

1-1 By: Van de Putte S.B. No. 1826  
1-2 (In the Senate - Filed March 14, 2003; March 24, 2003, read  
1-3 first time and referred to Committee on Health and Human Services;  
1-4 April 29, 2003, reported adversely, with favorable Committee  
1-5 Substitute by the following vote: Yeas 8, Nays 0; April 29, 2003,  
1-6 sent to printer.)

1-7 COMMITTEE SUBSTITUTE FOR S.B. No. 1826 By: Zaffirini

1-8 A BILL TO BE ENTITLED  
1-9 AN ACT

1-10 relating to certain violations under the Texas Food, Drug, and  
1-11 Cosmetic Act; providing penalties.

1-12 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-13 SECTION 1. Subdivision (23), Section 431.002, Health and  
1-14 Safety Code, is amended to read as follows:

1-15 (23) "Manufacture" means:

1-16 (A) the process of combining or purifying food or  
1-17 packaging food for sale to a person at wholesale or retail, and  
1-18 includes repackaging, ~~or~~ labeling, or relabeling of any food;

1-19 (B) the process of preparing, propagating,  
1-20 compounding, processing, packaging, repackaging, labeling,  
1-21 testing, or quality control of a drug or drug product, but does not  
1-22 include compounding that is done within the practice of pharmacy  
1-23 and pursuant to a prescription from a practitioner for a patient;

1-24 (C) the process of preparing, fabricating,  
1-25 assembling, processing, packing, repacking, labeling, or  
1-26 relabeling a device; or

1-27 (D) the making of any cosmetic product by  
1-28 chemical, physical, biological, or other procedures, including  
1-29 manipulation, sampling, testing, or control procedures applied to  
1-30 the product.

1-31 SECTION 2. Section 431.021, Health and Safety Code, is  
1-32 amended to read as follows:

1-33 Sec. 431.021. PROHIBITED ACTS. The following acts and the  
1-34 causing of the following acts within this state are unlawful and  
1-35 prohibited:

1-36 (a) the introduction or delivery for introduction into  
1-37 commerce of any food, drug, device, or cosmetic that is adulterated  
1-38 or misbranded;

1-39 (b) the adulteration or misbranding of any food, drug,  
1-40 device, or cosmetic in commerce;

1-41 (c) the receipt in commerce of any food, drug, device, or  
1-42 cosmetic that is adulterated or misbranded, and the delivery or  
1-43 proffered delivery thereof for pay or otherwise;

1-44 (d) the distribution in commerce of a consumer commodity, if  
1-45 such commodity is contained in a package, or if there is affixed to  
1-46 that commodity a label that does not conform to the provisions of  
1-47 this chapter and of rules adopted under the authority of this  
1-48 chapter; provided, however, that this prohibition shall not apply  
1-49 to persons engaged in business as wholesale or retail distributors  
1-50 of consumer commodities except to the extent that such persons:

1-51 (1) are engaged in the packaging or labeling of such  
1-52 commodities; or

1-53 (2) prescribe or specify by any means the manner in  
1-54 which such commodities are packaged or labeled;

1-55 (e) the introduction or delivery for introduction into  
1-56 commerce of any article in violation of Section 431.084, 431.114,  
1-57 or 431.115;

1-58 (f) the dissemination of any false advertisement;

1-59 (g) the refusal to permit entry or inspection, or to permit  
1-60 the taking of a sample or to permit access to or copying of any  
1-61 record as authorized by Sections 431.042-431.044; or the failure to  
1-62 establish or maintain any record or make any report required under  
1-63 Section 512(j), (l), or (m) of the federal Act, or the refusal to

2-1 permit access to or verification or copying of any such required  
2-2 record;

2-3 (h) the manufacture within this state of any food, drug,  
2-4 device, or cosmetic that is adulterated or misbranded;

2-5 (i) the giving of a guaranty or undertaking referred to in  
2-6 Section 431.059, which guaranty or undertaking is false, except by  
2-7 a person who relied on a guaranty or undertaking to the same effect  
2-8 signed by, and containing the name and address of the person  
2-9 residing in this state from whom the person received in good faith  
2-10 the food, drug, device, or cosmetic; or the giving of a guaranty or  
2-11 undertaking referred to in Section 431.059, which guaranty or  
2-12 undertaking is false;

2-13 (j) the use, removal, or disposal of a detained or embargoed  
2-14 article in violation of Section 431.048;

2-15 (k) the alteration, mutilation, destruction, obliteration,  
2-16 or removal of the whole or any part of the labeling of, or the doing  
2-17 of any other act with respect to a food, drug, device, or cosmetic,  
2-18 if such act is done while such article is held for sale after  
2-19 shipment in commerce and results in such article being adulterated  
2-20 or misbranded;

2-21 (1)(1) forging, counterfeiting, simulating, or falsely  
2-22 representing, or without proper authority using any mark, stamp,  
2-23 tag, label, or other identification device authorized or required  
2-24 by rules adopted under this chapter or the regulations promulgated  
2-25 under the provisions of the federal Act;

2-26 (2) making, selling, disposing of, or keeping in  
2-27 possession, control, or custody, or concealing any punch, die,  
2-28 plate, stone, or other thing designed to print, imprint, or  
2-29 reproduce the trademark, trade name, or other identifying mark,  
2-30 imprint, or device of another or any likeness of any of the  
2-31 foregoing on any drug or container or labeling thereof so as to  
2-32 render such drug a counterfeit drug;

2-33 (3) the doing of any act that causes a drug to be a  
2-34 counterfeit drug, or the sale or dispensing, or the holding for sale  
2-35 or dispensing, of a counterfeit drug;

2-36 (m) the using by any person to the person's own advantage,  
2-37 or revealing, other than to the commissioner, an authorized agent,  
2-38 a health authority or to the courts when relevant in any judicial  
2-39 proceeding under this chapter, of any information acquired under  
2-40 the authority of this chapter concerning any method or process that  
2-41 as a trade secret is entitled to protection;

2-42 (n) the using, on the labeling of any drug or device or in  
2-43 any advertising relating to such drug or device, of any  
2-44 representation or suggestion that approval of an application with  
2-45 respect to such drug or device is in effect under Section 431.114 or  
2-46 Section 505, 515, or 520(g) of the federal Act, as the case may be,  
2-47 or that such drug or device complies with the provisions of such  
2-48 sections;

2-49 (o) the using, in labeling, advertising or other sales  
2-50 promotion of any reference to any report or analysis furnished in  
2-51 compliance with Sections 431.042-431.044 or Section 704 of the  
2-52 federal Act;

2-53 (p) in the case of a prescription drug distributed or  
2-54 offered for sale in this state, the failure of the manufacturer,  
2-55 packer, or distributor of the drug to maintain for transmittal, or  
2-56 to transmit, to any practitioner licensed by applicable law to  
2-57 administer such drug who makes written request for information as  
2-58 to such drug, true and correct copies of all printed matter that is  
2-59 required to be included in any package in which that drug is  
2-60 distributed or sold, or such other printed matter as is approved  
2-61 under the federal Act. Nothing in this subsection shall be  
2-62 construed to exempt any person from any labeling requirement  
2-63 imposed by or under other provisions of this chapter;

2-64 (q)(1) placing or causing to be placed on any drug or device  
2-65 or container of any drug or device, with intent to defraud, the  
2-66 trade name or other identifying mark, or imprint of another or any  
2-67 likeness of any of the foregoing;

2-68 (2) selling, dispensing, disposing of or causing to be  
2-69 sold, dispensed, or disposed of, or concealing or keeping in

3-1 possession, control, or custody, with intent to sell, dispense, or  
3-2 dispose of, any drug, device, or any container of any drug or  
3-3 device, with knowledge that the trade name or other identifying  
3-4 mark or imprint of another or any likeness of any of the foregoing  
3-5 has been placed thereon in a manner prohibited by Subdivision (1) of  
3-6 this subsection; or

3-7 (3) making, selling, disposing of, causing to be made,  
3-8 sold, or disposed of, keeping in possession, control, or custody,  
3-9 or concealing with intent to defraud any punch, die, plate, stone,  
3-10 or other thing designed to print, imprint, or reproduce the  
3-11 trademark, trade name, or other identifying mark, imprint, or  
3-12 device of another or any likeness of any of the foregoing on any  
3-13 drug or container or labeling of any drug or container so as to  
3-14 render such drug a counterfeit drug;

3-15 (r) dispensing or causing to be dispensed a different drug  
3-16 in place of the drug ordered or prescribed without the express  
3-17 permission in each case of the person ordering or prescribing;

3-18 (s) the failure to register in accordance with Section 510  
3-19 of the federal Act, the failure to provide any information required  
3-20 by Section 510(j) or (k) of the federal Act, or the failure to  
3-21 provide a notice required by Section 510(j)(2) of the federal Act;

3-22 (t)(1) the failure or refusal to:

3-23 (A) comply with any requirement prescribed under  
3-24 Section 518 or 520(g) of the federal Act; or

3-25 (B) furnish any notification or other material or  
3-26 information required by or under Section 519 or 520(g) of the  
3-27 federal Act;

3-28 (2) with respect to any device, the submission of any  
3-29 report that is required by or under this chapter that is false or  
3-30 misleading in any material respect;

3-31 (u) the movement of a device in violation of an order under  
3-32 Section 304(g) of the federal Act or the removal or alteration of  
3-33 any mark or label required by the order to identify the device as  
3-34 detained;

3-35 (v) the failure to provide the notice required by Section  
3-36 412(b) or 412(c), the failure to make the reports required by  
3-37 Section 412(d)(1)(B), or the failure to meet the requirements  
3-38 prescribed under Section 412(d)(2) of the federal Act;

3-39 (w) except as provided under Subchapter M, the acceptance by  
3-40 a person of an unused prescription or drug, in whole or in part, for  
3-41 the purpose of resale, after the prescription or drug has been  
3-42 originally dispensed, or sold;

3-43 (x) engaging in the wholesale distribution of drugs or  
3-44 operating as a distributor or manufacturer of devices in this state  
3-45 without filing a licensing statement with the commissioner as  
3-46 required by Section 431.202 or having a license as required by  
3-47 Section 431.272, as applicable;

3-48 (y) engaging in the manufacture of food in this state or  
3-49 operating as a food wholesaler in this state without having a  
3-50 license as required by Section 431.222; ~~or~~

3-51 (z) unless approved by the United States Food and Drug  
3-52 Administration pursuant to the federal Act, the sale, delivery,  
3-53 holding, or offering for sale of a self-testing kit designed to  
3-54 indicate whether a person has a human immunodeficiency virus  
3-55 infection, acquired immune deficiency syndrome, or a related  
3-56 disorder or condition; or

3-57 (aa) making a false statement or false representation in an  
3-58 application for a license or in a statement, report, or other  
3-59 instrument to be filed with the board, the commissioner, or the  
3-60 department under this chapter.

3-61 SECTION 3. Subsection (a), Section 431.059, Health and  
3-62 Safety Code, is amended to read as follows:

3-63 (a) A person commits an offense if the person violates any  
3-64 of the provisions of Section 431.021 relating to unlawful or  
3-65 prohibited acts. A first [An] offense under this subsection is a  
3-66 Class A misdemeanor unless it is shown on the trial of an offense  
3-67 under this subsection that the defendant was previously convicted  
3-68 of an offense under this subsection, in which event the offense is a  
3-69 state jail felony. In a criminal proceeding under this section, it

4-1 is not necessary to prove intent, knowledge, recklessness, or  
4-2 criminal negligence of the defendant beyond the degree of  
4-3 culpability, if any, stated in Section 431.021 to establish  
4-4 criminal responsibility for the violation.

4-5 SECTION 4. This Act takes effect September 1, 2003.

4-6 SECTION 5. (a) The change in law made by this Act to  
4-7 Sections 431.002, 431.021, and 431.059, Health and Safety Code,  
4-8 applies only to an offense committed on or after the effective date  
4-9 of this Act. For purposes of this section, an offense is committed  
4-10 before the effective date of this Act if any element of the offense  
4-11 occurs before that date.

4-12 (b) An offense committed before the effective date of this  
4-13 Act is covered by the law in effect when the offense was committed,  
4-14 and the former law is continued in effect for that purpose.

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