HOUSE BILL 157

IN THE HOUSE

January 13, 1979	Introduced and referred to Committee on Human Services.
January 18, 1979	Committee recommend bill, do not pass.
January 19, 1979	Report adopted.

HOUSE BILL NO. 157

INTRODUCED BY South

A BILL FOR AN ACT ENTITLED: "AN ACT TO REQUIRE THE LABEL OF A PRESCRIPTION DRUG TO INDICATE THE DRUG'S COMPATIBILITY WITH ALCOHOL; AMENDING SECTIONS 50-31-306 AND 50-31-308, MCA."

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

Section 1. Section 50-31-306, MCA, is amended to read:

"50-31-306. When drug or device misbranded. (1) A drug or device shall be deemed to be misbranded:

(a) if its labeling is false or misleading in any particular;

(b) if in package form unless it bears a label containing:

(i) the name and place of business of the manufacturer, packer, or distributor; and

(ii) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided that reasonable variation shall be permitted and exemptions as to small packages shall be allowed in accordance with regulations prescribed by the department or issued under the federal act;

(c) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(d) if it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, sulphonmethane, or any chemical derivative of such substance which, after investigation, has been found to be and designated as habit-forming by regulations issued by the department under this chapter or by regulations issued pursuant to section 502(d) of the federal act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning--May be habit-forming";

(e) if it is a drug, unless its label bears to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula):

(i) the established name (as defined in 50-31-301(1))

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of the drug, if such there be; and

(ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein; provided that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subsection (1)(e)(ii), shall apply only to prescription drugs; provided further that, to the extent that compliance with the requirements of this subsection (1)(e)(ii) is impracticable, exemptions shall be allowed under regulations promulgated by the department or under the federal act;

(f) unless its labeling bears:

(i) adequate directions for use; provided that, where any requirement of this subsection (1)(f)(i), as applied to any drug or device, is not necessary for the protection of the public health, the department shall promulgate regulations exempting such drug or device from such

requirements; provided further that articles exempted under regulations issued under section 502(f) of the federal act may also be exempt; and

(ii) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;

(g) if it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided that the method of packing may be modified with the consent of the department or if consent is obtained under the federal act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirement of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeophathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia; provided further that, in the event of inconsistency between the requirements of this subsection and those of subsection (e) as to the name by which the drug or its ingredients shall be designated, the requirements of subsection (e)

shall prevail.

(h) if it has been found by the department or under the federal act to be a drug liable to deterioration, unless it is packaged in such form and manner and its label bears a statement of such precautions as the regulations issued by the department or under the federal act require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the department shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) if it is a drug and its container is so made, formed, or filled as to be misleading;

(j) if it is an imitation of another drug;

(k) if it is offered for sale under the name of another drug;

(l) if it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

(m) if it is, purports to be, or is represented as a drug composed wholly or partly of insulin, unless:

(i) it is from a batch with respect to which a certificate or release has been issued pursuant to section

506 of the federal act; and

(ii) such certificate or release is in effect with respect to such drug;

(n) if it is, purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, any other antibiotic drug, or any derivative thereof, unless:

(i) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the federal act; and

(ii) such certificate or release is in effect with respect to such drug; provided that subsection (1)(n) shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the federal act;

(o) if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of 50-31-108 or of the federal act;

(p) in the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor thereof includes in all

advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of:

(i) the established name, as defined in 50-31-301(l);

(ii) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) of the federal act; and

(iii) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the federal act;

(q) if a trademark, trade name, or other identifying mark, imprint, or device or another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.;

(r) in the case of any prescription drug, if it does not indicate the drug's compatibility with the consumption of specified amounts of alcohol.

(2) A drug which is subject to 50-31-307 shall be deemed to be misbranded if, at any time prior to dispensing, its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which 50-31-307 does not apply shall be deemed to be misbranded if, at any time prior to dispensing, its label

bears the caution statement quoted in the preceding sentence."

"50-31-308. Prescription drugs exempt from certain provisions of chapter. Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of 50-31-306, except subsections (1)(a), (1)(j), (1)(k), (1)(m), (1)(n), and the packaging requirements of subsections (1)(g), and (1)(h), and (1)(r), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and if stated in the prescription, the name of the patient and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to a drug dispensed in violation of 50-31-307."

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shall prevail.

(h) if it has been found by the department or under the federal act to be a drug liable to deterioration, unless it is packaged in such form and manner and its label bears a statement of such precautions as the regulations issued by the department or under the federal act require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the department shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) if it is a drug and its container is so made, formed, or filled as to be misleading;

(j) if it is an imitation of another drug;

(k) if it is offered for sale under the name of another drug;

(l) if it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

(m) if it is, purports to be, or is represented as a drug composed wholly or partly of insulin, unless:

(i) it is from a batch with respect to which a certificate or release has been issued pursuant to section

506 of the federal act; and

(ii) such certificate or release is in effect with respect to such drug;

(n) if it is, purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, any other antibiotic drug, or any derivative thereof, unless:

(i) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the federal act; and

(ii) such certificate or release is in effect with respect to such drug; provided that subsection (1)(n) shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the federal act;

(o) if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of 50-31-108 or of the federal act;

(p) in the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor thereof includes in all

advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of:

(i) the established name, as defined in 50-31-301(1);

(ii) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) of the federal act; and

(iii) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the federal act;

(q) if a trademark, trade name, or other identifying mark, imprint, or device or another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud;

(r) in the case of any prescription drug, if it does not indicate the drug's compatibility with the consumption of specified amounts of alcohol.

(2) A drug which is subject to 50-31-307 shall be deemed to be misbranded if, at any time prior to dispensing, its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which 50-31-307 does not apply shall be deemed to be misbranded if, at any time prior to dispensing, its label

bears the caution statement quoted in the preceding sentence."

"50-31-308. Prescription drugs exempt from certain provisions of chapter. Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of 50-31-306, except subsections (1)(a), (1)(j), (1)(k), (1)(m), (1)(n), and the packaging requirements of subsections (1)(g), and (1)(h), and (1)(r), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and if stated in the prescription, the name of the patient and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to a drug dispensed in violation of 50-31-307."

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