H-0661.1			

HOUSE BILL 1268

State of Washington 59th Legislature 2005 Regular Session

By Representatives Schual-Berke, Jarrett, Tom, Sommers, Dickerson, Cody, Hankins, Murray, Hudgins, B. Sullivan, Fromhold, Haler, Appleton, Wallace, Kagi, Dunshee, Springer, Upthegrove, Kenney, Quall, Pettigrew, Morris, Darneille, Moeller, Morrell, Hunt, Lovick, Kessler, Williams, Roberts, Chase, Santos and McIntire

Read first time 01/19/2005. Referred to Committee on Health Care.

- 1 AN ACT Relating to stem cell research; adding a new chapter to 2 Title 70 RCW; and prescribing penalties.
- 3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

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- 4 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, Huntington's disease, Parkinson's disease, heart disease, spinal cord injury, and other diseases.
- 18 (3) Washington state is home to several large medical research 19 institutions and an expanding biomedical research industry. These

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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 and will promote advances in other areas of biomedical research.

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- (4) Stem cell therapy was born in Washington state over thirty years ago, with the pioneering work of nobel laureate, E. Donnall Thomas, and his colleagues at the Fred Hutchinson cancer research center. The Fred Hutchinson cancer research center remains the premier center for adult stem cell transplantation in the world. Support for stem cell research at this critical juncture represents a commitment to continue this distinguished legacy.
- (5) Several states have supported policies and institutions in partnership with the biomedical research industry to promote and advance embryonic stem cell research. Washington state must demonstrate a similar commitment to these initiatives in order to reaffirm itself as a leader in this area of biomedical research.
- (6) Stem cell research, including the use of embryonic stem cells for medical research, raises significant ethical concerns that must be balanced with medical considerations.
- (7) While therapeutic cloning stem cell research holds enormous potential for treating or even curing some diseases, the reproductive cloning of human beings is morally and ethically unacceptable. Furthermore, the reproductive 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. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.
 - (1) "Blastocyst" means a preimplantation embryo consisting of approximately one hundred fifty cells that are organized into an inner and outer cell layer surrounding a fluid-filled cavity. The cells of the inner layer, from which embryonic stem cells are derived, consists of undifferentiated cells that have the potential to become any type of cell in the human body.
 - (2) "Department" means the department of health.

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- 1 (3) "Human somatic cell" means a diploid cell obtained or derived 2 from a living or deceased human at any stage of development.
 - (4) "Oocyte" means the unfertilized human ovum.

- (5) "Reproductive cloning of a human being" means asexual reproduction of a human being by transplanting a blastocyst that has been created by somatic cell nuclear transfer into a uterus or substitute for a uterus with the purpose of creating a human being.
 - (6) "Secretary" means the secretary of health.
- 9 (7) "Somatic cell nuclear transfer" or "therapeutic cloning" means 10 a technique in which the nucleus of an oocyte is replaced with the 11 nucleus of a donated human somatic cell and stimulated to divide until 12 it reaches the blastocyst stage.
 - NEW SECTION. Sec. 3. (1) The human stem cell research advisory committee is created and consists of thirteen members appointed by the governor. Members of the initial committee shall be appointed to staggered terms of one to two years, and thereafter all terms of appointment shall be for four years. The governor shall consider such candidates as may be recommended for appointment by the University of Washington and the biomedical research community. The committee shall consist of the following members:
 - (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 blastocysts and oocytes; and
 - (d) Two members of the public.
 - (2) The advisory committee shall develop guidelines for research involving the derivation or use of human embryonic stem cells in Washington by January 1, 2006. The guidelines shall address the balance between the state policy of promoting research involving the derivation of human embryonic stem cells, by any method, including somatic cell nuclear transfer, and the ethical considerations that arise with such research. After adoption of the initial guidelines, the advisory committee may revise the guidelines or issue advisory

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opinions, as necessary, to account for developments in research and medicine as they may affect the research and ethical considerations associated with the use of human embryonic stem cells.

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- (3) To develop the guidelines, the committee 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.
- 9 (4) The department shall provide administrative support to the 10 advisory committee.
- NEW SECTION. Sec. 4. (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 blastocysts remaining following the fertility treatment.
 - (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 blastocysts, donating unused blastocysts to another individual, discarding unused blastocysts, or donating unused blastocysts 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 blastocysts. The form must indicate the time limit on storage of the blastocysts at the clinic or storage facility and provide, at a minimum, the following choices for disposition of the blastocysts based on the following circumstances:
 - (a) Upon written notice of the death of a patient or patient's partner, the blastocysts must be disposed of by one of the following actions:
 - (i) Making the blastocysts available to the living partner, if any;
 - (ii) Donating the blastocysts for research purposes;
- 33 (iii) Thawing the blastocysts without any further action;
- 34 (iv) Donating the blastocysts to another person; or
- 35 (v) Disposing of the blastocysts in any other clearly stated 36 method.

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- 1 (b) Upon written notice of the separation or divorce of the 2 partners, the blastocysts must be disposed of by any of the following 3 actions:
 - (i) Making the blastocysts available to the female partner;
 - (ii) Making the blastocysts available to the male partner;
 - (iii) Donating the blastocysts for research purposes;
 - (iv) Thawing the blastocysts without any further action;
 - (v) Donating the blastocysts to another person; or

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- 9 (vi) Disposing of the blastocysts in any other clearly stated 10 method.
 - (c) Upon the partners' decision, or the decision of a patient who is without a partner, to abandon the blastocysts by written request or a failure to pay storage fees, the blastocysts must be disposed of by one of the following actions:
 - (i) Donating the blastocysts for research purposes;
 - (ii) Thawing the blastocysts without any further action;
 - (iii) Donating the blastocysts to another person; or
- 18 (iv) Disposing of the blastocysts in any other clearly stated 19 method.
 - (3) A health care provider delivering fertility treatment must obtain written consent from any person who elects to donate blastocysts 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 blastocysts 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) Information that would permit the donor to be individually identified will be removed before deriving human embryonic stem cell lines;
- 31 (c) That donors will not receive any information about subsequent 32 testing on the blastocysts or the derived human pluripotent cells;
 - (d) That derived cells or cell lines 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;
- 37 (f) That the human pluripotent stem cell research is not intended 38 to provide direct medical benefit to the donor; and

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- 1 (g) That human blastocysts donated for research will not be 2 transferred to a woman's uterus and will be destroyed during the stem 3 cell derivation process. Research will be conducted in accordance with 4 the advisory committee established in section 3 of this act.
- NEW SECTION. Sec. 5. (1) No person may knowingly engage or assist in reproductive cloning of a human being or attempting reproductive cloning of a human being.

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- (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. 6. No person may use human eggs or human sperm that have been donated for purposes of assisted reproduction as defined in chapter 26.26 RCW, to create human embryonic stem cells for use in research, without the written consent of the donor to use the eggs or sperm for research purposes after receiving the information specified in section 4(3) of this act.
- NEW SECTION. Sec. 7. 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. 8. Sections 1 through 7 of this act constitute a new chapter in Title 70 RCW.

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