

By: Parker

S.B. No. 773

A BILL TO BE ENTITLED

AN ACT

1
2 relating to access to certain investigational drugs, biological
3 products, and devices used in clinical trials by patients with
4 severe chronic diseases.

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

6 SECTION 1. (a) This Act shall be known as the "Medical
7 Freedom Act."

8 (b) The legislature finds that:

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

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

18 (3) patients who are battling a severe chronic disease
19 that is debilitating or causes severe pain do not have the luxury of
20 waiting until the United States Food and Drug Administration gives
21 final approval for an investigational drug, biological product, or
22 device;

23 (4) the United States Food and Drug Administration
24 standards for the use of investigational drugs, biological

1 products, and devices may deny the benefits of potentially
2 life-altering treatment to patients with a severe chronic disease;

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

7 (6) the use of available investigational drugs,
8 biological products, and devices is a decision that a patient with a
9 severe chronic disease should make in consultation with the
10 patient's physician and is not a decision the government should
11 make; and

12 (7) the decision to use an investigational drug,
13 biological product, or device should be made with full awareness of
14 the potential risks, benefits, and consequences to a patient with a
15 severe chronic disease and the patient's family.

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

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

21 CHAPTER 490. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS

22 WITH SEVERE CHRONIC DISEASES

23 SUBCHAPTER A. GENERAL PROVISIONS

24 Sec. 490.001. DEFINITIONS. In this chapter:

25 (1) "Commissioner" means the commissioner of state
26 health services.

27 (2) "Executive commissioner" means the executive

1 commissioner of the Health and Human Services Commission.

2 (3) "Investigational drug, biological product, or
3 device" means a drug, biological product, or device that has
4 successfully completed phase one of a clinical trial but the United
5 States Food and Drug Administration or its international equivalent
6 has not yet approved for general use and that remains under
7 investigation in the clinical trial. The term does not include
8 low-THC cannabis, as defined by Section 169.001, Occupations Code,
9 or a product containing marihuana, as defined by Section 481.002,
10 regardless of whether the cannabis or product successfully
11 completed phase one of a clinical trial.

12 (4) "Severe chronic disease" means a condition,
13 injury, or illness that:

14 (A) may be treated;

15 (B) may not be cured or eliminated; and

16 (C) entails significant functional impairment or
17 severe pain.

18 Sec. 490.002. DESIGNATION OF SEVERE CHRONIC DISEASES. The
19 commissioner shall designate the medical conditions considered to
20 be severe chronic diseases under this chapter.

21 Sec. 490.003. RULES. The executive commissioner shall
22 adopt rules necessary to administer this chapter.

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

25 Sec. 490.051. PATIENT ELIGIBILITY. A patient is eligible
26 to access and use an investigational drug, biological product, or
27 device under this chapter if:

1 (1) the patient has a severe chronic disease the
2 commissioner designates under Section 490.002 that the patient's
3 treating physician confirms in writing;

4 (2) the use of the investigational drug, biological
5 product, or device is consistent with this chapter and rules
6 adopted under this chapter; and

7 (3) the patient's physician:

8 (A) in consultation with the patient, considers
9 all other treatment options the United States Food and Drug
10 Administration has currently approved and determines those
11 treatment options are unavailable or unlikely to provide relief for
12 the significant impairment or severe pain associated with the
13 patient's severe chronic disease; and

14 (B) recommends or prescribes in writing the
15 patient's use of a specific class of investigational drug,
16 biological product, or device.

17 Sec. 490.052. INFORMED CONSENT. (a) Before receiving an
18 investigational drug, biological product, or device, an eligible
19 patient must sign a written informed consent. If the patient is a
20 minor or lacks the mental capacity to provide informed consent, a
21 parent, guardian, or conservator may provide informed consent on
22 the patient's behalf.

23 (b) The commissioner may prescribe a form for the informed
24 consent required under this section.

25 Sec. 490.053. CAUSE OF ACTION NOT CREATED. This chapter
26 does not create a private or state cause of action against a
27 manufacturer of an investigational drug, biological product, or

1 device or against any other person or entity involved in the care of
2 an eligible patient using the investigational drug, biological
3 product, or device for any harm to the patient resulting from the
4 investigational drug, biological product, or device.

5 Sec. 490.054. STATE MAY NOT INTERFERE WITH ACCESS TO
6 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official,
7 employee, or agent of this state may not block or attempt to block
8 an eligible patient's access to an investigational drug, biological
9 product, or device under this chapter unless the drug, biological
10 product, or device is considered adulterated or misbranded under
11 Chapter 431. For purposes of this section, a governmental entity
12 may not consider the drug, biological product, or device to be
13 adulterated or misbranded based solely on the United States Food
14 and Drug Administration not yet finally approving the drug,
15 biological product, or device.

16 SUBCHAPTER C. HEALTH INSURANCE

17 Sec. 490.101. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL
18 TRIAL ENROLLEES. This chapter does not affect the coverage of
19 enrollees in clinical trials under Chapter 1379, Insurance Code.

20 SUBCHAPTER D. PHYSICIANS

21 Sec. 490.151. ACTION AGAINST PHYSICIAN'S LICENSE
22 PROHIBITED. Notwithstanding any other law, the Texas Medical Board
23 may not revoke, fail to renew, suspend, or take any action against
24 a physician's license under Subchapter B, Chapter 164, Occupations
25 Code, based solely on the physician's recommendations to an
26 eligible patient regarding access to or treatment with an
27 investigational drug, biological product, or device, provided that

1 the recommendations meet the medical standard of care and the
2 requirements of this chapter.

3 SECTION 3. (a) As soon as practicable after the effective
4 date of this Act, the commissioner of state health services shall
5 designate the medical conditions considered to be severe chronic
6 diseases as required by Section 490.002, Health and Safety Code, as
7 added by this Act.

8 (b) As soon as practicable after the effective date of this
9 Act, the executive commissioner of the Health and Human Services
10 Commission shall adopt the rules required by Section 490.003,
11 Health and Safety Code, as added by this Act. The executive
12 commissioner may adopt initial rules in the manner provided by law
13 for emergency rules.

14 SECTION 4. This Act takes effect immediately if it receives
15 a vote of two-thirds of all the members elected to each house, as
16 provided by Section 39, Article III, Texas Constitution. If this
17 Act does not receive the vote necessary for immediate effect, this
18 Act takes effect September 1, 2023.