

By: Burnam

H.B. No. 3389

A BILL TO BE ENTITLED

AN ACT

relating to regulation of distressed devices.

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

ARTICLE 1. REGULATION OF DISTRESSED DEVICES

SECTION 1.01. Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 442 to read as follows:

CHAPTER 442. REGULATION OF DISTRESSED DEVICES

Sec. 442.001. DEFINITIONS. In this chapter:

(1) "Department" means the Texas Department of Health.

(2) "Device" means an instrument, apparatus, or contrivance, or a component, part, or accessory of an instrument, apparatus, or contrivance, that is designed or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, or that is designed or intended to affect the structure or any function of the body of a human or other animal.

Sec. 442.002. DISTRESSED DEVICE; APPLICATION. A device is distressed for purposes of this chapter if the device has been subjected to fire, flood, excessive heat or cold, or other conditions that affect or may have affected the device's fitness for use.

Sec. 442.003. NOTICE BEFORE SALE OR DISTRIBUTION; INSPECTION. (a) A person who knowingly holds a distressed device shall notify the department before the sale or distribution of the

1 device. This subsection applies without regard to whether the
2 person is the owner of the distressed device.

3 (b) On receipt of a notice under Subsection (a), the
4 department may require that the device be inspected before the
5 device is sold or distributed.

6 Sec. 442.004. PROHIBITION. A person may not sell or
7 distribute a distressed device if the device has been declared
8 unfit for use by the department.

9 ARTICLE 2. CONFORMING AMENDMENTS

10 SECTION 2.01. Section 431.008(a), Health and Safety Code,
11 is amended to read as follows:

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

16 SECTION 2.02. The chapter heading to Chapter 432, Health
17 and Safety Code, is amended to read as follows:

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

19 SECTION 2.03. Sections 432.001 and 432.002, Health and
20 Safety Code, are amended to read as follows:

21 Sec. 432.001. SHORT TITLE. This chapter may be cited as the
22 Texas Food, Drug, [~~Device,~~] and Cosmetic Salvage Act.

23 Sec. 432.002. PURPOSE. The purpose of this chapter is to
24 protect the health of the people of this state by preventing the
25 sale or distribution of adulterated or misbranded food, drugs,
26 [~~devices,~~] or cosmetics.

27 SECTION 2.04. Sections 432.003(6), (9), and (10), Health

1 and Safety Code, are amended to read as follows:

2 (6) "Distressed merchandise" means any food, drug,
3 [~~device,~~] or cosmetic that is adulterated or misbranded for
4 purposes of Section 431.081 (Adulterated Food), 431.082
5 (Misbranded Food), 431.111 (Adulterated Drug or Device), 431.112
6 (Misbranded Drug or Device), 431.141 (Adulterated Cosmetic), or
7 431.142 (Misbranded Cosmetic), as interpreted by board rule and
8 judicial decision. The term includes a food, drug, [~~device,~~] or
9 cosmetic that:

10 (A) has lost its label or is otherwise
11 unidentified;

12 (B) has been subjected to prolonged or improper
13 storage;

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

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

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

23 (9) "Manufacture" means the combining, purifying,
24 processing, packing, or repacking of food, drugs, [~~devices,~~] or
25 cosmetics for wholesale or retail sale.

26 (10) "Manufacturer" includes a person who represents
27 himself as responsible for the purity and proper labeling of a food,

1 drug, [~~device,~~] or cosmetic.

2 SECTION 2.05. Section 432.004, Health and Safety Code, is
3 amended by adding Subsection (c) to read as follows:

4 (c) This chapter does not apply to the manufacture, sale or
5 distribution, or processing of a distressed device.

6 SECTION 2.06. Section 432.010, Health and Safety Code, is
7 amended to read as follows:

8 Sec. 432.010. FUND. A fee collected by the department under
9 this chapter shall be deposited in the state treasury to the credit
10 of the food, drug, [~~device,~~] and cosmetic salvage fund. The fund may
11 be used only to implement this chapter.

12 SECTION 2.07. Section 432.011(b), Health and Safety Code,
13 is amended to read as follows:

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

16 SECTION 2.08. Section 432.020(a), Health and Safety Code,
17 is amended to read as follows:

18 (a) The commissioner or the commissioner's designee may
19 issue an emergency order, either mandatory or prohibitory,
20 concerning the sale or distribution of distressed foods, drugs,
21 [~~devices,~~] or cosmetics in the department's jurisdiction if the
22 commissioner or the commissioner's designee determines that:

23 (1) the sale or distribution of those foods, drugs,
24 [~~devices,~~] or cosmetics creates or poses an immediate and serious
25 threat to human life or health; and

26 (2) other procedures available to the department to
27 remedy or prevent the occurrence of the situation will result in

1 unreasonable delay.

2 ARTICLE 3. EFFECTIVE DATE

3 SECTION 3.01. This Act takes effect immediately if it
4 receives a vote of two-thirds of all the members elected to each
5 house, as provided by Section 39, Article III, Texas Constitution.
6 If this Act does not receive the vote necessary for immediate
7 effect, this Act takes effect September 1, 2003.