H.C.R. No. 273

HOUSE CONCURRENT RESOLUTION

WHEREAS, House Bill No. 2192 has been adopted by the house of representatives and the senate and is being prepared for enrollment; and

WHEREAS, The bill contains technical errors that should be corrected; now, therefore, be it

RESOLVED by the 78th Legislature of the State of Texas, That the enrolling clerk of the house be instructed to correct House Bill No. 2192 by striking SECTION 15 of the bill, as added by Committee Amendment No. 1 by Van de Putte, and substituting the following SECTIONS, appropriately numbered:

SECTION __. Section 431.002(8), Health and Safety Code, is amended to read as follows:

(8) "Consumer commodity," except as otherwise provided by this subdivision, means any food, drug, device, or cosmetic, as those terms are defined by this chapter or by the federal Act, and any other article, product, or commodity of any kind or class that is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or for use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and that usually is consumed or expended in the course of the consumption or use. The term does not include:

(A) a meat or meat product, poultry or poultry product, or tobacco or tobacco product;

(B) a commodity subject to packaging or labeling requirements imposed under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136), or The [~~Section 8,~~] Virus-Serum-Toxin Act (21 U.S.C. 151 et seq. [~~158~~]);

(C) a drug subject to the provisions of Section 431.113(c)(1) [~~or 431.112(k),~~] or Section 503(b)(1) [~~or 506~~] of the federal Act;

(D) a beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C. 205(e)); or

(E) a commodity subject to the provisions of Chapter 61, Agriculture Code, relating to the inspection, labeling, and sale of agricultural and vegetable seed.

SECTION __. Section 431.112, Health and Safety Code, is amended to read as follows:

Sec. 431.112. MISBRANDED DRUG OR DEVICE. A drug or device shall be deemed to be misbranded:

(a)(1) if its labeling is false or misleading in any particular; or

(2) if its labeling or packaging fails to conform with the requirements of Section 431.181.

(b) if in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under Subdivision (2) reasonable variations shall be permitted, and exemptions as to small packages shall be allowed in

accordance with regulations prescribed by the secretary 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, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be designated as habit forming, by regulations issued by the secretary under 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)~~] (1) if it is a drug, unless:

(A) 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 Subdivision (3)) of the drug, if any; and

(ii) in case it is fabricated from two or

more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and 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 subparagraph shall apply only to prescription drugs; and

(B) for any prescription drug the established name of the drug or ingredient, as the case may be, on the label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; and provided, that to the extent that compliance with the requirements of Paragraph (A)(ii) or this paragraph is impracticable, exemptions shall be allowed under regulations promulgated by the secretary under the federal Act;

(2) if it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in Subdivision (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with this

subdivision is impracticable, exemptions shall be allowed under regulations promulgated by the secretary under the federal Act;

(3) as used in Subdivision (1), the term "established name," with respect to a drug or ingredient thereof, means:

(A) the applicable official name designated pursuant to Section 508 of the federal Act; or

(B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium; or

(C) if neither Paragraph (A) nor Paragraph (B) applies, then the common or usual name, if any, of such drug or of such ingredient; provided further, that where Paragraph (B) applies to an article recognized in the United States Pharmacopoeia National Formulary, the official title used in the United States Pharmacopoeia National Formulary shall apply;

(4) as used in Subdivision (2), the term "established name" with respect to a device means:

(A) the applicable official name of the device designated pursuant to Section 508 of the federal Act;

(B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium; or

(C) if neither Paragraph (A) nor Paragraph (B) applies, then any common or usual name of such device;

(e) [~~(f)~~] unless its labeling bears:

(1) adequate directions for use; and

(2) 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 durations of administration or application, in such manner and form, as are necessary for the protection of users unless the drug or device has been exempted from those requirements by the regulations adopted by the secretary;

(f) [~~(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 unless the method of packing has been modified with the consent of the secretary. Whenever a drug is recognized in the United States Pharmacopoeia National Formulary, it shall be subject to the requirements of the United States Pharmacopoeia National Formulary with respect to packaging and labeling. If there is an inconsistency between the requirements of this subsection and those of Subsection (d) [~~(e)~~] as to the name by which the drug or its ingredients shall be designated, the requirements of Subsection (d) [~~(e)~~] prevail;

(g) [~~(h)~~] if it has been found by the secretary 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 secretary shall by regulations require as necessary for the protection of public health;

(h) [~~(i)~~] if:

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

(2) it is an imitation of another drug; or

(3) it is offered for sale under the name of another

drug;

(i) [~~(j)~~] if it is dangerous to health when used in the dosage, or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

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

[~~(1) 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~~

[~~(2) such certificate or release is in effect with respect to such drug;~~

[~~(l) if it is, or purports to be, or is represented as a drug (except a drug for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless:~~

[~~(1) 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~~

[~~(2) the certificate or release is in effect with respect to the drug; provided, that this subdivision shall not apply to any drug or class of drugs exempted by regulations promulgated under Section 507(c) or (d) of the federal Act;~~]

(j) [~~(m)~~] if it is a color additive, the intended use of which 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, as may be contained

in rules issued under Section 431.161(b);

(k) [~~(n)~~] 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:

(1) the established name as defined in Subsection (d) [~~(e)~~], printed prominently and in type at least half as large as that used for any trade or brand name;

(2) the formula showing quantitatively each ingredient of the drug to the extent required for labels under Subsection (d) [~~(e)~~]; and

(3) other information in brief summary relating to side effects, contraindications, and effectiveness as required in regulations issued under Section 701(e) of the federal Act;

(l) [~~(o)~~] if it was manufactured, prepared, propagated, compounded, or processed in an establishment in this state not registered under Section 510 of the federal Act, if it was not included in a list required by Section 510(j) of the federal Act, if a notice or other information respecting it was not provided as required by that section or Section 510(k) of the federal Act, or if it does not bear symbols from the uniform system for identification of devices prescribed under Section 510(e) of the federal Act as required by regulation;

(m) [~~(p)~~] if it is a drug and its packaging or labeling is in violation of an applicable regulation issued under Section 3 or 4 of

the federal [~~Federal~~] Poison Prevention Packaging Act of 1970 (15 [~~21~~] U.S.C. 1472 or 1473);

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

(o) [~~(r)~~] in the case of any restricted device distributed or offered for sale in this state, if:

(1) its advertising is false or misleading in any particular; or

(2) it is sold, distributed, or used in violation of regulations prescribed under Section 520(e) of the federal Act;

(p) [~~(s)~~] in the case of any restricted device 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 by the manufacturer, packer, or distributor with respect to that device:

(1) a true statement of the device's established name as defined in Section 502(e) of the federal Act, printed prominently and in type at least half as large as that used for any trade or brand name thereof; and

(2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and in the case of specific devices made subject to regulations issued under the federal Act, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations under the federal Act;

(q) [~~(t)~~] if it is a device subject to a performance standard established under Section 514 of the federal Act, unless it bears such labeling as may be prescribed in such performance standard; or

(r) [~~(u)~~] if it is a device and there was a failure or refusal:

(1) to comply with any requirement prescribed under Section 518 of the federal Act respecting the device; or

(2) to furnish material required by or under Section 519 of the federal Act respecting the device.

SECTION __. Section 431.113(c)(2), Health and Safety Code, is amended to read as follows:

(2) 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 Section 431.112, except Sections 431.112(a)(1), (h)(2), and (h)(3), [~~(i)(2), (i)(3), (k), and (l),~~] and the packaging requirements of Sections 431.112(f), (g), and (m) [~~431.112(g), (h), and (p)~~], 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 drugs dispensed in the course of the conduct of business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of Subdivision (1).

SECTION __. To the extent of any conflict between Sections 431.002(8), 431.112, and 431.113(c)(2), Health and Safety Code, and those provisions as amended by Sections 1, 4, and 5 of S.B. No. 1400, Acts of the 78th Legislature, Regular Session, 2003, this Act prevails.

Keel

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President of the Senate Speaker of the House

I certify that H.C.R. No. 273 was adopted by the House on May 29, 2003, by a non-record vote.

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Chief Clerk of the House

I certify that H.C.R. No. 273 was adopted by the Senate on May 29, 2003, by a viva-voce vote.

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Secretary of the Senate

APPROVED: _____

Date

_____

Governor