

A-Engrossed
House Bill 2598

Ordered by the House April 14
Including House Amendments dated April 14

Sponsored by Representatives GALIZIO, GREENLICK; Representatives BAILEY, BARKER, BEYER, BOONE, BUCKLEY, CANNON, COWAN, DEMBROW, C EDWARDS, GARRETT, GELSER, HOLVEY, KAHL, KOTEK, MATTHEWS, NOLAN, READ, RILEY, ROBLAN, SCHAUFLEER, SHIELDS, J SMITH, STIEGLER, TOMEI, VANORMAN, WITT, Senators BONAMICI, DINGFELDER

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.

[Establishes] **Creates** Human Stem Cell Research Committee in Department of Human Services. **Requires committee to develop procedures to ensure legality of research involving derivation or use of human stem cells.** Requires committee to *[develop]* **adopt** guidelines for research involving derivation or use of human stem cells. Instructs committee to report **procedures and 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 Department of Human Services for purposes of Act. Appropriates moneys from General Fund to department to provide administrative support to committee.

Creates crime of *[human]* **reproductive** cloning. Punishes violation by maximum of five years' imprisonment, \$125,000 fine, or both.

Imposes penalties for failure to obtain written informed consent from donor prior to donation and use of human egg or sperm cell for research. Directs committee to study nature of informed consent provided and to make recommendations to Governor, Legislative Assembly and Oregon Health and Science University.

[Declares emergency, effective July 1, 2009.]

A BILL FOR AN ACT

1
2 Relating to stem cell research; and appropriating money.

3 Whereas an estimated 128 million Americans suffer from chronic, degenerative and acute dis-
4 eases, including diabetes, Alzheimer's disease, cancer, Huntington's disease, Parkinson's disease,
5 heart disease and spinal cord injury; and

6 Whereas the crippling economic and psychological burdens of such diseases result in billions of
7 dollars every year in costs of treatment and lost productivity as well as extreme human loss and
8 emotional suffering; and

9 Whereas stem cell research offers immense promise for developing new medical therapies for
10 these debilitating diseases and a critical means to explore fundamental questions of biology; and

11 Whereas stem cell research could lead to unprecedented treatments and potential cures for
12 diabetes, Alzheimer's disease, cancer, Huntington's disease, Parkinson's disease, heart disease, spinal
13 cord injury and other diseases; and

14 Whereas Oregon is home to a large medical research institution and an expanding biomedical
15 research industry; and

16 Whereas these organizations are committed to improving the lives of Americans suffering from
17 chronic, degenerative and acute diseases; and

18 Whereas encouraging stem cell research is essential to realizing the promise of stem cell re-

NOTE: Matter in **boldfaced** type in an amended section is new; matter *[italic and bracketed]* is existing law to be omitted. New sections are in **boldfaced** type.

1 search and will promote advances in other areas of biomedical research; and

2 Whereas several states have supported policies and institutions in partnership with the
3 biomedical research industry to promote and advance stem cell research; and

4 Whereas Oregon must demonstrate a similar commitment to these initiatives in order to reaffirm
5 itself as a leader in this area of biomedical research; and

6 Whereas stem cell research, including the use of stem cells for medical research, raises signif-
7 icant ethical concerns that must be balanced with medical considerations; and

8 Whereas while stem cell research holds enormous potential for treating or even curing some
9 diseases, the reproductive cloning of human beings is morally and ethically unacceptable; and

10 Whereas the reproductive cloning of human beings poses grave health risks to any child who
11 may be produced in this manner; and

12 Whereas any attempt to clone a human being is in direct conflict with the policies of this state;
13 now, therefore,

14 **Be It Enacted by the People of the State of Oregon:**

15 **SECTION 1. (1) The Human Stem Cell Research Committee is created in the Department**
16 **of Human Services. The committee consists of nine members appointed by the Governor.**

17 **(2) The term of office of each member is four years, but a member serves at the pleasure**
18 **of the Governor. Before the expiration of the term of a member, the Governor shall appoint**
19 **a successor, whose term begins upon the expiration of the term of the current member. A**
20 **member is eligible for reappointment. If there is a vacancy for any cause, the Governor shall**
21 **make an appointment to become immediately effective for the unexpired term.**

22 **(3) The Governor may consider persons recommended for appointment by the Oregon**
23 **Health and Science University and the biomedical research community. The Governor shall**
24 **appoint the following members:**

25 **(a) Five scientists with experience in biomedical research in fields such as developmental**
26 **biology, stem cell sciences, molecular biology, assisted reproduction, cell differentiation, nu-**
27 **clear reprogramming, tissue formation and regeneration, regenerative medicine or related**
28 **fields;**

29 **(b) One medical ethicist;**

30 **(c) One person with a background in legal issues related to human stem cell research or**
31 **in vitro fertilization; and**

32 **(d) Two members of the public.**

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

36 **(5) A majority of the members of the committee constitutes a quorum for the transaction**
37 **of business.**

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

42 **(7) Members of the committee are not entitled to compensation or reimbursement for**
43 **expenses and serve as volunteers on the committee.**

44 **(8) In accordance with applicable provisions of ORS chapter 183, the committee may**
45 **adopt rules necessary for carrying out the provisions of sections 2, 3, 4 and 6 of this 2009**

1 **Act.**

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

4 **SECTION 2.** (1) The Human Stem Cell Research Committee shall develop procedures to
5 ensure that research involving the derivation or use of human stem cells in Oregon is con-
6 ducted in accordance with federal regulations, requirements and guidelines for the conduct
7 of stem cell research. The committee may adopt a set of guidelines to be followed when ad-
8 herence to another set of guidelines is not required for funding eligibility or for other pur-
9 poses. After development of the procedures and adoption of the guidelines, the committee
10 may revise the procedures and guidelines, as necessary, to account for changes in national
11 and international guidelines and developments in research and medicine as they may affect
12 the research and ethical considerations associated with the use of human stem cells.

13 (2) In developing the procedures and adopting the guidelines, the committee may consider
14 other applicable guidelines developed or used in the United States and in other countries,
15 including guidelines developed by the National Academy of Sciences, the National Institutes
16 of Health and the International Society for Stem Cell Research.

17 (3) The committee shall report the procedures developed and guidelines adopted by the
18 committee, and any revision to those procedures or guidelines to the Governor, to the Leg-
19 islative Assembly in the manner provided for in ORS 192.245 and to the Oregon Health and
20 Science University.

21 **SECTION 3.** (1) The Human Stem Cell Research Committee may solicit, receive and re-
22 view applications from public and private agencies, organizations and research institutions
23 for grants from the Human Stem Cell Research Grant Fund established under section 4 of
24 this 2009 Act to conduct research programs in this state that focus on the development of
25 treatments for debilitating diseases and spinal cord injuries utilizing stem cells.

26 (2) After reviewing a grant application, if the application meets the criteria established
27 by the committee by rule and if moneys exist in the Human Stem Cell Research Grant Fund,
28 the committee shall grant approval of the application and direct the Department of Human
29 Services to disburse moneys from the fund.

30 (3) The committee may only grant moneys to institutions that agree to abide by the
31 guidelines required by the National Institutes of Health or adopted by the committee under
32 section 2 of this 2009 Act.

33 (4) The committee shall report to the Governor and the Legislative Assembly no later
34 than January 31 of each odd-numbered year, summarizing the status of grants for stem cell
35 research and the progress of the committee in encouraging stem cell research.

36 **SECTION 4.** (1) The Human Stem Cell Research Grant Fund is established separate and
37 distinct from the General Fund. Moneys received from contributions to the Human Stem Cell
38 Research Grant Fund, from public and private sources, by the Human Stem Cell Research
39 Committee shall be deposited into the State Treasury and credited to the fund.

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

42 (3) All moneys in the Human Stem Cell Research Grant Fund are continuously appro-
43 priated to the Department of Human Services for the purposes of carrying out sections 1,
44 2, 3, 6 and 9 of this 2009 Act.

45 (4) The committee may solicit contributions to the Human Stem Cell Research Grant

1 Fund from public and private sources.

2 **SECTION 5.** Notwithstanding the term of office specified by section 1 of this 2009 Act,
3 of the members first appointed to the Human Stem Cell Research Committee:

4 (1) Four shall serve for terms ending January 1, 2012.

5 (2) Five shall serve for terms ending January 1, 2013.

6 **SECTION 6.** (1) The Human Stem Cell Research Committee shall study the nature of in-
7 formed consent that should be provided in conjunction with human stem cell research funded
8 under section 3 of this 2009 Act.

9 (2) No later than April 1, 2011, the committee shall make recommendations about the
10 nature of and method for providing informed consent to the Governor, to the Legislative
11 Assembly in the manner provided in ORS 192.245 and to the Oregon Health and Science
12 University.

13 **SECTION 7.** (1) A person commits the crime of reproductive cloning if the person
14 knowingly or intentionally:

15 (a) Conducts in vitro culture of an intact human embryo, regardless of the method of
16 derivation of the embryo, for more than 14 days or beyond the time at which formation of
17 the primitive streak begins, whichever occurs first;

18 (b) Introduces human embryonic stem cells into nonhuman primate blastocysts or in-
19 troduces any embryonic stem cells into human blastocysts; or

20 (c) Breeds an animal into which human embryonic stem cells have been introduced.

21 (2) Reproductive cloning is a Class C felony.

22 (3) As used in this section:

23 (a) "Blastocyst" means a preimplantation embryo of 50 to 250 cells, which consists of a
24 sphere made up of an outer layer of cells and a fluid-filled cavity.

25 (b) "Embryo" means an animal in the early stages of growth and differentiation that is
26 characterized by cleavage, laying down of fundamental tissues and the formation of primitive
27 organs and organ systems, including the developing human individual from the time of im-
28 plantation to the end of the eighth week after conception.

29 (c) "Embryonic stem cells" means primitive or undifferentiated cells derived from the
30 early embryo that have the potential to become a wide variety of specialized cell types.

31 (d) "In vitro" means in a laboratory dish, test tube or other artificial environment.

32 (e) "Primitive streak" means the initial band of cells from which an embryo begins to
33 develop and that establishes and reveals the embryo's head-tail and left-right orientations.

34 **SECTION 8.** A person may not use human eggs or human sperm that have been donated
35 for purposes of assisted reproduction to create human stem cells for use in research without
36 obtaining the written informed consent of the donor to use the eggs or sperm for purposes
37 of stem cell research.

38 **SECTION 9.** (1) In addition to any other penalty imposed by law, the Department of Hu-
39 man Services may impose a civil penalty on any person for violation of section 7 or 8 of this
40 2009 Act. The civil penalty imposed under this subsection may not exceed \$10,000 for each
41 violation.

42 (2) Civil penalties imposed under this section shall be imposed in the manner provided
43 by ORS 183.745.

44 (3) Civil penalties collected under this section shall be deposited in the Human Stem Cell
45 Research Grant Fund established under section 4 of this 2009 Act.

1 **SECTION 10.** The Department of Human Services may adopt rules necessary to imple-
2 ment the provisions of section 9 of this 2009 Act.

3 **SECTION 11.** Sections 3, 7, 8 and 9 of this 2009 Act become operative on July 1, 2011.

4 **SECTION 12.** No later than April 1, 2011, the Human Stem Cell Research Committee shall
5 develop the procedures and adopt the guidelines required under section 2 of this 2009 Act.

6 **SECTION 13.** There is appropriated to the Department of Human Services, for the
7 biennium beginning July 1, 2009, out of the General Fund, the amount of \$159,366 for the
8 purpose of providing administrative support to the Human Stem Cell Research Committee
9 under section 1 of this 2009 Act.

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