

110TH CONGRESS
1ST SESSION

S. _____

To intensify research to derive human pluripotent stem cell lines.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

A BILL

To intensify research to derive human pluripotent stem cell
lines.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Hope Offered through
5 Principled and Ethical Stem Cell Research Act” or the
6 “HOPE Act”.

7 **SEC. 2. PURPOSES.**

8 It is the purpose of this Act to—

- 9 (1) intensify research that may result in im-
10 proved understanding of or treatments for diseases
11 and other adverse health conditions; and

1 (2) promote the derivation of pluripotent stem
2 cell lines without the creation of human embryos for
3 research purposes and without the destruction or
4 discarding of, or risk of injury to, a human embryo
5 or embryos other than those that are naturally dead.

6 **SEC. 3. HUMAN PLURIPOTENT STEM CELL RESEARCH.**

7 Part H of title IV of the Public Health Service Act
8 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
9 tion 498C the following:

10 **“SEC. 498D. HUMAN PLURIPOTENT STEM CELL RESEARCH.**

11 “(a) IN GENERAL.—The Secretary shall conduct and
12 support basic and applied research to develop techniques
13 for the isolation, derivation, production, or testing of stem
14 cells, including pluripotent stem cells that have the flexi-
15 bility of embryonic stem cells (whether or not they have
16 an embryonic source), that may result in improved under-
17 standing of or treatments for diseases and other adverse
18 health conditions, provided that the isolation, derivation,
19 production, or testing of such cells will not involve—

20 “(1) the creation of a human embryo or em-
21 bryos for research purposes; or

22 “(2) the destruction or discarding of, or risk of
23 injury to, a human embryo or embryos other than
24 those that are naturally dead.

1 “(b) GUIDELINES.—Not later than 90 days after the
2 date of the enactment of this section, the Secretary, after
3 consultation with the Director of NIH, shall issue final
4 guidelines 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 animal research to en-
9 sure that any research involving human cells using
10 these techniques would clearly be consistent with the
11 standards established under subsection (a);

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

14 “(3) consistent with standards established
15 under subsection (a), take into account techniques
16 outlined by the President’s Council on Bioethics and
17 any other appropriate techniques and research; and

18 “(4) in the case of research involving stem cells
19 from a naturally dead embryo, require assurances
20 from grant applicants that no alteration of the tim-
21 ing, methods, or procedures used to create, main-
22 tain, or intervene in the development of a human
23 embryo was made solely for the purpose of deriving
24 the stem cells.

1 “(c) REPORTING REQUIREMENTS.—Not later than
2 January 1 of each year, the Secretary shall prepare and
3 submit to the appropriate committees of the Congress a
4 report describing the activities carried out under this sec-
5 tion during the fiscal year, including a description of the
6 research conducted under this section.

7 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
8 tion shall be construed as altering the policy in effect on
9 the date of enactment of this section regarding the eligi-
10 bility of stem cell lines for funding by the National Insti-
11 tutes of Health.

12 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
13 is authorized to be appropriated such sums as may be nec-
14 essary to carry out this section.

15 “(f) DEFINITIONS.—In this section:

16 “(1) NATURALLY DEAD.—The term ‘naturally
17 dead’ means having naturally and irreversibly lost
18 the capacity for integrated cellular division, growth,
19 and differentiation that is characteristic of an orga-
20 nism, even if some cells of the former organism may
21 be alive in a disorganized state.

22 “(2) HUMAN EMBRYO OR EMBRYOS.—The term
23 ‘human embryo or embryos’ includes any organism,
24 not protected as a human subject under part 46 of
25 title 45, Code of Federal Regulations, as of the date

1 of enactment of this section, that is derived by fer-
2 tilization, parthenogenesis, cloning, or any other
3 means from one or more human gametes or human
4 diploid cells.

5 “(3) RISK OF INJURY.—The term ‘risk of in-
6 jury’ means subjecting a human embryo or embryos
7 to risk of injury or death greater than that allowed
8 for research on fetuses in utero under section
9 46.204(b) of title 45, Code of Federal Regulations,
10 and section 498(b) of this Act.”

11 **SEC. 4. NATIONAL AMNIOTIC AND PLACENTAL STEM CELL**
12 **BANK.**

13 (a) IN GENERAL.—The Secretary of Health and
14 Human Services shall enter into a contract with the Insti-
15 tute of Medicine for the conduct of a study to recommend
16 an optimal structure for an amniotic and placental stem
17 cell bank program and to address pertinent issues to maxi-
18 mize the potential of such technology, including collection,
19 storage, standards setting, information sharing, distribu-
20 tion, reimbursement, research, and outcome measures. In
21 conducting such study, the Institute should receive input
22 from relevant experts including the existing operators of
23 federal tissue bank programs and the biomedical research
24 programs within the Department of Defense.

1 (b) REPORT.—Not later than 180 days after the date
2 of enactment of this Act, the Institute of Medicine shall
3 complete the study under subsection (a) and submit to the
4 Secretary of Health and Human Services and the appro-
5 priate committees of Congress a report on the results of
6 such study.