By: Toth H.B. No. 638

A BILL TO BE ENTITLED

AN ACT

relating to access to certain investigational drugs, biological products, treatments, and devices by patients.

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

SECTION 1. (a) This Act shall be known as the "Mary Lou's Law."

(b) The legislature finds that:

(1) the Right To Try Act, as added by Chapter 502 (H.B. 21), Acts of the 84th Legislature, Regular Session, 2015, has had tremendous success in saving the lives of many patients with a terminal illness;

(2) the process for approving the use of investigational drugs, biological products, treatments and devices by patients without a terminal illness who need access to the drugs, products, treatments or devices continues to take many years in the United States;

(3) patients who are battling a severe chronic disease that is debilitating or causes severe pain, 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;

(4) the standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, treatments, and devices may deny the benefits of

potentially life-altering treatment to patients with a severe chronic disease;

(5) patients with a severe chronic disease have a fundamental right to attempt to pursue the preservation of their state of life by accessing available investigational drugs, biological products, and devices;

(6) the use of available investigational drugs, biological products, and devices is a decision that should be made by a patient with a severe chronic disease in consultation with the patient's physician and is not a decision to be made by the government; and

(7) 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 a patient with a severe chronic disease and the patient's family.

(c) It is the intent of the legislature to allow patients with a severe chronic disease to use potentially life-altering investigational drugs, biological products, and devices.

SECTION 2. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 490 to read as follows:

CHAPTER 490. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH SEVERE CHRONIC DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 490.001. 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 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 or its international equivalent and remains under investigation in the clinical trial.

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

(A) requires medical attention; and

(B) entails significant functional impairment or severe pain that limits a person's activities of daily life.

Sec. 490.002. DESIGNATION OF SEVERE CHRONIC DISEASES. The executive commissioner by rule shall designate the medical conditions that are considered severe chronic diseases under this chapter.

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

Sec. 490.051. 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 severe chronic disease designated by the executive commissioner under Section 490.002 and attested to by the patient's treating physician;

(2) the use of the investigational drug, biological product, or device is consistent with this chapter and rules adopted under this chapter; 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 provide relief for the significant impairment or severe pain associated with the patient's severe chronic disease; and

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

Sec. 490.052. INFORMED CONSENT. (a) Before receiving an investigational drug, biological product, or device, an eligible patient must sign a written informed consent. 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.

(b) The executive commissioner by rule may adopt a form for the informed consent required under this section.

Sec. 490.053. 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. 490.054. 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. 490.101. 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. 490.151. 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 recommendations made to the patient meet the medical standard of care.

SECTION 3. As soon as practicable after the effective date of this Act, the executive commissioner of the Health and Human Services Commission by rule shall designate the medical conditions that are severe chronic diseases as required by Section 490.002, Health and Safety Code, as added by 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, 2023.