

GENERAL ASSEMBLY OF NORTH CAROLINA
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HOUSE PRINCIPAL CLERK

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HOUSE DRH20189-MGqq-128 (04/01)

Short Title: Right to Try Act for Terminally Ill Patients. (Public)

Sponsors: Representatives Blackwell, Hager, Lambeth, and Reives (Primary Sponsors).

Referred to:

1 A BILL TO BE ENTITLED
2 AN ACT ESTABLISHING A RIGHT TO TRY ACT TO PROVIDE EXPANDED ACCESS
3 TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR
4 PATIENTS DIAGNOSED WITH TERMINAL ILLNESS.

5 The General Assembly of North Carolina enacts:

6 SECTION 1. Chapter 90 of the General Statutes is amended by adding a new
7 Article to read:

8 "Article 23A.

9 "Right to Try Act.

10 "§ 90-325. Short title; purpose.

11 (a) This Article shall be known and may be cited as The Right to Try Act.

12 (b) The purpose of this Article is to authorize access to and use of experimental
13 treatments for patients with a terminal illness; to establish conditions for use of experimental
14 treatment; to prohibit sanctions of health care providers solely for recommending or providing
15 experimental treatment; to clarify duties of a health insurer with regard to experimental
16 treatment authorized under this Article; to prohibit certain actions by State officials, employees,
17 and agents; and to restrict certain causes of action arising from experimental treatment.

18 "§ 90-325.1. Definitions.

19 The following definitions apply in this Article, unless the context requires otherwise:

20 (1) Eligible patient. – An individual who meets all of the following criteria:

21 a. Has a terminal illness, attested to by a treating physician.

22 b. Has, in consultation with a treating physician, considered all other
23 treatment options currently approved by the United States Food and
24 Drug Administration.

25 c. Has received a recommendation from the treating physician for use
26 of an investigational drug, biological product, or device for treatment
27 of the terminal illness.

28 d. Has given informed consent in writing to use of the investigational
29 drug, biological product, or device for treatment of the terminal
30 illness or, if the individual is a minor or is otherwise incapable of
31 providing informed consent, the parent or legal guardian has given
32 informed consent in writing to use of the investigational drug,
33 biological product, or device.

34 e. Has documentation from the treating physician that the individual
35 meets all of the criteria for this definition.



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- 1 (2) Investigational drug, biological product, or device. – A drug, biological
2 product, or device that has successfully completed Phase I of a clinical trial
3 but has not yet been approved for general use by the United States Food and
4 Drug Administration and remains under investigation in a clinical trial
5 approved by the United States Food and Drug Administration.
- 6 (3) Terminal illness. – A progressive disease or medical or surgical condition
7 that (i) entails significant functional impairment, (ii) is not considered by a
8 treating physician to be reversible even with administration of available
9 treatments approved by the United States Food and Drug Administration,
10 and (iii) will soon result in death without life-sustaining procedures.
- 11 (4) Written, informed consent. – A written document that is signed by an
12 eligible patient; or if the patient is a minor, by a parent or legal guardian; or
13 if the patient is incapacitated, by a health care power of attorney, that at a
14 minimum includes all of the following:
- 15 a. An explanation of the currently approved products and treatments for
16 the eligible patient's terminal illness.
- 17 b. An attestation that the eligible patient concurs with the treating
18 physician in believing that all currently approved treatments are
19 unlikely to prolong the eligible patient's life.
- 20 c. Clear identification of the specific investigational drug, biological
21 product, or device proposed for treatment of the eligible patient's
22 terminal illness.
- 23 d. A description of the potentially best and worst outcomes resulting
24 from use of the investigational drug, biological product, or device to
25 treat the eligible patient's terminal illness, along with a realistic
26 description of the most likely outcome. The description shall be
27 based on the treating physician's knowledge of the proposed
28 treatment in conjunction with an awareness of the eligible patient's
29 terminal illness and shall include a statement acknowledging that
30 new, unanticipated, different, or worse symptoms might result from,
31 and that death could be hastened by, the proposed treatment.
- 32 e. A statement that eligibility for hospice care may be withdrawn if the
33 eligible patient begins treatment of the terminal illness with an
34 investigational drug, biological product, or device and that care may
35 be reinstated if such treatment ends and the eligible patient meets
36 hospice eligibility requirements.
- 37 f. A statement that the eligible patient's health benefit plan or
38 third-party administrator and provider are not obligated to pay for
39 any care or treatments consequent to the use of the investigational
40 drug, biological product, or device, unless specifically required to do
41 so by law or contract.
- 42 g. A statement that the eligible patient understands that he or she is
43 liable for all expenses consequent to the use of the investigational
44 drug, biological product, or device and that this liability extends to
45 the eligible patient's estate, unless a contract between the patient and
46 the manufacturer of the drug, biological product, or device states
47 otherwise.
- 48 h. A statement that the eligible patient or, for an eligible patient who is
49 a minor or lacks capacity to provide informed consent, a statement
50 that the parent or legal guardian consents to the use of the

1 investigational drug, biological product, or device for treatment of
2 the terminal condition.

3 **"§ 90-325.2. Authorized access to and use of investigational drugs, biological products,**
4 **and devices.**

5 (a) A manufacturer of an investigational drug, biological product, or device may make
6 available, and an eligible patient may request, the manufacturer's investigational drug,
7 biological product, or device. However, nothing in this Article shall be construed to require a
8 manufacturer of an investigational drug, biological product, or device to make such
9 investigational drug, biological product, or device available to an eligible patient.

10 (b) A manufacturer of an investigational drug, biological product, or device may
11 provide the investigational drug, biological product, or device to an eligible patient without
12 receiving compensation, or may require the eligible patient to pay the costs of, or the costs
13 associated with, the manufacture of the investigational drug, biological product, or device.

14 **"§ 90-325.3. No liability to heirs for outstanding debt related to use of investigational**
15 **drugs, biological products, or devices.**

16 If an eligible patient dies while being treated with an investigational drug, biological
17 product, or device, the eligible patient's heirs are not liable for any outstanding debt related to
18 the treatment, including any costs attributed to lack of insurance coverage for the treatment.

19 **"§ 90-325.4. Sanctions against health care providers prohibited.**

20 (a) A licensing board shall not revoke, fail to renew, suspend, or take any other
21 disciplinary action against a health care provider licensed under this Chapter, based solely on
22 the health care provider's recommendations to an eligible patient regarding access to or
23 treatment with an investigational drug, biological product, or device.

24 (b) An entity responsible for Medicare certification shall not take action against a health
25 care provider's Medicare certification based solely on the health care provider's
26 recommendation that a patient have access to an investigational drug, biological product, or
27 device.

28 **"§ 90-325.5. Prohibited conduct by State officials.**

29 No official, employee, or agent of this State shall block or attempt to block an eligible
30 patient's access to an investigational drug, biological product, or device. Counseling, advice, or
31 a recommendation consistent with medical standards of care from a licensed health care
32 provider does not constitute a violation of this section.

33 **"§ 90-325.6. No private right of action against manufacturers of investigational drugs,**
34 **biological products, or devices.**

35 No private right of action may be brought against a manufacturer of an investigational drug,
36 biological product, or device, or against any other person or entity involved in the care of an
37 eligible patient using an investigational drug, biological product, or device, for any harm
38 caused to the eligible patient resulting from use of the investigational drug, biological product,
39 or device as long as the manufacturer or other person or entity has made a good-faith effort to
40 comply with the provisions of this Article and has exercised reasonable care in actions
41 undertaken pursuant to this Article.

42 **"§ 90-325.7. Insurance coverage of clinical trials.**

43 Nothing in this Article shall be construed to affect a health benefit plan's obligation to
44 provide coverage for an insured's participation in a clinical trial pursuant to G.S. 58-3-255."

45 **SECTION 2.** This act becomes effective October 1, 2015.