

By: Canales

H.B. No. 438

A BILL TO BE ENTITLED

AN ACT

relating to authorizing patients with certain terminal conditions to access certain investigational drugs, biological products, and devices that are in clinical trials.

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

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

(b) The legislature finds that:

(1) the process of approval for investigational drugs, biological products, and devices in the United States protects future patients from premature, ineffective, and unsafe medications and treatments over the long run, but the process often takes many years;

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

(3) patients with a terminal condition have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices;

(4) the use of available investigational drugs, biological products, and devices is a decision that should be made by the patient with a terminal condition in consultation with the

1 patient's physician and the patient's health care team, if
2 applicable; and

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

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

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

12 CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS
13 WITH TERMINAL CONDITIONS

14 SUBCHAPTER A. GENERAL PROVISIONS

15 Sec. 489.001. DEFINITIONS. In this chapter:

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

22 (2) "Terminal condition" means an incurable condition
23 caused by injury, disease, or illness that, without life-sustaining
24 procedures, will soon result in death or a state of permanent
25 unconsciousness from which recovery is unlikely.

26 SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL
27 PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL CONDITIONS

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

4 (1) the patient has a terminal condition, attested to
5 by the patient's treating physician;

6 (2) the patient's physician:

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

12 (B) has recommended in writing that the patient
13 use a specific investigational drug, biological product, or device;
14 and

15 (3) the patient:

16 (A) is unable to participate in a clinical trial
17 of the recommended investigational drug, biological product, or
18 device within 100 miles of the patient's home address; or

19 (B) has not been accepted to the clinical trial
20 before the eighth calendar day after the patient completed the
21 application process for the trial.

22 Sec. 489.052. INFORMED CONSENT. (a) Before receiving an
23 investigational drug, biological product, or device, an eligible
24 patient must sign a written informed consent described by this
25 section that is attested to by the patient's physician and a
26 witness.

27 (b) The informed consent must:

1 (1) explain the currently approved products and
2 treatments for the disease or condition from which the patient
3 suffers;

4 (2) attest to the fact that the patient concurs with
5 the patient's physician in believing that all currently approved
6 and conventionally recognized treatments are unlikely to prolong
7 the patient's life;

8 (3) identify the specific proposed investigational
9 drug, biological product, or device that the patient is seeking to
10 use;

11 (4) describe the potentially best and worst outcomes
12 of using the investigational drug, biological product, or device
13 with a realistic description of the most likely outcome, including
14 the possibility that new, unanticipated, different, or worse
15 symptoms might result, and that death could be hastened by the
16 proposed treatment, based on the physician's knowledge of the
17 proposed treatment in conjunction with an awareness of the
18 patient's condition;

19 (5) state that the patient's health benefit plan is not
20 obligated to pay for any care or treatments resulting from the use
21 of the investigational drug, biological product, or device;

22 (6) state that the patient's eligibility for hospice
23 care may be withdrawn if the patient begins curative treatment and
24 that care may be reinstated if the curative treatment ends and the
25 patient meets hospice eligibility requirements;

26 (7) state that in-home health care may be denied if
27 treatment begins; and

1 (8) state that the patient understands that the
2 patient is liable for all expenses resulting from the use of the
3 investigational drug, biological product, or device, and that this
4 liability extends to the patient's estate, unless a contract
5 between the patient and the manufacturer of the drug, biological
6 product, or device provides otherwise.

7 (c) The executive commissioner of the Health and Human
8 Services Commission by rule may adopt a form for the informed
9 consent under this section.

10 Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG,
11 BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) A manufacturer
12 of an investigational drug, biological product, or device may make
13 available the manufacturer's investigational drug, biological
14 product, or device to eligible patients in accordance with this
15 chapter if the patient provides to the manufacturer the informed
16 consent required under Section 489.052.

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

20 (c) A manufacturer may:

21 (1) provide an investigational drug, biological
22 product, or device to an eligible patient without receiving
23 compensation; or

24 (2) require an eligible patient to pay the costs of, or
25 the costs associated with, the manufacture of the investigational
26 drug, biological product, or device.

27 Sec. 489.054. NO CAUSE OF ACTION CREATED. This chapter does

1 not create a private cause of action against a manufacturer of an
2 investigational drug, biological product, or device or against any
3 other person or entity involved in the care of an eligible patient
4 using the investigational drug, biological product, or device for
5 any harm done to the eligible patient resulting from the
6 investigational drug, biological product, or device.

7 Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO
8 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. (a) An
9 official, employee, or agent of this state may not block or attempt
10 to block an eligible patient's access to an investigational drug,
11 biological product, or device under this section.

12 (b) Counseling, advice, or a recommendation consistent with
13 medical standards of care from a licensed health care provider is
14 not a violation of this section.

15 SUBCHAPTER C. HEALTH INSURANCE

16 Sec. 489.101. APPLICABILITY OF SUBCHAPTER. (a) This
17 subchapter applies only to a health benefit plan that provides
18 benefits for medical or surgical expenses incurred as a result of a
19 health condition, accident, or sickness, including an individual,
20 group, blanket, or franchise insurance policy or insurance
21 agreement, a group hospital service contract, or a small or large
22 employer group contract or similar coverage document that is
23 offered by:

- 24 (1) an insurance company;
25 (2) a group hospital service corporation operating
26 under Chapter 842, Insurance Code;
27 (3) a fraternal benefit society operating under

Chapter 885, Insurance Code;

(4) a stipulated premium company operating under Chapter 884, Insurance Code;

(5) a reciprocal exchange operating under Chapter 942, Insurance Code;

(6) a health maintenance organization operating under Chapter 843, Insurance Code;

(7) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846, Insurance Code; or

(8) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844, Insurance Code.

(b) This subchapter applies to group health coverage made available by a school district in accordance with Section 22.004, Education Code.

(c) Notwithstanding Section 172.014, Local Government Code, or any other law, this subchapter applies to health and accident coverage provided by a risk pool created under Chapter 172, Local Government Code.

(d) Notwithstanding any provision in Chapter 1551, 1575, 1579, or 1601, Insurance Code, or any other law, this subchapter applies to:

(1) a basic coverage plan under Chapter 1551, Insurance Code;

(2) a basic plan under Chapter 1575, Insurance Code;

(3) a primary care coverage plan under Chapter 1579, Insurance Code; and

(4) basic coverage under Chapter 1601, Insurance Code.

1 (e) Notwithstanding any other law, this subchapter applies
2 to coverage under:

3 (1) the child health plan program under Chapter 62 or
4 the health benefits plan for children under Chapter 63; and

5 (2) the medical assistance program under Chapter 32,
6 Human Resources Code.

7 Sec. 489.102. HEALTH BENEFIT PLANS. (a) A health benefit
8 plan may, but is not required to, provide coverage for the cost of
9 an investigational drug, biological product, or device.

10 (b) Except as otherwise provided by this section, a health
11 benefit plan may deny coverage to an eligible patient from the date
12 the eligible patient begins use of the investigational drug,
13 biological product, or device until the 181st day after the date the
14 patient ceases using the investigational drug, biological product,
15 or device.

16 (c) A health benefit plan issuer may not deny covered
17 benefits under Subsection (b) for a condition that existed before
18 the date the eligible patient begins use of the investigational
19 drug, biological product, or device, regardless of whether the
20 issuer was providing benefits for the condition before that date.

21 Sec. 489.103. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL
22 TRIAL ENROLLEES. This chapter does not affect the coverage of
23 enrollees in clinical trials under Chapter 1379, Insurance Code.

24 SUBCHAPTER D. PHYSICIANS

25 Sec. 489.151. ACTION AGAINST PHYSICIAN'S LICENSE
26 PROHIBITED. Notwithstanding any other law, the Texas Medical Board
27 may not revoke, fail to renew, suspend, or take any action against

1 a physician's license issued under Subchapter B, Chapter 164,
2 Occupations Code, based solely on the physician's recommendations
3 to an eligible patient regarding access to or treatment with an
4 investigational drug, biological product, or device.

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