By: Kacal H.B. No. 21

A BILL TO BE ENTITLED

AN ACT

relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials.

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

SECTION 1. (a) This Act shall be known as the "Right To Try Act."

(b) The legislature finds that:

(1) the process for approval of investigational drugs, biological products, and devices in the United States takes many years;

(2) patients with a terminal illness do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States Food and Drug Administration;

(3) the standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatment to patients with a terminal illness;

(4) patients with a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices;

(5) the use of available investigational drugs,

biological products, and devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's physician and the patient's family and is not a decision to be made by the government; and

(6) the decision to use an investigational drug, biological product, or device should be made with full awareness of the potential risks, benefits, and consequences to the patient with a terminal illness and the patient's family.

(c) It is the intent of the legislature to allow for patients with a terminal illness to use potentially life-saving investigational drugs, biological products, and devices.

SECTION 2. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 489 to read as follows:

CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH TERMINAL ILLNESSES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 489.001. DEFINITIONS. In this chapter:

(1) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial.

(2) "Terminal illness" means an advanced stage of a disease with an unfavorable prognosis and that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL

PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES

Sec. 489.051. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational drug, biological product, or device under this chapter if:

(1) the patient has a terminal illness, attested to by the patient's treating physician; and

(2) the patient's physician:

(A) in consultation with the patient, has considered all other treatment options currently approved by the United States Food and Drug Administration and determined that those treatment options are unavailable or unlikely to prolong the patient's life; and

(B) has recommended or prescribed in writing that the patient use a specific class of investigational drug, biological product, or device.

Sec. 489.052. INFORMED CONSENT. (a) Before receiving an investigational drug, biological product, or device, an eligible patient must sign a written informed consent described by this section that is attested to by the patient's physician and a witness.

(b) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf.

(c) The executive commissioner of the Health and Human Services Commission by rule shall adopt a form for the informed consent required under this section.

Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG,

BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients in accordance with this chapter if the patient provides to the manufacturer the informed consent required under Section 489.052.

(b) This chapter does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(c) A manufacturer may:

(1) provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(2) require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

Sec. 489.054. NO CAUSE OF ACTION CREATED. This chapter does not create a private or state cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device.

Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official, employee, or agent of this state may not block or attempt to block

an eligible patient's access to an investigational drug, biological product, or device under this chapter.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 489.101. HEALTH BENEFIT PLANS. A health benefit plan may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device.

Sec. 489.102. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES. This chapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

SUBCHAPTER D. PHYSICIANS

Sec. 489.151. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license under Subchapter B, Chapter 164, Occupations Code, based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device.

SECTION 3. The executive commissioner of the Health and Human Services Commission by rule shall adopt the form for informed consent as required by Section 489.052(c), Health and Safety Code, as added by this Act, not later than the 30th day after the effective date of this Act.

SECTION 4. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2015.