By: Parker H.B. No. 2908

Substitute the following for H.B. No. 2908:

By: Crownover C.S.H.B. No. 2908

A BILL TO BE ENTITLED

AN ACT

relating to authorizing patients with certain terminal illnesses and severe chronic diseases 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 "Medical Freedom 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 or severe chronic disease 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 or severe chronic disease;

(4) patients with a terminal illness or severe chronic disease 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 or severe chronic disease in consultation with the patient's physician 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 or severe chronic disease and the patient's family.

(c) It is the intent of the legislature to allow for patients with a terminal illness or severe chronic disease 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 OR SEVERE CHRONIC DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 489.001. DEFINITIONS. In this chapter:

(1) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that is being studied and administered to human participants in a clinical trial but has not yet been approved for general use by the United States

Food and Drug Administration. The term may include a treatment using stem cells other than embryonic stem cells.

(3) "Severe chronic disease" means a condition, injury, or illness that:

(A) may be treated;

(B) is never cured or eliminated; and

(C) entails significant functional impairment or severe pain.

(4) "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.

Sec. 489.002. RULES. (a) The executive commissioner by rule may designate a condition as a terminal illness or a severe chronic disease.

(b) The executive commissioner shall adopt rules specifying which treatments may be accessed by patients under this chapter and the manner in which those treatments may be accessed.

(c) The executive commissioner may approve for treatment an investigational drug, biological product, or device that has completed or is in the appropriate phase of a clinical trial in another country, provided that the executive commissioner determines that the benefit of authorizing the treatment outweighs the potential risk.

(d) For any treatment approved under this section, the executive commissioner shall specify the safety parameters and protocols the executive commissioner considers necessary for

patient use of the drug, product, or device.

Sec. 489.003. EXCLUSION OF CERTAIN TREATMENTS. This chapter does not authorize the use of cannabis to treat patients with terminal illnesses or severe chronic diseases.

SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES OR SEVERE CHRONIC DISEASES

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 or severe chronic disease, attested to by the patient's treating physician;

(2) the use of the investigational drug, biological product, or device is consistent with rules adopted under Section 489.002; and

(3) 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.

(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, in collaboration with the Texas Medical Board, by rule shall adopt a form for the informed consent 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.

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, provided that the care provided or recommendations made to the patient meet the standard of care and the requirements of this chapter.

SECTION 3. 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.