

HOUSE BILL NO. 688

INTRODUCED BY SIMON, HAGER

BY REQUEST OF THE DEPARTMENT OF HEALTH AND  
ENVIRONMENTAL SCIENCES

IN THE HOUSE

FEBRUARY 14, 1989

INTRODUCED AND REFERRED TO COMMITTEE  
ON HUMAN SERVICES & AGING.

FIRST READING.

FEBRUARY 18, 1989

COMMITTEE RECOMMEND BILL  
DO PASS AS AMENDED. REPORT ADOPTED.

FEBRUARY 20, 1989

PRINTING REPORT.

SECOND READING, DO PASS.

FEBRUARY 21, 1989

ENGROSSING REPORT.

THIRD READING, PASSED.  
AYES, 76; NOES, 23.

TRANSMITTED TO SENATE.

IN THE SENATE

FEBRUARY 28, 1989

INTRODUCED AND REFERRED TO COMMITTEE  
ON PUBLIC HEALTH, WELFARE & SAFETY.

FIRST READING.

MARCH 21, 1989

COMMITTEE RECOMMEND BILL BE  
CONCURRED IN AS AMENDED. REPORT  
ADOPTED.

MARCH 22, 1989

PASS CONSIDERATION.

MARCH 23, 1989

SECOND READING, CONCURRED IN AS  
AMENDED.

MARCH 28, 1989

THIRD READING, CONCURRED IN.  
AYES, 44; NOES, 6.

RETURNED TO HOUSE WITH AMENDMENTS.

IN THE HOUSE

MARCH 30, 1989

RECEIVED FROM SENATE.

SENT TO ENROLLING.

REPORTED CORRECTLY ENROLLED.

1 *House* BILL NO. *688*  
2 INTRODUCED BY *Simon Hager*  
3 BY REQUEST OF THE DEPARTMENT OF HEALTH AND  
4 ENVIRONMENTAL SCIENCES  
5

6 A BILL FOR AN ACT ENTITLED: "AN ACT TO ALLOW REGISTERED  
7 NURSES EMPLOYED BY FAMILY PLANNING CLINICS TO DISPENSE  
8 PREPACKAGED PRESCRIPTION CONTRACEPTIVES; AMENDING SECTIONS  
9 37-2-104, 37-7-103, 50-31-103, 50-31-307, AND 50-32-205,  
10 MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."  
11

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

13 **Section 1.** Section 37-2-104, MCA, is amended to read:

14 "37-2-104. Dispensing of drugs by medical practitioners  
15 unlawful -- exceptions. (1) Except as otherwise provided by  
16 this section, it is unlawful for a medical practitioner to  
17 engage, directly or indirectly, in the dispensing of drugs.

18 (2) Nothing in this section prohibits:

19 (a) a medical practitioner from furnishing a patient  
20 any drug in an emergency;

21 (b) the administration of a unit dose of a drug to a  
22 patient by or under the supervision of such a medical  
23 practitioner;

24 (c) dispensing a drug to a patient by a medical  
25 practitioner whenever there is no community pharmacy

1 available to the patient;

2 (d) the dispensing of drugs occasionally, but not as a  
3 usual course of doing business, by a medical practitioner;

4 (e) a medical practitioner from dispensing drug  
5 samples-;

6 (f) the dispensing of factory prepackaged oral  
7 contraceptives by a registered nurse employed by a family  
8 planning clinic under contract with the department of health  
9 and environmental sciences if the dispensing is in  
10 accordance with:

11 (i) a physician's written protocol specifying the  
12 circumstances under which dispensing is appropriate; and

13 (ii) the drug labeling, storage, and logging  
14 requirements of the board of pharmacy."

15 **Section 2.** Section 37-7-103, MCA, is amended to read:

16 "37-7-103. Exemptions. Subject only to 37-7-401 and  
17 37-7-402:

18 (1) nothing in this chapter subjects a person duly  
19 licensed in this state to practice medicine, dentistry, or  
20 veterinary medicine to inspection by the board or prevents  
21 such person from compounding or using drugs, medicines,  
22 chemicals, or poisons in his practice or prevents one duly  
23 licensed to practice medicine from furnishing to a patient  
24 such drugs, medicines, chemicals, or poisons as he considers  
25 proper in the treatment of such the patient;

(2) nothing herein in this chapter prevents the sale of drugs, medicines, chemicals, or poisons at wholesale;

(3) nothing herein in this chapter prevents the sale of drugs, chemicals, or poisons either at wholesale or retail for use for commercial purposes or in the arts or changes any of the provisions of this code relating to the sale of insecticides and fungicides, and nothing in this chapter prevents the sale of common household preparations and other drugs, provided stores selling them are licensed under the terms of this chapter;

(4) nothing herein in this chapter applies to or may interfere with manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature for use for nonmedicinal purposes;

(5) nothing in this chapter prevents a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences from dispensing factory prepackaged oral contraceptives if the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate and with the board of pharmacy's requirements for labeling, storage, and logging of drugs."

**Section 3.** Section 50-31-307, MCA, is amended to read:

"50-31-307. Dispensing of prescription drugs. (1) A

drug intended for use by man which that falls in one of the categories in subsection (2) may be dispensed only:

(a) is a habit-forming drug to which 50-31-306(i)(d) applies;

(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(c) is limited by an approved application under section 505 of the federal act or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer such drug shall be dispensed only:

(i)(a) upon a written prescription of a practitioner licensed by law to administer such the drug;

(ii)(b) upon an oral prescription of such the practitioner which that is reduced promptly to writing and filed by the pharmacist; or

(iii)(c) by refilling any such written or oral prescription if such the refilling is authorized by the prescriber either in the original prescription or by oral order which that is reduced promptly to writing and filed by the pharmacist.

(2) A drug must be dispensed as provided in subsection (1) if the drug:

(a) is a habit-forming drug to which 50-31-306(1)(d) applies;

(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or

(c) is limited by an approved application under section 505 of the federal act or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer the drug.

(3) If the drug is a factory prepackaged oral contraceptive, it may be dispensed as provided in subsection (1) or by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences pursuant to a physician's written protocol specifying the circumstances under which dispensing is appropriate and pursuant to the board of pharmacy's rules concerning labeling, storage, and logging of drugs.

{2}(4) The act of dispensing a drug contrary to the provisions of this section shall--be--deemed--to--be is considered an act which that results in a drug being misbranded while held for sale."

**Section 4.** Section 50-31-103, MCA, is amended to read:

**"50-31-103. Definitions.** Unless the context requires

otherwise, in this chapter the following definitions apply:

(1) "Advertisement" means representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(2) "Beef patty mix" means "hamburger" or "ground beef" to which has been added binders or extenders as those terms are understood by general custom and usage in the food industry.

(3) "Color" includes black, white, and intermediate grays.

(4) (a) "Color additive" means a material which:

(i) is a dye, pigment, or other substance made by a process of synthesis or similar artifice or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; or

(ii) when added or applied to a food, drug, or cosmetic or to the human body is capable (alone or through reaction with other substance) of imparting color thereto.

(b) This term does not include material which has been or hereafter is exempted under the federal act.

(5) "Consumer commodity", except as otherwise specifically provided by this subsection, means any food,

1 drug, device, or cosmetic as those terms are defined by this  
2 chapter or by the federal act and regulations pursuant  
3 thereto. The term does not include:

4 (a) any tobacco or tobacco product;

5 (b) a commodity subject to packaging or labeling  
6 requirements imposed under the Federal Insecticide,  
7 Fungicide, and Rodenticide Act or the provisions of the  
8 eighth paragraph under the heading "Bureau of Animal  
9 Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21  
10 U.S.C. 151-157), commonly known as the virus, serum, and  
11 toxin act;

12 (c) a drug subject to 50-31-306(1)(m) or  
13 ~~50-31-307(1)(c)~~ 50-31-307(2)(c) or section 503(b)(1) or 506  
14 of the federal act;

15 (d) a beverage subject to or complying with packaging  
16 or labeling requirements imposed under the Federal Alcohol  
17 Administration Act (27 U.S.C., et seq.); or

18 (e) a commodity subject to the Federal Seed Act (7  
19 U.S.C. 1551-1610).

20 (6) "Contaminated with filth" applies to a food, drug,  
21 device, or cosmetic not securely protected from dust, dirt,  
22 and, as far as may be necessary by all reasonable means,  
23 from foreign or injurious contaminations.

24 (7) "Cosmetic" means:

25 (a) articles intended to be rubbed, poured, sprinkled,

1 sprayed on, introduced into, or otherwise applied to the  
2 human body for cleansing, beautifying, promoting  
3 attractiveness, or altering the appearance;

4 (b) articles intended for use as a component of these  
5 articles, except that the term does not include soap.

6 (8) "Counterfeit drug" means a drug, drug container, or  
7 drug label which, without authorization bears the trademark,  
8 trade name, or other identifying mark, imprint, or device or  
9 any likeness thereof of a drug manufacturer, processor,  
10 packer, or distributor other than the person who in fact  
11 manufactured, processed, packed, or distributed the drug and  
12 which falsely purports or is represented to be the product  
13 of or to have been packed or distributed by the other drug  
14 manufacturer, processor, packer, or distributor.

15 (9) "Department" means the department of health and  
16 environmental sciences provided for in Title 2, chapter 15,  
17 part 21.

18 (10) "Device" (except when used in 50-31-107(2),  
19 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and  
20 50-31-501(10)) means instruments, apparatus, and  
21 contrivances, including their components, parts, and  
22 accessories, intended:

23 (a) for use in the diagnosis, cure, mitigation,  
24 treatment, or prevention of disease in man or other animals;

25 (b) to affect the structure or function of the body of

1 man or other animals.

2 (11) "Drug" means:

3 (a) articles recognized in the official United States  
4 Pharmacopoeia, official National Formulary, or a supplement  
5 to either of these;

6 (b) articles intended for use in the diagnosis, cure,  
7 mitigation, treatment, or prevention of disease in man or  
8 other animals;

9 (c) articles (other than food) intended to affect the  
10 structure or function of the body of man or other animals;

11 (d) articles intended for use as components of any  
12 article specified in subsections (a), (b), or (c) but does  
13 not include devices or their components, parts, or  
14 accessories.

15 (12) "Federal act" means the Federal Food, Drug, and  
16 Cosmetic Act, as amended (Title 21 U.S.C. 301, et seq.).

17 (13) "Food" means:

18 (a) articles used for food or drink for man or other  
19 animals;

20 (b) chewing gum; and

21 (c) articles used for components of these articles.

22 (14) (a) "Food additive" means a substance, the intended  
23 use of which results or may be reasonably expected to  
24 result, directly or indirectly, in its becoming a component  
25 or otherwise affecting the characteristics of food

1 (including a substance intended for use in producing,  
2 manufacturing, packing, processing, preparing, treating,  
3 packaging, transporting, or holding food and including a  
4 source of radiation intended for this use), if the substance  
5 is not generally recognized, among experts qualified by  
6 scientific training and experience to evaluate its safety,  
7 as having been adequately shown through scientific  
8 procedures (or, in the case of a substance used in a food  
9 prior to January 1, 1958, through either scientific  
10 procedures or experience based on common use in food) to be  
11 safe under the conditions of its intended use.

12 (b) This term does not include:

13 (i) a pesticide chemical in or on a raw agricultural  
14 commodity;

15 (ii) a pesticide chemical to the extent that it is  
16 intended for use or is used in the production, storage, or  
17 transportation of a raw agricultural commodity;

18 (iii) a color additive;

19 (iv) a substance used in accordance with a sanction or  
20 approval granted prior to the enactment of the Food  
21 Additives Amendment of 1958, pursuant to the federal act,  
22 the Poultry Products Inspection Act (21 U.S.C. 451, et  
23 seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat.  
24 1260), as amended and extended (21 U.S.C. 71, et seq.).

25 (15) "Food service establishment" means a restaurant,

1 catering vehicle, vending machine, delicatessen, fast-food  
2 retailer, or any other place that serves food to the public  
3 for consumption either at or away from the point of service,  
4 and any facility operated by a governmental entity where  
5 food is served.

6 (16) "Hamburger" or "ground beef" means ground fresh or  
7 frozen beef or a combination of both fresh and frozen beef,  
8 with or without the addition of suet, to which no water,  
9 binders, or extenders are added. There are three grades of  
10 hamburger or ground beef:

11 (a) "economy hamburger" or "economy ground beef" may  
12 have a fat content no greater than the federal standard set  
13 forth in 9 C.F.R. 319.15;

14 (b) "regular hamburger" or "regular ground beef" may  
15 have a fat content no greater than 21%;

16 (c) "extra lean hamburger" or "extra lean ground beef"  
17 may have a fat content no greater than 18%.

18 (17) "Honey" means the nectar and saccharine exudations  
19 of plants gathered, modified, and stored in the comb by  
20 honey bees; is levorotatory, contains not more than 25% of  
21 water, not more than .25% of ash, and not more than 8%  
22 sucrose.

23 (18) "Label" means a display of written, printed, or  
24 graphic matter on the immediate container of an article.  
25 ("Immediate container" does not include package liners.)

1 (19) "Labeling" means labels and other written, printed,  
2 or graphic matter:

3 (a) on an article or its containers or wrappers;

4 (b) accompanying the article.

5 (20) "Menu" means any list presented to the patron which  
6 states the food items for sale in a food service  
7 establishment.

8 (21) "New drug" means a drug, the composition of which  
9 is such that:

10 (a) it is not generally recognized, among experts  
11 qualified by scientific training and experience to evaluate  
12 the safety and effectiveness of drugs, as safe and effective  
13 for use under the conditions prescribed, recommended, or  
14 suggested in its labeling; or

15 (b) the drug, as a result of investigations to  
16 determine its safety and effectiveness for use under the  
17 conditions prescribed, has become so recognized but which  
18 has not, otherwise than in the investigations, been used to  
19 a material extent or for a material time under the  
20 conditions prescribed.

21 (22) "Official compendium" means the official United  
22 States Pharmacopoeia, official National Formulary, or a  
23 supplement to either of these.

24 (23) "Organic food" means food that conforms to the  
25 definition in 50-31-222.



(24) "Package" means a container or wrapping in which a consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers but does not include:

(a) shipping containers or wrappings used solely for the transportation of a consumer commodity in bulk or in quantity to manufacturers, packers, or processors or to wholesale or retail distributors;

(b) shipping containers or outer wrappings used by retailers to ship or deliver a commodity to retail customers if the containers and wrappings bear no printed matter pertaining to a particular commodity.

(25) "Person" includes an individual, partnership, corporation, and association.

(26) "Pesticide chemical" means a substance which alone, in chemical combination, or in formulation with one or more other substances is an "economic poison" under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., secs. 135-135k), as amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(27) "Placard" means any nonpermanent sign used to display or describe food items for sale in a food service establishment or retail establishment.

(28) "Principal display panel" means that part of a label that is most likely to be displayed, presented, shown,

or examined under normal and customary conditions of display for retail sale.

(29) "Processing" means cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, freezing, or otherwise manufacturing a food or changing the physical characteristics of a food, and the enclosure of such food in a package.

(30) "Raw agricultural commodity" means food in its raw or natural state, including fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(31) "Retail establishment" means a commercial establishment at which meat or meat products are displayed for sale or provision to the public with or without charge.

(32) "State board" or "board" means the board of health and environmental sciences provided for in 2-15-2104.

(33) "Synthetically compounded" means a product formulated by a process that chemically changes a material or substance extracted from naturally occurring plant, animal, or mineral sources, except for microbiological processes."

**Section 5.** Section 50-32-205, MCA, is amended to read:

**"50-32-205. Nonprescription drugs not to be scheduled.**

The board shall exclude any nonnarcotic drug from a schedule if such the drug may, under the Federal Food, Drug, and

LC 0861/01

1   Cosmetic Act and ~~50-31-307(1)(b)~~ 50-31-307(2)(b) of the  
2   Montana Food, Drug, and Cosmetic Act, be lawfully sold over  
3   the counter without a prescription."

4       NEW SECTION. **Section 6.** Extension of authority. Any  
5   existing authority to make rules on the subject of the  
6   provisions of [this act] is extended to the provisions of  
7   [this act].

8       NEW SECTION. **Section 7.** Effective date. [This act] is  
9   effective on passage and approval.

-End-

APPROVED BY COMM. ON  
HUMAN SERVICES AND AGING

HOUSE BILL NO. 688

INTRODUCED BY SIMON, HAGER

BY REQUEST OF THE DEPARTMENT OF HEALTH AND

ENVIRONMENTAL SCIENCES

A BILL FOR AN ACT ENTITLED: "AN ACT TO ALLOW REGISTERED NURSES EMPLOYED BY FAMILY PLANNING CLINICS TO DISPENSE PREPACKAGED PRESCRIPTION CONTRACEPTIVES; AMENDING SECTIONS 37-2-104, 37-7-103, 50-31-103, 50-31-307, AND 50-32-205, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."

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

**Section 1.** Section 37-2-104, MCA, is amended to read:

"37-2-104. Dispensing of drugs by medical practitioners unlawful -- exceptions. (1) Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.

(2) Nothing in this section prohibits:

(a) a medical practitioner from furnishing a patient any drug in an emergency;

(b) the administration of a unit dose of a drug to a patient by or under the supervision of such a medical practitioner;

(c) dispensing a drug to a patient by a medical

practitioner whenever there is no community pharmacy available to the patient;

(d) the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner;

(e) a medical practitioner from dispensing drug samples;

(f) the dispensing of factory prepackaged oral contraceptives by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences if the dispensing is in accordance with:

(i) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(ii) the drug labeling, storage, and logging RECORDKEEPING requirements of the board of pharmacy."

**Section 2.** Section 37-7-103, MCA, is amended to read:

"37-7-103. Exemptions. Subject only to 37-7-401 and 37-7-402:

(1) nothing in this chapter subjects a person duly licensed in this state to practice medicine, dentistry, or veterinary medicine to inspection by the board or prevents such person from compounding or using drugs, medicines, chemicals, or poisons in his practice or prevents one duly licensed to practice medicine from furnishing to a patient such drugs, medicines, chemicals, or poisons as he considers

proper in the treatment of ~~such the~~ patient;

(2) nothing ~~herein~~ in this chapter prevents the sale of drugs, medicines, chemicals, or poisons at wholesale;

(3) nothing ~~herein~~ in this chapter prevents the sale of drugs, chemicals, or poisons either at wholesale or retail for use for commercial purposes or in the arts or changes any of the provisions of this code relating to the sale of insecticides and fungicides, and nothing in this chapter prevents the sale of common household preparations and other drugs, provided stores selling them are licensed under the terms of this chapter;

(4) nothing ~~herein~~ in this chapter applies to or may interfere with manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature for use for nonmedicinal purposes;

(5) nothing in this chapter prevents a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences from dispensing factory prepackaged oral contraceptives if the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate and with the board of pharmacy's requirements for labeling, storage, and logging RECORDKEEPING of drugs.

**Section 3.** Section 50-31-307, MCA, is amended to read:

"50-31-307. Dispensing of prescription drugs. (1) A drug intended for use by man ~~which that~~ falls in one of the categories in subsection (2) ~~may be dispensed only:~~

~~{a}--is--a--habit-forming-drug-to-which-50-31-306(i){d} applies;~~

~~{b}--because-of-its-toxicity-or-other-potentiality--for harmful--effect,--the--method--of-its-use,--or-the-collateral measures-necessary-to-its-use,--is-not-safe--for--use--except under--the--supervision-of-a-practitioner-licensed-by-law-to administer-such-drug;--or~~

~~{c}--is--limited--by--an--approved--application---under section-505-of-the-federal-act-or-50-31-311-to-use-under-the professional--supervision--of-a-practitioner-licensed-by-law to-administer-such-drug-shall-be-dispensed-only;~~

~~{i}{a}~~ upon a written prescription of a practitioner licensed by law to administer ~~such the~~ drug;

~~{ii}{b}~~ upon an oral prescription of ~~such the~~ practitioner ~~which that~~ is reduced promptly to writing and filed by the pharmacist; or

~~{iii}{c}~~ by refilling any ~~such~~ written or oral prescription if ~~such the~~ refilling is authorized by the prescriber either in the original prescription or by oral order ~~which that~~ is reduced promptly to writing and filed by the pharmacist.

(2) A drug must be dispensed as provided in subsection

1 (1) if the drug:

2 (a) is a habit-forming drug to which 50-31-306(1)(d)  
3 applies;

4 (b) because of its toxicity or other potentiality for  
5 harmful effect, the method of its use, or the collateral  
6 measures necessary to its use, is not safe for use except  
7 under the supervision of a practitioner licensed by law to  
8 administer the drug; or

9 (c) is limited by an approved application under  
10 section 505 of the federal act or 50-31-311 to use under the  
11 professional supervision of a practitioner licensed by law  
12 to administer the drug.

13 (3) If the drug is a factory prepackaged oral  
14 contraceptive, it may be dispensed as provided in subsection  
15 (1) or by a registered nurse employed by a family planning  
16 clinic under contract with the department of health and  
17 environmental sciences pursuant to a physician's written  
18 protocol specifying the circumstances under which dispensing  
19 is appropriate and pursuant to the board of pharmacy's rules  
20 concerning labeling, storage, and logging RECORDKEEPING of  
21 drugs.

22 {2}(4) The act of dispensing a drug contrary to the  
23 provisions of this section shall--be--deemed--to--be is  
24 considered an act which that results in a drug being  
25 misbranded while held for sale."

1 **Section 4.** Section 50-31-103, MCA, is amended to read:

2 **"50-31-103. Definitions.** Unless the context requires  
3 otherwise, in this chapter the following definitions apply:

4 (1) "Advertisement" means representations disseminated  
5 in any manner or by any means, other than by labeling, for  
6 the purpose of inducing or which are likely to induce,  
7 directly or indirectly, the purchase of food, drugs,  
8 devices, or cosmetics.

9 (2) "Beef patty mix" means "hamburger" or "ground  
10 beef" to which has been added binders or extenders as those  
11 terms are understood by general custom and usage in the food  
12 industry.

13 (3) "Color" includes black, white, and intermediate  
14 grays.

15 (4) (a) "Color additive" means a material which:

16 (i) is a dye, pigment, or other substance made by a  
17 process of synthesis or similar artifice or extracted,  
18 isolated, or otherwise derived, with or without intermediate  
19 or final change of identity, from a vegetable, animal,  
20 mineral, or other source; or

21 (ii) when added or applied to a food, drug, or cosmetic  
22 or to the human body is capable (alone or through reaction  
23 with other substance) of imparting color thereto.

24 (b) This term does not include material which has been  
25 or hereafter is exempted under the federal act.

1 (5) "Consumer commodity", except as otherwise  
 2 specifically provided by this subsection, means any food,  
 3 drug, device, or cosmetic as those terms are defined by this  
 4 chapter or by the federal act and regulations pursuant  
 5 thereto. The term does not include:

6 (a) any tobacco or tobacco product;  
 7 (b) a commodity subject to packaging or labeling  
 8 requirements imposed under the Federal Insecticide,  
 9 Fungicide, and Rodenticide Act or the provisions of the  
 10 eighth paragraph under the heading "Bureau of Animal  
 11 Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21  
 12 U.S.C. 151-157), commonly known as the virus, serum, and  
 13 toxin act;

14 (c) a drug subject to 50-31-306(1)(m) or  
 15 ~~50-31-307(1)(c)~~ 50-31-307(2)(c) or section 503(b)(1) or 506  
 16 of the federal act;

17 (d) a beverage subject to or complying with packaging  
 18 or labeling requirements imposed under the Federal Alcohol  
 19 Administration Act (27 U.S.C., et seq.); or

20 (e) a commodity subject to the Federal Seed Act (7  
 21 U.S.C. 1551-1610).

22 (6) "Contaminated with filth" applies to a food, drug,  
 23 device, or cosmetic not securely protected from dust, dirt,  
 24 and, as far as may be necessary by all reasonable means,  
 25 from foreign or injurious contaminations.

1 (7) "Cosmetic" means:

2 (a) articles intended to be rubbed, poured, sprinkled,  
 3 sprayed on, introduced into, or otherwise applied to the  
 4 human body for cleansing, beautifying, promoting  
 5 attractiveness, or altering the appearance;

6 (b) articles intended for use as a component of these  
 7 articles, except that the term does not include soap.

8 (8) "Counterfeit drug" means a drug, drug container,  
 9 or drug label which, without authorization bears the  
 10 trademark, trade name, or other identifying mark, imprint,  
 11 or device or any likeness thereof of a drug manufacturer,  
 12 processor, packer, or distributor other than the person who  
 13 in fact manufactured, processed, packed, or distributed the  
 14 drug and which falsely purports or is represented to be the  
 15 product of or to have been packed or distributed by the  
 16 other drug manufacturer, processor, packer, or distributor.

17 (9) "Department" means the department of health and  
 18 environmental sciences provided for in Title 2, chapter 15,  
 19 part 21.

20 (10) "Device" (except when used in 50-31-107(2),  
 21 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and  
 22 50-31-501(10)) means instruments, apparatus, and  
 23 contrivances, including their components, parts, and  
 24 accessories, intended:

25 (a) for use in the diagnosis, cure, mitigation,

1 treatment, or prevention of disease in man or other animals;  
 2 (b) to affect the structure or function of the body of  
 3 man or other animals.  
 4 (11) "Drug" means:  
 5 (a) articles recognized in the official United States  
 6 Pharmacopoeia, official National Formulary, or a supplement  
 7 to either of these;  
 8 (b) articles intended for use in the diagnosis, cure,  
 9 mitigation, treatment, or prevention of disease in man or  
 10 other animals;  
 11 (c) articles (other than food) intended to affect the  
 12 structure or function of the body of man or other animals;  
 13 (d) articles intended for use as components of any  
 14 article specified in subsections (a), (b), or (c) but does  
 15 not include devices or their components, parts, or  
 16 accessories.  
 17 (12) "Federal act" means the Federal Food, Drug, and  
 18 Cosmetic Act, as amended (Title 21 U.S.C. 301, et seq.).  
 19 (13) "Food" means:  
 20 (a) articles used for food or drink for man or other  
 21 animals;  
 22 (b) chewing gum; and  
 23 (c) articles used for components of these articles.  
 24 (14) (a) "Food additive" means a substance, the  
 25 intended use of which results or may be reasonably expected

1 to result, directly or indirectly, in its becoming a  
 2 component or otherwise affecting the characteristics of food  
 3 (including a substance intended for use in producing,  
 4 manufacturing, packing, processing, preparing, treating,  
 5 packaging, transporting, or holding food and including a  
 6 source of radiation intended for this use), if the substance  
 7 is not generally recognized, among experts qualified by  
 8 scientific training and experience to evaluate its safety,  
 9 as having been adequately shown through scientific  
 10 procedures (or, in the case of a substance used in a food  
 11 prior to January 1, 1958, through either scientific  
 12 procedures or experience based on common use in food) to be  
 13 safe under the conditions of its intended use.  
 14 (b) This term does not include:  
 15 (i) a pesticide chemical in or on a raw agricultural  
 16 commodity;  
 17 (ii) a pesticide chemical to the extent that it is  
 18 intended for use or is used in the production, storage, or  
 19 transportation of a raw agricultural commodity;  
 20 (iii) a color additive;  
 21 (iv) a substance used in accordance with a sanction or  
 22 approval granted prior to the enactment of the Food  
 23 Additives Amendment of 1958, pursuant to the federal act,  
 24 the Poultry Products Inspection Act (21 U.S.C. 451, et  
 25 seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat.

1 1260), as amended and extended (21 U.S.C. 71, et seq.).

2 (15) "Food service establishment" means a restaurant,  
3 catering vehicle, vending machine, delicatessen, fast-food  
4 retailer, or any other place that serves food to the public  
5 for consumption either at or away from the point of service,  
6 and any facility operated by a governmental entity where  
7 food is served.

8 (16) "Hamburger" or "ground beef" means ground fresh or  
9 frozen beef or a combination of both fresh and frozen beef,  
10 with or without the addition of suet, to which no water,  
11 binders, or extenders are added. There are three grades of  
12 hamburger or ground beef:

13 (a) "economy hamburger" or "economy ground beef" may  
14 have a fat content no greater than the federal standard set  
15 forth in 9 C.F.R. 319.15;

16 (b) "regular hamburger" or "regular ground beef" may  
17 have a fat content no greater than 21%;

18 (c) "extra lean hamburger" or "extra lean ground beef"  
19 may have a fat content no greater than 18%.

20 (17) "Honey" means the nectar and saccharine exudations  
21 of plants gathered, modified, and stored in the comb by  
22 honey bees; is levorotatory, contains not more than 25% of  
23 water, not more than .25% of ash, and not more than 8%  
24 sucrose.

25 (18) "Label" means a display of written, printed, or

1 graphic matter on the immediate container of an article.  
2 ("Immediate container" does not include package liners.)

3 (19) "Labeling" means labels and other written,  
4 printed, or graphic matter:

5 (a) on an article or its containers or wrappers;

6 (b) accompanying the article.

7 (20) "Menu" means any list presented to the patron  
8 which states the food items for sale in a food service  
9 establishment.

10 (21) "New drug" means a drug, the composition of which  
11 is such that:

12 (a) it is not generally recognized, among experts  
13 qualified by scientific training and experience to evaluate  
14 the safety and effectiveness of drugs, as safe and effective  
15 for use under the conditions prescribed, recommended, or  
16 suggested in its labeling; or

17 (b) the drug, as a result of investigations to  
18 determine its safety and effectiveness for use under the  
19 conditions prescribed, has become so recognized but which  
20 has not, otherwise than in the investigations, been used to  
21 a material extent or for a material time under the  
22 conditions prescribed.

23 (22) "Official compendium" means the official United  
24 States Pharmacopoeia, official National Formulary, or a  
25 supplement to either of these.



1 (23) "Organic food" means food that conforms to the  
2 definition in 50-31-222.

3 (24) "Package" means a container or wrapping in which a  
4 consumer commodity is enclosed for use in the delivery or  
5 display of that consumer commodity to retail purchasers but  
6 does not include:

7 (a) shipping containers or wrappings used solely for  
8 the transportation of a consumer commodity in bulk or in  
9 quantity to manufacturers, packers, or processors or to  
10 wholesale or retail distributors;

11 (b) shipping containers or outer wrappings used by  
12 retailers to ship or deliver a commodity to retail customers  
13 if the containers and wrappings bear no printed matter  
14 pertaining to a particular commodity.

15 (25) "Person" includes an individual, partnership,  
16 corporation, and association.

17 (26) "Pesticide chemical" means a substance which  
18 alone, in chemical combination, or in formulation with one  
19 or more other substances is an "economic poison" under the  
20 Federal Insecticide, Fungicide, and Rodenticide Act (7  
21 U.S.C., secs. 135-135k), as amended, and which is used in  
22 the production, storage, or transportation of raw  
23 agricultural commodities.

24 (27) "Placard" means any nonpermanent sign used to  
25 display or describe food items for sale in a food service

1 establishment or retail establishment.

2 (28) "Principal display panel" means that part of a  
3 label that is most likely to be displayed, presented, shown,  
4 or examined under normal and customary conditions of display  
5 for retail sale.

6 (29) "Processing" means cooking, baking, heating,  
7 drying, mixing, grinding, churning, separating, extracting,  
8 cutting, freezing, or otherwise manufacturing a food or  
9 changing the physical characteristics of a food, and the  
10 enclosure of such food in a package.

11 (30) "Raw agricultural commodity" means food in its raw  
12 or natural state, including fruits that are washed, colored,  
13 or otherwise treated in their unpeeled natural form prior to  
14 marketing.

15 (31) "Retail establishment" means a commercial  
16 establishment at which meat or meat products are displayed  
17 for sale or provision to the public with or without charge.

18 (32) "State board" or "board" means the board of health  
19 and environmental sciences provided for in 2-15-2104.

20 (33) "Synthetically compounded" means a product  
21 formulated by a process that chemically changes a material  
22 or substance extracted from naturally occurring plant,  
23 animal, or mineral sources, except for microbiological  
24 processes."

25 **Section 5.** Section 50-32-205, MCA, is amended to read:

1       **"50-32-205. Nonprescription drugs not to be scheduled.**

2       The board shall exclude any nonnarcotic drug from a schedule  
3       if ~~such~~ the drug may, under the Federal Food, Drug, and  
4       Cosmetic Act and ~~50-31-307(1)(b)~~ 50-31-307(2)(b) of the  
5       Montana Food, Drug, and Cosmetic Act, be lawfully sold over  
6       the counter without a prescription."

7       NEW SECTION.   **Section 6.** Extension of authority. Any  
8       existing authority to make rules on the subject of the  
9       provisions of [this act] is extended to the provisions of  
10      [this act].

11      NEW SECTION.   **Section 7.** Effective date. [This act] is  
12      effective on passage and approval.

-End-

APPROVED BY COMM. ON  
HUMAN SERVICES AND AGING

1 HOUSE BILL NO. 688  
2 INTRODUCED BY SIMON, HAGER  
3 BY REQUEST OF THE DEPARTMENT OF HEALTH AND  
4 ENVIRONMENTAL SCIENCES  
5  
6 A BILL FOR AN ACT ENTITLED: "AN ACT TO ALLOW REGISTERED  
7 NURSES EMPLOYED BY FAMILY PLANNING CLINICS TO DISPENSE  
8 PREPACKAGED PRESCRIPTION CONTRACEPTIVES; AMENDING SECTIONS  
9 37-2-104, 37-7-103, 50-31-103, 50-31-307, AND 50-32-205,  
10 MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."  
11  
12 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:  
13 **Section 1.** Section 37-2-104, MCA, is amended to read:  
14 "37-2-104. Dispensing of drugs by medical  
15 practitioners unlawful -- exceptions. (1) Except as  
16 otherwise provided by this section, it is unlawful for a  
17 medical practitioner to engage, directly or indirectly, in  
18 the dispensing of drugs.  
19 (2) Nothing in this section prohibits:  
20 (a) a medical practitioner from furnishing a patient  
21 any drug in an emergency;  
22 (b) the administration of a unit dose of a drug to a  
23 patient by or under the supervision of such a medical  
24 practitioner;  
25 (c) dispensing a drug to a patient by a medical

There is no change on HB 688 and will not be  
reprinted. Please refer to second reading  
(yellow) for complete text.

SENATE STANDING COMMITTEE REPORT

page 1 of 2  
March 20, 1989

SENATE COMMITTEE ON PUBLIC HEALTH, HB 688  
page 2 of 2

MR. PRESIDENT:

We, your committee on Public Health, Welfare, and Safety, having had under consideration HB 688 (third reading copy -- blue), respectfully report that HB 688 be amended and as so amended be concurred in:

Sponsor: Simon (Hager)

1. Page 2, lines 7 through 15.

Strike: subsection (f) in its entirety

Insert: "(f) the dispensing of the first month's cycle, or one month's emergency cycle in the event of an unscheduled appointment, of factory prepackaged oral contraceptives by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences if:

(i) the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(ii) a registered pharmacist has prelabeled the factory packaged oral contraceptive for use as an initial or emergency cycle in accordance with Class IV regulations contained in Rule 8.40.706, Administrative Rules of Montana. The registered nurse shall complete the label by adding the patient's name and date of issue."

2. Page 3, lines 17 through 24.

Strike: subsection (5) in its entirety

Insert: "(5) nothing in this chapter prevents a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences from dispensing the first month's cycle or an emergency cycle of a factory prepackaged oral contraceptive if:

(a) the dispensing is in accordance with the physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(b) a registered pharmacist has prelabeled the oral contraceptive in accordance with Class IV regulations contained in Rule 8.40.706, Administrative Rules of Montana."

3. Page 5, lines 13 through 21.

Strike: subsection (3) in its entirety

Insert: "(3) If the drug is the first month's cycle or an emergency cycle of a factory prepackaged oral contraceptive, it may be dispensed as provided in subsection (1) or by a registered nurse employed by a family planning clinic under contract with the

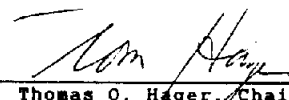
department of health and environmental sciences pursuant to:

(a) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(b) the board of pharmacy's rules for Class IV pharmacies contained in Rule 8.40.706, Administrative Rules of Montana."

AND AS AMENDED BE CONCURRED IN

Signed:

  
Thomas O. Hager, Chairman

continued

SCRHB688.320

SENATE  
HB 688

**SENATE COMMITTEE OF THE WHOLE AMENDMENT**

March 23, 1989 8:23 am

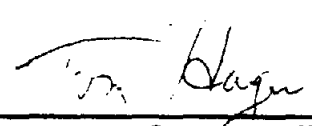
Mr. Chairman: I move to amend HB 688 (third reading copy -- blue) as follows:

1. Strike: The Senate Committee on Public Health, Welfare, and Safety amendments to HB 688 (third reading copy -- blue) dated March 20, 1989, in their entirety

**ADOPT**

**REJECT**

Signed: \_\_\_\_\_

  
Senator Hager

**HB 688**

**SENATE**

## HOUSE BILL NO. 688

INTRODUCED BY SIMON, HAGER

BY REQUEST OF THE DEPARTMENT OF HEALTH AND

ENVIRONMENTAL SCIENCES

A BILL FOR AN ACT ENTITLED: "AN ACT TO ALLOW REGISTERED NURSES EMPLOYED BY FAMILY PLANNING CLINICS TO DISPENSE PREPACKAGED PRESCRIPTION CONTRACEPTIVES; AMENDING SECTIONS 37-2-104, 37-7-103, 50-31-103, 50-31-307, AND 50-32-205, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE."

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

**Section 1.** Section 37-2-104, MCA, is amended to read:

"37-2-104. Dispensing of drugs by medical practitioners unlawful -- exceptions. (1) Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.

(2) Nothing in this section prohibits:

(a) a medical practitioner from furnishing a patient any drug in an emergency;

(b) the administration of a unit dose of a drug to a patient by or under the supervision of such a medical practitioner;

(c) dispensing a drug to a patient by a medical

practitioner whenever there is no community pharmacy available to the patient;

(d) the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner;

(e) a medical practitioner from dispensing drug samples;

(f) the dispensing of factory prepackaged oral contraceptives by a registered nurse employed by a family planning clinic under contract with the department of health and environmental sciences if the dispensing is in accordance with:

(i) a physician's written protocol specifying the circumstances under which dispensing is appropriate; and

(ii) the drug labeling, storage, and logging RECORDKEEPING requirements of the board of pharmacy;

(F) THE DISPENSING OF THE FIRST MONTH'S CYCLE OR ONE MONTH'S EMERGENCY CYCLE IN THE EVENT OF AN UNSCHEDULED APPOINTMENT OF FACTORY PREPACKAGED ORAL CONTRACEPTIVES BY A REGISTERED NURSE EMPLOYED BY A FAMILY PLANNING CLINIC UNDER CONTRACT WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES IF:

(i) THE DISPENSING IS IN ACCORDANCE WITH A PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING IS APPROPRIATE; AND

(ii) A REGISTERED PHARMACIST HAS PRELABELED THE FACTORY

PACKAGED--ORAL--CONTRACEPTIVE--FOR--USE--AS--AN--INITIAL--OR  
EMERGENCY--CYCLE--IN--ACCORDANCE--WITH--CLASS-IV-REGULATIONS  
CONTAINED--IN--RULE--8-40-7067--ADMINISTRATIVE-RULES-OF-MONTANA--  
THE-REGISTERED-NURSE-SHALL-COMPLETE-THE-LABEL-BY-ADDING--THE  
PATIENT'S-NAME-AND-DATE-OF-ISSUE.

(F) THE DISPENSING OF FACTORY PREPACKAGED ORAL  
CONTRACEPTIVES BY A REGISTERED NURSE EMPLOYED BY A FAMILY  
PLANNING CLINIC UNDER CONTRACT WITH THE DEPARTMENT OF HEALTH  
AND ENVIRONMENTAL SCIENCES IF THE DISPENSING IS IN  
ACCORDANCE WITH:

(I) A PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE  
CIRCUMSTANCES UNDER WHICH DISPENSING IS APPROPRIATE; AND

(II) THE DRUG LABELING, STORAGE, AND RECORDKEEPING  
REQUIREMENTS OF THE BOARD OF PHARMACY."

**Section 2.** Section 37-7-103, MCA, is amended to read:

**"37-7-103. Exemptions.** Subject only to 37-7-401 and  
 37-7-402:

(1) nothing in this chapter subjects a person duly  
 licensed in this state to practice medicine, dentistry, or  
 veterinary medicine to inspection by the board or prevents  
 such person from compounding or using drugs, medicines,  
 chemicals, or poisons in his practice or prevents one duly  
 licensed to practice medicine from furnishing to a patient  
 such drugs, medicines, chemicals, or poisons as he considers  
 proper in the treatment of such the patient;

(2) nothing herein in this chapter prevents the sale  
 of drugs, medicines, chemicals, or poisons at wholesale;

(3) nothing herein in this chapter prevents the sale  
 of drugs, chemicals, or poisons either at wholesale or  
 retail for use for commercial purposes or in the arts or  
 changes any of the provisions of this code relating to the  
 sale of insecticides and fungicides, and nothing in this  
 chapter prevents the sale of common household preparations  
 and other drugs, provided stores selling them are licensed  
 under the terms of this chapter;

(4) nothing herein in this chapter applies to or may  
 interfere with manufacture, wholesaling, vending, or  
 retailing of flavoring extracts, toilet articles, cosmetics,  
 perfumes, spices, and other commonly used household articles  
 of a chemical nature for use for nonmedicinal purposes;

(5)--nothing-in--this--chapter--prevents--a--registered  
nurse--employed--by--a-family-planning-clinic-under-contract  
with-the-department-of--health--and--environmental--sciences  
from--dispensing--factory-prepackaged-oral-contraceptives-if  
the-dispensing-is-in-accordance-with-a-physician's-written  
protocol-specifying-the-circumstances-under-which-dispensing  
is-appropriate-and-with-the-board-of-pharmacy's-requirements  
for--labeling--storage--and logging RECORDKEEPING of-drugs.

(5)--NOTHING-IN-THIS-CHAPTER-PREVENTS-A-REGISTERED  
NURSE--EMPLOYED--BY--A-FAMILY-PLANNING-CLINIC-UNDER-CONTRACT

WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES  
FROM DISPENSING THE FIRST MONTH'S CYCLE OR AN EMERGENCY  
CYCLE OF A FACTORY PREPACKAGED ORAL CONTRACEPTIVE IF:

{A} THE DISPENSING IS IN ACCORDANCE WITH THE  
PHYSICIAN'S WRITTEN PROTOCOL SPECIFYING THE CIRCUMSTANCES  
UNDER WHICH DISPENSING IS APPROPRIATE, AND

{B} A REGISTERED PHARMACIST HAS PRELABELED THE ORAL  
CONTRACEPTIVE IN ACCORDANCE WITH CLASS IV REGULATIONS  
CONTAINED IN RULE 8.40.706, ADMINISTRATIVE RULES OF MONTANA.

(5) NOTHING IN THIS CHAPTER PREVENTS A REGISTERED  
NURSE EMPLOYED BY A FAMILY PLANNING CLINIC UNDER CONTRACT  
WITH THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES  
FROM DISPENSING FACTORY PREPACKAGED ORAL CONTRACEPTIVES IF  
THE DISPENSING IS IN ACCORDANCE WITH A PHYSICIAN'S WRITTEN  
PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING  
IS APPROPRIATE AND WITH THE BOARD OF PHARMACY'S REQUIREMENTS  
FOR LABELING, STORAGE, AND RECORDKEEPING OF DRUGS."

**Section 3.** Section 50-31-307, MCA, is amended to read:

**"50-31-307.** Dispensing of prescription drugs. (1) A drug intended for use by man which that falls in one of the categories in subsection (2) may be dispensed only:

{a} is a habit-forming drug to which 50-31-306{1}{d}  
applies;

{b} because of its toxicity or other potentiality for  
harmful effect, the method of its use, or the collateral

measures necessary to its use, is not safe for use except  
under the supervision of a practitioner licensed by law to  
administer such drug; or

{c} is limited by an approved application under  
section 505 of the federal act or 50-31-311 to use under the  
professional supervision of a practitioner licensed by law  
to administer such drug shall be dispensed only:

{i}{a} upon a written prescription of a practitioner  
licensed by law to administer such the drug;

{ii}{b} upon an oral prescription of such the  
practitioner which that is reduced promptly to writing and  
filed by the pharmacist; or

{iii}{c} by refilling any such written or oral  
prescription if such the refilling is authorized by the  
prescriber either in the original prescription or by oral  
order which that is reduced promptly to writing and filed by  
the pharmacist.

(2) A drug must be dispensed as provided in subsection  
(1) if the drug:

(a) is a habit-forming drug to which 50-31-306(1)(d)  
applies;

(b) because of its toxicity or other potentiality for  
harmful effect, the method of its use, or the collateral  
measures necessary to its use, is not safe for use except  
under the supervision of a practitioner licensed by law to



1 administer the drug; or

2 (c) is limited by an approved application under  
3 section 505 of the federal act or 50-31-311 to use under the  
4 professional supervision of a practitioner licensed by law  
5 to administer the drug.

6 ~~{3}--if--the---drug--is--a--factory--prepackaged--oral~~  
7 ~~contraceptive,--it--may--be--dispensed--as--provided--in--subsection~~  
8 ~~{1}--or--by--a--registered--nurse--employed--by--a--family--planning~~  
9 ~~clinic--under--contract--with--the--department--of--health--and~~  
10 ~~environmental--sciences--pursuant--to--a--physician's--written~~  
11 ~~protocol--specifying--the--circumstances--under--which--dispensing~~  
12 ~~is--appropriate--and--pursuant--to--the--board--of--pharmacy's--rules~~  
13 ~~concerning--labeling,--storage,--and--logging RECORDKEEPING of~~  
14 ~~drugs:~~

15 ~~{3}--IF--THE--DRUG--IS--THE--FIRST--MONTH'S--CYCLE--OR--AN~~  
16 ~~EMERGENCY--CYCLE--OF--A--FACTORY--PREPACKAGED--ORAL--CONTRACEPTIVE,~~  
17 ~~IF--MAY--BE--DISPENSED--AS--PROVIDED--IN--SUBSECTION--(1)--OR--BY--A~~  
18 ~~REGISTERED--NURSE--EMPLOYED--BY--A--FAMILY--PLANNING--CLINIC--UNDER~~  
19 ~~CONTRACT--WITH--THE--DEPARTMENT--OF--HEALTH--AND--ENVIRONMENTAL~~  
20 ~~SCIENCES--PURSUANT--TO:~~

21 ~~{A}--A--PHYSICIAN'S--WRITTEN--PROTOCOL--SPECIFYING--THE~~  
22 ~~CIRCUMSTANCES--UNDER--WHICH--DISPENSING--IS--APPROPRIATE,--AND~~

23 ~~{B}--THE--BOARD--OF--PHARMACY'S--RULES--FOR--CLASS--IV~~  
24 ~~PHARMACIES--CONTAINED--IN--RULE--8.40.706,--ADMINISTRATIVE--RULES~~  
25 ~~OF--MONTANA:~~

1 (3) IF THE DRUG IS A FACTORY PREPACKAGED ORAL  
2 CONTRACEPTIVE, IT MAY BE DISPENSED AS PROVIDED IN SUBSECTION  
3 (1) OR BY A REGISTERED NURSE EMPLOYED BY A FAMILY PLANNING  
4 CLINIC UNDER CONTRACT WITH THE DEPARTMENT OF HEALTH AND  
5 ENVIRONMENTAL SCIENCES PURSUANT TO A PHYSICIAN'S WRITTEN  
6 PROTOCOL SPECIFYING THE CIRCUMSTANCES UNDER WHICH DISPENSING  
7 IS APPROPRIATE AND PURSUANT TO THE BOARD OF PHARMACY'S RULES  
8 CONCERNING LABELING, STORAGE, AND RECORDKEEPING OF DRUGS.

9 {2}{4} The act of dispensing a drug contrary to the  
10 provisions of this section shall--be--deemed--to--be is  
11 considered an act which that results in a drug being  
12 misbranded while held for sale."

13 **Section 4.** Section 50-31-103, MCA, is amended to read:

14 "50-31-103. Definitions. Unless the context requires  
15 otherwise, in this chapter the following definitions apply:

16 (1) "Advertisement" means representations disseminated  
17 in any manner or by any means, other than by labeling, for  
18 the purpose of inducing or which are likely to induce,  
19 directly or indirectly, the purchase of food, drugs,  
20 devices, or cosmetics.

21 (2) "Beef patty mix" means "hamburger" or "ground  
22 beef" to which has been added binders or extenders as those  
23 terms are understood by general custom and usage in the food  
24 industry.

25 (3) "Color" includes black, white, and intermediate

1 grays.

2 (4) (a) "Color additive" means a material which:

3 (i) is a dye, pigment, or other substance made by a  
4 process of synthesis or similar artifice or extracted,  
5 isolated, or otherwise derived, with or without intermediate  
6 or final change of identity, from a vegetable, animal,  
7 mineral, or other source; or

8 (ii) when added or applied to a food, drug, or cosmetic  
9 or to the human body is capable (alone or through reaction  
10 with other substance) of imparting color thereto.

11 (b) This term does not include material which has been  
12 or hereafter is exempted under the federal act.

13 (5) "Consumer commodity", except as otherwise  
14 specifically provided by this subsection, means any food,  
15 drug, device, or cosmetic as those terms are defined by this  
16 chapter or by the federal act and regulations pursuant  
17 thereto. The term does not include:

18 (a) any tobacco or tobacco product;

19 (b) a commodity subject to packaging or labeling  
20 requirements imposed under the Federal Insecticide,  
21 Fungicide, and Rodenticide Act or the provisions of the  
22 eighth paragraph under the heading "Bureau of Animal  
23 Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21  
24 U.S.C. 151-157), commonly known as the virus, serum, and  
25 toxin act;

1 (c) a drug subject to 50-31-306(1)(m) or  
2 ~~50-31-307(1)(c)~~ 50-31-307(2)(c) or section 503(b)(1) or 506  
3 of the federal act;

4 (d) a beverage subject to or complying with packaging  
5 or labeling requirements imposed under the Federal Alcohol  
6 Administration Act (27 U.S.C., et seq.); or

7 (e) a commodity subject to the Federal Seed Act (7  
8 U.S.C. 1551-1610).

9 (6) "Contaminated with filth" applies to a food, drug,  
10 device, or cosmetic not securely protected from dust, dirt,  
11 and, as far as may be necessary by all reasonable means,  
12 from foreign or injurious contaminations.

13 (7) "Cosmetic" means:

14 (a) articles intended to be rubbed, poured, sprinkled,  
15 sprayed on, introduced into, or otherwise applied to the  
16 human body for cleansing, beautifying, promoting  
17 attractiveness, or altering the appearance;

18 (b) articles intended for use as a component of these  
19 articles, except that the term does not include soap.

20 (8) "Counterfeit drug" means a drug, drug container,  
21 or drug label which, without authorization bears the  
22 trademark, trade name, or other identifying mark, imprint,  
23 or device or any likeness thereof of a drug manufacturer,  
24 processor, packer, or distributor other than the person who  
25 in fact manufactured, processed, packed, or distributed the

1 drug and which falsely purports or is represented to be the  
2 product of or to have been packed or distributed by the  
3 other drug manufacturer, processor, packer, or distributor.

4 (9) "Department" means the department of health and  
5 environmental sciences provided for in Title 2, chapter 15,  
6 part 21.

7 (10) "Device" (except when used in 50-31-107(2),  
8 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and  
9 50-31-501(10)) means instruments, apparatus, and  
10 contrivances, including their components, parts, and  
11 accessories, intended:

12 (a) for use in the diagnosis, cure, mitigation,  
13 treatment, or prevention of disease in man or other animals;

14 (b) to affect the structure or function of the body of  
15 man or other animals.

16 (11) "Drug" means:

17 (a) articles recognized in the official United States  
18 Pharmacopoeia, official National Formulary, or a supplement  
19 to either of these;

20 (b) articles intended for use in the diagnosis, cure,  
21 mitigation, treatment, or prevention of disease in man or  
22 other animals;

23 (c) articles (other than food) intended to affect the  
24 structure or function of the body of man or other animals;

25 (d) articles intended for use as components of any

1 article specified in subsections (a), (b), or (c) but does  
2 not include devices or their components, parts, or  
3 accessories.

4 (12) "Federal act" means the Federal Food, Drug, and  
5 Cosmetic Act, as amended (Title 21 U.S.C. 301, et seq.).

6 (13) "Food" means:

7 (a) articles used for food or drink for man or other  
8 animals;

9 (b) chewing gum; and

10 (c) articles used for components of these articles.

11 (14) (a) "Food additive" means a substance, the  
12 intended use of which results or may be reasonably expected  
13 to result, directly or indirectly, in its becoming a  
14 component or otherwise affecting the characteristics of food  
15 (including a substance intended for use in producing,  
16 manufacturing, packing, processing, preparing, treating,  
17 packaging, transporting, or holding food and including a  
18 source of radiation intended for this use), if the substance  
19 is not generally recognized, among experts qualified by  
20 scientific training and experience to evaluate its safety,  
21 as having been adequately shown through scientific  
22 procedures (or, in the case of a substance used in a food  
23 prior to January 1, 1958, through either scientific  
24 procedures or experience based on common use in food) to be  
25 safe under the conditions of its intended use.

1 (b) This term does not include:

2 (i) a pesticide chemical in or on a raw agricultural  
3 commodity;

4 (ii) a pesticide chemical to the extent that it is  
5 intended for use or is used in the production, storage, or  
6 transportation of a raw agricultural commodity;

7 (iii) a color additive;

8 (iv) a substance used in accordance with a sanction or  
9 approval granted prior to the enactment of the Food  
10 Additives Amendment of 1958, pursuant to the federal act,  
11 the Poultry Products Inspection Act (21 U.S.C. 451, et  
12 seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat.  
13 1260), as amended and extended (21 U.S.C. 71, et seq.).

14 (15) "Food service establishment" means a restaurant,  
15 catering vehicle, vending machine, delicatessen, fast-food  
16 retailer, or any other place that serves food to the public  
17 for consumption either at or away from the point of service,  
18 and any facility operated by a governmental entity where  
19 food is served.

20 (16) "Hamburger" or "ground beef" means ground fresh or  
21 frozen beef or a combination of both fresh and frozen beef,  
22 with or without the addition of suet, to which no water,  
23 binders, or extenders are added. There are three grades of  
24 hamburger or ground beef:

25 (a) "economy hamburger" or "economy ground beef" may

1 have a fat content no greater than the federal standard set  
2 forth in 9 C.F.R. 319.15;

3 (b) "regular hamburger" or "regular ground beef" may  
4 have a fat content no greater than 21%;

5 (c) "extra lean hamburger" or "extra lean ground beef"  
6 may have a fat content no greater than 18%.

7 (17) "Honey" means the nectar and saccharine exudations  
8 of plants gathered, modified, and stored in the comb by  
9 honey bees; is levorotatory, contains not more than 25% of  
10 water, not more than .25% of ash, and not more than 8%  
11 sucrose.

12 (18) "Label" means a display of written, printed, or  
13 graphic matter on the immediate container of an article.  
14 ("Immediate container" does not include package liners.)

15 (19) "Labeling" means labels and other written,  
16 printed, or graphic matter:

17 (a) on an article or its containers or wrappers;

18 (b) accompanying the article.

19 (20) "Menu" means any list presented to the patron  
20 which states the food items for sale in a food service  
21 establishment.

22 (21) "New drug" means a drug, the composition of which  
23 is such that:

24 (a) it is not generally recognized, among experts  
25 qualified by scientific training and experience to evaluate

1 the safety and effectiveness of drugs, as safe and effective  
2 for use under the conditions prescribed, recommended, or  
3 suggested in its labeling; or

4 (b) the drug, as a result of investigations to  
5 determine its safety and effectiveness for use under the  
6 conditions prescribed, has become so recognized but which  
7 has not, otherwise than in the investigations, been used to  
8 a material extent or for a material time under the  
9 conditions prescribed.

10 (22) "Official compendium" means the official United  
11 States Pharmacopoeia, official National Formulary, or a  
12 supplement to either of these.

13 (23) "Organic food" means food that conforms to the  
14 definition in 50-31-222.

15 (24) "Package" means a container or wrapping in which a  
16 consumer commodity is enclosed for use in the delivery or  
17 display of that consumer commodity to retail purchasers but  
18 does not include:

19 (a) shipping containers or wrappings used solely for  
20 the transportation of a consumer commodity in bulk or in  
21 quantity to manufacturers, packers, or processors or to  
22 wholesale or retail distributors;

23 (b) shipping containers or outer wrappings used by  
24 retailers to ship or deliver a commodity to retail customers  
25 if the containers and wrappings bear no printed matter

1 pertaining to a particular commodity.

2 (25) "Person" includes an individual, partnership,  
3 corporation, and association.

4 (26) "Pesticide chemical" means a substance which  
5 alone, in chemical combination, or in formulation with one  
6 or more other substances is an "economic poison" under the  
7 Federal Insecticide, Fungicide, and Rodenticide Act (7  
8 U.S.C., secs. 135-135k), as amended, and which is used in  
9 the production, storage, or transportation of raw  
10 agricultural commodities.

11 (27) "Placard" means any nonpermanent sign used to  
12 display or describe food items for sale in a food service  
13 establishment or retail establishment.

14 (28) "Principal display panel" means that part of a  
15 label that is most likely to be displayed, presented, shown,  
16 or examined under normal and customary conditions of display  
17 for retail sale.

18 (29) "Processing" means cooking, baking, heating,  
19 drying, mixing, grinding, churning, separating, extracting,  
20 cutting, freezing, or otherwise manufacturing a food or  
21 changing the physical characteristics of a food, and the  
22 enclosure of such food in a package.

23 (30) "Raw agricultural commodity" means food in its raw  
24 or natural state, including fruits that are washed, colored,  
25 or otherwise treated in their unpeeled natural form prior to

1 marketing.

2 (31) "Retail establishment" means a commercial  
3 establishment at which meat or meat products are displayed  
4 for sale or provision to the public with or without charge.

5 (32) "State board" or "board" means the board of health  
6 and environmental sciences provided for in 2-15-2104.

7 (33) "Synthetically compounded" means a product  
8 formulated by a process that chemically changes a material  
9 or substance extracted from naturally occurring plant,  
10 animal, or mineral sources, except for microbiological  
11 processes."

12 **Section 5.** Section 50-32-205, MCA, is amended to read:

13 "50-32-205. Nonprescription drugs not to be scheduled.  
14 The board shall exclude any nonnarcotic drug from a schedule  
15 if such the drug may, under the Federal Food, Drug, and  
16 Cosmetic Act and ~~50-31-307(1)(b)~~ 50-31-307(2)(b) of the  
17 Montana Food, Drug, and Cosmetic Act, be lawfully sold over  
18 the counter without a prescription."

19 NEW SECTION. **Section 6.** Extension of authority. Any  
20 existing authority to make rules on the subject of the  
21 provisions of [this act] is extended to the provisions of  
22 [this act].

23 NEW SECTION. **Section 7.** Effective date. [This act] is  
24 effective on passage and approval.

-End-