

ENGROSSED HOUSE
BILL NO. 2599

By: Thornbrugh of the House

and

Hendrick and Fisher of
the Senate

An Act relating to public health and safety; amending 63 O.S. 1991, Sections 1-1401 and 1-1408, as amended by Section 3, Chapter 52, O.S.L. 1992 (63 O.S. Supp. 1997, Section 1-1408), which relates to adulterated drugs; modifying definition; providing for construction of article; clarifying persons who are not subject to act; prohibiting article from being construed to regulate or attempt to regulate practice of healing arts; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 63 O.S. 1991, Section 1-1401, is amended to read as follows:

Section 1-1401. A. For the purposes of this article:

~~(a) The term "drug" 1. "Drug" means (1):~~

a. articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; ~~and (2),~~

- b. articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or ~~other~~ animals; ~~and (3)~~
- c. articles ~~(, other than food)~~, intended to affect the structure or any function of the body of man or ~~other~~ animals; ~~and (4)~~
- d. articles intended for use as ~~a component~~ components of any article specified in ~~clause (1), (2)~~ subparagraph a, b or (3); c of this paragraph,

but does not include devices or their components, parts or accessories;

~~(b) The term "device" (~~ 2. "Device", except when used in paragraph ~~(k) 9~~ of this ~~Section~~ subsection and in ~~Sections 1402(i), 1409(e)~~ paragraph (i) of Section 1-1402 of this title, paragraph (c) of Section 1-1409 of this title, and 1411(e) paragraph (c) of Section 1-1411 of this Article) title, means instruments, apparatus and contrivances, including their components, parts and accessories, intended ~~(1):~~

- a. for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or ~~other~~ animals; ~~and (2)~~
- b. to affect the structure or any function of the body of man or ~~other~~ animals;

~~(c) The term "cosmetic" 3. "Cosmetic" means (1):~~

- a. articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and ~~(2)~~
- b. articles intended for use as a component of any such articles, except that such term shall not include soap;

~~(d) The term "official"~~ 4. "Official compendium" means the official United States Pharmacopoeia, official ~~Homoeopathic~~ Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;

~~(e) The term "label"~~ 5. "Label" means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this article that any word, statement, or other information appear on the label shall not be considered to be complied with unless such work, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper;

~~(f) The term "immediate"~~ 6. "Immediate container" does not include package liners;

~~(g) The term "labeling"~~ 7. "Labeling" means all labels and other written, printed or graphic matter ~~(1)~~;

a. upon an article or any of its containers or wrappers, or ~~(2)~~

b. accompanying such article;

~~(h)~~ 8. "Advertisement" means all representations disseminated in any manner or by any means, other than labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics;

9. "Contaminated with filth" applies to any drug, device, or cosmetic not securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, from all foreign or injurious contaminations; and

10. "Federal act" means the Federal Food, Drug, and Cosmetic Act, as amended.

B. If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be

false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be taken into account ~~(, among other things),~~ not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

~~(i) The term "advertisement" means all representations disseminated in any manner or by any means, other than labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.~~

~~(j) C.~~ The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

~~(k) The term "contaminated with filth" applies to any drug, device, or cosmetic not securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.~~

~~(l) D.~~ The provisions of this article regarding the selling of drugs, devices, or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such article in the conduct of any drug or cosmetic manufacturing establishment. The provisions of this section shall

not be construed to prohibit the administering or prescribing of a drug or device in the course of professional practice by a person who is a physician, dentist, or veterinarian, licensed or authorized to practice pursuant to the laws of this state and in good faith, in the course of such person's professional practice.

~~(m) The term "Federal Act" means the Federal Food, Drug, and Cosmetic Act, as amended.~~

SECTION 2. AMENDATORY 63 O.S. 1991, Section 1-1408, as amended by Section 3, Chapter 52, O.S.L. 1992 (63 O.S. Supp. 1997, Section 1-1408), is amended to read as follows:

Section 1-1408. A drug or device shall be deemed to be adulterated:

1. If it consists in whole or in part of any filthy, putrid or decomposed substance;

2. If it has been produced, prepared, packed or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

3. If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

4. If it is a drug and it bears or contains, for purposes of coloring only, a coal tar color other than one from a batch certified under the authority of the Federal Food, Drug and Cosmetic Act, 21 U.S.C., Section 301 et seq.;

5. If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or, in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official

compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality or purity therefor set forth in such compendium, if its difference in strength, quality or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the ~~Homoeopathic~~ Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a ~~homoeopathic~~ homeopathic drug, in which case it shall be subject to the provisions of the ~~Homoeopathic~~ Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia;

6. If it is not subject to the provisions of paragraph 2 of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;

7. If it is a drug and any substance has been:

- a. mixed or packed therewith so as to reduce its quality or strength, ~~or~~ or
- b. substituted wholly or in part therefor; or

8. If it is ~~sold or offered for sale and is not lawfully marketed~~ adulterated under the federal act ~~for the purpose for which, and in the form in which, it is sold or offered for sale,~~ unless the drug or device has been exempted from the requirements of this ~~paragraph~~ article by the Commissioner of Health, or if the drug is compounded by a registered pharmacist pursuant to a prescription by a licensed practitioner. The provisions of this paragraph shall not be construed to regulate the lawful practice of the healing arts pursuant to Chapter 16 of Title 59 of the Oklahoma Statutes.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-1416 of Title 63, unless there is created a duplication in numbering, reads as follows:

Nothing in this article shall be interpreted as or construed as regulating or attempting to regulate the lawful practice of the

healing arts pursuant to Chapter 16 of Title 59 of the Oklahoma Statutes.

SECTION 4. This act shall become effective November 1, 1998.

Passed the House of Representatives the 2nd day of March, 1998.

Speaker of the House of
Representatives

Passed the Senate the ____ day of _____, 1998.

President of the Senate