House Bill 2801

Sponsored by Representatives GALIZIO, GREENLICK; Representatives BARKER, BARNHART, BERGER, BOONE, BUCKLEY, CANNON, CLEM, COWAN, D EDWARDS, GELSER, HOLVEY, HUNT, JENSON, MERKLEY, NOLAN, READ, ROBLAN, ROSENBAUM, SCHAUFLER, SHIELDS, TOMEI, WITT, Senator BATES

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced**.

Establishes Human Stem Cell Research Committee in Department of Human Services. Requires committee to develop guidelines for research involving derivation or use of human embryonic stem cells. Instructs committee to report guidelines developed to Legislative Assembly, Governor and Oregon Health and Science University.

Establishes Human Stem Cell Research Grant Fund. Authorizes committee to seek private and public contributions for purpose of funding research grants from fund. Continuously appropriates moneys in fund to committee for purposes of Act.

Requires health care provider delivering fertility services to provide information to patient about stem cell research and obtain written informed consent of person who elects to donate blastocyst after fertility treatment. Imposes penalties for failure to obtain written informed consent from donor prior to donation and use of human egg or sperm cell for research.

A BILL FOR AN ACT

Relating to stem cell research; and appropriating money.
Whereas an estimated 128 million Americans suffer from chronic, degenerative and acute dis-
eases, including diabetes, Alzheimer's disease, cancer, Huntington's disease, Parkinson's disease,
heart disease and spinal cord injury; and
Whereas 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; and
Whereas 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; and
Whereas 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; and
Whereas Oregon is home to a large medical research institution and an expanding biomedical
research industry; and
Whereas these organizations are committed to improving the lives of Americans suffering from
chronic, degenerative and acute diseases; and
Whereas encouraging stem cell research is essential to realizing the promise of stem cell re-
search and will promote advances in other areas of biomedical research; and
Whereas several states have supported policies and institutions in partnership with the
biomedical research industry to promote and advance embryonic stem cell research; and
Whereas Oregon must demonstrate a similar commitment to these initiatives in order to reaffirm
itself as a leader in this area of biomedical research; and
Whereas stem cell research, including the use of embryonic stem cells for medical research,
raises significant ethical concerns that must be balanced with medical considerations; and

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Whereas while therapeutic cloning stem cell research holds enormous potential for treating or 1 2 even curing some diseases, the reproductive cloning of human beings is morally and ethically unacceptable; and 3 Whereas the reproductive cloning of human beings poses grave health risks to any child who 4 may be produced in this manner; and $\mathbf{5}$ Whereas any attempt to clone a human being is in direct conflict with the policies of this state; 6 7 now, therefore, Be It Enacted by the People of the State of Oregon: 8 9 SECTION 1. As used in this section and sections 2, 3, 4, 5, 7 and 8 of this 2007 Act: (1) "Blastocyst" means a preimplantation embryo consisting of approximately 150 cells 10 that are organized into an inner and outer cell layer surrounding a fluid-filled cavity. The 11 12 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. 13 (2) "Human somatic cell" means a diploid cell obtained or derived from a living or de-14 15 ceased human at any stage of development. 16(3) "Oocyte" means an unfertilized human ovum. (4) "Somatic cell nuclear transfer" or "therapeutic cloning" means a technique in which 1718 the nucleus of an oocyte is replaced with the nucleus of a donated human somatic cell and stimulated to divide until it reaches the blastocyst stage. 19 20SECTION 2. (1) The Human Stem Cell Research Committee is created in the Department 21of Human Services. The committee shall consist of 13 members appointed by the Governor. 22(2) The term of office of each member is four years, but a member serves at the pleasure 23of the Governor. Before the expiration of the term of a member, the Governor shall appoint a successor, whose term begins upon the expiration of the term of the current member. A 24 25member is eligible for reappointment. If there is a vacancy for any cause, the Governor shall make an appointment to become immediately effective for the unexpired term. 2627(3) The Governor may consider persons recommended for appointment by the Oregon Health and Science University and the biomedical research community. The committee shall 28include the following members: 2930 (a) Seven scientists with experience in biomedical research in the fields of cell differen-31 tiation, nuclear reprogramming, tissue formation and regeneration, stem cell biology, developmental biology or regenerative medicine or related fields; 32(b) Two medical ethicists; 33 34 (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 35 36 oocytes; and 37 (d) Two members of the public.

(4) The committee shall select one of its members as chairperson and another as vice
 chairperson, for such terms and with duties and powers necessary for the performance of
 the functions of such offices as the committee determines.

41 (5) A majority of the members of the committee constitutes a quorum for the transaction
42 of business.

(6) The committee shall meet at least once every three months at a place, day and hour
determined by the chairperson of the committee. The committee may also meet at other
times and places specified by the call of the chairperson or of a majority of the members of

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the committee. 1

2 (7) A member of the committee is entitled to compensation and expenses as provided in ORS 292.495. 3

(8) In accordance with applicable provisions of ORS chapter 183, the committee may 4 adopt rules necessary for carrying out the provisions of sections 3 and 4 of this 2007 Act. $\mathbf{5}$

(9) The Department of Human Services shall provide administrative support to the com-6 mittee. 7

SECTION 3. (1) The Human Stem Cell Research Committee shall develop guidelines for 8 9 research involving the derivation or use of human embryonic stem cells in Oregon by January 1, 2008. The guidelines shall address the balance between the state policy of promoting 10 research involving the derivation of human embryonic stem cells, by any method, including 11 12 somatic cell nuclear transfer, and the ethical considerations that arise with such research. 13 After adoption of the initial guidelines, the committee may revise the guidelines or issue advisory opinions, as necessary, to account for developments in research and medicine as 14 15 they may affect the research and ethical considerations associated with the use of human embryonic stem cells. 16

(2) In developing the guidelines, the committee may consider other applicable guidelines 1718 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. 19

(3) The committee shall report the guidelines developed to the Governor, to the Legisla-20tive Assembly in the manner provided for in ORS 192.245 and to the Oregon Health and Sci-2122ence University.

23SECTION 4. (1) The Human Stem Cell Research Committee may solicit, receive and review applications from public and private agencies, organizations and research institutions 24for grants from the Human Stem Cell Research Grant Fund created under section 5 of this 252007 Act to conduct research programs that focus on the development of the treatment of 2627debilitating diseases and spinal cord injuries.

(2) After review of a grant application, the committee shall grant approval of the appli-28cation and disburse moneys from the Human Stem Cell Research Grant Fund if the applica-2930 tion meets the criteria established by the committee and if money exists in the fund.

(3) The committee may solicit contributions to the fund from public and private sources.

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(4) The committee shall provide the Governor and the Legislative Assembly with a 32biennial report no later than January 31 of each odd-numbered year that summarizes the 33 34 status of funds granted for stem cell research and the progress of the committee in en-35 couraging stem cell research.

SECTION 5. (1) The Human Stem Cell Research Grant Fund is established separate and 36 37 distinct from the General Fund. All moneys received by the Human Stem Cell Research 38 Committee shall be deposited into the State Treasury and credited to the Human Stem Cell **Research Grant Fund.** 39

(2) Interest earned by the Human Stem Cell Research Grant Fund shall be credited to 40 the fund. 41

(3) All moneys in the Human Stem Cell Research Grant Fund are continuously appro-42priated to the Human Stem Cell Research Committee for the purposes of sections 2, 3, 4, 5, 43 7 and 8 of this 2007 Act. 44

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SECTION 6. Notwithstanding the term of office specified by section 2 of this 2007 Act,

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1 of the members first appointed to the Human Stem Cell Research Committee:

2 (1) Three shall serve for terms ending January 1, 2009.

3 (2) Three shall serve for terms ending January 1, 2010.

4 (3) Three shall serve for terms ending January 1, 2011.

5 (4) Four shall serve for terms ending December 31, 2012.

6 <u>SECTION 7.</u> (1) A health care provider delivering fertility treatment must provide the 7 patient with timely, relevant and appropriate information about stem cell research to allow 8 the patient to make an informed and voluntary choice about the disposition of any human 9 blastocysts remaining following the fertility treatment.

(2) Any person to whom information is provided pursuant to subsection (1) of this section 10 must be presented with the option of storing any unused blastocysts, donating unused 11 12 blastocysts to another individual, discarding unused blastocysts or donating unused blastocysts for research. Prior to providing fertility treatment, the health care provider must 13 provide a form to the male and female partner, or the patient without a partner, as appli-14 15 cable, that sets forth advanced written directives regarding the disposition of unused 16 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 17 18 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:

21 (A) Making the blastocysts available to the living partner, if any;

22 (B) Donating the blastocysts for research purposes;

23 (C) Thawing the blastocysts without any further action;

24 (D) Donating the blastocysts to another person; or

25 (E) Disposing of the blastocysts in any other clearly stated method.

26 (b) Upon written notice of the separation or divorce of the partners, the blastocysts must

- 27 be disposed of by any of the following actions:
- 28 (A) Making the blastocysts available to the female partner;
- 29 (B) Making the blastocysts available to the male partner;
- 30 (C) Donating the blastocysts for research purposes;
- 31 (D) Thawing the blastocysts without any further action;
- 32 (E) Donating the blastocysts to another person; or

33 (F) Disposing of the blastocysts in any other clearly stated method.

34 (c) Upon the partners' decision, or the decision of a patient without a partner, to abandon

the blastocysts by written request or upon a failure to pay storage fees, the blastocysts must

- 36 be disposed of by one of the following actions:
- 37 (A) Donating the blastocysts for research purposes;

38 (B) Thawing the blastocysts without any further action;

39 (C) Donating the blastocysts to another person; or

40 (D) Disposing of the blastocysts in any other clearly stated method.

41 (3) A health care provider delivering fertility treatment must obtain written informed

42 consent from any person who elects to donate blastocysts remaining after fertility treatment

43 for research. To obtain informed consent, the health care provider must obtain signed con-

- 44 firmation that the person donating blastocysts has been informed that:
- 45 (a) The blastocysts may be used to derive human pluripotent stem cells for research and

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that the cells may be used, at some future time, for human transplantation research; 1 2 (b) Information that would permit the donor to be individually identified will be removed before deriving human embryonic stem cell lines; 3 (c) Donors will not receive any information about subsequent testing on the blastocysts 4 or the derived human pluripotent stem cells; 5 (d) Derived cells or cell lines may be kept for many years; 6 (e) The donated material may have commercial potential, and the donor will not receive 7 financial or any other benefits from any future commercial development; 8 9 (f) The human pluripotent stem cell research is not intended to provide direct medical benefit to the donor; 10 (g) Human blastocysts donated for research may not be transferred to a woman's uterus 11 12and will be destroyed during the stem cell derivation process; and (h) Research using donated blastocysts will be conducted in accordance with the guide-13 lines developed by the committee under section 3 of this 2007 Act. 14 15 SECTION 8. A person may not use human eggs or human sperm that have been donated for purposes of assisted reproduction to create human embryonic stem cells for use in re-16 search without obtaining the written informed consent of the donor to use the eggs or sperm 17 for research purposes required in section 7 of this 2007 Act. 18 SECTION 9. (1) In addition to any other penalty imposed by law, the Department of Hu-19 man Services may impose a civil penalty on any person for violation of section 7 or 8 of this 202007 Act. The civil penalty imposed under this subsection may not exceed \$10,000 for each 2122violation. 23(2) Civil penalties imposed under this subsection shall be imposed in the manner provided by ORS 183.745. 24(3) Penalties collected under this section shall be deposited in the Human Stem Cell Re-25search Grant Fund established under section 5 of this 2007 Act. 2627SECTION 10. The Department of Human Services may adopt rules necessary to implement the provisions of sections 7 and 8 of this 2007 Act. 2829