

By: Van de Putte

S.B. No. 1826

A BILL TO BE ENTITLED

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AN ACT

relating to certain violations under the Texas Food, Drug, and  
Cosmetic Act; providing penalties.

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

SECTION 1. Subdivision (23), Section 431.002, Health and  
Safety Code, is amended to read as follows:

(23) "Manufacture" means:

(A) the process of combining or purifying food or  
packaging food for sale to a person at wholesale or retail, and  
includes repackaging, ~~or~~ labeling, or relabeling of any food;

(B) the process of preparing, propagating,  
compounding, processing, packaging, repackaging, labeling,  
testing, or quality control of a drug or drug product, but does not  
include compounding that is done within the practice of pharmacy  
and pursuant to a prescription from a practitioner for a patient;

(C) the process of preparing, fabricating,  
assembling, processing, packing, repacking, labeling, or  
relabeling a device; or

(D) the making of any cosmetic product by  
chemical, physical, biological, or other procedures, including  
manipulation, sampling, testing, or control procedures applied to  
the product.

SECTION 2. Section 431.021, Health and Safety Code, is  
amended to read as follows:

1           Sec. 431.021. PROHIBITED ACTS. The following acts and the  
2 causing of the following acts within this state are unlawful and  
3 prohibited:

4           (a) the introduction or delivery for introduction into  
5 commerce of any food, drug, device, or cosmetic that is adulterated  
6 or misbranded;

7           (b) the adulteration or misbranding of any food, drug,  
8 device, or cosmetic in commerce;

9           (c) the receipt in commerce of any food, drug, device, or  
10 cosmetic that is adulterated or misbranded, and the delivery or  
11 proffered delivery thereof for pay or otherwise;

12           (d) the distribution in commerce of a consumer commodity, if  
13 such commodity is contained in a package, or if there is affixed to  
14 that commodity a label that does not conform to the provisions of  
15 this chapter and of rules adopted under the authority of this  
16 chapter; provided, however, that this prohibition shall not apply  
17 to persons engaged in business as wholesale or retail distributors  
18 of consumer commodities except to the extent that such persons:

19                 (1) are engaged in the packaging or labeling of such  
20 commodities; or

21                 (2) prescribe or specify by any means the manner in  
22 which such commodities are packaged or labeled;

23           (e) the introduction or delivery for introduction into  
24 commerce of any article in violation of Section 431.084, 431.114,  
25 or 431.115;

26           (f) the dissemination of any false advertisement;

27           (g) the refusal to permit entry or inspection, or to permit

1 the taking of a sample or to permit access to or copying of any  
2 record as authorized by Sections 431.042-431.044; or the failure to  
3 establish or maintain any record or make any report required under  
4 Section 512(j), (l), or (m) of the federal Act, or the refusal to  
5 permit access to or verification or copying of any such required  
6 record;

7 (h) the manufacture within this state of any food, drug,  
8 device, or cosmetic that is adulterated or misbranded;

9 (i) the giving of a guaranty or undertaking referred to in  
10 Section 431.059, which guaranty or undertaking is false, except by  
11 a person who relied on a guaranty or undertaking to the same effect  
12 signed by, and containing the name and address of the person  
13 residing in this state from whom the person received in good faith  
14 the food, drug, device, or cosmetic; or the giving of a guaranty or  
15 undertaking referred to in Section 431.059, which guaranty or  
16 undertaking is false;

17 (j) the use, removal, or disposal of a detained or embargoed  
18 article in violation of Section 431.048;

19 (k) the alteration, mutilation, destruction, obliteration,  
20 or removal of the whole or any part of the labeling of, or the doing  
21 of any other act with respect to a food, drug, device, or cosmetic,  
22 if such act is done while such article is held for sale after  
23 shipment in commerce and results in such article being adulterated  
24 or misbranded;

25 (l)(1) forging, counterfeiting, simulating, or falsely  
26 representing, or without proper authority using any mark, stamp,  
27 tag, label, or other identification device authorized or required

1 by rules adopted under this chapter or the regulations promulgated  
2 under the provisions of the federal Act;

3 (2) making, selling, disposing of, or keeping in  
4 possession, control, or custody, or concealing any punch, die,  
5 plate, stone, or other thing designed to print, imprint, or  
6 reproduce the trademark, trade name, or other identifying mark,  
7 imprint, or device of another or any likeness of any of the  
8 foregoing on any drug or container or labeling thereof so as to  
9 render such drug a counterfeit drug;

10 (3) the doing of any act that causes a drug to be a  
11 counterfeit drug, or the sale or dispensing, or the holding for sale  
12 or dispensing, of a counterfeit drug;

13 (m) the using by any person to the person's own advantage,  
14 or revealing, other than to the commissioner, an authorized agent,  
15 a health authority or to the courts when relevant in any judicial  
16 proceeding under this chapter, of any information acquired under  
17 the authority of this chapter concerning any method or process that  
18 as a trade secret is entitled to protection;

19 (n) the using, on the labeling of any drug or device or in  
20 any advertising relating to such drug or device, of any  
21 representation or suggestion that approval of an application with  
22 respect to such drug or device is in effect under Section 431.114 or  
23 Section 505, 515, or 520(g) of the federal Act, as the case may be,  
24 or that such drug or device complies with the provisions of such  
25 sections;

26 (o) the using, in labeling, advertising or other sales  
27 promotion of any reference to any report or analysis furnished in

1 compliance with Sections 431.042-431.044 or Section 704 of the  
2 federal Act;

3 (p) in the case of a prescription drug distributed or  
4 offered for sale in this state, the failure of the manufacturer,  
5 packer, or distributor of the drug to maintain for transmittal, or  
6 to transmit, to any practitioner licensed by applicable law to  
7 administer such drug who makes written request for information as  
8 to such drug, true and correct copies of all printed matter that is  
9 required to be included in any package in which that drug is  
10 distributed or sold, or such other printed matter as is approved  
11 under the federal Act. Nothing in this subsection shall be  
12 construed to exempt any person from any labeling requirement  
13 imposed by or under other provisions of this chapter;

14 (q)(1) placing or causing to be placed on any drug or device  
15 or container of any drug or device, with intent to defraud, the  
16 trade name or other identifying mark, or imprint of another or any  
17 likeness of any of the foregoing;

18 (2) selling, dispensing, disposing of or causing to be  
19 sold, dispensed, or disposed of, or concealing or keeping in  
20 possession, control, or custody, with intent to sell, dispense, or  
21 dispose of, any drug, device, or any container of any drug or  
22 device, with knowledge that the trade name or other identifying  
23 mark or imprint of another or any likeness of any of the foregoing  
24 has been placed thereon in a manner prohibited by Subdivision (1) of  
25 this subsection; or

26 (3) making, selling, disposing of, causing to be made,  
27 sold, or disposed of, keeping in possession, control, or custody,

1 or concealing with intent to defraud any punch, die, plate, stone,  
2 or other thing designed to print, imprint, or reproduce the  
3 trademark, trade name, or other identifying mark, imprint, or  
4 device of another or any likeness of any of the foregoing on any  
5 drug or container or labeling of any drug or container so as to  
6 render such drug a counterfeit drug;

7 (r) dispensing or causing to be dispensed a different drug  
8 in place of the drug ordered or prescribed without the express  
9 permission in each case of the person ordering or prescribing;

10 (s) the failure to register in accordance with Section 510  
11 of the federal Act, the failure to provide any information required  
12 by Section 510(j) or (k) of the federal Act, or the failure to  
13 provide a notice required by Section 510(j)(2) of the federal Act;

14 (t)(1) the failure or refusal to:

15 (A) comply with any requirement prescribed under  
16 Section 518 or 520(g) of the federal Act; or

17 (B) furnish any notification or other material or  
18 information required by or under Section 519 or 520(g) of the  
19 federal Act;

20 (2) with respect to any device, the submission of any  
21 report that is required by or under this chapter that is false or  
22 misleading in any material respect;

23 (u) the movement of a device in violation of an order under  
24 Section 304(g) of the federal Act or the removal or alteration of  
25 any mark or label required by the order to identify the device as  
26 detained;

27 (v) the failure to provide the notice required by Section

1 412(b) or 412(c), the failure to make the reports required by  
2 Section 412(d)(1)(B), or the failure to meet the requirements  
3 prescribed under Section 412(d)(2) of the federal Act;

4 (w) except as provided under Subchapter M, the acceptance by  
5 a person of an unused prescription or drug, in whole or in part, for  
6 the purpose of resale, after the prescription or drug has been  
7 originally dispensed, or sold;

8 (x) engaging in the wholesale distribution of drugs or  
9 operating as a distributor or manufacturer of devices in this state  
10 without filing a licensing statement with the commissioner as  
11 required by Section 431.202 or having a license as required by  
12 Section 431.272, as applicable;

13 (y) engaging in the manufacture of food in this state or  
14 operating as a food wholesaler in this state without having a  
15 license as required by Section 431.222; ~~or~~

16 (z) unless approved by the United States Food and Drug  
17 Administration pursuant to the federal Act, the sale, delivery,  
18 holding, or offering for sale of a self-testing kit designed to  
19 indicate whether a person has a human immunodeficiency virus  
20 infection, acquired immune deficiency syndrome, or a related  
21 disorder or condition; or

22 (aa) making a false statement or false representation in an  
23 application for a license or in a statement, report, or other  
24 instrument to be filed with the board, the commissioner, or the  
25 department under this chapter.

26 SECTION 3. Subsection (a), Section 431.059, Health and  
27 Safety Code, is amended to read as follows:

1           (a) A person commits an offense if the person violates any  
2 of the provisions of Section 431.021 relating to unlawful or  
3 prohibited acts. A first [An] offense under this subsection is a  
4 Class A misdemeanor unless it is shown on the trial of an offense  
5 under this subsection that the defendant was previously convicted  
6 of an offense under this subsection, in which event the offense is a  
7 state jail felony. In a criminal proceeding under this section, it  
8 is not necessary to prove intent, knowledge, recklessness, or  
9 criminal negligence of the defendant beyond the degree of  
10 culpability, if any, stated in Section 431.021 to establish  
11 criminal responsibility for the violation.

12           SECTION 4. This Act takes effect September 1, 2003.

13           SECTION 5. (a) The change in law made by this Act to  
14 Sections 431.002, 431.021, and 431.059, Health and Safety Code,  
15 applies only to an offense committed on or after the effective date  
16 of this Act. For purposes of this section, an offense is committed  
17 before the effective date of this Act if any element of the offense  
18 occurs before that date.

19           (b) An offense committed before the effective date of this  
20 Act is covered by the law in effect when the offense was committed,  
21 and the former law is continued in effect for that purpose.