

1 SB16
2 187540-2
3 By Senator Allen
4 RFD: Health and Human Services
5 First Read: 09-JAN-18
6 PFD: 10/05/2017

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8 SYNOPSIS: Under existing law, there is no provision to
9 allow for the administering of certain
10 investigational stem cell treatments to patients
11 with severe chronic diseases or terminal illnesses.

12 This bill would provide for the availability
13 of stem cell treatment options for certain patients
14 with terminal illnesses or severe chronic illnesses
15 under certain conditions.

16 Amendment 621 of the Constitution of Alabama
17 of 1901, now appearing as Section 111.05 of the
18 Official Recompilation of the Constitution of
19 Alabama of 1901, as amended, prohibits a general
20 law whose purpose or effect would be to require a
21 new or increased expenditure of local funds from
22 becoming effective with regard to a local
23 governmental entity without enactment by a 2/3 vote
24 unless: it comes within one of a number of
25 specified exceptions; it is approved by the
26 affected entity; or the Legislature appropriates

1 funds, or provides a local source of revenue, to
2 the entity for the purpose.

3 The purpose or effect of this bill would be
4 to require a new or increased expenditure of local
5 funds within the meaning of the amendment. However,
6 the bill does not require approval of a local
7 governmental entity or enactment by a 2/3 vote to
8 become effective because it comes within one of the
9 specified exceptions contained in the amendment.

10
11 A BILL
12 TO BE ENTITLED
13 AN ACT
14

15 Relating to health; to provide for the availability
16 of certain investigational stem cell treatments; to provide
17 for informed consent; to specify treatment requirements; to
18 provide for oversight by an institutional review board; to
19 provide certain record keeping requirements; to provide
20 criminal penalties for the purchase or sale of adult stem
21 cells for certain investigational treatments; and in
22 connection therewith would have as its purpose or effect the
23 requirement of a new or increased expenditure of local funds
24 within the meaning of Amendment 621 of the Constitution of
25 Alabama of 1901, now appearing as Section 111.05 of the
26 Official Recompilation of the Constitution of Alabama of 1901,
27 as amended.

1 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

2 Section 1. This act shall be known and may be cited
3 as the Steve Bowman Act.

4 Section 2. For the purposes of this act, the
5 following terms shall have the following meanings:

6 (1) INVESTIGATIONAL STEM CELL TREATMENT. An adult
7 stem cell treatment that satisfies both of the following:

8 a. Is under investigation in a clinical trial and
9 being administered to human participants in that trial.

10 b. Has not yet been approved for general use by the
11 United States Food and Drug Administration.

12 (2) SEVERE CHRONIC DISEASE. A condition, injury, or
13 illness that satisfies all of the following:

14 a. May be treated.

15 b. Is never cured or eliminated.

16 c. Entails significant functional treatment or
17 severe pain.

18 (3) TERMINAL ILLNESS. An advanced stage of a disease
19 with an unfavorable prognosis that, without life-sustaining
20 procedures, will soon result in death or a state of permanent
21 unconsciousness from which recovery is unlikely.

22 Section 3. In addition to any authority granted
23 under Chapter 5D of Title 22, Code of Alabama 1975, a patient
24 is eligible to access and use an investigational stem cell
25 treatment under this act if both of the following are
26 satisfied:

1 (1) The patient has a severe chronic disease or
2 terminal illness that is attested to by the patient's treating
3 physician.

4 (2) The patient's physician does both of the
5 following:

6 a. In consultation with the patient, has considered
7 all other treatment options currently approved by the United
8 States Food and Drug Administration and determined that those
9 treatment options are unavailable or unlikely to alleviate the
10 significant impairment or severe pain associated with the
11 severe chronic disease or terminal illness.

12 b. Has recommended or prescribed in writing that the
13 patient use a specific class of investigational stem cell
14 treatment.

15 Section 4. (a) Before receiving an investigational
16 stem cell treatment, an eligible patient must sign a written
17 informed consent.

18 (b) If the patient is a minor or lacks the mental
19 capacity to provide informed consent, a parent, guardian, or
20 conservator may provide informed consent on the patient's
21 behalf.

22 (c) The Alabama Department of Public Health, by
23 rule, may adopt a form for the informed consent under this
24 section.

25 Section 5. (a) Treatment under this act must be
26 administered directly by a physician certified under
27 subsection (c) and overseen by an institutional review board

1 described in subsection (d). The treatment must be provided at
2 a hospital licensed under the laws of this state, an
3 ambulatory surgical center licensed under the laws of this
4 state, or a hospital associated with an accredited medical
5 school and teaching facility.

6 (b) A physician administering an investigational
7 stem cell treatment under this act shall comply with all
8 applicable rules of the Alabama Board of Medical Examiners.

9 (c) All treatment shall be overseen by an
10 institutional review board described in subsection (d). The
11 board may certify a physician to provide an investigational
12 stem cell treatment under this act.

13 (d) An institutional review board that oversees
14 investigational stem cell treatments administered under this
15 act must be affiliated with a licensed hospital or an
16 accredited medical school and teaching facility.

17 Section 6. (a) An institutional review board
18 overseeing an investigational stem cell treatment under this
19 act shall keep a record on each person to whom a physician
20 administers the treatment and document in the record the
21 provision of each treatment and the effects of the treatment
22 on the person throughout the period the treatment is
23 administered to the person.

24 (b) Each institutional review board overseeing an
25 investigational stem cell treatment under this act shall
26 submit an annual report to the Alabama Board of Medical
27 Examiners on the review board's findings based on records kept

1 under subsection (a). The report may not include any patient
2 identifying information and must be made available to the
3 public in both written and electronic form.

4 Section 7. (a) This act does not affect or authorize
5 a person to violate any state or federal law regulating the
6 possession, use, or transfer of fetal tissue, fetal stem
7 cells, adult stem cells, or human organs.

8 (b) The Alabama Board of Medical Examiners may not
9 revoke, fail to renew, suspend, or take any action against a
10 physician's license in this state based solely on the
11 physician's recommendations to an eligible patient regarding
12 access to or use of an investigational stem cell treatment,
13 provided that the care provided or recommendations made to the
14 patient meet the standard of care and the requirements of this
15 act.

16 Section 8. The Alabama Department of Public Health
17 may adopt rules for the implementation and administration of
18 this act.

19 Section 9. (a) For the purposes of this section, the
20 following terms shall have the following meanings:

21 (1) ADULT STEM CELL. An undifferentiated cell that
22 satisfies both of the following:

23 a. Is found in differentiated tissue.

24 b. Is able to renew itself and differentiate to
25 yield all or nearly all of the specialized cell types of the
26 tissue from which the cell originated.

1 (2) INVESTIGATIONAL STEM CELL TREATMENT. An adult
2 stem cell treatment that satisfies both of the following:

3 a. Is under investigation in a clinical trial and
4 being administered to human participants in that trial.

5 b. Has not yet been approved for general use by the
6 United States Food and Drug Administration.

7 (b) It shall be unlawful for a person to knowingly
8 offer to buy, offer to sell, acquire, receive, sell, or
9 otherwise transfer any adult stem cells for valuable
10 consideration for use in an investigational stem cell
11 treatment, except under the following circumstances:

12 (1) A fee is paid to a physician or to other medical
13 personnel for services rendered in the usual course of medical
14 practice or a fee paid for hospital or other clinical
15 services.

16 (2) Reimbursement of legal or medical expenses
17 incurred for the benefit of the ultimate receiver of the
18 investigational stem cell treatment is made.

19 (3) Reimbursement of expenses of travel, housing,
20 and lost wages incurred by the donor of adult stem cells is
21 made in connection with the donation of the adult stem cells.

22 (c) A violation of subsection (b) is a Class A
23 misdemeanor.

24 Section 10. Although this bill would have as its
25 purpose or effect the requirement of a new or increased
26 expenditure of local funds, the bill is excluded from further
27 requirements and application under Amendment 621, now

1 appearing as Section 111.05 of the Official ReCompilation of
2 the Constitution of Alabama of 1901, as amended, because the
3 bill defines a new crime or amends the definition of an
4 existing crime.

5 Section 11. This act shall become effective on the
6 first day of the third month following its passage and
7 approval by the Governor, or its otherwise becoming law.