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H.B. No. 21

A BILL TO BE ENTITLED

1 AN ACT  
2 relating to authorizing patients with certain terminal illnesses to  
3 access certain investigational drugs, biological products, and  
4 devices that are in clinical trials.

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

6 SECTION 1. (a) This Act shall be known as the Right To Try  
7 Act.

8 (b) The legislature finds that:

9 (1) the process for the approval of investigational  
10 drugs, biological products, and devices in the United States takes  
11 many years;

12 (2) patients with a terminal illness do not have the  
13 luxury of waiting until an investigational drug, biological  
14 product, or device receives final approval from the United States  
15 Food and Drug Administration;

16 (3) the standards of the United States Food and Drug  
17 Administration for the use of investigational drugs, biological  
18 products, and devices may deny the benefits of potentially  
19 life-saving treatments to patients with a terminal illness;

20 (4) patients with a terminal illness have a  
21 fundamental right to attempt to pursue the preservation of their  
22 own lives by accessing available investigational drugs, biological  
23 products, and devices;

24 (5) the use of available investigational drugs,  
25 biological products, and devices is a decision that should be made

1 by the patient with a terminal illness in consultation with the  
2 patient's physician and is not a decision to be made by the  
3 government; and

4 (6) the decision to use an investigational drug,  
5 biological product, or device should be made with full awareness of  
6 the potential risks, benefits, and consequences to the patient with  
7 a terminal illness and the patient's family.

8 (c) It is the intent of the legislature to allow for  
9 patients with a terminal illness to use potentially life-saving  
10 investigational drugs, biological products, and devices.

11 SECTION 2. Subtitle C, Title 6, Health and Safety Code, is  
12 amended by adding Chapter 489 to read as follows:

13 CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS

14 WITH TERMINAL ILLNESSES

15 SUBCHAPTER A. GENERAL PROVISIONS

16 Sec. 489.001. DEFINITIONS. In this chapter:

17 (1) "Investigational drug, biological product, or  
18 device" means a drug, biological product, or device that has  
19 successfully completed phase one of a clinical trial but has not yet  
20 been approved for general use by the United States Food and Drug  
21 Administration and remains under investigation in the clinical  
22 trial.

23 (2) "Terminal illness" means an advanced stage of a  
24 disease with an unfavorable prognosis that, without  
25 life-sustaining procedures, will soon result in death or a state of  
26 permanent unconsciousness from which recovery is unlikely.

1        SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL  
2        PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES

3        Sec. 489.051. PATIENT ELIGIBILITY. A patient is eligible  
4 to access and use an investigational drug, biological product, or  
5 device under this chapter if:

6            (1) the patient has a terminal illness, attested to by  
7 the patient's treating physician; and

8            (2) the patient's physician:

9                    (A) in consultation with the patient, has  
10 considered all other treatment options currently approved by the  
11 United States Food and Drug Administration and determined that  
12 those treatment options are unavailable or unlikely to prolong the  
13 patient's life; and

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

17        Sec. 489.052. INFORMED CONSENT. (a) Before receiving an  
18 investigational drug, biological product, or device, an eligible  
19 patient must sign a written informed consent described by this  
20 section that is attested to by the patient's physician and a  
21 witness.

22            (b) If the patient is a minor or lacks the mental capacity to  
23 provide informed consent, a parent, guardian, or conservator may  
24 provide informed consent on the patient's behalf.

25            (c) The executive commissioner of the Health and Human  
26 Services Commission, in collaboration with the Texas Medical Board,  
27 by rule shall adopt a form for the informed consent required under

1 this section.

2 Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG,  
3 BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) A manufacturer  
4 of an investigational drug, biological product, or device may make  
5 available the manufacturer's investigational drug, biological  
6 product, or device to eligible patients in accordance with this  
7 chapter if the patient provides to the manufacturer the informed  
8 consent required under Section 489.052.

9 (b) This chapter does not require that a manufacturer make  
10 available an investigational drug, biological product, or device to  
11 an eligible patient.

12 (c) A manufacturer may:

13 (1) provide an investigational drug, biological  
14 product, or device to an eligible patient without receiving  
15 compensation; or

16 (2) require an eligible patient to pay the costs of, or  
17 the costs associated with, the manufacture of the investigational  
18 drug, biological product, or device.

19 Sec. 489.054. NO CAUSE OF ACTION CREATED. This chapter does  
20 not create a private or state cause of action against a manufacturer  
21 of an investigational drug, biological product, or device or  
22 against any other person or entity involved in the care of an  
23 eligible patient using the investigational drug, biological  
24 product, or device for any harm done to the eligible patient  
25 resulting from the investigational drug, biological product, or  
26 device.

27 Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO

1 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official,  
2 employee, or agent of this state may not block or attempt to block  
3 an eligible patient's access to an investigational drug, biological  
4 product, or device under this chapter.

5 Sec. 489.056. CORRECTIONAL MANAGED CARE. A person covered  
6 by the correctional managed health care plan under Subchapter E,  
7 Chapter 501, Government Code, is an eligible patient for purposes  
8 of this chapter only to the extent that the correctional managed  
9 health care Offender Health Services Plan and federal law governing  
10 offender participation in biomedical research permit the  
11 offender's access to and use of the investigational drug,  
12 biological product, or device.

13 SUBCHAPTER C. HEALTH INSURANCE

14 Sec. 489.101. HEALTH BENEFIT PLANS. A health benefit plan  
15 may, but is not required to, provide coverage for the cost of an  
16 investigational drug, biological product, or device.

17 Sec. 489.102. 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. 489.151. 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 a  
24 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 care provided or recommendations made to the patient meet the  
2 standard of care and the requirements of this chapter.

3 SECTION 3. The executive commissioner of the Health and  
4 Human Services Commission by rule shall adopt the form for informed  
5 consent as required by Section 489.052(c), Health and Safety Code,  
6 as added by this Act, not later than the 30th day after the  
7 effective date of this Act.

8 SECTION 4. This Act takes effect immediately if it receives  
9 a vote of two-thirds of all the members elected to each house, as  
10 provided by Section 39, Article III, Texas Constitution. If this  
11 Act does not receive the vote necessary for immediate effect, this  
12 Act takes effect September 1, 2015.