

JAN 22 2007

A BILL FOR AN ACT

RELATING TO STEM CELL RESEARCH.

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

1 PART I

2 SECTION 1. The legislature finds that an estimated one
3 hundred twenty eight million Americans suffer from the crippling
4 economic and psychological burden of chronic, degenerative, and
5 acute diseases, including diabetes, Parkinson's disease, cancer,
6 and Alzheimer's disease. The costs of treatment and lost
7 productivity of chronic, degenerative, and acute diseases in the
8 United States run into hundreds of billions of dollars every
9 year. Yet, the estimates of these economic costs do not account
10 for the extreme cost in human loss and suffering associated with
11 these conditions.

12 On the other hand, stem cell research could lead to
13 unprecedented treatments and potential cures for diabetes,
14 Alzheimer's disease, cancer, and other diseases. Stem cell
15 research offers immense promise for developing new medical
16 therapies for these debilitating diseases.



1 The United States has historically been a haven for open
2 scientific inquiry and technological innovation; and this
3 environment, combined with the commitment of public and private
4 resources, has made the United States the preeminent world
5 leader in biomedicine and biotechnology. The biomedical
6 industry is a critical and growing component of Hawaii's
7 economy, and its development would be significantly hampered by
8 any limitation imposed on stem cell research.

9 Open scientific inquiry and research endeavors supported by
10 public funding will be essential to realizing the promise of
11 stem cell research. Publicly funded stem cell research,
12 conducted under established standards of open scientific
13 exchange, peer review, and public oversight, offers the most
14 efficient and responsible means of fulfilling the promise of the
15 use of stem cells in providing regenerative medical therapies.

16 The legislature further finds that stem cell research,
17 including the use of embryonic stem cells for medical research,
18 raises significant ethical and policy concerns. Public policy
19 on stem cell research must balance ethical and medical
20 considerations. While not unique, these ethical and policy
21 concerns associated with stem cell research must be well thought
22 out. The policy of this State must be based on an understanding



1 of the science associated with stem cell research and grounded
2 on a thorough consideration of the ethical concerns regarding
3 this research. Public policy on stem cell research must be
4 crafted to ensure that researchers have the research and ethical
5 tools necessary to fulfill the promise of stem cell research.

6 SECTION 2. Chapter 321, Hawaii Revised Statutes, is
7 amended by adding a new part to be appropriately designated and
8 to read as follows:

9 "PART . STEM CELL RESEARCH; POLICY

10 §321- Stem cell research; policy. (a) The policy of
11 the State relating to stem cell research shall be as follows:

12 (1) Research involving the derivation and use of human
13 embryonic stem cells, human embryonic germ cells, and
14 human adult stem cells from any source, including
15 somatic cell nuclear transplantation, shall be:

- 16 (A) Permitted in this State;
- 17 (B) Conducted with full consideration of the ethical
18 and medical implications of this research; and
- 19 (C) Reviewed by an approved institutional review
20 board;

21 (2) A physician, or other health care provider, delivering
22 fertility treatment shall provide the patient with



1 timely, relevant, and appropriate information to allow
2 the patient to make an informed and voluntary choice
3 regarding the disposition of any human embryos
4 remaining following the fertility treatment;

5 (3) Any individual to whom information is provided
6 pursuant to paragraph (2) shall be presented with the
7 option of storing unused embryos, donating them to
8 another individual, discarding the embryos, or
9 donating the remaining embryos for research;

10 (4) Any individual who elects to donate embryos remaining
11 after fertility treatments for research shall provide
12 written consent; and

13 (5) A person may not knowingly, for valuable
14 consideration, purchase or sell embryonic or cadaveric
15 fetal tissue for research purposes pursuant to this
16 chapter.

17 (b) For purposes of this section, "valuable consideration"
18 does not include reasonable payment for the removal, processing,
19 disposal, preservation, quality control, storage,
20 transplantation, or implantation of embryonic or cadaveric fetal
21 tissue.



1 (c) Embryonic or cadaveric fetal tissue may be donated for
2 research purposes pursuant to this part.

3 (d) The director of health shall adopt rules in accordance
4 with chapter 91 to implement this part."

5 PART II

6 SECTION 3. The legislature finds that the reestablishment
7 of the University of Hawaii's school of medicine in the Kakaako
8 area is generating an enormous stimulus towards medical and
9 scientific innovation and presents a tremendous opportunity for
10 the State to improve its position in the leading edge field of
11 biotechnology and stem cell research. In conjunction with the
12 state policy on stem cell research, an institute for
13 regenerative medicine located at the University of Hawaii school
14 of medicine could become a world leader in innovative stem cell
15 research. Not only will humanity benefit, but this type of
16 medical research will also significantly reduce state health
17 care costs in the future. The State will benefit from
18 royalties, patents, and licensing fees arising from discoveries
19 and innovations relating to stem cell research. This research
20 will create significant numbers of high-end jobs and generate
21 millions of dollars as it expands the State's tax base.



1 The purpose of this part is to lay the foundation for the
2 establishment of an institute for regenerative medicine at the
3 University of Hawaii's school of medicine.

4 SECTION 4. (a) The president shall develop and the board
5 of regents of the University of Hawaii shall approve for
6 submission to the legislature a plan to establish an institute
7 for regenerative medicine at the school of medicine. The
8 institute for regenerative medicine shall have the following
9 purposes:

- 10 (1) Support stem cell research and other vital research
11 opportunities to realize therapies, protocols, and
12 medical procedures that will result in, as speedily as
13 possible, the cure for or substantial mitigation of
14 major diseases, injuries, and orphan diseases;
- 15 (2) Support all stages of the process of developing cures,
16 from laboratory research through successful clinical
17 trials; and
- 18 (3) Establish the appropriate regulatory standards and
19 oversight bodies for research and facilities
20 development.

21 (b) The plan to be developed by the president and approved
22 by the board of regents of the University of Hawaii concerning



1 the establishment of the institute for regenerative medicine
2 shall ensure that:

- 3 (1) Use of research funds made available to the institute
4 will be maximized by giving priority to stem cell
5 research that has the greatest potential for therapies
6 and cures, specifically focused on pluripotent stem
7 cell and progenitor cell research among other vital
8 research opportunities that cannot, or are unlikely
9 to, receive timely or sufficient federal funding,
10 unencumbered by limitations that would impede the
11 research; provided that research shall be subject to
12 accepted patient disclosure and patient consent
13 standards;
- 14 (2) Research is conducted safely and ethically by
15 including provisions to require compliance with
16 standards based on national models that protect
17 patient safety, patient rights, and patient privacy;
- 18 (3) Use of any funds made available to the institute is
19 prohibited for human reproductive cloning;
- 20 (4) The Hawaii health care system is improved and the
21 long-term health care cost burden on Hawaii is reduced
22 through the development of therapies that treat



1 diseases and injuries with the ultimate goal to cure
2 them; and

3 (5) Strict fiscal and public accountability is implemented
4 through mandatory independent audits, open meetings,
5 public hearings, and annual reports to the public.

6 (c) The institute for regenerative medicine shall have the
7 right to conduct stem cell research, which includes research
8 involving adult stem cells, cord blood stem cells, pluripotent
9 stem cells, and progenitor cells. For the purposes of this
10 section, "pluripotent stem cells" are cells that are capable of
11 self-renewal and have broad potential to differentiate into
12 multiple adult cell types. Pluripotent stem cells may be
13 derived from somatic cell nuclear transfer or from surplus
14 products of in vitro fertilization treatments, when such
15 products are donated under appropriate informed consent
16 procedures. "Progenitor cells" are multipotent or precursor
17 cells that are partially differentiated, but retain the ability
18 to divide and give rise to differentiated cells.

19 (d) No funds authorized for, or made available to, the
20 institute for regenerative medicine shall be used for research
21 involving human reproductive cloning.



1 (e) The University of Hawaii may issue general obligation
2 bonds to fund the development and construction of the institute
3 for regenerative medicine.

4 (f) The president shall develop and the board of regents
5 shall approve the plan to establish the institute for
6 regenerative medicine no later than November 30, 2008, and
7 submit the finalized plan to the legislature no later than
8 December 31, 2008, together with any necessary proposed
9 legislation, such as funding needs, for introduction in the
10 regular session of 2009.

11 PART III

12 SECTION 5. This Act shall take effect upon its approval.

13 INTRODUCED BY:

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Report Title:

Human Stem Cell Research

Description:

Sets state policy for stem cell research in the State. Requires the University of Hawaii to develop plan to establish an institute for regenerative medicine at school of medicine no later than 12/31/2008.

