

110TH CONGRESS
1ST SESSION

S. 363

To provide increased Federal funding for stem cell research, to expand the number of embryonic stem cell lines available for Federally funded research, to provide ethical guidelines for stem cell research, to derive human pluripotent stem cell lines using techniques that do not create an embryo or embryos for research or knowingly harm human embryo or embryos, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 23, 2007

Mr. COLEMAN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide increased Federal funding for stem cell research, to expand the number of embryonic stem cell lines available for Federally funded research, to provide ethical guidelines for stem cell research, to derive human pluripotent stem cell lines using techniques that do not create an embryo or embryos for research or knowingly harm human embryo or embryos, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Hope Offered through
3 Principled, Ethically-Sound Stem Cell Research Act” or
4 the “HOPE Act”.

5 **SEC. 2. PURPOSES.**

6 It is the purpose of this Act to—

- 7 (1) intensify research that may result in im-
8 proved understanding of or treatments for diseases
9 and other adverse health conditions; and
10 (2) promote the derivation of pluripotent stem
11 cell lines without the creation of human embryos for
12 research purposes or discarding, destroying, or
13 knowingly harming a human embryo.

14 **SEC. 3. DEFINITIONS.**

15 In this Act:

- 16 (1) **ALTERED NUCLEAR TRANSFER.**—The term
17 “altered nuclear transfer” means a method for ob-
18 taining pluripotent stem cells using a modified form
19 of somatic cell nuclear transfer to produce a biologi-
20 cal artifact.
21 (2) **BIOLOGICAL ARTIFACT.**—The term “biologi-
22 cal artifact” means an artificially created non-em-
23 bryonic cellular system, engineered to lack the essen-
24 tial elements of embryogenesis but still capable of
25 some cell division and growth.

1 (3) DIRECT REPROGRAMMING OF ADULT
2 CELLS.—The term “direct reprogramming of adult
3 cells” means a procedure whereby differentiated, so-
4 matic cells are restored to a more undifferentiated,
5 multipotent condition. Such process is also known as
6 “dedifferentiation”.

7 (4) EMBRYO ADOPTION.—The term “embryo
8 adoption” means the occurrence of a woman receiv-
9 ing into her uterus a human embryo or embryos to
10 which neither she nor her partner has contributed a
11 gamete for the purpose of child bearing.

12 (5) EMBRYONIC STEM CELLS.—The term “em-
13 bryonic stem cells” means primitive cells derived
14 from the inner cell mass of the human embryo or
15 embryos, that have the potential to become a wide
16 variety of specialized cell types.

17 (6) HUMAN EMBRYO OR EMBRYOS.—The term
18 “human embryo or embryos” includes any organism,
19 not protected as a human subject under part 46 of
20 title 45, Code of Federal Regulations, as of the date
21 of enactment of this section, that is derived by fer-
22 tilization, parthenogenesis, cloning, or any other
23 means from one or more human gametes or human
24 diploid cells.

1 (7) IN VITRO FERTILIZATION.—The term “in
2 vitro fertilization” means the union of an egg and
3 sperm, where the event takes place outside the body
4 and in an artificial environment.

5 (8) OOCYTE.—The term “oocyte” means an
6 unfertilized human egg cell.

7 (9) ORGANISMICALLY DEAD EMBRYO.—The
8 term “organismically dead embryo” means the irre-
9 versible loss of the capacity of continued and inte-
10 grated cellular division, growth and differentiation.

11 (10) PLURIPOTENT CELL.—The term
12 “pluipotent cell” means a cell that can produce all
13 the cell types of the developing body. Embryonic
14 stem cells, as well as the inner cell mass cells of the
15 blastocyst, are pluripotent cells.

16 (11) PLURIPOTENT STEM CELLS.—The term
17 “pluripotent stem cells” means precursor cells that
18 are capable both of perpetuating themselves as stem
19 cells and of producing all or almost all the cell types
20 of the developing body, and that have functional ca-
21 pacity (stable pluripotency) as an embryonic stem
22 cell, though not necessarily the same origin.

23 (12) REVIEW BOARD.—The term “Review
24 Board” means the National Stem Cell Review Board
25 established under section 5.

1 (13) SECRETARY.—The term “Secretary”
2 means the Secretary of Health and Human Services.

3 (14) STEM CELL LINE.—The term “stem cell
4 line” means stem cells which have been cultured
5 under in vitro conditions that allow proliferation
6 without differentiation from months to years.

7 **SEC. 4. PROVISION OF FEDERAL FUNDING.**

8 (a) BASIC AND APPLIED RESEARCH.—

9 (1) IN GENERAL.—The Secretary shall conduct
10 and support basic and applied research to develop
11 techniques for the isolation, derivation, production,
12 or testing of pluripotent stem cells that have the
13 flexibility of embryonic stem cells (whether or not
14 they have an embryonic source), and may result in
15 improved understanding of or treatments for dis-
16 eases and other adverse health conditions, provided
17 that such isolation, derivation, production, or testing
18 will not involve—

19 (A) the creation of a human embryo or em-
20 bryos for research purposes; or

21 (B) the destruction or discarding of a
22 human embryo or embryos, or knowingly sub-
23 jecting a human embryo or embryos to risk of
24 injury or death greater than that allowed for re-
25 search on fetuses in utero under section 498(b)

1 of this Act and section 46.204(b) of title 45,
2 Code of Federal Regulations.

3 (2) INCLUSIONS.—Research under paragraph
4 (1) may include—

5 (A) Methods that use—

6 (i) cells derived from altered nuclear
7 transfer; or

8 (ii) cells derived from organismically
9 dead embryos; and

10 (B) the investigation of evidence for
11 pluripotent potential in adult stem cells from
12 various sources; or

13 (C) the direct reprogramming of adult
14 cells, the derivation of stem cells from human
15 germ cells, and other methods that do not harm
16 or destroy a human embryo or embryos and
17 that are certified by the Review Board.

18 (b) LIMITATIONS.—If any research described in sub-
19 section (a) is determined by the Secretary to create an
20 embryo or embryos for research purposes, or harm or de-
21 stroy a human embryo or embryos, such research shall im-
22 mediately be terminated until such determination is re-
23 viewed and resolved to the satisfaction of the Review
24 Board.

1 (c) GUIDELINES.—Not later than 90 days after the
2 date of the enactment of this section, the Secretary, after
3 consultation with the Director, shall issue final guidelines
4 that—

5 (1) provide guidance concerning the next steps
6 required for additional research, which shall include
7 a determination of the extent to which specific tech-
8 niques may require additional basic or animal re-
9 search to ensure that any research involving human
10 cells using these techniques would clearly be con-
11 sistent with subsection (a);

12 (2) prioritize research with the greatest poten-
13 tial for near-term clinical benefit; and

14 (3) consistent with subsection (a), take into ac-
15 count techniques outlined by the President’s Council
16 on Bioethics and any other appropriate techniques
17 and research.

18 (d) REPORTING REQUIREMENTS.—Not later than
19 January 1 of each year, the Secretary shall prepare and
20 submit to the appropriate committees of the Congress a
21 report describing the activities carried out under this sec-
22 tion during the fiscal year, including a description of the
23 research conducted under this section.

24 (e) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion shall be construed as altering the policy in effect on

1 the date of enactment of this section regarding the eligi-
2 bility of stem cell lines for funding by the National Insti-
3 tutes of Health.

4 **SEC. 5. NATIONAL STEM CELL RESEARCH REVIEW BOARD.**

5 (a) IN GENERAL.—There shall be established within
6 the Department of Health and Human Services a board
7 to be known as the “National Stem Cell Research Review
8 Board” which shall be responsible for—

9 (1) monitoring research to ensure that it is in
10 compliance with the principles of this Act;

11 (2) prioritizing research with the greatest po-
12 tential for near term benefits;

13 (3) ensuring fair consideration of both embry-
14 onic stem cell and adult stem cell research for fund-
15 ing; and

16 (4) completing their duties under this section in
17 a timely matter to promote rather than hinder ap-
18 propriate research.

19 (b) COMPOSITION.—

20 (1) IN GENERAL.—The Review Board shall be
21 composed of 11 individuals, to be appointed by the
22 Secretary.

23 (2) REQUIREMENTS.—The members appointed
24 under paragraph (1) shall include—

1 (A) scientists or physicians with relevant
2 expertise (including areas of assisted reproduc-
3 tion, developmental biology, and clinical medi-
4 cine), including scientists that are not directly
5 engaged in the research considered by the
6 Board;

7 (B) ethicists or professionals from other
8 disciplines with a specialized ability to interpret
9 the moral justifications and implications of the
10 research considered by the Board;

11 (C) members or advisors familiar with rel-
12 evant national legal statutes governing the re-
13 search considered by the Board; and

14 (D) community members, unaffiliated with
15 the institutions involved through employment or
16 other remunerative relationships, who are objec-
17 tive and reasonably familiar with the views and
18 needs of research subjects, patients and patient
19 communities who could be benefitted or harmed
20 by stem cell research, and community stand-
21 ards.

22 (3) TERMS OF OFFICE.—

23 (A) IN GENERAL.—The term of office of a
24 member of a the Review Board appointed under
25 paragraph (1) shall be 4 years, except that any

1 member appointed to fill a vacancy for an unex-
2 pired term shall serve for the remainder of such
3 term. The Secretary shall ensure that appoint-
4 ments are made to the Board in such a manner
5 as to ensure that the terms of the members not
6 all expire in the same year and that not all
7 members' terms concur with the 4-year Presi-
8 dential term. A member of the Board may serve
9 after the expiration of such member's term
10 until a successor has been appointed and taken
11 office.

12 (B) TIME FOR APPOINTMENT.—If a va-
13 cancy occurs among the members of the Review
14 Board, the Secretary shall ensure that an ap-
15 pointment to fill such vacancy occurs within 90
16 days from the date the vacancy occurs.

17 (c) LIMITATION.—The Review Board shall not be re-
18 sponsible for dispersing funds. The Board shall ensure
19 that funds which are to be provided by the Federal Gov-
20 ernment are being used appropriately and under the provi-
21 sions of this Act.

22 (d) ADDITIONAL ADMINISTRATIVE PROVISIONS.—

23 (1) COMPENSATION.—Members of the Review
24 Board who are officers or employees of the United
25 States shall not receive any compensation for service

1 on the Board. The remaining members of the Board
2 shall receive, for each day (including travel time)
3 they are engaged in the performance of the functions
4 of the advisory council, compensation at rates not to
5 exceed the daily equivalent to the annual rate in ef-
6 fect for grade GS-15 of the General Schedule.

7 (2) EXECUTIVE SECRETARY AND STAFF.—The
8 Review Board may appoint an individual to serve as
9 the Executive Secretary of the Board. The Secretary
10 shall make available to the Board such staff, infor-
11 mation, and other assistance as it may require to
12 carry out its functions.

13 **SEC. 6. INFORMED CONSENT PROVISIONS.**

14 (a) PURPOSE.—It is the purpose of this section to
15 ensure that individuals are empowered to make voluntary
16 and informed decisions regarding the use of human em-
17 bryo or embryos created using their biological materials
18 or their oocytes.

19 (b) TIMING OF CONSENT.—Consent from an indi-
20 vidual for the donation of materials for research described
21 in this Act shall be obtained from such individual, in writ-
22 ing, at the time of the proposed transfer of the donated
23 materials from the storage site to the research team.

24 (c) PROVISION OF INFORMATION TO DONORS.—At
25 the time that the consent described in subsection (b) is

1 given, the donor shall be informed, verbally and in writing,
 2 that the donor retains the right to withdraw such consent
 3 until such time as the donated materials involved are actu-
 4 ally utilized in research.

5 **SEC. 7. PRIVACY.**

6 Provisions protecting individually identifiable infor-
 7 mation under the regulations promulgated under section
 8 264(e) of the Health Insurance Portability and Account-
 9 ability Act of 1996 (42 U.S.C. 1320d-2 note) shall apply
 10 to donors under this Act.

11 **SEC. 8. PROHIBITION ON PROFITEERING FROM COMMERCE**

12 **IN EMBRYOS, HUMAN OVUMS, OR EMBRYONIC**
 13 **STEM CELL LINES.**

14 (a) NO VALUABLE CONSIDERATION.—Section 301 of
 15 the National Organ Transplant Act (42 U.S.C. 274e) is
 16 amended—

17 (1) in subsection (a), by inserting “, human
 18 ovum, human blastocyst, human embryo, or stem
 19 cell derived from a human embryo” after “any
 20 human organ”; and

21 (2) in subsection (c)(2)—

22 (A) by striking “human organ” each place
 23 the term appears and inserting “human organ,
 24 human ovum, human blastocyst, human em-

1 bryo, or stem cell derived from a human em-
2 bryo”; and

3 (B) by inserting “, ovum, blastocyst, em-
4 bryo, or stem cell” after “the organ”.

5 (b) NO PROFITS FROM THERAPIES THAT DESTROY
6 HUMAN EMBRYOS.—Part H of title IV of the Public
7 Health Service Act (42 U.S.C. 289 et seq.) is amended
8 by adding at the end the following:

9 **“SEC. 498D. REQUIREMENTS FOR RESEARCH INVOLVING**
10 **HUMAN EMBRYOS.**

11 “(a) ENSURING ACCESS TO AFFORDABLE TREAT-
12 MENTS.—

13 “(1) IN GENERAL.—It shall be unlawful for any
14 person to knowingly receive any valuable consider-
15 ation for any therapy that—

16 “(A) affects interstate commerce or is
17 funded, in full or in part, by Federal assistance;
18 and

19 “(B) utilizes cells from a human embryo,
20 if the process of deriving such cells destroyed
21 the embryo.

22 “(2) DEFINITION OF VALUABLE CONSIDER-
23 ATION.—In this subsection, the term ‘valuable con-
24 sideration’ does not include the reasonable produc-

1 tion and administrative costs associated with devel-
2 oping a therapy described in paragraph (1).”.

3 **SEC. 9. FUNDING FOR STEM CELL RESEARCH.**

4 (a) IN GENERAL.—There is authorized to be appro-
5 priated to carry out this Act, \$5,000,000,000 for the pe-
6 riod beginning with fiscal year 2008 and ending with fiscal
7 year 2017.

8 (b) DISTRIBUTION OF FUNDS.—

9 (1) IN GENERAL.—Not less than 90 percent of
10 the amount appropriated in each fiscal year under
11 subsection (a) shall be allocated by the Secretary for
12 the research and administrative costs described in
13 this Act.

14 (2) REMAINDER.—Not more than 10 percent of
15 the amount appropriated in each fiscal year under
16 subsection (a) shall be allocated by the Secretary
17 for—

18 (A) the Federal promotion of human em-
19 bryo or embryos adoption from in vitro fertiliza-
20 tion clinics;

21 (B) research towards prevention and med-
22 ical treatment of genetic conditions consistent
23 with this Act that do not involve harming or de-
24 stroying human embryos in order to promote
25 the health of the population; and

1 (C) research to advance the understanding
2 of clinical techniques to minimize the creation
3 of human embryo or embryos that remain
4 unimplanted after clinical in vitro fertilization
5 treatments.

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