

By: Janek

S.B. No. 1392

A BILL TO BE ENTITLED

AN ACT

1
2 relating to medical device licensing under the Texas Food, Drug,
3 and Cosmetic Salvage Act.

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

5 SECTION 1. Section 431.008, Health and Safety Code, is
6 amended by amending Subsections (a) and (c) to read as follows:

7 (a) This chapter applies to a food, drug, [~~device,~~] or
8 cosmetic that is distressed merchandise for purposes of Chapter 432
9 or that has been subject to reconditioning in accordance with
10 Chapter 432.

11 (c) A person who holds a license under Chapter 432 and is
12 engaging in conduct within the scope of that license is not required
13 to hold a license as a wholesale drug distributor under Subchapter
14 I, a food wholesaler under Subchapter J[~~, or a device distributor~~
15 ~~under Subchapter I~~].

16 SECTION 2. Section 431.023, Health and Safety Code, is
17 amended to read as follows:

18 Sec. 431.023. Limited Exemption for Distressed Food, Drugs,
19 [~~Devices,~~] or Cosmetics. In relation to a food, drug, [~~device,~~] or
20 cosmetic that is distressed merchandise for purposes of Chapter
21 432, Sections 431.021(a), (c), and (d) do not prohibit:

22 (1) the introduction or delivery for introduction into
23 commerce of the merchandise for the purpose of reconditioning in
24 accordance with Chapter 432 and not for sale to the ultimate

1 consumer;

2 (2) the receipt in commerce of the merchandise for the
3 purpose of reconditioning in accordance with Chapter 432 and not
4 for sale to the ultimate consumer;

5 (3) the holding of merchandise for the purpose of
6 reconditioning in accordance with Chapter 432 and not for resale to
7 the ultimate consumer; or

8 (4) the reconditioning of the merchandise in
9 accordance with Chapter 432.

10 SECTION 3. Chapter 432, Health and Safety Code, is amended
11 to read as follows:

12 CHAPTER 432. FOOD, DRUG, [~~DEVICE~~] AND COSMETIC SALVAGE ACT

13 SECTION 4. Section 432.001, Chapter 432, Health and Safety
14 Code, is amended to read as follows:

15 Sec. 432.001. Short Title. This chapter may be cited as the
16 Texas Food, Drug, [~~Device~~] and Cosmetic Salvage Act.

17 SECTION 5. Section 432.002, Chapter 432, Health and Safety
18 Code, is amended to read as follows:

19 Sec. 432.002. Purpose. The purpose of this chapter is to
20 protect the health of the people of this state by preventing the
21 sale or distribution of adulterated or misbranded food, drugs,
22 [~~devices~~] or cosmetics.

23 SECTION 6. Section 432.003, Chapter 432, Health and Safety
24 Code, is amended by amending Subsection 6 to read as follows:

25 (6) "Distressed merchandise" means any food, drug,
26 [~~device~~] or cosmetic that is adulterated or misbranded for
27 purposes of Section 431.081 (Adulterated Food), 431.082

1 (Misbranded Food), 431.111 (Adulterated Drug [~~or Device~~]), 431.112
2 (Misbranded Drug [~~or Device~~]), 431.141 (Adulterated Cosmetic), or
3 431.142 (Misbranded Cosmetic), as interpreted by board rule and
4 judicial decision. The term includes a food, drug, [~~device,~~] or
5 cosmetic that:

6 (A) has lost its label or is otherwise
7 unidentified;

8 (B) has been subjected to prolonged or improper
9 storage;

10 (C) has been subjected for any reason to abnormal
11 environmental conditions, including temperature extremes,
12 humidity, smoke, water, fumes, pressure, or radiation;

13 (D) has been subjected to conditions that result
14 in either its strength, purity, or quality falling below that which
15 it purports or is represented to possess; or

16 (E) may have been rendered unsafe or unsuitable
17 for human consumption or use for any reason other than those
18 specified by this subdivision.

19 SECTION 7. Section 432.003, Chapter 432, Health and Safety
20 Code, is amended by adding Subsection 19 to read as follows:

21 (19) "Refurbishing a device" means painting, cleaning,
22 routine maintenance or repair, or similar activity that does not
23 change original manufacturer safety or performance specifications,
24 or original intended use of a medical device.

25 SECTION 8. Section 432.004, Chapter 432, Health and Safety
26 Code, is amended by amending Subsection (a) as follows:

27 Sec. 432.004. Exemptions. (a) This chapter does not apply

1 to:

2 (1) a manufacturer, distributor, or processor of a
3 food, drug, [~~device,~~] or cosmetic who, in the normal course of
4 business, reconditions the items manufactured, distributed, or
5 processed by or for that person and not purchased by that person
6 solely for the purpose of reconditioning and sale;

7 (2) a common carrier, or the common carrier's agent,
8 who disposes of or otherwise transfers undamaged or distressed
9 food, drugs, [~~devices,~~] or cosmetics to a person who is exempt under
10 this section or to a licensed salvage broker or salvage operator;

11 (3) a person who transfers distressed merchandise to a
12 licensed salvage broker or salvage operator; or

13 (4) a nonprofit organization that distributes food to
14 the needy under Chapter 76, Civil Practice and Remedies Code (Good
15 Faith Donor Act), but that does not recondition the food.

16 (5) a person or organization who engages in
17 refurbishing medical devices for purposes of selling.

18 SECTION 9. Section 432.010, Chapter 432, Health and Safety
19 Code, is amended to read as follows:

20 Sec. 432.010. Fund. A fee collected by the department under
21 this chapter shall be deposited in the state treasury to the credit
22 of the food, drug, [~~device,~~] and cosmetic salvage fund. The fund
23 may be used only to implement this chapter.

24 SECTION 10. Section 432.011, Chapter 432, Health and Safety
25 Code, is amended by amending Subsection (b) as follows:

26 (b) The rules shall prescribe standards for food, drugs,
27 [~~devices,~~] and cosmetics in separate subchapters.

1 SECTION 11. Section 432.020, Chapter 432, Health and Safety
2 Code, is amended to read as follows:

3 Sec. 432.020. Emergency Order. (a) The commissioner or
4 the commissioner's designee may issue an emergency order, either
5 mandatory or prohibitory, concerning the sale or distribution of
6 distressed foods, drugs, [~~devices,~~] or cosmetics in the
7 department's jurisdiction if the commissioner or the commissioner's
8 designee determines that:

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