

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2019

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HOUSE BILL 934  
Committee Substitute Favorable 4/30/19  
Senate Health Care Committee Substitute Adopted 6/13/19

Short Title: Right to Try Adult Stem Cell Treatments.

(Public)

Sponsors:

Referred to:

April 22, 2019

1 A BILL TO BE ENTITLED  
2 AN ACT EXPANDING THE RIGHT TO TRY ACT TO PROVIDE ACCESS TO  
3 INVESTIGATIONAL ADULT STEM CELL TREATMENTS FOR PATIENTS  
4 DIAGNOSED WITH A TERMINAL OR CHRONIC ILLNESS.

5 The General Assembly of North Carolina enacts:

6 **SECTION 1.** Article 23A of Chapter 90 of the General Statutes reads as rewritten:

7 "Article 23A.

8 "Right to Try Act.

9 "Part 1. Experimental Treatments.

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 Part 1 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 treatment  
16 authorized under this ~~Article~~; Part; to prohibit certain actions by State officials, employees, and  
17 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~~, Part, 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 of  
26 an investigational drug, biological product, or device for treatment of  
27 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 illness  
30 or, if the individual is a minor or is otherwise incapable of providing  
31 informed consent, the parent or legal guardian has given informed  
32 consent in writing to use of the investigational drug, biological  
33 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



1 include an attestation from the treating physician that the treating  
2 physician was consulted in the creation of the written, informed  
3 consent required under this ~~Article-Part~~.

4 ...

5 **"§ 90-325.2. Authorized access to and use of investigational drugs, biological products, and**  
6 **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-Part~~ 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 provide  
13 the investigational drug, biological product, or device to an eligible patient without receiving  
14 compensation or may require the eligible patient to pay the costs of, or the costs associated with,  
15 the manufacture of the investigational drug, biological product, or device.

16 ...

17 **"§ 90-325.6. No private right of action against manufacturers of investigational drugs,**  
18 **biological products, or devices.**

19 No private right of action may be brought against a manufacturer of an investigational drug,  
20 biological product, or device, or against any other person or entity involved in the care of an  
21 eligible patient using an investigational drug, biological product, or device, for any harm caused  
22 to the eligible patient resulting from use of the investigational drug, biological product, or device  
23 as long as the manufacturer or other person or entity has made a good-faith effort to comply with  
24 the provisions of this ~~Article-Part~~ and has exercised reasonable care in actions undertaken  
25 pursuant to this ~~Article-Part~~.

26 **"§ 90-325.7. Insurance coverage of clinical trials.**

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

29 **"§ 90-325.8. Reserved.**

30 **"§ 90-325.9. Reserved.**

31 "Part 2. Investigational Adult Stem Cell Treatments.

32 **"§ 90-325.10. Purpose.**

33 The purpose of Part 2 of this Article is to authorize access to and use of certain investigational  
34 adult stem cell treatments for patients with certain severe chronic diseases or terminal illnesses;  
35 to regulate the possession, use, and transfer of adult stem cells; and to create a criminal offense  
36 for the purchase and sale of adult stem cells for certain investigational treatments.

37 **"§ 90-325.11. Definitions.**

38 The following definitions apply in this Part unless the context requires otherwise:

- 39 (1) Adult stem cell. – An undifferentiated cell that is (i) found in postnatal  
40 differentiated tissue and (ii) able to renew itself and differentiate to yield all  
41 or nearly all of the specialized cell types of the tissue from which the cell  
42 originated.
- 43 (2) Clinical trial. – A research study in which one or more human subjects are  
44 prospectively assigned to one or more interventions using adult stem cells  
45 administered under United States Food and Drug Administration protocols for  
46 Investigational New Drugs or Investigational Device Exemptions.
- 47 (3) Investigational adult stem cell treatment. – Adult stem cell treatment that  
48 meets all of the following criteria:
- 49 a. Is under investigation in a clinical trial and being administered to  
50 human participants in that trial.

- 1                    b. Has not yet been approved for general use by the United States Food  
2                    and Drug Administration.
- 3                    (4) Eligible patient. – An individual who meets all of the following criteria:  
4                    a. Has a severe chronic disease or terminal illness, attested to by a  
5                    treating physician.  
6                    b. Has, in consultation with a treating physician, considered all other  
7                    treatment options currently approved by the United States Food and  
8                    Drug Administration.  
9                    c. Has received a recommendation from the treating physician for use of  
10                    an investigational adult stem cell treatment for the severe chronic  
11                    disease or terminal illness.  
12                    d. Has given informed consent in writing to use of the investigational  
13                    adult stem cell treatment or, if the individual is a minor or is otherwise  
14                    incapable of providing informed consent, the parent or legal guardian  
15                    has given informed consent in writing to use of the investigational  
16                    adult stem cell treatment.  
17                    e. Has documentation from the treating physician that the individual  
18                    meets all of the criteria for this definition. This documentation shall  
19                    include an attestation from the treating physician that the treating  
20                    physician was consulted in the creation of the written, informed  
21                    consent required under this Part.
- 22                    (5) Severe chronic disease. – A condition, injury, or illness that meets all of the  
23                    following criteria:  
24                    a. May be treated.  
25                    b. Is never cured or eliminated.  
26                    c. Entails significant functional impairment or severe pain.
- 27                    (6) Terminal illness. – As defined in G.S. 90-325.1(3).
- 28                    (7) Written, informed consent. – A written document that is signed by an eligible  
29                    patient; or if the patient is a minor, by a parent or legal guardian; or if the  
30                    patient is incapacitated, by a designated health care agent pursuant to a health  
31                    care power of attorney, that at a minimum includes all of the following:  
32                    a. An explanation of the currently approved products and treatments for  
33                    the eligible patient's severe chronic disease or terminal illness.  
34                    b. An attestation that the eligible patient concurs with the treating  
35                    physician in believing that all currently approved treatments are  
36                    unlikely to alleviate the significant impairment or severe pain  
37                    associated with a severe chronic disease or unlikely to prolong the life  
38                    of an eligible patient with a terminal illness.  
39                    c. Clear identification of the specific investigational adult stem cell  
40                    treatment proposed for treatment of the eligible patient's severe  
41                    chronic disease or terminal illness.  
42                    d. A description of the potentially best and worst outcomes resulting  
43                    from use of the investigational adult stem cell treatment to treat the  
44                    eligible patient's severe chronic disease or terminal illness, along with  
45                    a realistic description of the most likely outcome. The description shall  
46                    be based on the treating physician's knowledge of the proposed  
47                    treatment in conjunction with an awareness of the eligible patient's  
48                    severe chronic disease or terminal illness and shall include a statement  
49                    acknowledging that new, unanticipated, different, or worse symptoms  
50                    might result from, and that death could be hastened by, the proposed  
51                    treatment.

- 1           e.     A statement that eligibility for hospice care may be withdrawn if the  
2                   eligible patient begins treatment of the terminal illness with an  
3                   investigational adult stem cell treatment and that hospice care may be  
4                   reinstated if such treatment ends and the eligible patient meets hospice  
5                   eligibility requirements.
- 6           f.     A statement that the eligible patient's health benefit plan or third-party  
7                   administrator and provider are not obligated to pay for any care or  
8                   treatments consequent to the use of the investigational adult stem cell  
9                   treatment, unless specifically required to do so by law or contract.
- 10          g.     A statement that the eligible patient understands that he or she is liable  
11                   for all expenses consequent to the investigational adult stem cell  
12                   treatment and that this liability extends to the eligible patient's estate,  
13                   unless a contract between the patient and provider of the  
14                   investigational stem cell treatment states otherwise.
- 15          h.     A statement that the eligible patient or, for an eligible patient who is a  
16                   minor or lacks capacity to provide informed consent, that the parent or  
17                   legal guardian consents to the use of the investigational adult stem cell  
18                   treatment for treatment of the severe chronic disease or terminal  
19                   condition.

20     **"§ 90-325.12. Authorized treatments.**

21         (a)     An eligible patient is authorized to access and use an investigational adult stem cell  
22     treatment under this Part, if the investigational adult stem cell treatment meets all of the following  
23     requirements:

- 24           (1)     Is administered directly by a physician certified by an institutional review  
25                   board that meets the requirements of G.S. 90-325.13.
- 26           (2)     Is overseen by an institutional review board that meets the requirements of  
27                   G.S. 90-325.13.
- 28           (3)     Is provided at an accredited medical school located in this State, an affiliated  
29                   facility of an accredited medical school located in this State, or any other  
30                   facility approved by the institutional review board overseeing the treatment.

31         (b)     A physician administering an investigational adult stem cell treatment under this Part  
32     shall comply with all applicable rules of the North Carolina Medical Board.

33         (c)     This Part does not affect or authorize a person to violate any applicable laws  
34     regulating the possession, use, or transfer of human organs, fetal tissue, fetal stem cells, adult  
35     stem cells, or embryonic stem cells or their derivatives.

36     **"§ 90-325.13. Institutional review boards; annual report; rules.**

37         (a)     An institutional review board that oversees investigational adult stem cell treatments  
38     administered under this Part is required to be affiliated with an accredited medical school located  
39     in this State, or an affiliated facility of an accredited medical school located in this State. An  
40     institutional review board that meets the requirements of this subsection may certify physicians  
41     to provide investigational adult stem cell treatment under this Part.

42         (b)     An institutional review board overseeing an investigational adult stem cell treatment  
43     under this Part shall keep a record on each person to whom a physician administers the treatment  
44     and document in the record the provision of each treatment and the effects of the treatment on  
45     the person throughout the period the treatment is administered to the person.

46         (c)     Each institutional review board overseeing an investigational adult stem cell  
47     treatment under this Part shall submit an annual report to the North Carolina Medical Board on  
48     the review board's findings based on records kept under subsection (b) of this section. The report  
49     shall not include any patient-identifying information and must be made available to the public in  
50     both written and electronic form.

1       (d)     The North Carolina Medical Board may adopt rules concerning the role and function  
2 of institutional review boards under this Part.

3 **"§ 90-325.14. Prohibited purchase and sale of adult stem cells for certain investigational**  
4 **treatments.**

5       (a)     Except as allowed under subsection (c) and subsection (d) of this section, it is  
6 unlawful to knowingly offer to buy, offer to sell, acquire, receive, sell, or otherwise transfer any  
7 adult stem cells for valuable consideration for use in an investigational adult stem cell treatment.

8       (b)     Subsection (a) of this section does not prohibit the following forms of valuable  
9 consideration for investigational adult stem cell treatment:

10           (1)   A fee paid to a health care provider for services rendered in the usual course  
11 of medical practice or a fee paid for hospital or other clinical services.

12           (2)   Reimbursement of legal or medical expenses incurred for the benefit of the  
13 ultimate receiver of the investigational adult stem cell treatment.

14           (3)   Reimbursement of expenses for travel, housing, and lost wages incurred by  
15 the donor of adult stem cells in connection with the donation of the adult stem  
16 cells.

17       (c)     It is an exception to the application of this section that the actor engaged in conduct  
18 authorized under G.S. 130A-412.31.

19       (d)     It is an exception to the application of this section that the actor is a health care  
20 provider, medical researcher, or biosciences professional who is either (i) engaged in research,  
21 clinical trials, or investigational adult stem cell treatment that is being overseen and has been  
22 approved by an institutional review board that meets the requirements of G.S. 90-325.13 or (ii)  
23 otherwise engaged in legal research, clinical trials, or investigational adult stem cell treatment.

24       (e)     A violation of this section is a Class A1 misdemeanor.

25 **"§ 90-325.15. Sanctions against physicians prohibited.**

26       (a)     A licensing board shall not revoke, fail to renew, suspend, or take any other  
27 disciplinary action against a physician licensed under this Chapter, based solely on the  
28 physician's recommendation that an eligible patient have access to an investigational adult stem  
29 cell treatment, or the physician's administration of an investigational adult stem cell treatment to  
30 the eligible patient, provided that the recommendation made or the care provided is consistent  
31 with the applicable standard of care and the requirements of this Part.

32       (b)     An entity responsible for Medicare certification shall not take action against a  
33 physician's Medicare certification based solely on the physician's recommendation that a patient  
34 have access to an investigational adult stem cell treatment, or the physician's administration of  
35 an investigational adult stem cell treatment to the eligible patient, provided that the  
36 recommendation made or the care provided meets the applicable standard of care and the  
37 requirements of this Part.

38 **"§ 90-325.16. Prohibited conduct by government officials.**

39       No official, employee, or agent of this State or any of its political subdivisions shall interfere  
40 with or attempt to interfere with an eligible patient's access to an investigational adult stem cell  
41 treatment authorized under this Part. Counseling, advice, or a recommendation consistent with  
42 medical standards of care from a licensed health care provider does not constitute a violation of  
43 this section.

44 **"§ 90-325.17. Insurance of clinical trials.**

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

47       **SECTION 2.** This act becomes effective December 1, 2019, and applies to acts  
48 committed on or after that date.