

1 HB463
2 167279-1
3 By Representative Weaver
4 RFD: Health
5 First Read: 09-APR-15

2
3
4
5
6
7
8 SYNOPSIS: This bill would authorize a terminally ill
9 patient to use a drug or device that has completed
10 phase 1 of a clinical trial under certain
11 conditions.

12
13 A BILL
14 TO BE ENTITLED
15 AN ACT
16

17 To authorize access to and use of experimental
18 treatments for patients with a terminal illness; to establish
19 conditions for use of experimental treatment; to prohibit
20 sanctions of health care providers solely for recommending or
21 providing experimental treatment; to clarify duties of a
22 health insurer with regard to experimental treatment
23 authorized under this act; to prohibit certain actions by
24 state officials, employees, and agents; and to restrict
25 certain causes of action arising from experimental treatment.
26 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

1 Section 1. This act shall be known and may be cited
2 as the Right to Try Act.

3 Section 2. As used in this act, the following words
4 have the following meanings:

5 (1) ELIGIBLE PATIENT. An individual who meets all of
6 the following conditions:

7 a. Has a terminal illness, attested to by the
8 patient's treating physician.

9 b. Has considered all other treatment options
10 currently approved by the U. S. Food and Drug Administration.

11 c. Has received a recommendation from his or her
12 physician for an investigational drug, biological product, or
13 device.

14 d. Has given written, informed consent for the use
15 of the investigational drug, biological product, or device.

16 e. Has documentation from his or her physician that
17 he or she meets the requirements of this subdivision.

18 (2) INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, or
19 DEVICE. A drug, biological product, or device that has
20 successfully completed phase 1 of a clinical trial but has not
21 yet been approved for general use by the U. S. Food and Drug
22 Administration and remains under investigation in a U. S. Food
23 and Drug Administration approved clinical trial.

24 (3) TERMINAL ILLNESS. A progressive disease or
25 medical or surgical condition that entails significant
26 functional impairment, that is not considered by a treating
27 physician to be reversible even with administration of current

1 federal drug administration approved and available treatments,
2 and that, without life-sustaining procedures, will not soon
3 result in death.

4 (4) WRITTEN, INFORMED CONSENT. A written document
5 that is signed by the patient or the parent or legal guardian,
6 if the patient is a minor, and attested to by the patient's
7 physician and a witness and that, at a minimum, includes all
8 of the following:

9 a. An explanation of the currently approved products
10 and treatments for the disease or condition from which the
11 patient suffers.

12 b. An attestation that the patient concurs with his
13 or her physician in believing that all currently approved and
14 conventionally recognized treatments are unlikely to prolong
15 the patient's life.

16 c. Clear identification of the specific proposed
17 investigational drug, biological product, or device that the
18 patient is seeking to use.

19 d. A description of the potentially best and worst
20 outcomes of using the investigational drug, biological
21 product, or device and a realistic description of the most
22 likely outcome. The description shall include the possibility
23 that new, unanticipated, different, or worse symptoms might
24 result and that death could be hastened by the proposed
25 treatment. The description shall be based on the physician's
26 knowledge of the proposed treatment in conjunction with an
27 awareness of the patient's condition.

1 e. A statement that the patient's health plan or
2 third party administrator and provider are not obliged to pay
3 for any care or treatments consequent to the use of the
4 investigational drug, biological product, or device, unless
5 they are specifically required to do so by law or contract.

6 f. A statement that the patient's eligibility for
7 hospice care may be withdrawn if the patient begins curative
8 treatment with the investigational drug, biological product,
9 or device and that care may be reinstated if this treatment
10 ends and the patient meets hospice eligibility requirements.

11 g. A statement that the patient understands that he
12 or she is liable for all expenses consequent to the use of the
13 investigational drug, biological product, or device and that
14 this liability extends to the patient's estate, unless a
15 contract between the patient and the manufacturer of the
16 investigational drug, biological product, or device states
17 otherwise.

18 Section 3. (a) The manufacturer of an
19 investigational drug, biological product, or device may make
20 available and an eligible patient may request the
21 manufacturer's investigational drug, biological product, or
22 device under this act. This act does not require that a
23 manufacturer make available an investigational drug,
24 biological product, or device to an eligible patient.

25 (b) A manufacturer may do all of the following:

1 (1) Provide an investigational drug, biological
2 product, or device to an eligible patient without receiving
3 compensation.

4 (2) Require an eligible patient to pay the costs of,
5 or the costs associated with, the manufacture of the
6 investigational drug, biological product, or device.

7 Section 4. (a) This act does not expand the coverage
8 required of an insurer.

9 (b) A health plan, third party administrator, or
10 governmental agency is not required to but may provide
11 coverage for the cost of an investigational drug, biological
12 product, or device, or the cost of services related to the use
13 of an investigational drug, biological product, or device
14 under this act.

15 (c) This act does not require any governmental
16 agency to pay costs associated with the use, care, or
17 treatment of a patient with an investigational drug,
18 biological product, or device.

19 (d) This act does not require a hospital or other
20 health care facility to provide new or additional services,
21 unless approved by the hospital or facility.

22 Section 5. If a patient dies while being treated by
23 an investigational drug, biological product, or device, the
24 patient's heirs are not liable for any outstanding debt
25 related to the treatment or lack of insurance due to the
26 treatment.

1 Section 6. A licensing board or disciplinary
2 subcommittee shall not revoke, fail to renew, suspend, or take
3 any action against a health care provider's license issued
4 under Title 34, Code of Alabama 1975, based solely on the
5 health care provider's recommendations to an eligible patient
6 regarding access to or treatment with an investigational drug,
7 biological product, or device. An entity responsible for
8 Medicare certification shall not take action against a health
9 care provider's Medicare certification based solely on the
10 health care provider's recommendation that a patient have
11 access to an investigational drug, biological product, or
12 device.

13 Section 7. An official, employee, or agent of this
14 state shall not block or attempt to block an eligible
15 patient's access to an investigational drug, biological
16 product, or device. Counseling, advice, or a recommendation
17 consistent with medical standards of care from a licensed
18 health care provider is not a violation of this section.

19 Section 8. This act does not create a private cause
20 of action against a manufacturer of an investigational drug,
21 biological product, or device or against any other person or
22 entity involved in the care of an eligible patient using the
23 investigational drug, biological product, or device for any
24 harm done to the eligible patient resulting from the
25 investigational drug, biological product, or device, if the
26 manufacturer or other person or entity is complying in good

1 faith with the terms of this act and has exercised reasonable
2 care.

3 Section 9. This act shall become effective on the
4 first day of the third month following its passage and
5 approval by the Governor, or its otherwise becoming law.