

By: Parker

S.B. No. 773

A BILL TO BE ENTITLED

1 AN ACT  
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 marijuana, 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. PROVISION OF INVESTIGATIONAL DRUG,  
26 BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) A manufacturer  
27 of an investigational drug, biological product, or device may make

1 available the manufacturer's investigational drug, biological  
2 product, or device to eligible patients in accordance with this  
3 chapter if the patient provides to the manufacturer the informed  
4 consent required under Section 490.052.

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

8 (c) If a manufacturer makes available an investigational  
9 drug, biological product, or device to an eligible patient under  
10 this subchapter, the manufacturer must provide the investigational  
11 drug, biological product, or device to the eligible patient without  
12 receiving compensation.

13 Sec. 490.054. CAUSE OF ACTION NOT CREATED. This chapter  
14 does not create a private or state cause of action against a  
15 manufacturer of an investigational drug, biological product, or  
16 device or against any other person or entity involved in the care of  
17 an eligible patient using the investigational drug, biological  
18 product, or device for any harm to the patient resulting from the  
19 investigational drug, biological product, or device.

20 Sec. 490.055. STATE MAY NOT INTERFERE WITH ACCESS TO  
21 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official,  
22 employee, or agent of this state may not block or attempt to block  
23 an eligible patient's access to an investigational drug, biological  
24 product, or device under this chapter unless the drug, biological  
25 product, or device is considered adulterated or misbranded under  
26 Chapter 431. For purposes of this section, a governmental entity  
27 may not consider the drug, biological product, or device to be

1 adulterated or misbranded based solely on the United States Food  
2 and Drug Administration not yet finally approving the drug,  
3 biological product, or device.

4 SUBCHAPTER C. HEALTH INSURANCE

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

8 SUBCHAPTER D. PHYSICIANS

9 Sec. 490.151. ACTION AGAINST PHYSICIAN'S LICENSE  
10 PROHIBITED. Notwithstanding any other law, the Texas Medical Board  
11 may not revoke, fail to renew, suspend, or take any action against  
12 a physician's license under Subchapter B, Chapter 164, Occupations  
13 Code, based solely on the physician's recommendations to an  
14 eligible patient regarding access to or treatment with an  
15 investigational drug, biological product, or device, provided that  
16 the recommendations meet the medical standard of care and the  
17 requirements of this chapter.

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

23 (b) As soon as practicable after the effective date of this  
24 Act, the executive commissioner of the Health and Human Services  
25 Commission shall adopt the rules required by Section 490.003,  
26 Health and Safety Code, as added by this Act. The executive  
27 commissioner may adopt initial rules in the manner provided by law

1 for emergency rules.

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