

## **BILL ANALYSIS**

C.S.H.B. 3651  
By: Coleman  
Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

Currently, it is difficult to prosecute a person who manufactures, sells, distributes, or misrepresents a drug that is not approved by the U.S. Food and Drug Administration (FDA) because the relevant laws are limited in scope. These unapproved drugs can be dangerous to the public because the manufacturing and supply chain is outside of the FDA's regulatory control. The purpose of C.S.H.B. 3651 is to put pressure on both the supply side and the demand side to combat the dangers of unapproved drugs.

### **CRIMINAL JUSTICE IMPACT**

It is the committee's opinion that this bill expressly does one or more of the following: creates a criminal offense, increases the punishment for an existing criminal offense or category of offenses, or changes the eligibility of a person for community supervision, parole, or mandatory supervision.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

### **ANALYSIS**

C.S.H.B. 3651 amends the Health and Safety Code to make it a state jail felony to manufacture, sell, distribute, or possess with the intent to deliver an unapproved drug, defined by the bill as a drug that is unsafe for self-medication, not approved by the U.S. Food and Drug Administration (FDA), and not listed in Schedules I through V or Penalty Groups 1 through 4 of the Texas Controlled Substances Act. The bill excludes from this offense any drug, regardless of whether the drug is FDA-approved, 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 or a foreign drug that is not FDA-approved and is imported in compliance with federal or state law or an announcement by the FDA authorizing the import of the drug.

C.S.H.B. 3651 makes it a state jail felony to falsely represent to an individual to whom the actor or another person is selling or distributing a substance that the substance is a drug approved for human use by the FDA or intended for use in the cure, mitigation, treatment, or prevention of disease in humans and enhances the penalty for the offense to a third degree felony if the substance is an unapproved drug. The bill makes it a state jail felony to falsely represent to an individual to whom the actor or another person is selling or distributing a drug that is approved for human use by the FDA that the drug is a different drug approved for human use by the FDA or intended for use in the cure, mitigation, treatment, or prevention of a disease in humans when the drug is not approved or used in clinical practice for that purpose and enhances the penalty for the offense to a third degree felony if the drug is authorized to be dispensed only by prescription or is not approved for use in humans.

C.S.H.B. 3651 makes it a Class A misdemeanor to possess for use or use an unapproved drug and establishes a defense to prosecution for the offense if the actor obtained the unapproved drug from a practitioner, pharmacist, or other person authorized to dispense prescription drugs and the person dispensing the unapproved drug made the representation to the actor that the drug was approved by the FDA for prescription use. The bill establishes that a person who is subject to prosecution under the bill's provisions or other law may be prosecuted under either or both laws.

**EFFECTIVE DATE**

September 1, 2015.

**COMPARISON OF ORIGINAL AND SUBSTITUTE**

While C.S.H.B. 3651 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

**INTRODUCED**

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.

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.

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

(1) federal or state law; or

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

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

**HOUSE COMMITTEE SUBSTITUTE**

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.

Sec. 431.122. OFFENSE: MANUFACTURE, SALE, OR DISTRIBUTION OF UNAPPROVED DRUG.

(c) This section does not apply to:

(1) 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; or

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

(A) federal or state law; or

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

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

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

Sec. 431.124. OFFENSE: MISREPRESENTATION OF SUBSTANCE OR DRUG.

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

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

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

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

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

Sec. 431.126. EFFECT ON OTHER LAWS.

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

(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.

Sec. 431.123. OFFENSE: MISREPRESENTATION OF SUBSTANCE OR DRUG.

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

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

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

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

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

Sec. 431.125. EFFECT ON OTHER LAWS.

SECTION 2. Same as introduced version.