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BILL TEXT

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INTRODUCED BY Senator Ortiz

FEBRUARY 19, 2003

An act to add and repeal Sections 125118, 125118.5, 125119, 125119.3, and 125119.5 of the Health and Safety Code, relating to medical research.

LEGISLATIVE COUNSEL'S DIGEST

SB 322, Ortiz. Stem cell research.

Existing law states the policy of the state that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given, and that research involving the derivation and use of these cells shall be reviewed by an approved institutional review board.

This bill would require the State Department of Health Services, on or before January 1, 2005, to develop guidelines for research involving the derivation or use of human embryonic stem cells in the state, and would require the Director of Health Services to establish a Human Stem Cell Research Advisory Committee, comprised of specified members, for purposes of developing these guidelines. It would also authorize the department to contract with a public or private organization, to the extent permitted by state law, for assistance in developing the guidelines.

This bill would require all human embryonic stem cell research projects to be reviewed and approved by an institutional review board (IRB) that is established in accordance with federal regulations, as specified.

This bill would require an IRB to conduct continuing review of human stem cell research projects, as specified, and would authorize an IRB to require modifications to the plan or design of a continuing research project before permitting the research to continue. This bill would require IRBs to report to the department, as specified, and would require the department to report to the Legislature on human embryonic stem cell research activity.

This bill would repeal its provisions as of January 1, 2007.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. (a) The Legislature finds and declares all of the following:

(1) Isolation of human embryonic stem cells represents a major step forward in human biology and has generated much interest among scientists and the public, particularly among patients and their advocates regarding the benefits of human embryonic stem cells and stem cell research.

(2) Because human embryonic stem cells can give rise to many different types of cells, such as muscle cells, nerve cells, heart cells, and others, they are enormously important to science and hold great promise for advances in health care.

(3) Research using human embryonic stem cells may help scientists generate cells and tissue that could be used for transplantation and may someday be used as replacement cells and tissue to treat many chronic diseases and conditions, including Parkinson's disease, spinal injury, stroke, burns, heart disease, diabetes, arthritis, and liver disease.

(4) Research involving human embryonic stem cells may also improve understanding of the complex events that occur during normal human development and what causes diseases and conditions including birth defects, pediatric brain injury, and cancer, and may improve the way new drugs are developed and tested for safety and efficacy.

(5) In view of the scientific and medical benefits that may result from research using human embryonic stem cells, it is essential that this research be supported and encouraged. However, in view of the ethical, legal, and social issues relevant to human embryonic stem cell research, it is essential that this research be subject to oversight that complements and goes beyond the oversight of human subject research provided by the Office for Human Research Protections within the United States Department of Health and Human Services.

(6) The National Institutes of Health currently has no comprehensive guidelines concerning the ethical, legal, and social issues involved with the derivation and use of human embryonic stem cells in medical research.

(b) Therefore, it is the intent of the Legislature that the State Department of Health Services develop guidelines for human embryonic stem cell research in California in order to ensure that this research is guided by ethical and legal standards.

SEC. 2. Section 125118 is added to the Health and Safety Code, to read:

125118. (a) On or before January 1, 2005, the department shall develop guidelines for research involving the derivation or use of human embryonic stem cells in California.

(b) In developing the guidelines specified in subdivision (a), the department may consider other applicable guidelines developed or in use in the United States and in other countries, including, but not limited to, the Guidelines for Research Using Human Pluripotent Stem Cells developed by the National Institutes of Health and published in August 2000, and corrected in November 2000.

(c) The department may contract with a public or private organization, to the extent permitted by state law, for assistance in developing the guidelines.

(d) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 3. Section 125118.5 is added to the Health and Safety Code,

to read:

125118.5. (a) For purposes of developing the guidelines required by Section 125118, the director shall establish a Human Stem Cell Research Advisory Committee.

(b) The advisory committee shall consist of 13 members, as follows:

(1) Seven scientists with experience in biomedical research in the fields of cell differentiation, nuclear reprogramming, tissue formation and regeneration, stem cell biology, developmental biology, regenerative medicine, or related fields.

(2) Two medical ethicists.

(3) Two persons with backgrounds in legal issues related to human embryonic stem cell research, in vitro fertilization, or family law, as it applies to the donation of embryos and oocytes.

(4) Two persons who are members or leaders of religious organizations.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 4. Section 125119 is added to the Health and Safety Code, to read:

125119. (a) (1) All research projects involving the derivation or use of human embryonic stem cells shall be reviewed and approved by an institutional review board that is established in accordance with federal regulations, including Part 46 (commencing with Section 46.101) of Subchapter A of Subtitle A of Title 45 of the Code of Federal Regulations, prior to being undertaken. Any such institutional review board shall, in its review of human embryonic stem cell research projects, consider and apply the guidelines developed by the department pursuant to Section 125118. An institutional review board may require modifications to the plan or design of a proposed human embryonic stem cell research project as a condition of approving the research project.

(2) For purposes of this article, "IRB" means an institutional review board described in paragraph (1).

(b) Not less than once per year, an IRB shall conduct continuing review of human embryonic stem cell research projects reviewed and approved under this section in order to ensure that the research continues to meet the standards for IRB approval. Pursuant to its review in accordance with this subdivision, an IRB may revoke its prior approval of research under this section and require modifications to the plan or design of a continuing research project before permitting the research to continue.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 5. Section 125119.3 is added to the Health and Safety Code, to read:

125119.3. (a) Each IRB that has reviewed human embryonic stem cell research pursuant to Section 125119 shall report to the department, annually, on the number of human embryonic stem cell research projects that the IRB has reviewed, and the status and disposition of each of those projects.

(b) Each IRB shall also report to the department regarding unanticipated problems, unforeseen issues, or serious continuing investigator noncompliance with the requirements or determinations of the IRB with respect to the review of human embryonic stem cell research projects, and the actions taken by the IRB to respond to

these situations.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 6. Section 125119.5 is added to the Health and Safety Code, to read:

125119.5. (a) The department shall at least annually review reports from IRBs pursuant to Section 125120, and may revise the guidelines developed pursuant to Section 125118, as it deems necessary.

(b) The department shall report annually to the Legislature on human embryonic stem cell research activity. These annual reports shall be compiled from the reports from IRBs pursuant to Section 125120.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.