or under other provisions of this act.

24 ~~(m)~~ (13) (Counterfeiting trade-marks),

25 ~~(n)~~ (a) Placing or causing to be placed upon any drug

1 or device or container thereof, with intent to defraud, the
2 trade name or other identifying mark, or imprint of another
3 or any likeness of any of the foregoing; or

4 ~~(2)~~ (b) Selling, dispensing, disposing of, or causing
5 to be sold, dispensed, or disposed of or concealing or
6 keeping in possession, control, or custody, with intent to
7 sell, dispense, or dispose of, any drug, device, or any
8 container thereof, with knowledge that the trade name or
9 other identifying mark or imprint of another or any likeness
10 of any of the foregoing has been placed thereon in a manner
11 prohibited by subsection ~~(4)~~ (a) hereof; or

12 ~~(2)~~ (c) Making, selling, disposing of, or causing to be
13 made, sold, or disposed of or keeping in possession,
14 control, or custody, or concealing, with intent to defraud,
15 any punch, die, plate, or other thing designed to print,
16 imprint, or reproduce that trade name or other identifying
17 mark or imprint of another or any likeness of any of the
18 foregoing upon any drug, device, or container thereof.

19 ~~(4)~~ ~~Dispensing or causing to be dispensed a different~~
20 ~~drug or brand of drug in place of the drug or brand of drug~~
21 ~~ordered or prescribed without the express permission in each~~
22 ~~case of the person ordering or prescribing.~~

23 ~~(4)~~ (14) The using by any person to his own advantage,
24 or revealing, other than to the state board, or officers or
25 employees of the department, or to the courts when relevant

1 in any judicial proceeding under this act, any information
2 acquired under authority of this act concerning any method
3 or process which as a trade secret is entitled to
4 protection.

5 ~~(4)~~ (15) The distribution in commerce of a consumer
6 commodity, as defined in this act, if such commodity is
7 contained in a package, or if there is affixed to that
8 commodity a label, which does not conform to the provisions
9 of this act and of regulations promulgated under authority
10 of this act, ~~provided, however, that this~~ This prohibition
11 ~~shall~~ does not apply to persons engaged in business as
12 wholesale or retail distributors of consumer commodities
13 except to the extent that such persons;

14 ~~(4)~~ (a) are engaged in the packaging or labeling of
15 such commodities; or

16 ~~(2)~~ (b) prescribe or specify by any means the manner in
17 which such commodities are packaged or labeled.

18 ~~(4)~~ (16) The labeling or packaging of a food, drug, or
19 cosmetic which fails to conform with the requirements of
20 this act.

21 ~~(4)~~ (17) It is unlawful for any person to sell or offer
22 for sale any product which is in semblance of honey and
23 which is labeled, advertised, or otherwise represented to be
24 honey, if it is not honey. Any product sold in semblance of
25 honey which is a blend or mixture of honey and other

1 ingredients must be labeled in such a way that the name of
 2 the main ingredient added to the honey will be printed so
 3 that it will be as prominent and conspicuous as the word
 4 honey. The word "imitation" ~~shall may~~ not be used in the
 5 name of a product which is in semblance of honey whether or
 6 not it contains any honey. The label for a product which is
 7 not in semblance of honey and which contains honey may
 8 include the word "honey" in the name of the product, and the
 9 relative position of the word "honey" in the product name,
 10 and in the list of ingredients, when required, shall be
 11 determined by its prominence as an ingredient in the
 12 product."

13 Section 11. Section 66-1523, R.C.M. 1947, is amended
 14 to read as follows:

15 "66-1523. Wrongful labeling. (1) It ~~shall be~~ is
 16 unlawful for any person who prepares prescriptions, drugs,
 17 medicines, chemicals, or poisons ~~willfully, to purposefully~~
 18 or negligently, or ignorantly to omit to label the package
 19 or receptacle, or label it falsely, substitute an article
 20 different from the one ordered or deviate in any manner from
 21 the requirements of an order or prescription.

22 (2) No person may substitute a drug different from the
 23 one ordered or deviate in any manner from the requirements
 24 of an order or prescription, except as provided in the
 25 Montana Drug Product Selection Act.

1 ~~(2)~~(3) On prescription drugs, the label shall contain
 2 the name and strength of the drug, unless the prescriber
 3 otherwise specifies, except as provided in the Montana Drug
 4 Product Selection Act."

5 Section 12. Penalties. (1) In addition to all other
 6 penalties provided by law, a person who violates the
 7 provisions of [sections 3, 4, or 5] or any rule promulgated
 8 as provided in [section 9] shall be fined no more than \$250
 9 for each violation.

10 (2) The penalty imposed under this act may be remitted
 11 or mitigated upon such terms and conditions as the board of
 12 pharmacists considers proper and consistent with the public
 13 health and safety.

14 (3) A civil penalty imposed under this act becomes due
 15 and payable when the person incurring the penalty receives a
 16 notice in writing from the board of pharmacists. The notice
 17 shall be sent by registered or certified mail and must
 18 include:

19 (a) reference to the particular sections of the
 20 statute or rule;

21 (b) a short and plain statement of the matters
 22 asserted as charged;

23 (c) a statement of the amount of the penalty or
 24 penalties imposed; and

25 (d) a statement of the person's right to request a

1 hearing.

2 (4) The person to whom the notice is addressed has 20
3 days from the date of the notice in which to make written
4 application for a hearing before the board of pharmacists.

5 Section 13. Severability. If a part of this act is
6 invalid, all valid parts that are severable from the invalid
7 part remain in effect. If a part of this act is invalid in
8 one or more of its applications, the part remains in effect
9 in all valid applications that are severable from the
10 invalid applications.

-End-

Approved by Committee
on Public Health, Welfare
& Safety

HOUSE BILL NO. 286

INTRODUCED BY PALMER, HANSEN, KESSLER, COONEY

A BILL FOR AN ACT ENTITLED: "AN ACT TO BE CALLED THE MONTANA DRUG PRODUCT SELECTION ACT, ALLOWING FOR PRODUCT SELECTION OF CERTAIN PRESCRIBED DRUGS; AMENDING SECTIONS 27-703 AND 66-1523, R.C.M. 1947."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Short title. This act may be cited as the "Montana Drug Product Selection Act".

Section 2. Definitions. As used in this act the following definitions apply:

(1) "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

(2) "Bioequivalent" means a chemical equivalent which, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.

(3) "Brand name" means the proprietary or the registered trademark name given to a drug product by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at the time of packaging.

(4) "Chemical equivalent" means drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendium standards.

(5) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

(6) "Generic name" means the chemical or established name of a drug product or drug ingredients published in the latest edition of the official United States Pharmacopoeia or official Homeopathic Pharmacopoeia of the United States.

(7) "Present compendium standard" means the official standard for drug excipients and drug products listed in the latest revision of the United States Pharmacopoeia and the National Formulary.

(8) "Prescriber" means a practitioner licensed under the professional laws of the state to administer medicine and drugs.

(9) "Product selection" means to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed.

(10) "Therapeutically equivalent" means those chemical equivalents which, when administered in the same dosage regimen, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease

SECOND READING

1 and/or toxicity.

2 Section 3. Product selection permitted. (1) Except as
 3 limited by subsection (2) of this section and unless
 4 instructed otherwise by the purchaser, the pharmacist who
 5 receives a written or oral prescription for a specific drug
 6 product by brand or proprietary name may select an equally
 7 priced or less expensive drug product with the same generic
 8 name, the same strength, quantity, dose, and dosage form as
 9 the prescribed drug which is, in the pharmacist's
 10 professional opinion, therapeutically equivalent,
 11 ~~BIOEQUIVALENT, AND BIOAVAILABLE.~~

12 (2) If, in the professional opinion of the prescriber,
 13 it is medically necessary for his patient that an equivalent
 14 drug product not be selected, the prescriber may so indicate
 15 by certifying in his own handwriting that in his
 16 professional judgment the specific brand name drug product
 17 is medically necessary for that particular patient. An
 18 example of an acceptable certification would be the notation
 19 "medically necessary" or words of similar meaning on the
 20 face of a written prescription. In no case may a facsimile
 21 of the handwritten signature be preprinted to indicate
 22 "medically necessary". In the case of a prescription
 23 transmitted orally, the prescriber must expressly indicate
 24 to the pharmacist that the brand name drug product
 25 prescribed is medically necessary.

1 Section 4. Notice to purchaser. (1) A pharmacist who
 2 selects a drug product as provided in [section 3] shall
 3 notify the person presenting the prescription of the product
 4 selection, together with the existence and amount of the
 5 retail price difference between the brand name drug product
 6 and the drug product substituted for it and shall inform the
 7 person presenting the prescription that he may refuse the
 8 product selection as provided in [section 3].

9 (2) Each pharmacy shall display in a prominent place
 10 that is in clear and unobstructed public view, at or near
 11 the place where prescriptions are dispensed, a sign stating,
 12 "This pharmacy may be able to select a less expensive drug
 13 product which is therapeutically equivalent to the one
 14 prescribed by your physician unless you or your physician
 15 request otherwise." The printing on the sign shall be in
 16 block letters not less than 1 inch in height.

17 Section 5. Product selection when no increased cost.
 18 (1) A pharmacist may select a drug product under [section
 19 3] only when there will be a savings or no increased cost to
 20 the purchaser.

21 (2) A pharmacist selecting a less expensive drug
 22 product must pass on to the purchaser the full amount of the
 23 savings realized by the product selection. In no event may
 24 the pharmacist charge a different professional fee for
 25 dispensing a different drug product than the drug product

1 originally prescribed.

2 (3) If the prescriber prescribes a drug product by its
3 generic name, the pharmacist must, consistent with
4 reasonable judgment, dispense the lowest retail priced,
5 therapeutically equivalent brand which is in stock.

6 Section 6. Records required and labeling. (1) Each
7 pharmacist shall maintain a record of any product selection
8 of a generically equivalent drug product for a prescribed
9 brand name drug product as provided for in this act.

10 (2) Except as provided in subsection (3) of this
11 section, when a pharmacist dispenses a selected drug product
12 as authorized, he must label the prescription container with
13 the name of the dispensed drug product. If the dispensed
14 drug product does not have a brand name, the prescription
15 label must indicate the generic name of the drug product
16 dispensed along with the name of the drug product's
17 manufacturer.

18 (3) Unless the prescriber writes "do not label" or
19 words of similar meaning on the prescription or so
20 designates in an oral transmission of the prescription, a
21 prescription dispensed by a pharmacist must bear upon the
22 label the name of the medication in the container.

23 Section 7. Product selection not practice of medicine.
24 The selection of a drug product by a registered pharmacist
25 under the provisions of this act does not constitute the

1 practice of medicine.

2 Section 8. When product selection evidence of
3 negligence. (1) A pharmacist making a product selection
4 under the provisions of this act assumes no greater
5 responsibility for selecting the dispensed drug product than
6 he would incur in filling a prescription for a drug product
7 prescribed by a generic name.

8 (2) ~~In no event when~~ WHEN a pharmacist selects a drug
9 product ~~with~~ the prescriber be MAY NOT BE HELD liable in an
10 action for loss, damage, injury, or death to a person caused
11 by the use of the selected drug product ~~unless the original~~
12 ~~drug product was incorrectly prescribed.~~ EXCEPT THAT IF THE
13 ORIGINAL DRUG PRODUCT WAS INCORRECTLY PRESCRIBED, THE
14 PRESCRIBER IS NOT RELIEVED OF LIABILITY.

15 Section 9. Rule making authorized. The board of
16 pharmacists may adopt, amend, or repeal rules necessary for
17 the implementation, continuation, and enforcement of this
18 act in accordance with the Montana Administrative Procedure
19 Act.

20 Section 10. Section 27-703, R.C.M. 1947, is amended to
21 read as follows:

22 "27-703. Prohibited acts enumerated. The following
23 acts and the causing thereof within the state of Montana are
24 hereby prohibited:

25 (a)(1) The manufacture, sale or delivery, holding or

1 offering for sale of any food, drug, device₁ or cosmetic
2 that is adulterated or misbranded.

3 ~~(b)(12)~~ The adulteration or misbranding of any food,
4 drug, device₁ or cosmetic.

5 ~~(e)(13)~~ The receipt in commerce of any food, drug,
6 device₁ or cosmetic that is adulterated or misbranded, and
7 the delivery or proffered delivery thereof for pay or
8 otherwise.

9 ~~(d)(14)~~ The sale, delivery for sale, holding for sale₁
10 or offering for sale of any article in violation of section
11 27-712 or 27-717.

12 ~~(e)(15)~~ The dissemination of any false advertisement.

13 ~~(f)(16)~~ The refusal to permit entry or inspection or to
14 permit the taking of a sample, as authorized by section
15 27-722.

16 ~~(g)(17)~~ The giving of a guaranty or undertaking which
17 guaranty or undertaking is false, except by a person who
18 relied on a guaranty or undertaking to the same effect
19 ~~(effect)~~ signed by, and containing the name and address of
20 the person residing in the state of Montana from whom he
21 received in good faith the food, drug, device₁ or cosmetic.

22 ~~(h)(18)~~ The removal or disposal of a detained or
23 embargoed article in violation of section 27-706.

24 ~~(i)(19)~~ The alteration, mutilation, destruction,
25 obliteration₁ or removal of the whole or any part of the

1 labeling of, or the doing of any other act with respect to a
2 food, drug, device₁ or cosmetic, if such act is done while
3 such article is held for sale and results in such article
4 being adulterated or misbranded.

5 ~~(j)(10)~~ Forging, counterfeiting, simulating, or falsely
6 representing, or₁ without proper authority₁ using any mark,
7 stamp, tag, label₁ or other identification device authorized
8 or required by regulations promulgated under the provisions
9 of this act or of the ~~Federal Act~~ federal act.

10 ~~(k)(11)~~ The using, on the labeling of any drug or in
11 any advertisement relating to such drug, of any
12 representation or suggestion that an application with
13 respect to such drug is effective under section 27-717, or
14 that such drug complies with the provisions of such section.

15 ~~(l)(12)~~ In the case of a prescription drug distributed
16 or offered for sale in this state, the failure of the
17 manufacturer, packer₁ or distributor thereof to maintain for
18 transmittal, or to transmit, to any practitioner licensed by
19 applicable law to administer such drug who makes written
20 request for information as to such drug, true and correct
21 copies of all printed matter which is required to be
22 included in any package in which that drug is distributed or
23 sold, or such other printed matter as is approved under the
24 ~~Federal Act~~ federal act. Nothing in this paragraph shall be
25 construed to exempt any person from any labeling requirement

1 imposed by or under other provisions of this act.
 2 ~~(13)~~ (Counterfeiting trade-marks).
 3 ~~(14)~~ (a) Placing or causing to be placed upon any drug
 4 or device or container thereof, with intent to defraud, the
 5 trade name or other identifying mark or imprint of another
 6 or any likeness of any of the foregoing; or
 7 ~~(15)~~ (b) Selling, dispensing, disposing of or causing
 8 to be sold, dispensed or disposed of or concealing or
 9 keeping in possession, control or custody, with intent to
 10 sell, dispense or dispose of any drug, device or any
 11 container thereof, with knowledge that the trade name or
 12 other identifying mark or imprint of another or any likeness
 13 of any of the foregoing has been placed thereon in a manner
 14 prohibited by subsection ~~(14)~~ (a) hereof; or
 15 ~~(16)~~ (c) Making, selling, disposing of or causing to be
 16 made, sold or disposed of or keeping in possession,
 17 control or custody or concealing, with intent to defraud,
 18 any punch, die, plate or other thing designed to print,
 19 imprint, or reproduce that trade name or other identifying
 20 mark or imprint of another or any likeness of any of the
 21 foregoing upon any drug, device or container thereof.
 22 ~~(17) Dispensing or causing to be dispensed a different~~
 23 ~~drug or brand of drug in place of the drug or brand of drug~~
 24 ~~ordered or prescribed without the express permission in each~~
 25 ~~case of the person ordering or prescribing.~~

1 ~~(14)~~ The using by any person to his own advantage
 2 or revealing, other than to the state board, or officers or
 3 employees of the department, or to the courts when relevant
 4 in any judicial proceeding under this act, any information
 5 acquired under authority of this act concerning any method
 6 or process which as a trade secret is entitled to
 7 protection.
 8 ~~(15)~~ The distribution in commerce of a consumer
 9 commodity, as defined in this act, if such commodity is
 10 contained in a package or if there is affixed to that
 11 commodity a label which does not conform to the provisions
 12 of this act and of regulations promulgated under authority
 13 of this act, ~~provided, however, that this~~ This prohibition
 14 ~~shall~~ does not apply to persons engaged in business as
 15 wholesale or retail distributors of consumer commodities
 16 except to the extent that such persons
 17 ~~(16)~~ (a) are engaged in the packaging or labeling of
 18 such commodities; or
 19 ~~(16)~~ (b) prescribe or specify by any means the manner in
 20 which such commodities are packaged or labeled.
 21 ~~(17)~~ (16) The labeling or packaging of a food, drug, or
 22 cosmetic which fails to conform with the requirements of
 23 this act.
 24 ~~(18)~~ (17) It is unlawful for any person to sell or offer
 25 for sale any product which is in semblance of honey and

1 which is labeled, advertised, or otherwise represented to be
 2 honey, if it is not honey. Any product sold in semblance of
 3 honey which is a blend or mixture of honey and other
 4 ingredients must be labeled in such a way that the name of
 5 the main ingredient added to the honey will be printed so
 6 that it will be as prominent and conspicuous as the word
 7 honey. The word "imitation" ~~shall~~ may not be used in the
 8 name of a product which is in semblance of honey whether or
 9 not it contains any honey. The label for a product which is
 10 not in semblance of honey and which contains honey may
 11 include the word "honey" in the name of the product, and the
 12 relative position of the word "honey" in the product name
 13 and in the list of ingredients, when required, shall be
 14 determined by its prominence as an ingredient in the
 15 product."

16 Section 11. Section 66-1523, R.C.M. 1947, is amended
 17 to read as follows:

18 "66-1523. Wrongful labeling. (1) It ~~shall be~~ is
 19 unlawful for any person who prepares prescriptions, drugs,
 20 medicines, chemicals, or poisons ~~with intent, to purposefully~~
 21 ~~or negligently, or ignorantly to omit to label the package~~
 22 ~~or receptacle, or label it falsely, substitute an article~~
 23 ~~different from the one ordered or deviate in any manner from~~
 24 ~~the requirements of an order or prescription.~~

25 (2) No person may substitute a drug different from the

1 one ordered or deviate in any manner from the requirements
 2 of an order or prescription, except as provided in the
 3 Montana Drug Product Selection Act.

4 ~~(2)(3)~~ On prescription drugs, the label shall contain
 5 the name and strength of the drug, unless the prescriber
 6 otherwise specifies, except as provided in the Montana Drug
 7 Product Selection Act."

8 Section 12. Penalties. (1) In addition to all other
 9 penalties provided by law, a person who violates the
 10 provisions of [sections 3, 4, or 5] or any rule promulgated
 11 as provided in [section 9] shall be fined no more than \$250
 12 for each violation.

13 (2) The penalty imposed under this act may be remitted
 14 or mitigated upon such terms and conditions as the board of
 15 pharmacists considers proper and consistent with the public
 16 health and safety.

17 (3) A civil penalty imposed under this act becomes due
 18 and payable when the person incurring the penalty receives a
 19 notice in writing from the board of pharmacists. The notice
 20 shall be sent by registered or certified mail and must
 21 include:

22 (a) reference to the particular sections of the
 23 statute or rule;

24 (b) a short and plain statement of the matters
 25 asserted as charged;

1 (c) a statement of the amount of the penalty or
2 penalties imposed; and

3 (d) a statement of the person's right to request a
4 hearing.

5 (4) The person to whom the notice is addressed has 20
6 days from the date of the notice in which to make written
7 application for a hearing before the board of pharmacists.

8 Section 13. Severability. If a part of this act is
9 invalid, all valid parts that are severable from the invalid
10 part remain in effect. If a part of this act is invalid in
11 one or more of its applications, the part remains in effect
12 in all valid applications that are severable from the
13 invalid applications.

-End-

1 HOUSE BILL NO. 286

2 INTRODUCED BY PALMER, HANSEN, KESSLER, COONEY

3
4 A BILL FOR AN ACT ENTITLED: "AN ACT TO BE CALLED THE
5 MONTANA DRUG PRODUCT SELECTION ACT, ALLOWING FOR PRODUCT
6 SELECTION OF CERTAIN PRESCRIBED DRUGS; AMENDING SECTIONS
7 27-703 AND 66-1523, R.C.M. 1947."

8
9 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:10 Section 1. Short title. This act may be cited as the
11 "Montana Drug Product Selection Act".12 Section 2. Definitions. As used in this act the
13 following definitions apply:14 (1) "Bioavailability" means the extent and rate of
15 absorption from a dosage form as reflected by the
16 time-concentration curve of the administered drug in the
17 systemic circulation.18 (2) "Bioequivalent" means a chemical equivalent which,
19 when administered to the same individual in the same dosage
20 regimen, will result in comparable bioavailability.21 (3) "Brand name" means the proprietary or the
22 registered trademark name given to a drug product by its
23 manufacturer, labeler, or distributor and placed upon the
24 drug, its container, label, or wrapping at the time of
25 packaging.1 (4) "Chemical equivalent" means drug products that
2 contain the same amounts of the same therapeutically active
3 ingredients in the same dosage forms and that meet present
4 compendium standards.5 (5) "Drug product" means a dosage form containing one
6 or more active therapeutic ingredients along with other
7 substances included during the manufacturing process.8 (6) "Generic name" means the chemical or established
9 name of a drug product or drug ingredients published in the
10 latest edition of the official United States Pharmacopoeia
11 or official Homeopathic Pharmacopoeia of the United States.12 (7) "Present compendium standard" means the official
13 standard for drug excipients and drug products listed in the
14 latest revision of the United States Pharmacopoeia and the
15 National Formulary.16 (8) "Prescriber" means a practitioner licensed under
17 the professional laws of the state to administer medicine
18 and drugs.19 (9) "Product selection" means to dispense without the
20 prescriber's express authorization a different drug product
21 in place of the drug product prescribed.22 (10) "Therapeutically equivalent" means those chemical
23 equivalents which, when administered in the same dosage
24 regimen, will provide essentially the same therapeutic
25 effect as measured by the control of a symptom or a disease

1 and/or toxicity.

2 Section 3. Product selection permitted. (1) Except as
 3 limited by subsection (2) of this section and unless
 4 instructed otherwise by the purchaser, the pharmacist who
 5 receives a written or oral prescription for a specific drug
 6 product by brand or proprietary name may select an equally
 7 priced or less expensive drug product with the same generic
 8 name, the same strength, quantity, dose, and dosage form as
 9 the prescribed drug which is, in the pharmacist's
 10 professional opinion, therapeutically equivalent,
 11 BIOEQUIVALENT, AND BIOAVAILABLE.

12 (2) If, in the professional opinion of the prescriber,
 13 it is medically necessary for his patient that an equivalent
 14 drug product not be selected, the prescriber may so indicate
 15 by certifying in his own handwriting that in his
 16 professional judgment the specific brand name drug product
 17 is medically necessary for that particular patient. An
 18 example of an acceptable certification would be the notation
 19 "medically necessary" or words of similar meaning on the
 20 face of a written prescription. In no case may a facsimile
 21 of the handwritten signature be preprinted to indicate
 22 "medically necessary". In the case of a prescription
 23 transmitted orally, the prescriber must expressly indicate
 24 to the pharmacist that the brand name drug product
 25 prescribed is medically necessary.

1 Section 4. Notice to purchaser. (1) A pharmacist who
 2 selects a drug product as provided in [section 3] shall
 3 notify the person presenting the prescription of the product
 4 selection, ~~together with the existence and amount of the~~
 5 ~~retail price difference between the brand name drug product~~
 6 ~~and the drug product substituted for it and shall inform the~~
 7 ~~person presenting the prescription~~ that he may refuse the
 8 product selection as provided in [section 3].

9 (2) Each pharmacy shall display in a prominent place
 10 that is in clear and unobstructed public view, at or near
 11 the place where prescriptions are dispensed, a sign stating,
 12 "This pharmacy may be able to select a less expensive drug
 13 product which is therapeutically equivalent to the one
 14 prescribed by your physician unless you or your physician
 15 request otherwise." The printing on the sign shall be in
 16 block letters not less than 1 inch in height.

17 Section 5. Product selection when no increased cost.
 18 (1) A pharmacist may select a drug product under [section
 19 3] only when there will be a savings or no increased cost to
 20 the purchaser.

21 ~~(2) A pharmacist selecting a less expensive drug~~
 22 ~~product must pass on to the purchaser the full amount of the~~
 23 ~~savings realized by the product selection. In no event may~~
 24 ~~the pharmacist charge a different professional fee for~~
 25 ~~dispensing a different drug product than the drug product~~

1 ~~originally prescribed.~~

2 ~~{2}~~(2) If the prescriber prescribes a drug product by
3 its generic name, the pharmacist must, consistent with
4 reasonable judgment, dispense the lowest retail priced,
5 therapeutically equivalent brand which is in stock.

6 Section 6. Records required and labeling. (1) Each
7 pharmacist shall maintain a record of any product selection
8 of a generically equivalent drug product for a prescribed
9 brand name drug product as provided for in this act.

10 ~~{2}--Except as provided in subsection {3} of this~~
11 ~~section, when a pharmacist dispenses a selected drug product~~
12 ~~as authorized, he must label the prescription container with~~
13 ~~the name of the dispensed drug product. If the dispensed~~
14 ~~drug product does not have a brand name, the prescription~~
15 ~~label must indicate the generic name of the drug product~~
16 ~~dispensed along with the name of the drug product's~~
17 ~~manufacturer.~~

18 ~~{3}--Unless the prescriber writes "do not label" or~~
19 ~~words of similar meaning on the prescription or so~~
20 ~~designates in an oral transmission of the prescription, a~~
21 ~~prescription dispensed by a pharmacist must bear upon the~~
22 ~~label the name of the medication in the container.~~

23 Section 7. Product selection not practice of medicine.
24 The selection of a drug product by a registered pharmacist
25 under the provisions of this act does not constitute the

1 practice of medicine.

2 Section 8. When product selection evidence of
3 negligence. (1) A pharmacist making a product selection
4 under the provisions of this act assumes no greater
5 responsibility for selecting the dispensed drug product than
6 he would incur in filling a prescription for a drug product
7 prescribed by a generic name.

8 ~~{2} in no event when WHEN a pharmacist selects a drug~~
9 ~~product with the prescriber be MAY NOT BE HELD liable in an~~
10 ~~action for loss, damage, injury, or death to a person caused~~
11 ~~by the use of the selected drug product unless the original~~
12 ~~drug product was incorrectly prescribed. EXCEPT THAT IF THE~~
13 ~~ORIGINAL DRUG PRODUCT WAS INCORRECTLY PRESCRIBED, THE~~
14 ~~PRESCRIBER IS NOT RELIEVED OF LIABILITY.~~

15 Section 9. Rule making authorized. The board of
16 pharmacists may adopt, amend, or repeal rules necessary for
17 the implementation, continuation, and enforcement of this
18 act in accordance with the Montana Administrative Procedure
19 Act.

20 Section 10. Section 27-703, R.C.M. 1947, is amended to
21 read as follows:

22 *27-703. Prohibited acts enumerated. The following
23 acts and the causing thereof within the state of Montana are
24 hereby prohibited:

25 ~~{1}~~(1) The manufacture, sale or delivery, holding or

1 offering for sale of any food, drug, device₂ or cosmetic
2 that is adulterated or misbranded.

3 (b)(2) The adulteration or misbranding of any food,
4 drug, device₂ or cosmetic.

5 (c)(3) The receipt in commerce of any food, drug,
6 device₂ or cosmetic that is adulterated or misbranded, and
7 the delivery or proffered delivery thereof for pay or
8 otherwise.

9 (d)(4) The sale, delivery for sale, holding for sale,
10 or offering for sale of any article in violation of section
11 27-712 or 27-717.

12 (e)(5) The dissemination of any false advertisement.

13 (f)(6) The refusal to permit entry or inspection or to
14 permit the taking of a sample, as authorized by section
15 27-722.

16 (g)(7) The giving of a guaranty or undertaking which
17 guaranty or undertaking is false, except by a person who
18 relied on a guaranty or undertaking to the same effect
19 (effect) signed by, and containing the name and address of
20 the person residing in the state of Montana from whom he
21 received in good faith the food, drug, device₂ or cosmetic.

22 (h)(8) The removal or disposal of a detained or
23 embargoed article in violation of section 27-706.

24 (i)(9) The alteration, mutilation, destruction,
25 obliteration₂ or removal of the whole or any part of the

1 labeling of, or the doing of any other act with respect to a
2 food, drug, device₂ or cosmetic, if such act is done while
3 such article is held for sale and results in such article
4 being adulterated or misbranded.

5 (j)(10) Forging, counterfeiting, simulating, or falsely
6 representing, or, without proper authority₂ using any mark,
7 stamp, tag, label₂ or other identification device authorized
8 or required by regulations promulgated under the provisions
9 of this act or of the Federal Act federal act.

10 (k)(11) The using, on the labeling of any drug or in
11 any advertisement relating to such drug, of any
12 representation or suggestion that an application with
13 respect to such drug is effective under section 27-717, or
14 that such drug complies with the provisions of such section.

15 (l)(12) In the case of a prescription drug distributed
16 or offered for sale in this state, the failure of the
17 manufacturer, packer₂ or distributor thereof to maintain for
18 transmittal, or to transmit, to any practitioner licensed by
19 applicable law to administer such drug who makes written
20 request for information as to such drug, true and correct
21 copies of all printed matter which is required to be
22 included in any package in which that drug is distributed or
23 sold, or such other printed matter as is approved under the
24 Federal Act federal act. Nothing in this paragraph shall be
25 construed to exempt any person from any labeling requirement

1 imposed by or under other provisions of this act.

2 ~~(m)(13)~~ (Counterfeiting trade-marks).

3 ~~(1)(a)~~ Placing or causing to be placed upon any drug
4 or device or container thereof, with intent to defraud, the
5 trade name or other identifying mark or imprint of another
6 or any likeness of any of the foregoing; or

7 ~~(2)(b)~~ Selling, dispensing, disposing of, or causing
8 to be sold, dispensed, or disposed of or concealing or
9 keeping in possession, control, or custody, with intent to
10 sell, dispense, or dispose of, any drug, device, or any
11 container thereof, with knowledge that the trade name or
12 other identifying mark or imprint of another or any likeness
13 of any of the foregoing has been placed thereon in a manner
14 prohibited by subsection ~~(1)(a)~~ hereof; or

15 ~~(3)(c)~~ Making, selling, disposing of, or causing to be
16 made, sold, or disposed of or keeping in possession,
17 control, or custody, or concealing, with intent to defraud,
18 any punch, die, plate, or other thing designed to print,
19 imprint, or reproduce that trade name or other identifying
20 mark or imprint of another or any likeness of any of the
21 foregoing upon any drug, device, or container thereof.

22 ~~(n)--Dispensing or causing to be dispensed a different~~
23 ~~drug--or-brand-of-drug-in-place-of-the-drug-or-brand-of-drug~~
24 ~~ordered-or-prescribed-without-the-express-permission-in-each~~
25 ~~case-of-the-person-ordering-or-prescribing.~~

1 ~~(14)~~ The using by any person to his own advantage
2 or revealing, other than to the state board, or officers or
3 employees of the department, or to the courts when relevant
4 in any judicial proceeding under this act, any information
5 acquired under authority of this act concerning any method
6 or process which as a trade secret is entitled to
7 protection.

8 ~~(15)~~ The distribution in commerce of a consumer
9 commodity, as defined in this act, if such commodity is
10 contained in a package or if there is affixed to that
11 commodity a label which does not conform to the provisions
12 of this act and of regulations promulgated under authority
13 of this act, ~~provided, however, that this~~ this prohibition
14 ~~shall~~ does not apply to persons engaged in business as
15 wholesale or retail distributors of consumer commodities
16 except to the extent that such persons:

17 ~~(a)~~ are engaged in the packaging or labeling of
18 such commodities; or

19 ~~(b)~~ prescribe or specify by any means the manner in
20 which such commodities are packaged or labeled.

21 ~~(16)~~ The labeling or packaging of a food, drug, or
22 cosmetic which fails to conform with the requirements of
23 this act.

24 ~~(17)~~ It is unlawful for any person to sell or offer
25 for sale any product which is in semblance of honey and

1 which is labeled, advertised, or otherwise represented to be
 2 honey, if it is not honey. Any product sold in semblance of
 3 honey which is a blend or mixture of honey and other
 4 ingredients must be labeled in such a way that the name of
 5 the main ingredient added to the honey will be printed so
 6 that it will be as prominent and conspicuous as the word
 7 honey. The word "imitation" ~~shall~~ may not be used in the
 8 name of a product which is in semblance of honey whether or
 9 not it contains any honey. The label for a product which is
 10 not in semblance of honey and which contains honey may
 11 include the word "honey" in the name of the product, and the
 12 relative position of the word "honey" in the product name
 13 and in the list of ingredients, when required, shall be
 14 determined by its prominence as an ingredient in the
 15 product."

16 Section 11. Section 66-1523, R.C.M. 1947, is amended
 17 to read as follows:

18 "66-1523. Wrongful labeling. (1) It ~~shall--be~~ is
 19 unlawful for any person who prepares prescriptions, drugs,
 20 medicines, chemicals, or poisons ~~willfully~~ to purposefully
 21 or negligently, or ignorantly to omit to label the package
 22 or receptacle, or label it falsely, ~~substitute an article~~
 23 ~~different from the one ordered or deviate in any manner from~~
 24 ~~the requirements of an order or prescription.~~

25 (2) No person may substitute a drug different from the

1 one ordered or deviate in any manner from the requirements
 2 of an order or prescription, except as provided in the
 3 Montana Drug Product Selection Act.

4 (2)(3) On prescription drugs, the label shall contain
 5 the name and strength of the drug, unless the prescriber
 6 otherwise specifies, except as provided in the Montana Drug
 7 Product Selection Act."

8 Section 12. Penalties. (1) In addition to all other
 9 penalties provided by law, a person who violates the
 10 provisions of [sections 3, 4, or 5] or any rule promulgated
 11 as provided in [section 9] shall be fined no more than \$250
 12 for each violation.

13 (2) The penalty imposed under this act may be remitted
 14 or mitigated upon such terms and conditions as the board of
 15 pharmacists considers proper and consistent with the public
 16 health and safety.

17 (3) A civil penalty imposed under this act becomes due
 18 and payable when the person incurring the penalty receives a
 19 notice in writing from the board of pharmacists. The notice
 20 shall be sent by registered or certified mail and must
 21 include:

22 (a) reference to the particular sections of the
 23 statute or rule;

24 (b) a short and plain statement of the matters
 25 asserted as charged;

1 (c) a statement of the amount of the penalty or
2 penalties imposed; and

3 (d) a statement of the person's right to request a
4 hearing.

5 (4) The person to whom the notice is addressed has 20
6 days from the date of the notice in which to make written
7 application for a hearing before the board of pharmacists.

8 Section 13. Severability. If a part of this act is
9 invalid, all valid parts that are severable from the invalid
10 part remain in effect. If a part of this act is invalid in
11 one or more of its applications, the part remains in effect
12 in all valid applications that are severable from the
13 invalid applications.

-End-

April 2, 1977

STANDING COMMITTEE REPORT
Senate Committee on Public Health, Welfare & Safety

That House Bill No. 286 be amended as follows:

1. Amend page 3, section 3, line 6.

Following: "select"

Strike: "an equally priced or"

Insert: "a"

2. Amend page 3, section 3, line 17.

Following: "patient."

Strike: "An example of an acceptable certification would be the notation "medically necessary" or words of similar meaning on the face of a written prescription. In no case may a facsimile of the handwritten signature be preprinted to indicate "medically necessary."

3. Amend page 4, section 5, line 17.

Following: "Section 5."

Strike: lines 17 through 20 in their entirety.

Insert: "Savings passed on. (1) A pharmacist selecting a less expensive drug product must pass on to the purchaser the full amount of the savings realized by the product selection. In no event may the pharmacist charge a different professional fee for dispensing a different drug product than the drug product originally prescribed."

4. Amend page 5, section 6, lines 6 through 9.

Following: line 5

Strike: Section 6 in its entirety.

Renumber: subsequent sections.

5. Amend page 12, section 11, line 6.

Following: "specifies"

Strike: "except as provided in the Montana Drug Product Selection Act"

April 4, 1977

SENATE
COMMITTEE OF THE WHOLE

That House Bill No. 286, third reading, be amended as follows:

1. Amend page 2, section 1, line 8.

Following: line 7

Insert: "(6) Person means an individual, firm, partnership, association, corporation, or any other entity, whether organized for profit or not."

Renumber: all subsequent subsections

2. Amend page 3, section 3, line 15.

Following: "certifying"

Strike: "in his own handwriting"

3. Amend page 4, section 4, lines 3 and 4.

Following: "prescription"

Strike: "of the product selection"

4. Amend page 4, section 4, line 13.

Following: "which is"

Strike: "therapeutically"

HOUSE BILL NO. 286

INTRODUCED BY PALMER, HANSEN, KESSLER, COONEY

A BILL FOR AN ACT ENTITLED: "AN ACT TO BE CALLED THE MONTANA DRUG PRODUCT SELECTION ACT, ALLOWING FOR PRODUCT SELECTION OF CERTAIN PRESCRIBED DRUGS; AMENDING SECTIONS 27-703 AND 66-1523, R.C.M. 1947."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Short title. This act may be cited as the "Montana Drug Product Selection Act".

Section 2. Definitions. As used in this act the following definitions apply:

(1) "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

(2) "Bioequivalent" means a chemical equivalent which, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.

(3) "Brand name" means the proprietary or the registered trademark name given to a drug product by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at the time of packaging.

REFERENCE BILL

(4) "Chemical equivalent" means drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendium standards.

(5) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

~~(6) PERSON MEANS AN INDIVIDUAL, FIRM, PARTNERSHIP, ASSOCIATION, CORPORATION, OR ANY OTHER ENTITY, WHETHER ORGANIZED FOR PROFIT OR NOT.~~

~~(7)(7)~~ "Generic name" means the chemical or established name of a drug product or drug ingredients published in the latest edition of the official United States Pharmacopoeia or official Homeopathic Pharmacopoeia of the United States.

~~(7)(8)~~ "Present compendium standard" means the official standard for drug excipients and drug products listed in the latest revision of the United States Pharmacopoeia and the National Formulary.

~~(8)(9)~~ "Prescriber" means a practitioner licensed under the professional laws of the state to administer medicine and drugs.

~~(9)(10)~~ "Product selection" means to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed.

1 ~~(10)~~(11) "Therapeutically equivalent" means those
2 chemical equivalents which, when administered in the same
3 dosage regimen, will provide essentially the same
4 therapeutic effect as measured by the control of a symptom
5 or a disease and/or toxicity.

6 Section 3. Product selection permitted. (1) Except as
7 limited by subsection (2) of this section and unless
8 instructed otherwise by the purchaser, the pharmacist who
9 receives a written or oral prescription for a specific drug
10 product by brand or proprietary name may select ~~an equally~~
11 ~~priced or~~ A less expensive drug product with the same
12 generic name, the same strength, quantity, dose, and dosage
13 form as the prescribed drug which is, in the pharmacist's
14 professional opinion, therapeutically equivalent.
15 BIOEQUIVALENT, AND BIOAVAILABLE.

16 (2) If, in the professional opinion of the prescriber,
17 it is medically necessary for his patient that an equivalent
18 drug product not be selected, the prescriber may so indicate
19 by certifying ~~in his own handwriting~~ that in his
20 professional judgment the specific brand name drug product
21 is medically necessary for that particular patient. ~~An~~
22 ~~example of an acceptable certification would be the notation~~
23 ~~"medically necessary" or words of similar meaning on the~~
24 ~~face of a written prescription. In no case may a facsimile~~
25 ~~of the handwritten signature be preprinted to indicate~~

1 ~~"medically necessary"~~ In the case of a prescription
2 transmitted orally, the prescriber must expressly indicate
3 to the pharmacist that the brand name drug product
4 prescribed is medically necessary.

5 Section 4. Notice to purchaser. (1) A pharmacist who
6 selects a drug product as provided in [section 3] shall
7 notify the person presenting the prescription ~~of the product~~
8 ~~selection, together with the existence and amount of the~~
9 ~~retail price difference between the brand name drug product~~
10 ~~and the drug product substituted for it and shall inform the~~
11 ~~person presenting the prescription that he may refuse the~~
12 product selection as provided in [section 3].

13 (2) Each pharmacy shall display in a prominent place
14 that is in clear and unobstructed public view, at or near
15 the place where prescriptions are dispensed, a sign stating,
16 "This pharmacy may be able to select a less expensive drug
17 product which is ~~therapeutically~~ equivalent to the one
18 prescribed by your physician unless you or your physician
19 request otherwise." The printing on the sign shall be in
20 block letters not less than 1 inch in height.

21 Section 5. ~~Product selection when no increased costs~~
22 ~~(1) A pharmacist may select a drug product under [section~~
23 ~~3] only when there will be a savings or no increased cost to~~
24 ~~the purchaser.~~

25 SAVINGS PASSED ON. (1) A PHARMACIST SELECTING A LESS

1 EXPENSIVE DRUG PRODUCT MUST PASS ON TO THE PURCHASER THE
 2 FULL AMOUNT OF THE SAVINGS REALIZED BY THE PRODUCT
 3 SELECTION. IN NO EVENT MAY THE PHARMACIST CHARGE A DIFFERENT
 4 PROFESSIONAL FEE FOR DISPENSING A DIFFERENT DRUG PRODUCT
 5 THAN THE DRUG PRODUCT ORIGINALLY PRESCRIBED.

6 ~~{2}--A--pharmacist--selecting--a--less--expensive--drug~~
 7 ~~product--must--pass--on--to--the--purchaser--the--full--amount--of--the~~
 8 ~~savings--realized--by--the--product--selections--in--no--event--may~~
 9 ~~the--pharmacist--charge--a--different--professional--fee--for~~
 10 ~~dispensing--a--different--drug--product--than--the--drug--product~~
 11 ~~originally--prescribed.~~

12 ~~{3}{2}~~ If the prescriber prescribes a drug product by
 13 its generic name, the pharmacist must, consistent with
 14 reasonable judgment, dispense the lowest retail priced,
 15 therapeutically equivalent brand which is in stock.

16 ~~Section 6--Records--required--and--labeling--(1)--Each~~
 17 ~~pharmacist--shall--maintain--a--record--of--any--product--selection~~
 18 ~~of--a--generically--equivalent--drug--product--for--a--prescribed~~
 19 ~~brand--name--drug--product--as--provided--for--in--this--act.~~

20 ~~{2}--Except--as--provided--in--subsection--(3)--of--this~~
 21 ~~section,--when--a--pharmacist--dispenses--a--selected--drug--product~~
 22 ~~as--authorized,--he--must--label--the--prescription--container--with~~
 23 ~~the--name--of--the--dispensed--drug--product,--if--the--dispensed~~
 24 ~~drug--product--does--not--have--a--brand--name,--the--prescription~~
 25 ~~label--must--indicate--the--generic--name--of--the--drug--product~~

1 ~~dispensed--along--with--the--name--of--the--drug--product's~~
 2 ~~manufacturer.~~

3 ~~{3}--Unless--the--prescriber--writes--"do--not--label"--or~~
 4 ~~words--of--similar--meaning--on--the--prescription--or--so~~
 5 ~~designates--in--an--oral--transmission--of--the--prescription,--a~~
 6 ~~prescription--dispensed--by--a--pharmacist--must--bear--upon--the~~
 7 ~~label--the--name--of--the--medication--in--the--container.~~

8 Section 6. Product selection not practice of medicine.
 9 The selection of a drug product by a registered pharmacist
 10 under the provisions of this act does not constitute the
 11 practice of medicine.

12 Section 7. When product selection evidence of
 13 negligence. (1) A pharmacist making a product selection
 14 under the provisions of this act assumes no greater
 15 responsibility for selecting the dispensed drug product than
 16 he would incur in filling a prescription for a drug product
 17 prescribed by a generic name.

18 (2) ~~In--no--event--when~~ WHEN a pharmacist selects a drug
 19 product ~~with~~ the prescriber be MAY NOT BE HELD liable in an
 20 action for loss, damage, injury, or death to a person caused
 21 by the use of the selected drug product ~~unless--the--original~~
 22 ~~drug--product--was--incorrectly--prescribed,~~ EXCEPT THAT IF THE
 23 ORIGINAL DRUG PRODUCT WAS INCORRECTLY PRESCRIBED, THE
 24 PRESCRIBER IS NOT RELIEVED OF LIABILITY.

25 Section 8. Rule making authorized. The board of

1 pharmacists may adopt, amend, or repeal rules necessary for
 2 the implementation, continuation, and enforcement of this
 3 act in accordance with the Montana Administrative Procedure
 4 Act.

5 Section 9. Section 27-703, R.C.M. 1947, is amended to
 6 read as follows:

7 "27-703. Prohibited acts enumerated. The following
 8 acts and the causing thereof within the state of Montana are
 9 hereby prohibited:

10 (e)(1) The manufacture, sale or delivery, holding or
 11 offering for sale of any food, drug, device, or cosmetic
 12 that is adulterated or misbranded.

13 (b)(2) The adulteration or misbranding of any food,
 14 drug, device, or cosmetic.

15 (e)(3) The receipt in commerce of any food, drug,
 16 device, or cosmetic that is adulterated or misbranded, and
 17 the delivery or proffered delivery thereof for pay or
 18 otherwise.

19 (d)(4) The sale, delivery for sale, holding for sale,
 20 or offering for sale of any article in violation of section
 21 27-712 or 27-717.

22 (e)(5) The dissemination of any false advertisement.

23 (f)(6) The refusal to permit entry or inspection or to
 24 permit the taking of a sample, as authorized by section
 25 27-722.

1 (g)(7) The giving of a guaranty or undertaking which
 2 guaranty or undertaking is false, except by a person who
 3 relied on a guaranty or undertaking to the same effect
 4 (effect) signed by and containing the name and address of
 5 the person residing in the state of Montana from whom he
 6 received in good faith the food, drug, device, or cosmetic.

7 (h)(8) The removal or disposal of a detained or
 8 embargoed article in violation of section 27-706.

9 (i)(9) The alteration, mutilation, destruction,
 10 obliteration, or removal of the whole or any part of the
 11 labeling of, or the doing of any other act with respect to a
 12 food, drug, device, or cosmetic, if such act is done while
 13 such article is held for sale and results in such article
 14 being adulterated or misbranded.

15 (j)(10) Forging, counterfeiting, simulating, or falsely
 16 representing, or without proper authority, using any mark,
 17 stamp, tag, label, or other identification device authorized
 18 or required by regulations promulgated under the provisions
 19 of this act or of the ~~Federal Act~~ federal act.

20 (k)(11) The using, on the labeling of any drug or in
 21 any advertisement relating to such drug, of any
 22 representation or suggestion that an application with
 23 respect to such drug is effective under section 27-717, or
 24 that such drug complies with the provisions of such section.

25 (l)(12) In the case of a prescription drug distributed

1 or offered for sale in this state, the failure of the
 2 manufacturer, packer, or distributor thereof to maintain for
 3 transmittal or to transmit to any practitioner licensed by
 4 applicable law to administer such drug who makes written
 5 request for information as to such drug, true and correct
 6 copies of all printed matter which is required to be
 7 included in any package in which that drug is distributed or
 8 sold, or such other printed matter as is approved under the
 9 Federal ~~Act~~ federal act. Nothing in this paragraph shall be
 10 construed to exempt any person from any labeling requirement
 11 imposed by or under other provisions of this act.

12 ~~(13)~~ (Counterfeiting trade-marks).

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

17 ~~(2)(b)~~ Selling, dispensing, disposing of, or causing
 18 to be sold, dispensed, or disposed of or concealing or
 19 keeping in possession, control, or custody, with intent to
 20 sell, dispense, or dispose of, any drug, device, or any
 21 container thereof, with knowledge that the trade name or
 22 other identifying mark or imprint of another or any likeness
 23 of any of the foregoing has been placed thereon in a manner
 24 prohibited by subsection ~~(1)(a)~~ hereof; or

25 ~~(3)(c)~~ Making, selling, disposing of, or causing to be

1 made, sold, or disposed of or keeping in possession,
 2 control, or custody, or concealing, with intent to defraud,
 3 any punch, die, plate, or other thing designed to print,
 4 imprint, or reproduce that trade name or other identifying
 5 mark or imprint of another or any likeness of any of the
 6 foregoing upon any drug, device, or container thereof.

7 ~~(n) Dispensing or causing to be dispensed a different~~
 8 ~~drug or brand of drug in place of the drug or brand of drug~~
 9 ~~ordered or prescribed without the express permission in each~~
 10 ~~case of the person ordering or prescribing.~~

11 ~~(p)(14)~~ The using by any person to his own advantage
 12 or revealing, other than to the state board, or officers or
 13 employees of the department, or to the courts when relevant
 14 in any judicial proceeding under this act, any information
 15 acquired under authority of this act concerning any method
 16 or process which as a trade secret is entitled to
 17 protection.

18 ~~(p)(15)~~ The distribution in commerce of a consumer
 19 commodity, as defined in this act, if such commodity is
 20 contained in a package or if there is affixed to that
 21 commodity a label which does not conform to the provisions
 22 of this act and of regulations promulgated under authority
 23 of this act, ~~provided, however, that this~~ This prohibition
 24 ~~shall~~ does not apply to persons engaged in business as
 25 wholesale or retail distributors of consumer commodities

1 except to the extent that such persons:

2 ~~(1)(a)~~ are engaged in the packaging or labeling of

3 such commodities; ~~1~~ or

4 ~~(2)(b)~~ prescribe or specify by any means the manner in

5 which such commodities are packaged or labeled.

6 ~~(3)(16)~~ The labeling or packaging of a food, drug, or

7 cosmetic which fails to conform with the requirements of

8 this act.

9 ~~(4)(17)~~ It is unlawful for any person to sell or offer

10 for sale any product which is in semblance of honey and

11 which is labeled, advertised, or otherwise represented to be

12 honey, if it is not honey. Any product sold in semblance of

13 honey which is a blend or mixture of honey and other

14 ingredients must be labeled in such a way that the name of

15 the main ingredient added to the honey will be printed so

16 that it will be as prominent and conspicuous as the word

17 honey. The word "imitation" ~~shall~~ may not be used in the

18 name of a product which is in semblance of honey whether or

19 not it contains any honey. The label for a product which is

20 not in semblance of honey and which contains honey may

21 include the word "honey" in the name of the product, and the

22 relative position of the word "honey" in the product name

23 and in the list of ingredients, when required, shall be

24 determined by its prominence as an ingredient in the

25 product."

1 Section 10. Section 66-1523, R.C.M. 1947, is amended

2 to read as follows:

3 "66-1523. Wrongful labeling. (1) It ~~shall be~~ is

4 unlawful for any person who prepares prescriptions, drugs,

5 medicines, chemicals, or poisons ~~willfully~~ to purposefully

6 ~~or negligently~~ or ignorantly to omit to label the package

7 or receptacle, ~~or label it falsely, substitute an article~~

8 ~~different from the one ordered or deviate in any manner from~~

9 ~~the requirements of an order or prescription.~~

10 (2) No person may substitute a drug different from the

11 one ordered or deviate in any manner from the requirements

12 of an order or prescription, except as provided in the

13 Montana Drug Product Selection Act.

14 ~~(3)~~ (3) On prescription drugs, the label shall contain

15 the name and strength of the drug, unless the prescriber

16 otherwise specifies, ~~except as provided in the Montana Drug~~

17 ~~Product Selection Act."~~

18 Section 11. Penalties. (1) In addition to all other

19 penalties provided by law, a person who violates the

20 provisions of [sections 3, 4, or 5] or any rule promulgated

21 as provided in [section 9] shall be fined no more than \$250

22 for each violation.

23 (2) The penalty imposed under this act may be remitted

24 or mitigated upon such terms and conditions as the board of

25 pharmacists considers proper and consistent with the public

1 health and safety.

2 (3) A civil penalty imposed under this act becomes due
3 and payable when the person incurring the penalty receives a
4 notice in writing from the board of pharmacists. The notice
5 shall be sent by registered or certified mail and must
6 include:

7 (a) reference to the particular sections of the
8 statute or rule;

9 (b) a short and plain statement of the matters
10 asserted as charged;

11 (c) a statement of the amount of the penalty or
12 penalties imposed; and

13 (d) a statement of the person's right to request a
14 hearing.

15 (4) The person to whom the notice is addressed has 20
16 days from the date of the notice in which to make written
17 application for a hearing before the board of pharmacists.

18 Section 12. Severability. If a part of this act is
19 invalid, all valid parts that are severable from the invalid
20 part remain in effect. If a part of this act is invalid in
21 one or more of its applications, the part remains in effect
22 in all valid applications that are severable from the
23 invalid applications.

-End-