

Bill No. CS for SB 2496

Barcode 102970

	CHAMBER ACTION	
<u>Senate</u>		<u>House</u>

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The Committee on Commerce (Saunders) recommended the following amendment:

Senate Amendment (with title amendment)

Delete everything after the enacting clause

and insert:

Section 1. Section 381.99, Florida Statutes, is created to read:

381.99 Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act.--

(1) SHORT TITLE.--This section may be cited as the "Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act."

(2) DEFINITIONS.--As used in this section, the term:

(a) "Adult stem cell" means a cell found within differentiated tissue or an organ that can renew itself and give rise to the major cell types of the tissue or organ. This includes cells from the fetal to adult stages of development, including bone marrow.

(b) "Amniotic stem cell" means a stem cell extracted

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1 from human amniotic fluid.

2 (c) "Cord blood stem cell" means a stem cell extracted
3 from a human umbilical cord.

4 (d) "Placental stem cell" means a stem cell extracted
5 from a human placenta.

6 (e) "Embryonic stem cell" means a stem cell obtained
7 from the undifferentiated inner mass of an early stage embryo.

8 (f) "Stem cell" means a cell that can renew itself and
9 retains the potential to generate some or all other cell
10 types.

11 (3) STEM CELL RESEARCH AND ETHICS ADVISORY
12 COUNCIL.--There is created the Stem Cell Research and Ethics
13 Advisory Council within the Department of Health.

14 (a)1. The advisory council shall consist of the
15 Secretary of Health or his or her designee, who shall act as
16 chair, and six additional members, who shall be appointed as
17 follows:

18 a. Two persons appointed by the Governor, one of whom
19 shall be an academic researcher in the field of stem cell
20 research and one of whom shall have a background in bioethics.

21 b. One person appointed by the President of the
22 Senate, who shall have a background in private-sector stem
23 cell funding and development or public-sector biomedical
24 research and funding.

25 c. One person appointed by the Speaker of the House of
26 Representatives, who shall have a background in private-sector
27 stem cell funding and development or public-sector biomedical
28 research and funding.

29 d. One person appointed by the President of the
30 Senate, who shall have a background and experience in either
31 public-sector or private-sector stem cell research and

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1 development.

2 e. One person appointed by the Speaker of the House of
3 Representatives, who shall be an executive of a biotech
4 company, or his or her designee.

5 2. Each member shall demonstrate knowledge and
6 understanding of the ethical, medical, and scientific
7 implications of stem cell research. Each member shall serve a
8 term of 2 years commencing on July 15, 2007. No member shall
9 serve for more than two consecutive 2-year terms; however, for
10 the purpose of providing staggered terms, of the initial
11 appointments, three members shall be appointed to a 1-year
12 term and three members shall be appointed to a 2-year term.
13 Any vacancy on the advisory council shall be filled in the
14 same manner as the original appointment. All initial
15 appointments shall be made by July 15, 2007. The first meeting
16 shall take place no later than August 15, 2007. All meetings
17 are subject to the call of the chair. Members shall meet at
18 least twice a year or as often as necessary to discharge their
19 duties but shall have no more than four meetings during any
20 12-month period. Members shall serve without compensation but
21 may be reimbursed for per diem and travel expenses in
22 accordance with s. 112.061, subject to a specific
23 appropriation in the General Appropriations Act.

24 (b) The advisory council shall:

25 1. Develop a donated funds program for recommendation
26 to the Secretary of Health to encourage the development of
27 funds other than state appropriations for human adult,
28 amniotic, cord blood, and placental stem cell research in the
29 state.

30 2. Examine and identify specific ways to improve and
31 promote for-profit and not-for-profit human adult, amniotic,

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1 cord blood, and placental stem cell and related research in
 2 the state, including, but not limited to, identifying both
 3 public and private funding sources for such research,
 4 maintaining existing human adult, amniotic, cord blood, and
 5 placental stem cell-related businesses, recruiting new human
 6 adult, amniotic, cord blood, and placental stem cell-related
 7 businesses to the state, and recruiting scientists and
 8 researchers in such fields to the state and state
 9 universities.

10 3. Develop a biomedical research grant program for
 11 recommendation to the Secretary of Health that shall provide
 12 grants-in-aid to eligible state institutions for the
 13 advancement of human adult, amniotic, cord blood, and
 14 placental stem cell research.

15 4. Develop, no later than September 15, 2007, an
 16 application for grants-in-aid under this section for
 17 recommendation to the Secretary of Health for the purpose of
 18 conducting human adult, amniotic, cord blood, and placental
 19 stem cell research.

20 5. Review applications from eligible institutions for
 21 grants-in-aid on and after September 15, 2007, and provide to
 22 the Secretary of Health recommendations for grant awards.

23 6. Review the stem cell research conducted by eligible
 24 institutions that receive such grants-in-aid.

25 7. Review all stem cell research that is funded or
 26 supported in any manner through the Biomedical Research Trust
 27 Fund to ensure the adherence to ethical and safety guidelines
 28 and procedures as set forth by federal ethical standards
 29 established by the United States Department of Health and
 30 Human Services.

31 (c) The advisory council shall submit an annual

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1 progress report on the status of biomedical research in the
2 state to the Florida Center for Universal Research to
3 Eradicate Disease and to the Governor, the Secretary of
4 Health, the President of the Senate, and the Speaker of the
5 House of Representatives by June 30. The report must include:

6 1. The amount of grants-in-aid awarded to eligible
7 institutions from the Biomedical Research Trust Fund.

8 2. The names of the recipients of such grants-in-aid.

9 3. The current status and progress of stem cell
10 research in the state.

11 4. A list of research projects supported by
12 grants-in-aid awarded under the program.

13 5. A list of publications in peer-reviewed journals
14 involving research supported by grants-in-aid awarded under
15 the program.

16 6. The total amount of biomedical research funding
17 currently flowing into the state.

18 7. New grants for biomedical research that were funded
19 based on research supported by grants-in-aid awarded under the
20 program.

21 8. All other materials the advisory council deems
22 advisable to include.

23 (d) Advisory council members shall disclose any
24 conflict of interest or potential conflict of interest to the
25 Secretary of Health.

26 (e) The Department of Health shall provide
27 administrative staff to assist the advisory council in
28 developing the application for the grants-in-aid, reviewing
29 the applications, preparing the written consent form described
30 in paragraph (5)(b), and performing other administrative
31 functions as the advisory council requires.

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1 (4) BIOMEDICAL RESEARCH TRUST FUND AND

2 GRANTS-IN-AID.--

3 (a) The Secretary of Health shall make grants-in-aid
4 from the Biomedical Research Trust Fund in accordance with the
5 provisions of this section, subject to a specific
6 appropriation in the General Appropriations Act.

7 (b) The Department of Health shall require any
8 applicant for a grant-in-aid under this section, for the
9 purpose of conducting stem cell research, to submit a complete
10 description of the applicant's organization, the applicant's
11 plans for stem cell research, the applicant's proposed funding
12 for such research from sources other than the state, and the
13 applicant's proposed arrangements concerning financial
14 benefits to the state as a result of any patent, royalty
15 payment, or similar right resulting from any stem cell
16 research made possible by the awarding of the grant-in-aid.
17 The advisory council shall provide recommendation to the
18 Secretary of Health with respect to awarding such
19 grants-in-aid.

20 (5) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS.--

21 (a) Funds provided under this section may only be used
22 for research involving:

23 1. Human adult stem cells. Funding for research may be
24 given for human adult stem cells derived from postmortem
25 tissues, other than from medically induced abortions. Funds
26 may be used for studies of human adult stem cells obtained
27 from either normal or transformed tissues.

28 2. Amniotic stem cells extracted from human amniotic
29 fluid that are otherwise discarded after birth.

30 3. Cord blood stem cells extracted from a human
31 umbilical cord that are otherwise discarded after birth.

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1 4. Placental stem cells extracted from a human
2 placenta that are otherwise discarded after birth.

3 (b) Adult, amniotic, cord blood, and placental stem
4 cell material may only be donated for research purposes with
5 the informed consent of the donor.

6 (c) No funds shall be used for research with human
7 embryonic stem cells that are derived by a process entailing
8 the donor embryo's death or destruction.

9 (d) Funds provided under this section may only be used
10 for research that is conducted in facilities located in this
11 state.

12 Section 2. Paragraph (h) of subsection (1) of section
13 20.435, Florida Statutes, is amended to read:

14 20.435 Department of Health; trust funds.--

15 (1) The following trust funds are hereby created, to
16 be administered by the Department of Health:

17 (h) Biomedical Research Trust Fund.

18 1. Funds to be credited to the trust fund shall
19 consist of funds deposited pursuant to ss. ~~s.~~ 215.5601,
20 288.955, and 381.99 and any other funds appropriated by the
21 Legislature. Funds shall be used for the purposes of the James
22 and Esther King Biomedical Research Program, ~~and~~ the William
23 G. "Bill" Bankhead, Jr., and David Coley Cancer Research
24 Program, and the Florida Hope Offered through Principled,
25 Ethically Sound Stem Cell Research Act as specified in ss.
26 215.5602, 288.955, ~~and~~ 381.922, and 381.99. The trust fund is
27 exempt from the service charges imposed by s. 215.20.

28 2. Notwithstanding the provisions of s. 216.301 and
29 pursuant to s. 216.351, any balance in the trust fund at the
30 end of any fiscal year shall remain in the trust fund at the
31 end of the year and shall be available for carrying out the

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1 purposes of the trust fund. The department may invest these
2 funds independently through the Chief Financial Officer or may
3 negotiate a trust agreement with the State Board of
4 Administration for the investment management of any balance in
5 the trust fund.

6 3. Notwithstanding s. 216.301 and pursuant to s.
7 216.351, any balance of any appropriation from the Biomedical
8 Research Trust Fund which is not disbursed but which is
9 obligated pursuant to contract or committed to be expended may
10 be carried forward for up to 3 years following the effective
11 date of the original appropriation.

12 4. The trust fund shall, unless terminated sooner, be
13 terminated on July 1, 2008.

14 Section 3. Subsection (1) of section 381.86, Florida
15 Statutes, is amended to read:

16 381.86 Institutional Review Board.--

17 (1) The Institutional Review Board is created within
18 the Department of Health in order to satisfy federal
19 requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50
20 and 56 that an institutional review board review all
21 biomedical and behavioral research on human subjects which is
22 funded or supported in any manner by the department, except
23 that a separate Stem Cell Research and Ethics Advisory Council
24 shall be appointed under s. 381.99.

25 Section 4. (1) The Department of Health shall prepare
26 an educational publication, subject to a specific
27 appropriation in the General Appropriations Act, that includes
28 objective information regarding:

29 (a) The medical processes involved in the collection
30 of umbilical cord blood;

31 (b) The medical risks to the mother and her newborn

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1 child of umbilical cord blood collection;

2 (c) The options available to a mother relating to stem
3 cells that are contained in the umbilical cord blood after the
4 delivery of her newborn, including:

5 1. Discarding the stem cells;

6 2. Donating the stem cells to a public umbilical cord
7 blood bank;

8 3. Storing the stem cells in a family or private
9 umbilical cord blood bank for use by family members; or

10 4. Storing the stem cells for family use through a
11 family or sibling donor banking program that provides free
12 collection, processing, and storage where there is a medical
13 need;

14 (d) The current and potential future medical uses,
15 risks, and benefits of umbilical cord blood collection to a
16 mother, her newborn child, and her biological family;

17 (e) The current and potential future medical uses,
18 risks, and benefits of umbilical cord blood collection to
19 persons who are not biologically related to a mother or her
20 newborn child;

21 (f) Any costs that may be incurred by a pregnant woman
22 who chooses to make an umbilical cord blood donation;

23 (g) Options for ownership and future use of the
24 donated umbilical cord blood; and

25 (h) The average cost of public and private umbilical
26 cord blood banking.

27 (2) The department shall update the publication as
28 necessary.

29 (3) The department shall distribute the publication
30 free of charge to physicians and health care institutions on
31 request and shall make the publication available on its

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1 website in a printable format.

2 (4) The department shall encourage health and maternal
3 care professionals providing health care services to a
4 pregnant woman, when those health care services are directly
5 related to her pregnancy, to provide the pregnant woman with
6 the publication by the end of her second trimester.

7 Section 5. This act shall take effect July 1, 2007.

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10 ===== T I T L E A M E N D M E N T =====

11 And the title is amended as follows:

12 Delete everything before the enacting clause

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14 and insert:

15 A bill to be entitled

16 An act relating to stem cell research; creating
17 s. 381.99, F.S.; providing a short title;
18 providing definitions; creating the Stem Cell
19 Research and Ethics Advisory Council within the
20 Department of Health; providing for membership
21 and terms; providing duties and
22 responsibilities; providing per diem and travel
23 expenses, subject to a specific appropriation;
24 requiring the Secretary of Health to make
25 grants-in-aid from the Biomedical Research
26 Trust Fund for stem cell research subject to a
27 specific appropriation; providing requirements
28 relating to applications for and awards of such
29 grants-in-aid; providing specifications for
30 moneys to be made available from the trust fund
31 for stem cell research grants-in-aid; providing

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1 restrictions and requirements for uses of funds
2 from such grants-in-aid; amending s. 20.435,
3 F.S.; revising provisions relating to funding
4 sources of and use of funds in the Biomedical
5 Research Trust Fund; amending s. 381.86, F.S.;
6 providing an exception to the Institutional
7 Review Board's exclusive authority to review
8 certain biomedical and behavioral research on
9 human subjects to allow for the Stem Cell
10 Research and Ethics Advisory Council's duties
11 and responsibilities with respect to such
12 research; requiring the Department of Health to
13 prepare and distribute, subject to a specific
14 appropriation, a publication regarding the
15 process, options, medical uses, risks, and
16 benefits of umbilical cord blood collection;
17 providing an effective date.

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