Florida Senate - 2007

By Senator Haridopolos

26-1672A-07 See HB A bill to be entitled 1 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 б Advisory Council within the Department of 7 Health; providing for membership and terms; providing duties and responsibilities; 8 9 requiring the Secretary of Health to make 10 grants-in-aid from the Biomedical Research Trust Fund for stem cell research; providing 11 12 requirements relating to applications for and 13 awards of such grants-in-aid; providing specifications for moneys to be made available 14 from the trust fund for stem cell research 15 grants-in-aid; providing restrictions and 16 17 requirements for uses of funds from such grants-in-aid; providing prohibitions relating 18 to human cloning; providing for penalties; 19 providing an appropriation; amending s. 20.435, 20 21 F.S.; revising references; amending s. 381.86, 22 F.S.; providing an exception to the 23 Institutional Review Board for the Stem Cell Research Advisory Council and Biomedical Ethics 2.4 Advisory Council; providing an effective date. 25 26 27 Be It Enacted by the Legislature of the State of Florida: 28 Section 1. Section 381.99, Florida Statutes, is 29 30 created to read: 31

SB 2496

1	381.99 Florida Hope Offered through Principled,								
2	Ethically Sound Stem Cell Research Act								
3	(1) SHORT TITLEThis section may be cited as the								
4	"Florida Hope Offered through Principled, Ethically Sound Stem								
5	Cell Research Act."								
б	(2) DEFINITIONSAs used in this section, the term:								
7	(a) "Adult stem cell" means a cell found within								
8	differentiated tissue or an organ that can renew itself and								
9	give rise to the major cell types of the tissue or organ. This								
10	includes cells from the fetal to adult stages of development.								
11	(b) "Amniotic stem cell" means a cell extracted from								
12	<u>human amniotic fluid or a placenta.</u>								
13	(c) "Embryonic stem cell" means a cell obtained from								
14	the undifferentiated inner mass of an early stage embryo.								
15	(d) "Human cloning" means human asexual reproduction,								
16	accomplished by introducing nuclear material from one or more								
17	human somatic cells into a fertilized or unfertilized oocyte								
18	the nuclear material of which has been removed or inactivated								
19	so as to produce a living organism at any stage of development								
20	that is genetically virtually identical to an existing or								
21	previously existing human organism.								
22	(e) "Stem cell" means a cell that retains the								
23	potential to generate some or all other cell types.								
24	(3) STEM CELL RESEARCH ADVISORY COUNCILThere is								
25	created the Stem Cell Research Advisory Council within the								
26	Department of Health.								
27	(a)1. The advisory council shall consist of the								
28	Secretary of Health or his or her designee, who shall act as								
29	chair, and six additional members, who shall be appointed as								
30	<u>follows:</u>								
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1	a. Two persons appointed by the Governor, one of whom								
2	shall be an academic researcher in the field of stem cell								
3	research and one of whom shall have a background in bioethics.								
4	b. One person appointed by the President of the								
5	Senate, who shall have a background in private-sector stem								
6	cell funding and development or public-sector biomedical								
7	research and funding.								
8	c. One person appointed by the Speaker of the House of								
9	Representatives, who shall have a background in private-sector								
10	stem cell funding and development or public-sector biomedical								
11	research and funding.								
12	d. One person appointed by the President of the								
13	Senate, who shall have a background and experience in either								
14	public-sector or private-sector stem cell research and								
15	development.								
16	e. One person appointed by the Speaker of the House of								
17	Representatives, who shall be an executive of a biotech								
18	company, or his or her designee.								
19	2. Each member shall serve a term of 2 years								
20	commencing on October 1, 2007. No member shall serve for more								
21	than two consecutive 2-year terms; however, for the purpose of								
22	providing staggered terms, of the initial appointments, three								
23	members shall be appointed to a 1-year term and three members								
24	shall be appointed to a 2-year term. Any vacancy on the								
25	advisory council shall be filled in the same manner as the								
26	original appointment. All initial appointments shall be made								
27	by October 1, 2007. The first meeting shall take place no								
28	later than November 1, 2007. All meetings are subject to the								
29	call of the chair. Members shall meet at least twice a year or								
30	as often as necessary to discharge their duties but shall have								
31	no more than four meetings during any 12-month period. Members								

1 shall serve without compensation but may be reimbursed for per 2 diem and travel expenses in accordance with s. 112.061. 3 (b) The advisory council shall: 4 1. Develop a donated funds program for recommendation to the Secretary of Health to encourage the development of 5 6 funds other than state appropriations for human adult stem 7 cell research in the state. Examine and identify specific ways to improve and 8 2. promote for-profit and not-for-profit human adult stem cell 9 10 and related research in the state, including, but not limited to, identifying both public and private funding sources for 11 12 such research, maintaining existing human adult stem 13 cell-related businesses, recruiting new human adult stem cell-related businesses to the state, and recruiting 14 scientists and researchers in such fields to the state and 15 16 state universities. 17 3. Develop a biomedical research grant program for 18 recommendation to the Secretary of Health that shall provide 19 grants-in-aid to eligible state institutions for the advancement of human adult stem cell research. 2.0 21 4. Develop, no later than December 1, 2007, an 2.2 application for grants-in-aid under this section for 23 recommendation to the Secretary of Health for the purpose of conducting human adult stem cell research. 2.4 25 Review applications from eligible institutions for 5. grants-in-aid on and after December 1, 2007, and provide to 26 27 the Secretary of Health recommendations for grant awards. 2.8 6. Review the stem cell research conducted by eligible institutions that receive such grants-in-aid. 29 30 (c) The advisory council shall submit an annual progress report on the status of biomedical research in the 31

1 state to the Florida Center for Universal Research to 2 Eradicate Disease and to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the 3 4 House of Representatives by June 30. The report must include: 5 1. The amount of grants-in-aid awarded to eligible 6 institutions from the Biomedical Research Trust Fund. 7 2. The names of the recipients of such grants-in-aid. 3. The current status and progress of stem cell 8 research in the state. 9 10 4. A list of research projects supported by grants-in-aid awarded under the program. 11 12 A list of publications in peer-reviewed journals 5. involving research supported by grants-in-aid awarded under 13 14 the program. 6. The total amount of biomedical research funding 15 currently flowing into the state. 16 17 7. New grants for biomedical research that were funded 18 based on research supported by grants-in-aid awarded under the 19 program. 8. All other materials the advisory council deems 20 21 advisable to include. 22 (d) Advisory council members shall disclose any 23 conflict of interest or potential conflict of interest to the Secretary of Health. 2.4 25 (e) The Department of Health shall provide administrative staff to assist the advisory council in 26 27 developing the application for the grants-in-aid, reviewing 28 the applications, preparing the written consent form described in paragraph (6)(b), and performing other administrative 29 30 functions as the advisory council requires. 31

1	(4) BIOMEDICAL ETHICS ADVISORY COUNCILThere is								
2	created within the Department of Health the Biomedical Ethics								
3	Advisory Council.								
4	(a)1. The advisory council shall consist of the								
5	Secretary of Health or his or her designee, who shall act as								
б	chair, and six additional members, who shall be appointed as								
7	<u>follows:</u>								
8	a. Two persons appointed by the Governor.								
9	b. One person appointed by the President of the								
10	Senate.								
11	c. One person appointed by the Speaker of the House of								
12	Representatives.								
13	d. One person appointed by the Minority Leader of the								
14	Senate.								
15	e. One person appointed by the Minority Leader of the								
16	House of Representatives.								
17	2. All members must demonstrate knowledge and								
18	understanding of the ethical, medical, and scientific								
19	implications of stem cell research and should also demonstrate								
20	knowledge of related fields, including, but not limited to,								
21	genetics, cellular biology, and embryology. Each member shall								
22	serve a term of 4 years commencing on October 1, 2007;								
23	however, for the purpose of providing staggered terms, of the								
24	initial appointments, three members shall be appointed to a								
25	2-year term and three members shall be appointed to a 4-year								
26	term. No member shall serve for more than two consecutive								
27	terms. Any vacancy on the advisory council shall be filled in								
28	the same manner as the original appointment. All initial								
29	appointments shall be made by October 1, 2007. The first								
30	meeting shall take place no later than November 1, 2007. All								
31	meetings are subject to the call of the chair. Members shall								

1	meet at least twice a year or as often as necessary to								
2	discharge their duties but shall have no more than one meeting								
3	per month during any 12-month period. Members shall serve								
4	without compensation but may be reimbursed for per diem and								
5	travel expenses in accordance with s. 112.061.								
6	(b) The advisory council shall review all stem cell								
7	research that is funded or supported in any manner through the								
8	Biomedical Research Trust Fund to ensure the adherence to								
9	ethical and safety quidelines and procedures as set forth by								
10	federal ethical standards established by the United States								
11	Department of Health and Human Services.								
12	(5) BIOMEDICAL RESEARCH TRUST FUND AND								
13	<u>GRANTS-IN-AID</u>								
14	(a) The Secretary of Health shall make grants-in-aid								
15	from the Biomedical Research Trust Fund in accordance with the								
16	provisions of this section.								
17	(b) The Department of Health shall require any								
18	applicant for a grant-in-aid under this section, for the								
19	purpose of conducting stem cell research, to submit a complete								
20	description of the applicant's organization, the applicant's								
21	plans for stem cell research, the applicant's proposed funding								
22	for such research from sources other than the state, and the								
23	applicant's proposed arrangements concerning financial								
24	benefits to the state as a result of any patent, royalty								
25	payment, or similar right resulting from any stem cell								
26	research made possible by the awarding of the grant-in-aid.								
27	The Stem Cell Research Advisory Council shall provide								
28	recommendations to the Secretary of Health with respect to								
29	awarding such grants-in-aid after considering the								
30	recommendations of the Biomedical Ethics Advisory Council.								
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1	(c) Beginning with the 2007-2008 fiscal year, and for								
2	10 consecutive years thereafter, not less than \$20 million								
3	shall be made available annually from the Biomedical Research								
4	Trust Fund within the Department of Health for grants-in-aid								
5	to eligible institutions for the purpose of conducting adult								
6	stem cell research pursuant to this section. Up to 15 percent								
7	of the funds may be used for administrative costs. Any								
8	unexpended funds not used for grants-in-aid during the current								
9	fiscal year shall be carried forward for the following fiscal								
10	year to fund the grants-in-aid.								
11	(6) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS								
12	(a) Funds provided under this section may only be used								
13	for research involving:								
14	1. Human adult stem cells, including, but not limited								
15	to, adult stem cells derived from umbilical cord blood and								
16	bone marrow. Funding for research may be given for human adult								
17	stem cells derived from postmortem tissues, other than from								
18	medically induced abortions. Funds may be used for studies of								
19	human adult stem cells obtained from either normal or								
20	transformed tissues.								
21	2. Amniotic stem cells extracted from human amniotic								
22	fluid or placentas that are otherwise discarded after birth.								
23	(b) Amniotic and adult stem cell material may only be								
24	donated for research purposes with the informed consent of the								
25	donor.								
26	(c) No funds shall be used for research with human								
27	embryonic stem cells that are derived by a process entailing								
28	the donor embryo's death or destruction.								
29	(7) HUMAN CLONING; PROHIBITION; PENALTIES								
30	(a) It is unlawful for any person to knowingly:								
31	1. Perform or attempt to perform human cloning;								
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1	2. Participate or assist in an attempt to perform								
2	human cloning; or								
3	3. Ship or receive for any purpose an embryo produced								
4	by human reproductive cloning or any product derived from such								
5	embryo.								
б	(b) A person who violates paragraph (a) commits a								
7	felony of the second degree, punishable as provided in s.								
8	<u>775.082, s. 775.083, or s. 775.084.</u>								
9	(8) CONTINUING APPROPRIATIONBeginning in fiscal								
10	year 2007-2008, the sum of \$20 million is appropriated								
11	annually from recurring funds in the General Revenue Fund to								
12	the Biomedical Research Trust Fund within the Department of								
13	Health for the purpose of carrying out the provisions of this								
14	section. The amount of funds appropriated shall not exceed								
15	<u>\$200 million for the 10-year period beginning in fiscal year</u>								
16	2007-2008 and ending in fiscal year 2016-2017.								
17	Section 2. Paragraph (h) of subsection (1) of section								
18	20.435, Florida Statutes, is amended to read:								
19	20.435 Department of Health; trust funds								
20	(1) The following trust funds are hereby created, to								
21	be administered by the Department of Health:								
22	(h) Biomedical Research Trust Fund.								
23	1. Funds to be credited to the trust fund shall								
24	consist of funds deposited pursuant to <u>ss.</u> s. 215.5601 <u>,</u>								
25	288.955, and 381.99 and any other funds appropriated by the								
26	Legislature. Funds shall be used for the purposes of the James								
27	and Esther King Biomedical Research Program <u>,</u> and the William								
28	G. "Bill" Bankhead, Jr., and David Coley Cancer Research								
29	Program, and the Florida Hope Offered through Principled,								
30	Ethically Sound Stem Cell Research Act as specified in ss.								
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1 215.5602, 288.955, and 381.922, and 381.99. The trust fund is 2 exempt from the service charges imposed by s. 215.20. 3 2. Notwithstanding the provisions of s. 216.301 and pursuant to s. 216.351, any balance in the trust fund at the 4 end of any fiscal year shall remain in the trust fund at the 5 6 end of the year and shall be available for carrying out the 7 purposes of the trust fund. The department may invest these 8 funds independently through the Chief Financial Officer or may negotiate a trust agreement with the State Board of 9 Administration for the investment management of any balance in 10 11 the trust fund. 12 3. Notwithstanding s. 216.301 and pursuant to s. 13 216.351, any balance of any appropriation from the Biomedical Research Trust Fund which is not disbursed but which is 14 obligated pursuant to contract or committed to be expended may 15 be carried forward for up to 3 years following the effective 16 17 date of the original appropriation. 18 4. The trust fund shall, unless terminated sooner, be terminated on July 1, 2008. 19 Section 3. Subsection (1) of section 381.86, Florida 20 21 Statutes, is amended to read: 22 381.86 Institutional Review Board.--23 (1) The Institutional Review Board is created within the Department of Health in order to satisfy federal 2.4 requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50 25 and 56 that an institutional review board review all 26 27 biomedical and behavioral research on human subjects which is 2.8 funded or supported in any manner by the department, except that a separate Stem Cell Research Advisory Council and 29 30 Biomedical Ethics Advisory Council shall be appointed under s. <u>381.99</u>. 31

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SB 2496 See HB

1	Section	4.	This	act	shall	take	effect	July	1,	2007.	
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