

By: Keel

H.C.R. No. 273

CONCURRENT RESOLUTION

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

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

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

11 SECTION \_\_. Section 431.002(8), Health and Safety Code, is  
12 amended to read as follows:

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

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

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

5 (C) a drug subject to the provisions of Section  
6 431.113(c)(1) [~~or 431.112(k),~~] or Section 503(b)(1) [~~or 506~~] of the  
7 federal Act;

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

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

14 SECTION \_\_. Section 431.112, Health and Safety Code, is  
15 amended to read as follows:

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

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

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

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

1 accordance with regulations prescribed by the secretary under the  
2 federal Act;

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

10 (d) ~~[if it is for use by man and contains any quantity of the~~  
11 ~~narcotic or hypnotic substance alpha-eucaine, barbituric acid,~~  
12 ~~betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine,~~  
13 ~~codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote,~~  
14 ~~or sulphonmethane, or any chemical derivative of such substance,~~  
15 ~~which derivative, after investigation, has been found to be~~  
16 ~~designated as habit forming, by regulations issued by the secretary~~  
17 ~~under Section 502(d) of the federal Act, unless its label bears the~~  
18 ~~name and quantity or proportion of such substance or derivative and~~  
19 ~~in juxtaposition therewith the statement, "Warning: May be habit~~  
20 ~~forming",~~

21 [(e)] (1) if it is a drug, unless:

22 (A) its label bears, to the exclusion of any  
23 other nonproprietary name (except the applicable systematic  
24 chemical name or the chemical formula):

25 (i) the established name (as defined in  
26 Subdivision (3)) of the drug, if any; and

27 (ii) in case it is fabricated from two or

1 more ingredients, the established name and quantity of each active  
2 ingredient, including the quantity, kind, and proportion of any  
3 alcohol, and also including, whether active or not, the established  
4 name and quantity or proportion of any bromides, ether, chloroform,  
5 acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine,  
6 hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides,  
7 mercury, ouabain, strophanthin, strychnine, thyroid, or any  
8 derivative or preparation of any such substances, contained  
9 therein; provided, that the requirement for stating the quantity of  
10 the active ingredients, other than the quantity of those  
11 specifically named in this subparagraph shall apply only to  
12 prescription drugs; and

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

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

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

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

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

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

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

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

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

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

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

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

26 (1) adequate directions for use; and

27 (2) such adequate warnings against use in those

1 pathological conditions or by children where its use may be  
2 dangerous to health, or against unsafe dosage or methods or  
3 durations of administration or application, in such manner and  
4 form, as are necessary for the protection of users unless the drug  
5 or device has been exempted from those requirements by the  
6 regulations adopted by the secretary;

7 (f) [~~(g)~~] if it purports to be a drug the name of which is  
8 recognized in an official compendium, unless it is packaged and  
9 labeled as prescribed therein unless the method of packing has been  
10 modified with the consent of the secretary. Whenever a drug is  
11 recognized in the United States Pharmacopoeia National Formulary,  
12 it shall be subject to the requirements of the United States  
13 Pharmacopoeia National Formulary with respect to packaging and  
14 labeling. If there is an inconsistency between the requirements of  
15 this subsection and those of Subsection (d) [~~(e)~~] as to the name by  
16 which the drug or its ingredients shall be designated, the  
17 requirements of Subsection (d) [~~(e)~~] prevail;

18 (g) [~~(h)~~] if it has been found by the secretary to be a drug  
19 liable to deterioration, unless it is packaged in such form and  
20 manner, and its label bears a statement of such precautions, as the  
21 secretary shall by regulations require as necessary for the  
22 protection of public health;

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

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

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

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

1 drug;

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

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

7 [~~(1) it is from a batch with respect to which a  
8 certificate or release has been issued pursuant to Section 506 of  
9 the federal Act; and~~

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

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

17 [~~(1) it is from a batch with respect to which a  
18 certificate or release has been issued pursuant to Section 507 of  
19 the federal Act; and~~

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

24 (j) [~~(m)~~] if it is a color additive, the intended use of  
25 which is for the purpose of coloring only, unless its packaging and  
26 labeling are in conformity with such packaging and labeling  
27 requirements applicable to such color additive, as may be contained

1 in rules issued under Section 431.161(b);

2 (k) [~~(n)~~] in the case of any prescription drug distributed  
3 or offered for sale in this state, unless the manufacturer, packer,  
4 or distributor thereof includes in all advertisements and other  
5 descriptive printed matter issued or caused to be issued by the  
6 manufacturer, packer, or distributor with respect to that drug a  
7 true statement of:

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

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

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

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

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



1 the federal [~~Federal~~] Poison Prevention Packaging Act of 1970 (15  
2 [~~21~~] U.S.C. 1472 or 1473);

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

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

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

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

12 (p) [~~(s)~~] in the case of any restricted device distributed  
13 or offered for sale in this state, unless the manufacturer, packer,  
14 or distributor thereof includes in all advertisements and other  
15 descriptive printed matter issued by the manufacturer, packer, or  
16 distributor with respect to that device:

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

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

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

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

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

9                   (2) to furnish material required by or under Section  
10 519 of the federal Act respecting the device.

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

13                   (2) Any drug dispensed by filling or refilling a  
14 written or oral prescription of a practitioner licensed by law to  
15 administer such drug shall be exempt from the requirements of  
16 Section 431.112, except Sections 431.112(a)(1), (h)(2), and  
17 (h)(3), [~~(i)(2), (i)(3), (k), and (l),~~] and the packaging  
18 requirements of Sections 431.112(f), (g), and (m) [~~431.112(g), (h),~~  
19 ~~and (p)~~], if the drug bears a label containing the name and address  
20 of the dispenser, the serial number and date of the prescription or  
21 of its filling, the name of the prescriber, and, if stated in the  
22 prescription, the name of the patient, and the directions for use  
23 and cautionary statements, if any, contained in such prescription.  
24 This exemption shall not apply to any drugs dispensed in the course  
25 of the conduct of business of dispensing drugs pursuant to  
26 diagnosis by mail, or to a drug dispensed in violation of  
27 Subdivision (1).

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

