

By: Zedler

H.B. No. 27

A BILL TO BE ENTITLED

AN ACT

relating to the research, collection, and use of adult stem cells.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle H, Title 3, Education Code, is amended by adding Chapter 156 to read as follows:

CHAPTER 156. ADULT STEM CELL RESEARCH PROGRAM

Sec. 156.001. DEFINITIONS. In this chapter:

(1) "Adult stem cell" means an undifferentiated cell that is:

(A) found in differentiated tissue; and

(B) able to renew itself and differentiate to yield all or nearly all of the specialized cell types of the tissue from which the cell originated.

(2) "Biorepository" means a facility for the storage of stem cells for future use.

(3) "Consortium" means the Texas Adult Stem Cell Research Consortium.

(4) "Current good manufacturing practice" has the meaning assigned by the United States Food and Drug Administration.

(5) "Institution of higher education" means an institution of higher education as defined by Section 61.003 or a private college or university that receives state funds.

(6) "Program" means the adult stem cell research program established under this chapter.

1 (7) "Research board" means the Texas Adult Stem Cell
2 Research Board.

3 Sec. 156.002. COMPOSITION OF RESEARCH BOARD. (a) The Texas
4 Adult Stem Cell Research Board is composed of seven members
5 appointed as follows:

6 (1) one member of the Texas Higher Education
7 Coordinating Board, appointed by the governor;

8 (2) two members who are interested persons, appointed
9 by the governor;

10 (3) two members who are interested persons, appointed
11 by the lieutenant governor; and

12 (4) two members who are interested persons, appointed
13 by the speaker of the house of representatives.

14 (b) The governor shall designate as the presiding officer of
15 the research board a board member appointed under Subsection (a)(1)
16 or (2). The presiding officer serves in that capacity at the will
17 of the governor.

18 (c) The governor shall designate at least one member
19 appointed under Subsection (a)(1) or (2) as a stem cell expert, and
20 the speaker of the house of representatives shall designate at
21 least one member appointed under Subsection (a)(4) as a stem cell
22 advocate.

23 (d) The members of the research board serve staggered
24 six-year terms. If a vacancy occurs on the board, the appropriate
25 appointing authority shall appoint, in the same manner as the
26 original appointment, another person to serve for the remainder of
27 the unexpired term.

1 Sec. 156.003. CONFLICT OF INTEREST. (a) In this section,
2 "Texas trade association" means a cooperative and voluntarily
3 joined association of business or professional competitors in this
4 state designed to assist its members and its industry or profession
5 in dealing with mutual business or professional problems and in
6 promoting their common interest.

7 (b) A person may not be a member of the research board if:

8 (1) the person is an officer, employee, or paid
9 consultant of a Texas trade association in the field of medicine; or

10 (2) the person's spouse is an officer, manager, or paid
11 consultant of a Texas trade association in the field of medicine.

12 (c) A person may not be a member of the research board if the
13 person is required to register as a lobbyist under Chapter 305,
14 Government Code, because of the person's activities for
15 compensation on behalf of a profession related to the operation of
16 the research board.

17 Sec. 156.004. COMPOSITION OF CONSORTIUM. (a) The research
18 board shall establish the Texas Adult Stem Cell Research
19 Consortium.

20 (b) The consortium is composed of participating
21 institutions of higher education and businesses that:

22 (1) accept public money for adult stem cell research;
23 or

24 (2) otherwise agree to participate in the consortium.

25 Sec. 156.005. ADMINISTRATION OF PROGRAM; GUIDELINES AND
26 PROCEDURES. (a) The research board shall administer the program
27 to:

1 (1) from state money appropriated to the research
2 board, make grants, investments, or loans to consortium members
3 for:

4 (A) adult stem cell research activities and
5 projects, including:

6 (i) pre-clinical trials and studies;

7 (ii) treatment protocol development;

8 (iii) state or federal regulatory
9 submissions, including investigational new drug applications
10 submitted to and approvals from the United States Food and Drug
11 Administration;

12 (iv) clinical trials conducted in
13 coordination with contract research organizations and data safety
14 monitoring boards;

15 (v) intellectual property development; and

16 (vi) pathways and processes to
17 commercialization and to address the collection, development,
18 current good manufacturing practice production, biorepository
19 storage, characterization, and use of adult stem cells;

20 (B) the development of facilities to be used
21 solely for adult stem cell research projects, biorepository
22 storage, and current good manufacturing practice for adult stem
23 cell manufacturing and related projects; and

24 (C) the commercialization of products or
25 technology involving adult stem cell research and treatments;

26 (2) support consortium members in all stages of the
27 process of developing safe and effective treatments and cures based

1 on adult stem cell research, beginning with initial laboratory
2 research through current good manufacturing practice and
3 successful clinical trials that are:

4 (A) registered with the United States Food and
5 Drug Administration; and

6 (B) approved by an institutional review board
7 that reviews human subjects research protocols under United States
8 Department of Health and Human Services guidelines;

9 (3) establish appropriate regulatory standards and
10 oversight bodies for:

11 (A) adult stem cell research conducted by
12 consortium members; and

13 (B) the development of facilities for consortium
14 members conducting adult stem cell research, performing
15 biorepository storage, and conforming to current good
16 manufacturing practice; and

17 (4) assist consortium members in applying for grants,
18 investments, or loans under the program.

19 (b) The research board shall develop research priorities,
20 guidelines, and procedures for providing grants, investments, and
21 loans for specific research projects conducted by consortium
22 members. The priorities, guidelines, and procedures must require
23 the grants, investments, and loans to be made on a competitive,
24 peer-review basis.

25 Sec. 156.006. FUNDING. The program may be funded by gifts,
26 grants, investments, and donations described by Section 156.007 and
27 by money appropriated by the state.

1 Sec. 156.007. GIFTS, GRANTS, AND DONATIONS. The consortium
2 shall solicit, and the research board may accept on behalf of the
3 consortium, a gift, grant, investment, or donation made from any
4 public or private source for the purpose of promoting adult stem
5 cell research or commercialization.

6 Sec. 156.008. BIENNIAL REPORT. Not later than September 1
7 of each even-numbered year, the research board shall submit a
8 report of the research board's activities and recommendations to
9 the Texas Higher Education Coordinating Board and to the governor,
10 the lieutenant governor, the speaker of the house of
11 representatives, and the presiding officer of each legislative
12 standing committee or subcommittee with jurisdiction over higher
13 education.

14 SECTION 2. Section 162.001, Health and Safety Code, is
15 amended by adding Subdivision (4) to read as follows:

16 (4) "Adult stem cell" means an undifferentiated cell
17 that is:

18 (A) found in differentiated tissue; and

19 (B) able to renew itself and differentiate to
20 yield all or nearly all of the specialized cell types of the tissue
21 from which the cell originated.

22 SECTION 3. Chapter 162, Health and Safety Code, is amended
23 by adding Section 162.020 to read as follows:

24 Sec. 162.020. ADULT STEM CELL COLLECTION. Blood obtained
25 by a blood bank may be used for the collection of adult stem cells if
26 the donor consents in writing to that use.

27 SECTION 4. Section 241.003, Health and Safety Code, is

1 amended by amending Subdivision (1) and adding Subdivision (1-a) to
2 read as follows:

3 (1) "Adult stem cell" has the meaning assigned by
4 Section 162.001.

5 (1-a) "Advanced practice nurse" means a registered
6 nurse recognized as an advanced practice nurse by the Texas Board of
7 Nursing.

8 SECTION 5. Subchapter A, Chapter 241, Health and Safety
9 Code, is amended by adding Section 241.010 to read as follows:

10 Sec. 241.010. USE OF ADULT STEM CELLS. A hospital may use
11 adult stem cells in a procedure if:

12 (1) the stem cells meet current good manufacturing
13 practice standards of quality and safety set by the United States
14 Food and Drug Administration;

15 (2) a physician providing services at the hospital
16 determines that the use of adult stem cells in the procedure is
17 appropriate;

18 (3) applicable state and federal regulations are
19 followed; and

20 (4) the patient consents in writing to the use.

21 SECTION 6. (a) As soon as practicable after the effective
22 date of this Act, the governor, lieutenant governor, and speaker of
23 the house of representatives shall appoint members to the Texas
24 Adult Stem Cell Research Board, as required by Section 156.002,
25 Education Code, as added by this Act, as follows:

26 (1) the governor shall appoint one member to a term
27 expiring February 1, 2015, one member to a term expiring February 1,

1 2017, and one member to a term expiring February 1, 2019;

2 (2) the lieutenant governor shall appoint one member
3 to a term expiring February 1, 2017, and one member to a term
4 expiring February 1, 2019; and

5 (3) the speaker of the house of representatives shall
6 appoint one member to a term expiring February 1, 2017, and one
7 member to a term expiring February 1, 2019.

8 (b) Not later than September 1, 2014, the Texas Adult Stem
9 Cell Research Board shall submit the first report of the board's
10 activities and recommendations as required by Chapter 156,
11 Education Code, as added by this Act.

12 (c) Notwithstanding Section 156.005(a)(1), Education Code,
13 as added by this Act, the Texas Adult Stem Cell Research Board may
14 not make a grant, investment, or loan under that section until
15 September 1, 2015.

16 (d) Notwithstanding Section 156.006, Education Code, as
17 added by this Act, the Texas Adult Stem Cell Research Board may not
18 receive a legislative appropriation for the 2013-2014 or 2014-2015
19 state fiscal biennium.

20 (e) A gift, grant, investment, or donation received by the
21 Texas Adult Stem Cell Research Board before September 1, 2015, may
22 be spent only for administrative expenditures, board meetings, and
23 planning expenses.

24 SECTION 7. This Act takes effect on the 91st day after the
25 last day of the legislative session.