

The House Committee on Health offers the following substitute to HB 1275:

A BILL TO BE ENTITLED
AN ACT

1 To amend Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated,
2 relating to medical practice, so as to ensure that human stem cell therapies are used to
3 advance medical treatments and improve patient outcomes in an ethical manner that does not
4 involve human stem cells derived from aborted fetuses; to provide for definitions; to provide
5 for the designation of a physician assistant or nurse practitioner; to provide for certain
6 requirements and patient protections; to provide for notice; to provide for consent; to provide
7 for certain exceptions; to provide for the use of Georgia facilities; to provide for related
8 matters; to provide for legislative findings; to repeal conflicting laws; and for other purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 **SECTION 1.**

11 The General Assembly finds that:

- 12 (1) Significant potential of human stem cell therapies in advancing medical treatments and
13 improving patient outcomes exists;
- 14 (2) Protections need to be established to ensure that such therapies are provided using
15 umbilical cord human stem cells obtained in an ethical manner that does not involve human
16 stem cells derived from aborted fetuses;

17 (3) Medical innovation should be fostered while upholding ethical standards that respect
18 the sanctity of life; and

19 (4) By encouraging the use of human stem cell sources such as adult human stem cells;
20 umbilical cord Wharton's jelly mesenchymal human stem cells; and other ethically obtained
21 human cells, tissues, or cellular or tissue based products, the state will advance regenerative
22 medicine in a manner consistent with the values of this state.

23 **SECTION 2.**

24 Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to
25 medical practice, is amended by adding a new Code section to read as follows:

26 "43-34-49.

27 (a) As used in this Code section, the term:

28 (1) 'FDA' means the United States Food and Drug Administration.

29 (2) 'Human cells, tissues, or cellular or tissue based products' means articles containing
30 or consisting of human cells or tissues that are intended for implantation, transplantation,
31 infusion, or transfer into a human recipient. Such term does not include:

32 (A) Vascularized human organs for transplantation;

33 (B) Whole blood or blood components or blood derivative products;

34 (C) Secreted or extracted human products, such as milk, collagen, and cell factors,
35 other than semen; or

36 (D) Wharton's jelly extracted from donated umbilical cords.

37 (3) 'Human stem cell therapy' means a treatment involving the use of afterbirth placental
38 perinatal human stem cells, or human cells, tissues, or cellular or tissue based products,
39 which complies with the regulatory requirements provided in this Code section. Such
40 term shall not include treatment or research using human cells or tissues that were
41 derived from an aborted fetus or embryo.

42 (4) 'Minimally manipulated' means:

43 (A) For structural tissue, processing that does not alter the original relevant
44 characteristics of such tissue relating to the tissue's utility for reconstruction, repair, or
45 replacement; and

46 (B) For cells or nonstructural tissues, processing that does not alter the relevant
47 biological characteristics of such cells or tissues.

48 (5) 'Nurse practitioner' means a registered professional nurse licensed pursuant to
49 Article 1 of Chapter 26 of this title and authorized by the Georgia Board of Nursing to
50 engage in advanced practice registered nursing as a nurse practitioner.

51 (6) 'Physician' means a physician licensed under this article acting in the course and
52 scope of his or her employment.

53 (7) 'Physician assistant' means a person licensed as a physician assistant pursuant to
54 Article 4 of this chapter, the 'Physician Assistant Act.'

55 (8) 'Umbilical cord Wharton's jelly mesenchymal human stem cells' or 'Wharton's jelly'
56 means highly potent, multipotent human stem cells derived from gelatinous connective
57 tissue surrounding the umbilical cord vessels.

58 (b) A physician or, following a lawful designation from such physician, a physician
59 assistant or nurse practitioner, may perform human stem cell therapy that is not approved
60 by the FDA if such therapy is used for treatment or procedures that are within the scope of
61 practice of the physician, physician assistant, or nurse practitioner, so long as the patient
62 is advised and signs a consent form.

63 (c) To ensure that the retrieval, manufacture, storage, and use of human stem cells used
64 for therapies conducted under this Code section meet the highest standards, any human
65 stem cells used must fall under one of the following categories:

66 (1) Be retrieved, manufactured, and stored in a facility that is located in Georgia and
67 registered with the FDA; or

68 (2) Be retrieved, manufactured, and stored in a facility located in Georgia that is certified
69 and accredited by one of the following entities:

- 70 (A) National Marrow Donor Program;
71 (B) World Marrow Donor Association;
72 (C) Association for the Advancement of Blood and Biotherapies;
73 (D) American Association of Tissue Banks; or
74 (E) Such other entity as the Department of Public Health may determine appropriate.
- 75 (d) A physician or his or her designee performing human stem cell therapy shall not obtain
76 human stem cells for therapies from a facility engaging in the retrieval, manufacture, or
77 storage of human stem cells intended for human use under this Code section unless the
78 facility maintains a valid certification or accreditation as required by subsection (c) of this
79 Code section.
- 80 (e) The facility described in this Code section shall notify the physician within 30 days
81 after any change in certification or accreditation status, including renewal, suspension,
82 revocation, or expiration, occurs.
- 83 (f) In the performance of any procedure using or purporting to use human stem cells or
84 products containing human stem cells, the physician or his or her designee shall use human
85 stem cell therapy products obtained from facilities that adhere to the applicable current
86 good manufacturing practices for the collection, removal, processing, implantation, and
87 transfer of human stem cells, or products containing human stem cells, pursuant to the
88 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301, et seq.; 52 Stat. 1040 et
89 seq.; and 21 C.F.R. Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based
90 Products.
- 91 (g) A physician or his or her designee who conducts human stem cell therapy pursuant to
92 this Code section shall include the following in any form of advertisement:
- 93 'THIS NOTICE MUST BE PROVIDED TO YOU UNDER GEORGIA LAW. This
94 physician or his or her designee performs one or more human stem cell therapies that
95 have not yet been approved by the FDA. You are encouraged to consult with your
96 primary care provider before undergoing any human stem cell therapy.'

- 97 (h) The notice required under subsection (g) of this Code section must be clearly legible
98 and in a type size no smaller than the largest type size used in the advertisement of the
99 human stem cell therapy services being offered.
- 100 (i) A physician or his or her designee who conducts human stem cell therapy pursuant to
101 this Code section shall obtain a signed consent form from the patient before performing
102 such human stem cell therapy.
- 103 (j) The consent form shall be signed by the patient or if the patient is not legally
104 competent, the patient's representative, and shall state all of the following in a language the
105 patient or his or her representative may reasonably be expected to understand:
- 106 (1) The nature and character of the proposed treatment;
107 (2) The fact that the proposed human stem cell therapy has not yet been approved by the
108 FDA if it has not been approved at such time; and
109 (3) The anticipated results of the proposed treatment.
- 110 (k) This Code section does not apply to the following:
- 111 (1) A physician who has obtained approval for an investigational new drug or device
112 from the FDA for the use of human cells, tissues, or cellular or tissue based products and
113 is operating under such approval; or
- 114 (2) A physician or his or her designee who performs human stem cell therapy under an
115 employment or other contract on behalf of an institution certified or accredited by any of
116 the following:
- 117 (A) The Foundation for the Accreditation of Cellular Therapy;
118 (B) The Blood and Marrow Transplant Clinical Trials Network;
119 (C) The Association for the Advancement of Blood and Biotherapies; or
120 (D) An entity with expertise in human stem cell therapy as determined by the
121 Department of Public Health.
- 122 (l) A violation of this Code section may subject the physician or his or her designee to
123 disciplinary action by the licensee's respective professional board."

124

SECTION 3.

125 All laws and parts of laws in conflict with this Act are repealed.