

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2019

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HOUSE BILL 934
Committee Substitute Favorable 4/30/19
PROPOSED SENATE COMMITTEE SUBSTITUTE H934-PCS10661-BC-46

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



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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.