

107TH CONGRESS
1ST SESSION

S. 1349

To provide for a National Stem Cell Donor Bank regarding qualifying human stem cells, and for the conduct and support of research using such cells.

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 2001

Mr. ENSIGN (for himself and Mr. BROWNBACK) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for a National Stem Cell Donor Bank regarding qualifying human stem cells, and for the conduct and support of research using such cells.

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 “Responsible Stem Cell
5 Research Act of 2001”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) Past investments in biomedical research
9 have resulted in better health, an improved quality

1 of life for all Americans, and a reduction in national
2 health care expenditures.

3 (2) The Nation's commitment to biomedical re-
4 search has expanded the base of scientific knowledge
5 about health and disease and revolutionized the
6 practice of medicine.

7 (3) Research sponsored by the National Insti-
8 tutes of Health is responsible for the identification
9 of genetic mutations relating to nearly 100 diseases,
10 including Alzheimer's disease, cystic fibrosis, Hun-
11 tington's disease, osteoporosis, many forms of can-
12 cer, and immune deficiency disorders.

13 (4) Many Americans still face serious and life-
14 threatening health problems, both acute and chronic.

15 (5) Neurodegenerative diseases of the elderly,
16 such as Alzheimer's and Parkinson's disease, threat-
17 en to destroy the lives of millions of Americans.

18 (6) Cancer remains a comprehensive threat to
19 any tissue or organ of the body at any age, and re-
20 mains a leading cause of morbidity and mortality.

21 (7) The extent of psychiatric and neurological
22 diseases poses considerable challenges in under-
23 standing the workings of the brain and nervous sys-
24 tem.

1 (8) Diabetes, both insulin and noninsulin forms,
2 afflicts 16 million Americans and places them at risk
3 for acute and chronic complications, including blind-
4 ness, kidney failure, atherosclerosis, and nerve de-
5 generation.

6 (9) Recent scientific developments show that
7 human stem cell research based on ethically respon-
8 sible stem cell sources may lead to exponential im-
9 provements in the treatment of many terminal and
10 debilitating conditions, from cancer to Parkinson's
11 to Alzheimer's to diabetes to heart disease.

12 (10) To take full advantage of the tremendous
13 potential for finding a cure or effective treatment for
14 many debilitating diseases, the Federal investment
15 in ethical stem cell research must be expanded.

16 **SEC. 3. NATIONAL STEM CELL DONOR BANK.**

17 (a) IN GENERAL.—The Secretary of Health and
18 Human Services shall by contract establish and maintain
19 a National Stem Cell Donor Bank (in this section referred
20 to as the “Donor Bank”). The purpose of the Donor Bank
21 shall be to seek and preserve donations of qualifying
22 human stem cells and to make such donated cells available
23 for biomedical research and for therapeutic purposes.

24 (b) QUALIFYING HUMAN STEM CELLS.—For pur-
25 poses of this Act, the term “qualifying human stem cells”

1 means human stem cells obtained from human placentas,
 2 umbilical cord blood, organs or tissues of a living or de-
 3 ceased human being who has been born, or organs or tis-
 4 sues of unborn human offspring who died of natural
 5 causes (such as spontaneous abortion).

6 (c) ADMINISTRATION OF DONOR BANK.—The Donor
 7 Bank shall be under the general supervision of the Sec-
 8 retary, and under the direction of a board of directors
 9 meeting such criteria as the Secretary may establish.

10 (d) PATIENT REGISTRY.—The Donor Bank shall
 11 with respect to qualifying human stem cells—

12 (1) operate a registry of patients who are trans-
 13 plant candidates;

14 (2) establish a system for finding donors who
 15 are unrelated to the candidate patients and are suit-
 16 ably matched to the patients; and

17 (3) carry out informational and educational ac-
 18 tivities.

19 (e) CRITERIA.—The Secretary shall establish criteria
 20 for the Donor Bank and other entities that participate in
 21 the program under this section, including—

22 (1) quality standards and standards for tissue
 23 typing and obtaining the informed consent of do-
 24 nors, or the parents or legal representatives of do-
 25 nors as appropriate;

1 (2) donor selection criteria, based on estab-
2 lished medical criteria, to protect both donors and
3 transplant recipients and to prevent the trans-
4 mission of potentially harmful infectious diseases;

5 (3) procedures to ensure the proper collection
6 and transportation of qualifying human stem cells;
7 and

8 (4) standards that—

9 (A) require the establishment of a system
10 of strict confidentiality of records relating to
11 the identity and address of and medical infor-
12 mation on patients and donors; and

13 (B) prescribe the purposes for which the
14 records described in subparagraph (A) may be
15 disclosed, and the circumstances and extent of
16 the disclosure.

17 (f) AUTHORIZATION OF APPROPRIATIONS.—For the
18 purpose of carrying out this section, there are authorized
19 to be appropriated such sums as may be necessary for
20 each of the fiscal years 2002 through 2006.

21 **SEC. 4. USE OF QUALIFYING HUMAN STEM CELLS IN RE-**
22 **SEARCH CONDUCTED OR SUPPORTED BY NA-**
23 **TIONAL INSTITUTES OF HEALTH.**

24 (a) IN GENERAL.—The Secretary, acting through the
25 Director of the National Institutes of Health, may conduct

1 and support research that uses qualifying human stem
2 cells.

3 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out subsection (a), there are author-
5 ized to be appropriated \$275,000,000 for fiscal year 2002,
6 and such sums as may be necessary for each of the fiscal
7 years 2003 through 2006.

8 **SEC. 5. DEFINITIONS.**

9 For purposes of this Act:

10 (1) The term “qualifying human stem cells”
11 has the meaning given such term in section 3.

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

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