

By: Parker

H.B. No. 661

A BILL TO BE ENTITLED

1 AN ACT  
2 relating to access to certain investigational drugs, biological  
3 products, and devices that are 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 an investigational drug, biological product, or  
21 device receives final approval from the United States Food and Drug  
22 Administration;

23 (4) the standards of the United States Food and Drug  
24 Administration 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 should be made  
9 by a patient with a severe chronic disease in consultation with the  
10 patient's physician and is not a decision to be made by the  
11 government; 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) "Executive commissioner" means the executive  
26 commissioner of the Health and Human Services Commission.

27 (2) "Investigational drug, biological product, or

1 device" means a drug, biological product, or device that is being  
2 studied and administered to human participants in a clinical trial  
3 and that the United States Food and Drug Administration has not yet  
4 approved for general use.

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

7 (A) lasts for at least one year;

8 (B) requires ongoing medical attention; and

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

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

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

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

20 (1) the patient has a severe chronic disease  
21 designated by the executive commissioner under Section 490.002 and  
22 attested to by the patient's treating physician;

23 (2) the use of the investigational drug, biological  
24 product, or device is consistent with this chapter and rules  
25 adopted under this chapter; and

26 (3) the patient's physician:

27 (A) in consultation with the patient, has

1 considered all other treatment options currently approved by the  
2 United States Food and Drug Administration and determined that  
3 those treatment options are unavailable or unlikely to provide  
4 relief for the significant impairment or severe pain associated  
5 with the patient's severe chronic disease; and

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

9 Sec. 490.052. INFORMED CONSENT. (a) Before receiving an  
10 investigational drug, biological product, or device, an eligible  
11 patient must sign a written informed consent. If the patient is a  
12 minor or lacks the mental capacity to provide informed consent, a  
13 parent, guardian, or conservator may provide informed consent on  
14 the patient's behalf.

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

17 Sec. 490.053. NO CAUSE OF ACTION CREATED. This chapter does  
18 not create a private or state cause of action against a manufacturer  
19 of an investigational drug, biological product, or device or  
20 against any other person or entity involved in the care of an  
21 eligible patient using the investigational drug, biological  
22 product, or device for any harm done to the eligible patient  
23 resulting from the investigational drug, biological product, or  
24 device.

25 Sec. 490.054. STATE MAY NOT INTERFERE WITH ACCESS TO  
26 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official,  
27 employee, or agent of this state may not block or attempt to block

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

3 SUBCHAPTER C. HEALTH INSURANCE

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

7 SUBCHAPTER D. PHYSICIANS

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

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

22 SECTION 4. This Act takes effect immediately if it receives  
23 a vote of two-thirds of all the members elected to each house, as  
24 provided by Section 39, Article III, Texas Constitution. If this  
25 Act does not receive the vote necessary for immediate effect, this  
26 Act takes effect September 1, 2017.