

By: Coleman, Walle

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 or intended for the prevention or treatment of diseases in humans; 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. OFFENSE: MANUFACTURE, SALE, OR DISTRIBUTION OF UNAPPROVED DRUG. (a) A person commits an offense if the person manufactures, sells, distributes, or possesses with the intent to deliver an unapproved drug.

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

1 (c) This section does not apply to:

2 (1) any drug, regardless of whether approved by the
3 United States Food and Drug Administration, that is manufactured,
4 packaged, distributed, or possessed for use in pharmaceutical
5 compounding by a licensed pharmacist, physician, or registered
6 outsourcing facility in compliance with federal law; or

7 (2) a foreign drug not approved by the United States
8 Food and Drug Administration that is imported in compliance with:

9 (A) federal or state law; or

10 (B) an announcement by the United States Food and
11 Drug Administration authorizing the import of the drug, including
12 for clinical research, drug shortages, and pandemic preparedness
13 and response.

14 Sec. 431.123. OFFENSE: MISREPRESENTATION OF SUBSTANCE OR
15 DRUG. (a) A person commits an offense if the person falsely
16 represents to an individual to whom the actor or another person is
17 selling or distributing a substance that the substance is:

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

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

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

26 (1) a different drug approved for human use by the
27 United States Food and Drug Administration; or

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

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

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

11 Sec. 431.124. OFFENSE: POSSESSION OR USE OF UNAPPROVED
12 DRUG. (a) A person commits an offense if the person possesses for
13 use or uses an unapproved drug.

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

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

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

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

22 Sec. 431.125. EFFECT ON OTHER LAWS. A person who is subject
23 to prosecution under this subchapter or other law may be prosecuted
24 under either or both laws.

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