

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 terminally ill patients;

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,

1 biological products, and devices is a decision that should be made
2 by the patient with a terminal illness in consultation with the
3 patient's physician to pursue the preservation of the patient's own
4 life and is not a decision to be made by the government; and

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

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

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

14 CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS
15 WITH TERMINAL ILLNESSES

16 SUBCHAPTER A. GENERAL PROVISIONS

17 Sec. 489.001. DEFINITIONS. In this chapter:

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

24 (2) "Terminal illness" means an advanced stage of a
25 disease with an unfavorable prognosis that, without
26 life-sustaining procedures, will soon result in death or a state of
27 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. If the patient is a
20 minor or lacks the mental capacity to provide informed consent, a
21 parent or legal guardian may provide informed consent on the
22 patient's behalf.

23 (b) The executive commissioner of the Health and Human
24 Services Commission by rule may adopt a form for the informed
25 consent under this section.

26 Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG,
27 BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) A manufacturer

1 of an investigational drug, biological product, or device may make
2 available the manufacturer's investigational drug, biological
3 product, or device to eligible patients in accordance with this
4 chapter if the patient provides to the manufacturer the informed
5 consent required under Section 489.052.

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

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

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

22 Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO
23 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official,
24 employee, or agent of this state may not block or attempt to block
25 an eligible patient's access to an investigational drug, biological
26 product, or device under this chapter.

1 SUBCHAPTER C. HEALTH INSURANCE

2 Sec. 489.101. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL
3 TRIAL ENROLLEES. This chapter does not affect the coverage of
4 enrollees in clinical trials under Chapter 1379, Insurance Code.

5 SUBCHAPTER D. PHYSICIANS

6 Sec. 489.151. ACTION AGAINST PHYSICIAN'S LICENSE
7 PROHIBITED. Notwithstanding any other law, the Texas Medical Board
8 may not revoke, fail to renew, suspend, or take any action against a
9 physician's license under Subchapter B, Chapter 164, Occupations
10 Code, based solely on the physician's recommendations to an
11 eligible patient regarding access to or treatment with an
12 investigational drug, biological product, or device, provided that
13 the recommendations made to the patient meet the medical standard
14 of care.

15 SECTION 3. This Act takes effect immediately if it receives
16 a vote of two-thirds of all the members elected to each house, as
17 provided by Section 39, Article III, Texas Constitution. If this
18 Act does not receive the vote necessary for immediate effect, this
19 Act takes effect September 1, 2015.

President of the Senate

Speaker of the House

I certify that H.B. No. 21 was passed by the House on April 22, 2015, by the following vote: Yeas 145, Nays 0, 2 present, not voting; and that the House concurred in Senate amendments to H.B. No. 21 on May 23, 2015, by the following vote: Yeas 134, Nays 0, 1 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 21 was passed by the Senate, with amendments, on May 22, 2015, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

APPROVED: _____

Date

Governor