

By: Coleman

H.B. No. 3651

A BILL TO BE ENTITLED

AN ACT

relating to the manufacture, sale, distribution, possession, and use of drugs not approved by the United States Food and Drug Administration and the false representation that a substance is a drug approved by the United States Food and Drug Administration; creating criminal offenses.

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

SECTION 1. Chapter 431, Health and Safety Code, is amended by adding Subchapter E-1 to read as follows:

SUBCHAPTER E-1. DRUGS NOT APPROVED BY THE UNITED STATES FOOD AND

DRUG ADMINISTRATION

Sec. 431.121. DEFINITION. In this subchapter, "unapproved drug" means a drug that is:

(1) unsafe for self-medication;

(2) not approved by the United States Food and Drug Administration; and

(3) not listed in Schedules I through V or Penalty Groups 1 through 4 of Chapter 481.

Sec. 431.122. APPLICABILITY. (a) This subchapter does not apply to any drug, regardless of whether approved by the United States Food and Drug Administration, that is manufactured, packaged, distributed, or possessed for use in pharmaceutical compounding by a licensed pharmacist, physician, or registered outsourcing facility in compliance with federal law.

1 (b) This subchapter does not apply to a foreign drug not
2 approved by the United States Food and Drug Administration that is
3 imported in compliance with:

4 (1) federal or state law; or

5 (2) an announcement by the United States Food and Drug
6 Administration authorizing the import of the drug, including for
7 clinical research, drug shortages, and pandemic preparedness and
8 response.

9 (c) This subchapter does not apply to the dispensation or
10 sale of a drug according to a prescription issued by a practitioner.

11 Sec. 431.123. OFFENSE: MANUFACTURE, SALE, OR DISTRIBUTION
12 OF UNAPPROVED DRUG. (a) A person commits an offense if the person
13 manufactures, sells, or distributes an unapproved drug.

14 (b) An offense under this section is a state jail felony.

15 Sec. 431.124. OFFENSE: MISREPRESENTATION OF SUBSTANCE OR
16 DRUG. (a) A person commits an offense if the person falsely
17 represents to an individual to whom the actor or another person is
18 selling or distributing a substance that the substance is:

19 (1) a drug approved for human use by the United States
20 Food and Drug Administration; or

21 (2) intended for use in the cure, mitigation,
22 treatment, or prevention of disease in humans.

23 (b) A person commits an offense if the person falsely
24 represents to an individual to whom the actor or another person is
25 selling or distributing a drug that is approved for human use by the
26 United States Food and Drug Administration that the drug is:

27 (1) a different drug approved for human use by the

1 United States Food and Drug Administration; or

2 (2) intended for use in the cure, mitigation,
3 treatment, or prevention of a disease in humans when the drug is not
4 approved or used in clinical practice for that purpose.

5 (c) An offense under Subsection (a) is a state jail felony,
6 except that if the substance is an unapproved drug, the offense is a
7 felony of the third degree.

8 (d) An offense under Subsection (b) is a state jail felony,
9 except that if the drug may be dispensed only by prescription or is
10 not approved for use in humans, the offense is a felony of the third
11 degree.

12 Sec. 431.125. OFFENSE: POSSESSION OR USE OF UNAPPROVED
13 DRUG. (a) A person commits an offense if the person possesses or
14 uses an unapproved drug.

15 (b) An offense under this section is a Class A misdemeanor.

16 (c) It is a defense to prosecution under this section that:

17 (1) the actor obtained the unapproved drug from a
18 practitioner, pharmacist, or other person authorized to dispense
19 prescription drugs; and

20 (2) the person dispensing the unapproved drug made the
21 representation to the person that the drug was approved by the
22 United States Food and Drug Administration for prescription use.

23 Sec. 431.126. EFFECT ON OTHER LAWS. A person who is subject
24 to prosecution under this subchapter or other law may be prosecuted
25 under either or both laws.

26 SECTION 2. This Act takes effect September 1, 2015.