

By the Committee on Health Policy; and Senator Haridopolos

587-2376-07

1 A bill to be entitled
 2 An act relating to stem cell research; creating
 3 s. 381.99, F.S.; providing a short title;
 4 providing definitions; creating the Stem Cell
 5 Research Advisory Council and Biomedical Ethics
 6 Advisory Council within the Department of
 7 Health; providing for membership and terms;
 8 providing duties and responsibilities;
 9 requiring the Secretary of Health to make
 10 grants-in-aid from the Biomedical Research
 11 Trust Fund for stem cell research; providing
 12 requirements relating to applications for and
 13 awards of such grants-in-aid; providing
 14 specifications for moneys to be made available
 15 from the trust fund for stem cell research
 16 grants-in-aid; providing restrictions and
 17 requirements for uses of funds from such
 18 grants-in-aid; providing an appropriation;
 19 amending s. 20.435, F.S.; revising references;
 20 amending s. 381.86, F.S.; providing an
 21 exception to the Institutional Review Board for
 22 the Stem Cell Research Advisory Council and
 23 Biomedical Ethics Advisory Council; requiring
 24 the Department of Health to prepare and
 25 distribute a publication regarding the process,
 26 options, medical uses, risks, and benefits of
 27 umbilical cord blood collection; providing an
 28 effective date.
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 30 Be It Enacted by the Legislature of the State of Florida:
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1 Section 1. Section 381.99, Florida Statutes, is
2 created to read:

3 381.99 Florida Hope Offered through Principled,
4 Ethically Sound Stem Cell Research Act.--

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

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

9 (a) "Adult stem cell" means a cell found within
10 differentiated tissue or an organ which can renew itself and
11 give rise to the major cell types of the tissue or organ. This
12 includes cells from the fetal to adult stages of development.

13 (b) "Amniotic stem cell" means a cell extracted from
14 human amniotic fluid or a placenta.

15 (c) "Embryonic stem cell" means a cell obtained from
16 the undifferentiated inner mass of an early stage embryo.

17 (d) "Stem cell" means a cell that retains the
18 potential to generate some or all other cell types.

19 (3) STEM CELL RESEARCH ADVISORY COUNCIL.--There is
20 created the Stem Cell Research Advisory Council within the
21 Department of Health.

22 (a)1. The advisory council shall consist of the
23 Secretary of Health or his or her designee, who shall act as
24 chair, and six additional members, who shall be appointed as
25 follows:

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

29 b. One person appointed by the President of the
30 Senate, who shall have a background in private-sector stem
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1 cell funding and development or public-sector biomedical
2 research and funding.

3 c. One person appointed by the Speaker of the House of
4 Representatives, who shall have a background in private-sector
5 stem cell funding and development or public-sector biomedical
6 research and funding.

7 d. One person appointed by the President of the
8 Senate, who shall have a background and experience in
9 public-sector or private-sector stem cell research and
10 development.

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

14 2. Each member shall be appointed to a term of 2 years
15 commencing on October 1, 2007. A member may not serve for more
16 than two consecutive 2-year terms; however, for the purpose of
17 providing staggered terms, of the initial appointments, three
18 members shall be appointed to 1-year terms and three members
19 shall be appointed to 2-year terms. Any vacancy on the
20 advisory council shall be filled in the same manner as the
21 original appointment. All initial appointments shall be made
22 by October 1, 2007. The first meeting shall take place no
23 later than November 1, 2007. All meetings are subject to the
24 call of the chair. Members shall meet at least twice a year or
25 as often as necessary to discharge their duties but may not
26 hold more than four meetings during any 12-month period.
27 Members shall serve without compensation but are entitled to
28 reimbursement for per diem and travel expenses in accordance
29 with s. 112.061.

30 (b) The advisory council shall:
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1 1. Develop a donated funds program for recommendation
2 to the Secretary of Health to encourage the development of
3 funds other than state appropriations for human adult stem
4 cell research in the state.

5 2. Examine and identify specific ways to improve and
6 promote for-profit and not-for-profit human adult stem cell
7 and related research in the state, including, but not limited
8 to, identifying sources of public and private funding for such
9 research, maintaining existing human adult stem cell-related
10 businesses, recruiting new human adult stem cell-related
11 businesses to the state, and recruiting scientists and
12 researchers in such fields to the state and state
13 universities.

14 3. Develop a biomedical research grant program for
15 recommendation to the Secretary of Health which shall provide
16 grants-in-aid to eligible state institutions for the
17 advancement of human adult stem cell research.

18 4. Develop, no later than December 1, 2007, an
19 application for grants-in-aid under this section for
20 recommendation to the Secretary of Health for the purpose of
21 conducting human adult stem cell research.

22 5. Review applications from eligible institutions for
23 grants-in-aid on and after December 1, 2007, and provide to
24 the Secretary of Health recommendations for grant awards.

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

27 (c) The advisory council shall submit an annual
28 progress report on the status of biomedical research in the
29 state to the Florida Center for Universal Research to
30 Eradicate Disease and to the Governor, the Secretary of
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1 Health, the President of the Senate, and the Speaker of the
2 House of Representatives by June 30. The report must include:
3 1. The amount of grants-in-aid awarded to eligible
4 institutions from the Biomedical Research Trust Fund.
5 2. The names of the recipients of such grants-in-aid.
6 3. The current status and progress of stem cell
7 research in the state.
8 4. A list of research projects supported by
9 grants-in-aid awarded under the program.
10 5. A list of publications in peer-reviewed journals
11 involving research supported by grants-in-aid awarded under
12 the program.
13 6. The total amount of biomedical research funding
14 currently flowing into the state.
15 7. New grants for biomedical research which were
16 funded based on research supported by grants-in-aid awarded
17 under the program.
18 8. All other materials that the advisory council
19 considers advisable to include.
20 (d) Advisory council members shall disclose any
21 conflict of interest or potential conflict of interest to the
22 Secretary of Health.
23 (e) The Department of Health shall provide
24 administrative staff to assist the advisory council in
25 developing the application for the grants-in-aid, reviewing
26 the applications, preparing the written consent form described
27 in paragraph (6)(b), and performing other administrative
28 functions as the advisory council requires.
29 (4) BIOMEDICAL ETHICS ADVISORY COUNCIL.--There is
30 created within the Department of Health the Biomedical Ethics
31 Advisory Council.

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

5 a. Two persons appointed by the Governor.

6 b. One person appointed by the President of the
7 Senate.

8 c. One person appointed by the Speaker of the House of
9 Representatives.

10 d. One person appointed by the Minority Leader of the
11 Senate.

12 e. One person appointed by the Minority Leader of the
13 House of Representatives.

14 2. All members must demonstrate knowledge and
15 understanding of the ethical, medical, and scientific
16 implications of stem cell research and should also demonstrate
17 knowledge of related fields, including, but not limited to,
18 genetics, cellular biology, and embryology. Each member shall
19 be appointed to a term of 4 years commencing on October 1,
20 2007; however, for the purpose of providing staggered terms,
21 of the initial appointments, three members shall be appointed
22 to 2-year terms and three members shall be appointed to 4-year
23 terms. A member may not serve for more than two consecutive
24 terms. Any vacancy on the advisory council shall be filled in
25 the same manner as the original appointment. All initial
26 appointments shall be made by October 1, 2007. The first
27 meeting shall take place no later than November 1, 2007. All
28 meetings are subject to the call of the chair. Members shall
29 meet at least twice a year or as often as necessary to
30 discharge their duties but may not hold more than one meeting
31 per month during any 12-month period. Members shall serve

1 without compensation but are entitled to reimbursement for per
2 diem and travel expenses in accordance with s. 112.061.

3 (b) The advisory council shall review all stem cell
4 research that is funded or supported in any manner through the
5 Biomedical Research Trust Fund to ensure the adherence to
6 ethical and safety guidelines and procedures as set forth by
7 federal ethical standards established by the United States
8 Department of Health and Human Services.

9 (5) BIOMEDICAL RESEARCH TRUST FUND AND
10 GRANTS-IN-AID.--

11 (a) The Secretary of Health shall make grants-in-aid
12 from the Biomedical Research Trust Fund in accordance with the
13 provisions of this section.

14 (b) The Department of Health shall require any
15 applicant for a grant-in-aid under this section, for the
16 purpose of conducting stem cell research, to submit a complete
17 description of the applicant's organization, the applicant's
18 plans for stem cell research, the applicant's proposed funding
19 for such research from sources other than the state, and the
20 applicant's proposed arrangements concerning financial
21 benefits to the state as a result of any patent, royalty
22 payment, or similar right resulting from any stem cell
23 research made possible by the awarding of the grant-in-aid.
24 The Stem Cell Research Advisory Council shall provide
25 recommendations to the Secretary of Health with respect to
26 awarding such grants-in-aid after considering the
27 recommendations of the Biomedical Ethics Advisory Council.

28 (c) Beginning with the 2007-2008 fiscal year, and for
29 10 consecutive years thereafter, not less than \$20 million
30 shall be made available annually from the Biomedical Research
31 Trust Fund within the Department of Health for grants-in-aid

1 to eligible institutions for the purpose of conducting adult
2 stem cell research pursuant to this section. Up to 15 percent
3 of the funds may be used for administrative costs. Any
4 unexpended funds not used for grants-in-aid during the current
5 fiscal year shall be carried forward for the following fiscal
6 year to fund the grants-in-aid.

7 (6) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS.--

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

10 1. Human adult stem cells, including, but not limited
11 to, adult stem cells derived from umbilical cord blood and
12 bone marrow. Funding for research may be given for human adult
13 stem cells derived from postmortem tissues, other than from
14 medically induced abortions. Funds may be used for studies of
15 human adult stem cells obtained from normal or transformed
16 tissues.

17 2. Amniotic stem cells extracted from human amniotic
18 fluid or placentas which are otherwise discarded after birth.

19 (b) Amniotic and adult stem cell material may be
20 donated only for research purposes with the informed consent
21 of the donor.

22 (c) Funds may not be used for research using human
23 embryonic stem cells that are derived by a process entailing
24 the donor embryo's death or destruction.

25 (7) CONTINUING APPROPRIATION.--Beginning in the
26 2007-2008 fiscal year, the sum of \$20 million is appropriated
27 annually from recurring funds in the General Revenue Fund to
28 the Biomedical Research Trust Fund within the Department of
29 Health for the purpose of carrying out the provisions of this
30 section. The amount of funds appropriated may not exceed \$200
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1 million for the 10-year period beginning in the 2007-2008
2 fiscal year and ending in the 2016-2017 fiscal year.

3 Section 2. Paragraph (h) of subsection (1) of section
4 20.435, Florida Statutes, is amended to read:

5 20.435 Department of Health; trust funds.--

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

8 (h) Biomedical Research Trust Fund.

9 1. Funds to be credited to the trust fund shall
10 consist of funds deposited pursuant to ss. ~~s.~~ 215.5601,
11 288.955, and 381.99 and any other funds appropriated by the
12 Legislature. Funds shall be used for the purposes of the James
13 and Esther King Biomedical Research Program, ~~and~~ the William
14 G. "Bill" Bankhead, Jr., and David Coley Cancer Research
15 Program, and the Florida Hope Offered through Principled,
16 Ethically Sound Stem Cell Research Act as specified in ss.
17 215.5602, 288.955, ~~and~~ 381.922, and 381.99. The trust fund is
18 exempt from the service charges imposed by s. 215.20.

19 2. Notwithstanding the provisions of s. 216.301 and
20 pursuant to s. 216.351, any balance in the trust fund at the
21 end of any fiscal year shall remain in the trust fund at the
22 end of the year and shall be available for carrying out the
23 purposes of the trust fund. The department may invest these
24 funds independently through the Chief Financial Officer or may
25 negotiate a trust agreement with the State Board of
26 Administration for the investment management of any balance in
27 the trust fund.

28 3. Notwithstanding s. 216.301 and pursuant to s.
29 216.351, any balance of any appropriation from the Biomedical
30 Research Trust Fund which is not disbursed but which is
31 obligated pursuant to contract or committed to be expended may

1 be carried forward for up to 3 years following the effective
2 date of the original appropriation.

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

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

7 381.86 Institutional Review Board.--

8 (1) The Institutional Review Board is created within
9 the Department of Health in order to satisfy federal
10 requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50
11 and 56 that an institutional review board review all
12 biomedical and behavioral research on human subjects which is
13 funded or supported in any manner by the department, except
14 that a separate Stem Cell Research Advisory Council and
15 Biomedical Ethics Advisory Council shall be appointed under s.
16 381.99.

17 Section 4. (1) The Department of Health shall prepare
18 an educational publication that includes objective information
19 regarding:

20 (a) The medical processes involved in the collection
21 of umbilical cord blood;

22 (b) The medical risks to the mother and her newborn
23 child of umbilical cord blood collection;

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

27 1. Discarding the stem cells;

28 2. Donating the stem cells to a public umbilical cord
29 blood bank;

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

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

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

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

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

14 (g) Options for ownership and future use of the
15 donated material; and

16 (h) The average cost of public and private umbilical
17 cord blood banking.

18 (2) The department shall update the publication as
19 necessary.

20 (3) The department shall distribute the pamphlet free
21 of charge to physicians and health care institutions upon
22 request and shall make the pamphlet available on its website
23 in printable format.

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

29 Section 5. This act shall take effect July 1, 2007.
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STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
COMMITTEE SUBSTITUTE FOR
Senate Bill 2496

The committee substitute deletes the definition of human cloning. It deletes the prohibitions and penalties relating to human cloning. The committee substitute requires the Department of Health to prepare and distribute a publication regarding the process, options, medical uses, risks, and benefits of umbilical cord blood collection.