H-3655.1

HOUSE BILL 2336

State of Washington 58th Legislature 2004 Regular Session

By Representatives Schual-Berke, Wood, Ruderman, Chase, Sullivan, McIntire, Hunt, Hankins, Cody, Kagi and Sommers

Prefiled 1/7/2004. Read first time 01/12/2004. Referred to Committee on Health Care.

AN ACT Relating to stem cell research; adding a new chapter to Title 70 RCW; prescribing penalties; and providing an expiration date.

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

NEW SECTION. **Sec. 1.** The legislature finds and declares that:

(1) An estimated one hundred twenty-eight million Americans suffer from chronic, degenerative, and acute diseases, including diabetes, Alzheimer's disease, cancer, Huntington's disease, Parkinson's disease, heart disease, and spinal cord injury. The crippling economic and psychological burdens of such diseases result in billions of dollars every year in costs of treatment and lost productivity as well as extreme human loss and emotional suffering.

(2) Stem cell research offers immense promise for developing new medical therapies for these debilitating diseases and a critical means to explore fundamental questions of biology. Stem cell research could lead to unprecedented treatments and potential cures for diabetes, Alzheimer's disease, cancer, Huntington's disease, Parkinson's disease, heart disease, spinal cord injury, and other diseases.

(3) Washington state is home to several large medical research institutions and an expanding biomedical research industry. These

organizations are committed to improving the lives of Americans suffering from chronic, degenerative, and acute diseases. Encouraging stem cell research is essential to realizing the promise of stem cell research.

(4) Stem cell research, including the use of embryonic stem cells for medical research, raises significant ethical concerns that must be balanced with medical considerations.

(5) While stem cell research holds enormous potential for treating or even curing some diseases, the cloning of human beings is morally and ethically unacceptable. Furthermore, the cloning of human beings poses grave health risks to any child who may be produced in this manner. Any attempt to clone a human being is in direct conflict with the policies of this state.

NEW SECTION. **Sec. 2.** It is the policy of Washington state that:

(1) 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, is permitted upon full consideration of the ethical and medical implications of this research.

(2) Research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by an institutional review board.

NEW SECTION. **Sec. 3.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Cloning of a human being" means asexual reproduction by implanting or attempting to implant the product of nuclear transplantation into a uterus or substitute for a uterus with the purpose of producing a human being.

(2) "Department" means the department of health.

(3) "Nuclear transplantation" means transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been or will be removed or inactivated.

(4) "Human somatic cell" means a diploid cell obtained or derived from a living or deceased human at any stage of development.

(5) "Institutional review board" means any board, committee, or other group formally designated by an institution, or authorized under federal or state law, to review, approve the initiation of, or conduct periodic review of research programs to assure the protection of the rights and welfare of human research subjects.

(6) "Oocyte" means the unfertilized human ovum.

(7) "Secretary" means the secretary of health.

NEW SECTION. **Sec. 4.** (1) The department must develop guidelines for research involving the derivation or use of human embryonic stem cells in Washington by January 1, 2006.

(2) To develop the guidelines, the department may consider other applicable guidelines developed or used in the United States and in other countries, including the guidelines for research using human pluripotent stem cells developed by the national institutes of health published in August 2000, and corrected in November 2000.

(3) The department must review reports from institutional review boards pursuant to section 6 of this act, and may revise the guidelines, as necessary.

(4) The department must report annually to the legislature on human embryonic stem cell research activity. The annual reports must be compiled from the reports from institutional review boards required by section 6 of this act.

(5) The department may contract with a public or private organization for assistance in developing the guidelines.

(6) The human stem cell research advisory committee is established consisting of thirteen members appointed by the secretary, as follows:

(a) 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;

(b) Two medical ethicists;

(c) 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; and

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

NEW SECTION. **Sec. 5.** (1) All research projects involving the derivation or use of human embryonic stem cells must be reviewed and approved by an institutional review board before being undertaken. The institutional review board must consider and apply the guidelines developed by the department pursuant to section 4 of this act. The 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) At least once per year, the institutional review board must conduct continuing review of human embryonic stem cell research projects reviewed and approved under this section to ensure that the research continues to meet the standards for institutional review board approval. Pursuant to this review, the institutional review board 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.

NEW SECTION. **Sec. 6.** (1) Each institutional review board that has reviewed human embryonic stem cell research pursuant to section 5 of this act must report to the department annually the number of human embryonic stem cell research projects the board has reviewed and the status and disposition of each project.

(2) Each institutional review board must also report to the department unanticipated problems, unforeseen issues, or serious continuing investigator noncompliance with the requirements or determinations of the institutional review board with respect to the review of human embryonic stem cell research projects, and the actions taken by the institutional review board to respond to these situations.

NEW SECTION. **Sec. 7.** (1) The department must establish and maintain an anonymous registry of embryos that are available for research. The purpose of the registry is to provide researchers with access to embryos that are available for research purposes.

(2) The department may contract with the University of Washington, private organizations, or public entities to establish and administer the registry.

(3) The department may adopt rules to implement the registry

including methods for reporting embryos available for research to the registry.

NEW SECTION. **Sec. 8.** (1) A health care provider delivering fertility treatment must provide his or her patient with timely, relevant, and appropriate information to allow the patient to make an informed and voluntary choice about the disposition of any human embryos remaining following the fertility treatment. Failure to provide to a patient this information constitutes unprofessional conduct under chapter 18.130 RCW.

(2) Any person to whom information is provided pursuant to subsection (1) of this section must be presented with the option of storing any unused embryos, donating unused embryos to another individual, discarding unused embryos, or donating unused embryos for research. When providing fertility treatment, the health care provider must provide a form to the male and female partner, or the person without a partner, as applicable, that sets forth advanced written directives regarding the disposition of unused embryos. The form must indicate the time limit on storage of the embryos at the clinic or storage facility and provide, at a minimum, the following choices for disposition of the embryos based on the following circumstances:

(a) Upon the death of a patient or their partner, the embryos must be disposed of by one of the following actions:

(i) Making the embryos available to the living partner, if any;

(ii) Donating the embryos for research purposes;

(iii) Thawing the embryos without any further action;

(iv) Donating the embryos to another person; or

(v) Disposing of the embryos in any other clearly stated method.

(b) Upon separation or divorce of the partners, the embryos must be disposed of by any of the following actions:

(i) Making the embryos available to the female partner;

(ii) Making the embryos available to the male partner;

(iii) Donating the embryos for research purposes;

(iv) Thawing the embryos without any further action;

(v) Donating the embryos to another person; or

(vi) Disposing of the embryos in any other clearly stated method.

(c) Upon the partners' decision, or the decision of a patient who

is without a partner, to abandon the embryos by request or a failure to pay storage fees, the embryos must be disposed of by one of the following actions:

(i) Donating the embryos for research purposes;

(ii) Thawing the embryos without any further action;

(iii) Donating the embryos to another person; or

(iv) Disposing of the embryos in any other clearly stated method.

(3) A health care provider delivering fertility treatment must obtain written consent from any person who elects to donate embryos remaining after fertility treatment for research. To obtain informed consent, the health care provider must provide the following information to the person:

(a) That the early human embryos will be used to derive human pluripotent stem cells for research and that the cells may be used, at some future time, for human transplantation research;

(b) That all identifiers associated with the embryos will be removed before the derivation of human pluripotent stem cells;

(c) That donors will not receive any information about subsequent testing on the embryos or the derived human pluripotent cells;

(d) That derived cells or cell lines, with all identifiers removed, may be kept for many years;

(e) That the donor material may have commercial potential, and the donor will not receive financial or any other benefits from any future commercial development;

(f) That the human pluripotent stem cell research is not intended to provide direct medical benefit to the donor; and

(g) That early human embryos that are donated will not be transferred to a woman's uterus, will not survive the human pluripotent stem cell derivation process, and will be handled respectfully, as is appropriate for all human tissue used in research.

NEW SECTION. **Sec. 9.** (1) A person may donate human embryonic tissue or human cadaveric fetal tissue for research purposes.

(2) A person may not knowingly, for valuable consideration, purchase or sell human embryonic tissue or human cadaveric fetal tissue for research purposes.

(3) "Valuable consideration" does not include reasonable payment

for the removal, processing, disposal, preservation, quality control, storage, transportation, or implantation of human embryonic tissue or human cadaveric tissue.

(4) A person who violates this section is guilty of a felony and upon conviction is subject to a fine not to exceed fifty thousand dollars or imprisonment not to exceed five years, or both.

NEW SECTION. **Sec. 10.** (1) No person may knowingly engage or assist in cloning or attempting to clone a human being.

(2) The attorney general may bring an action to enjoin any person from violating subsection (1) of this section.

(3) Any person who violates subsection (1) of this section is subject to a civil penalty not to exceed one hundred thousand dollars for each violation. Civil penalties authorized by this subsection may be imposed in any civil action brought by the attorney general.

(4) Nothing in this section shall be construed to restrict areas of biomedical, agricultural, and scientific research not specifically prohibited by this section, including somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues.

NEW SECTION. **Sec. 11.** If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

NEW SECTION. **Sec. 12.** Sections 4 through 6 of this act expire January 1, 2008.

NEW SECTION. **Sec. 13.** Sections 1 through 12 of this act constitute a new chapter in Title 70 RCW.

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