

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2015

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HOUSE BILL 652  
Committee Substitute Favorable 4/20/15

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

(Public)

Sponsors:

Referred to:

April 14, 2015

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. This documentation shall  
36 include an attestation from the treating physician that the treating



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1                    physician was consulted in the creation of the written, informed  
2                    consent required under this Article.

3            (2)    Investigational drug, biological product, or device. – A drug, biological  
4            product, or device that has successfully completed Phase I of a clinical trial  
5            but has not yet been approved for general use by the United States Food and  
6            Drug Administration and remains under investigation in a clinical trial  
7            approved by the United States Food and Drug Administration.

8            (3)    Terminal illness. – A progressive disease or medical or surgical condition  
9            that (i) entails significant functional impairment, (ii) is not considered by a  
10           treating physician to be reversible even with administration of available  
11           treatments approved by the United States Food and Drug Administration,  
12           and (iii) will soon result in death without life-sustaining procedures.

13           (4)    Written, informed consent. – A written document that is signed by an  
14           eligible patient; or if the patient is a minor, by a parent or legal guardian; or  
15           if the patient is incapacitated, by a designated health care agent pursuant to a  
16           health care power of attorney, that at a minimum includes all of the  
17           following:

18           a.       An explanation of the currently approved products and treatments for  
19           the eligible patient's terminal illness.

20           b.       An attestation that the eligible patient concurs with the treating  
21           physician in believing that all currently approved treatments are  
22           unlikely to prolong the eligible patient's life.

23           c.       Clear identification of the specific investigational drug, biological  
24           product, or device proposed for treatment of the eligible patient's  
25           terminal illness.

26           d.       A description of the potentially best and worst outcomes resulting  
27           from use of the investigational drug, biological product, or device to  
28           treat the eligible patient's terminal illness, along with a realistic  
29           description of the most likely outcome. The description shall be  
30           based on the treating physician's knowledge of the proposed  
31           treatment in conjunction with an awareness of the eligible patient's  
32           terminal illness and shall include a statement acknowledging that  
33           new, unanticipated, different, or worse symptoms might result from,  
34           and that death could be hastened by, the proposed treatment.

35           e.       A statement that eligibility for hospice care may be withdrawn if the  
36           eligible patient begins treatment of the terminal illness with an  
37           investigational drug, biological product, or device and that hospice  
38           care may be reinstated if such treatment ends and the eligible patient  
39           meets hospice eligibility requirements.

40           f.       A statement that the eligible patient's health benefit plan or  
41           third-party administrator and provider are not obligated to pay for  
42           any care or treatments consequent to the use of the investigational  
43           drug, biological product, or device, unless specifically required to do  
44           so by law or contract.

45           g.       A statement that the eligible patient understands that he or she is  
46           liable for all expenses consequent to the use of the investigational  
47           drug, biological product, or device and that this liability extends to  
48           the eligible patient's estate, unless a contract between the patient and  
49           the manufacturer of the drug, biological product, or device states  
50           otherwise.

1                   h.     A statement that the eligible patient or, for an eligible patient who is  
2                         a minor or lacks capacity to provide informed consent, that the parent  
3                         or legal guardian consents to the use of the investigational drug,  
4                         biological product, or device for treatment of the terminal condition.

5     **"§ 90-325.2. Authorized access to and use of investigational drugs, biological products,**  
6     **and devices.**

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

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

16    **"§ 90-325.3. No liability to heirs for outstanding debt related to use of investigational**  
17    **drugs, biological products, or devices.**

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

21    **"§ 90-325.4. Sanctions against health care providers prohibited.**

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

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

30    **"§ 90-325.5. Prohibited conduct by State officials.**

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

35    **"§ 90-325.6. No private right of action against manufacturers of investigational drugs,**  
36    **biological products, or devices.**

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

44    **"§ 90-325.7. Insurance coverage of clinical trials.**

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

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