INTRODUCED BY H BILL NO. 286

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.

INTRODUCED 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) "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

and/or toxicity.

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

(2) If, in the professional opinion of the prescriber, it is medically necessary for his patient that an equivalent drug product not be selected, the prescriber may so indicate by certifying in his own handwriting that in his professional judgment the specific brand name drug product is medically necessary for that particular patient. 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". In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the brand name drug product prescribed is medically necessary.

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

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

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

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

(2) 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.

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

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

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

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

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

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

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

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

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

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

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

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

drug, device, or cosmetic.

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

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

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

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

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

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

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

being adulterated or misbranded.

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

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

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

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

~~(1)~~ (a) Placing or causing to be placed upon any drug

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

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

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

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

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

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

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

~~(1)~~ (a) are engaged in the packaging or labeling of such commodities, ; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

hearing.

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

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

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(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.

SECOND READING

(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.

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and/or toxicity.

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(2) If, in the professional opinion of the prescriber, it is medically necessary for his patient that an equivalent drug product not be selected, the prescriber may so indicate by certifying in his own handwriting that in his professional judgment the specific brand name drug product is medically necessary for that particular patient. 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". In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the brand name drug product prescribed is medically necessary.

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

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

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(2) 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.

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

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

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

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

practice of medicine.

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

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

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

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

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

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offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.

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

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

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

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

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

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

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

~~(i)~~(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the

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

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

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

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

imposed by or under other provisions of this act.

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

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

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

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

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

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

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

~~(i)~~(a) are engaged in the packaging or labeling of such commodities, or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

-End-

HOUSE BILL NO. 286

INTRODUCED BY PALMER, HANSEN, KESSLER, COONEY

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(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.

THIRD READING

(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.

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

(2) If, in the professional opinion of the prescriber, it is medically necessary for his patient that an equivalent drug product not be selected, the prescriber may so indicate by certifying in his own handwriting that in his professional judgment the specific brand name drug product is medically necessary for that particular patient. 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". In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the brand name drug product prescribed is medically necessary.

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

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

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

~~(2) 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.~~

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

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

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

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

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

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

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

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

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

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

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

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offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.

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

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

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

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

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

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

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

~~(i)~~(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the

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

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

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

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

imposed by or under other provisions of this act.

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

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

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

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

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

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

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

~~(1)~~(a) are engaged in the packaging or labeling of such commodities;, or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(6)~~(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.

~~(10)~~(11) "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 and/or toxicity.

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

(2) If, in the professional opinion of the prescriber, it is medically necessary for his patient that an equivalent drug product not be selected, the prescriber may so indicate by certifying ~~in his own handwriting~~ that in his professional judgment the specific brand name drug product is medically necessary for that particular patient. ~~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".~~ In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the brand name drug product prescribed is medically necessary.

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

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

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

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.

~~(2) 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.~~

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

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

~~(2) Except as provided in subsection (3) of this section, when a pharmacist dispenses a selected drug product as authorized, he must label the prescription container with the name of the dispensed drug product. If the dispensed drug product does not have a brand name, the prescription label must indicate the generic name of the drug product~~

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

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

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

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

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

Section 8. Rule making authorized. The board of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

except to the extent that such persons:

~~(1)~~(a) are engaged in the packaging or labeling of such commodities; or

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

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

~~(r)~~(17) It is unlawful for any person to sell or offer for sale any product which is in semblance of honey and which is labeled, advertised, or otherwise represented to be honey, if it is not honey. Any product sold in semblance of honey which is a blend or mixture of honey and other ingredients must be labeled in such a way that the name of the main ingredient added to the honey will be printed so that it will be as prominent and conspicuous as the word honey. The word "imitation" ~~shall~~ may not be used in the name of a product which is in semblance of honey whether or not it contains any honey. The label for a product which is not in semblance of honey and which contains honey may include the word "honey" in the name of the product, and the relative position of the word "honey" in the product name and in the list of ingredients, when required, shall be determined by its prominence as an ingredient in the product."

Section 10. Section 66-1523, R.C.M. 1947, is amended to read as follows:

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

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

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

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

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

health and safety.

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

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

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

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

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

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

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

-End-