

110TH CONGRESS
1ST SESSION

S. 957

To provide for the collection and maintenance of amniotic fluid and placental stem cells for the treatment of patients and research.

IN THE SENATE OF THE UNITED STATES

MARCH 22, 2007

Mr. BURR (for himself and 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 for the collection and maintenance of amniotic fluid and placental stem cells for the treatment of patients and research.

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 “Amniotic Fluid and
5 Placental Stem Cell Banking Act of 2007”.

6 **SEC. 2. AMNIOTIC FLUID AND PLACENTAL STEM CELL IN-**
7 **VENTORY.**

8 (a) IN GENERAL.—The Secretary shall enter into
9 one-time contracts with qualified amniotic fluid and pla-

1 cental stem cell banks to assist in the collection and main-
2 tenance of 100,000 new units of high-quality amniotic
3 fluid and placental stem cells to be made available for
4 treatment through the C.W. Bill Young Cell Transplan-
5 tation and Treatment Program and to carry out the re-
6 quirements of subsection (b).

7 (b) REQUIREMENTS.—The Secretary shall require
8 each recipient of a contract under this section—

9 (1) to acquire, tissue-type, test, cryopreserve,
10 and store donated units of amniotic fluid and pla-
11 cental stem cells acquired with the informed consent
12 of the donor, as determined by the Secretary pursu-
13 ant to section 379(c) of the Public Health Service
14 Act, in a manner that complies with applicable Fed-
15 eral and State regulations;

16 (2) to encourage donation from a genetically di-
17 verse population;

18 (3) to make amniotic fluid and placental stem
19 cells that are collected pursuant to this section or
20 otherwise and meet all applicable Federal standards
21 available to physicians for treatment;

22 (4) to make amniotic fluid and placental stem
23 cell units that are collected, but not appropriate for
24 clinical use, available for peer-reviewed research;

1 (5) to make data available, as required by the
2 Secretary and consistent with section 379(d)(3) of
3 the Public Health Service Act (42 U.S.C.
4 274k(d)(3)), as amended by this Act, in a standard-
5 ized electronic format, as determined by the Sec-
6 retary, for the C.W. Bill Young Cell Transplantation
7 and Treatment Program; and

8 (6) to submit data in a standardized electronic
9 format for inclusion in the stem cell therapeutic out-
10 comes database maintained under section 379A of
11 the Public Health Service Act, as amended by this
12 Act.

13 (c) APPLICATION.—To seek to enter into a contract
14 under this section, a qualified amniotic fluid and placental
15 stem cell bank shall submit an application to the Secretary
16 at such time, in such manner, and containing such infor-
17 mation as the Secretary may reasonably require. At a min-
18 imum, an application for a contract under this section
19 shall include a requirement that the applicant—

20 (1) will participate in the C.W. Bill Young Cell
21 Transplantation and Treatment Program for a pe-
22 riod of at least 10 years;

23 (2) will make amniotic fluid and placental stem
24 cell units collected pursuant to this section available
25 through the C.W. Bill Young Cell Transplantation

1 and Treatment Program in perpetuity or for such
 2 time as determined viable by the Secretary; and

3 (3) if the Secretary determines through an as-
 4 sessment, or through petition by the applicant, that
 5 an amniotic fluid and placental stem cell bank is no
 6 longer operational or does not meet the requirements
 7 of section 379(d)(4) of the Public Health Service
 8 Act (as added by this Act) and as a result may not
 9 distribute the units, transfer the units collected pur-
 10 suant to this section to another qualified amniotic
 11 fluid and placental stem cell bank approved by the
 12 Secretary to ensure continued availability of
 13 amniotic fluid and placental stem cell units.

14 (d) DURATION OF CONTRACTS.—

15 (1) IN GENERAL.—Except as provided in para-
 16 graph (2), the term of each contract entered into by
 17 the Secretary under this section shall be for 10
 18 years. The Secretary shall ensure that no Federal
 19 funds shall be obligated under any such contract
 20 after the earlier of—

21 (A) the date that is 3 years after the date
 22 on which the contract is entered into; or

23 (B) September 30, 2012.

24 (2) EXTENSIONS.—Subject to paragraph
 25 (1)(B), the Secretary may extend the period of fund-

1 ing under a contract under this section to exceed a
2 period of 3 years if—

3 (A) the Secretary finds that 100,000 new
4 units of high-quality amniotic fluid and pla-
5 cental stem cells have not yet been collected
6 pursuant to this section; and

7 (B) the Secretary does not receive an ap-
8 plication for a contract under this section from
9 any qualified amniotic fluid and placental stem
10 cell bank that has not previously entered into a
11 contract under this section or the Secretary de-
12 termines that the outstanding inventory need
13 cannot be met by the one or more qualified
14 amniotic fluid and placental stem cell banks
15 that have submitted an application for a con-
16 tract under this section.

17 (3) PREFERENCE.—In considering contract ex-
18 tensions under paragraph (2), the Secretary shall
19 give preference to qualified amniotic fluid and pla-
20 cental stem cell banks that the Secretary determines
21 have demonstrated a superior ability to satisfy the
22 requirements described in subsection (b) and to
23 achieve the overall goals for which the contract was
24 awarded.

1 (e) REGULATIONS.—The Secretary may promulgate
2 regulations to carry out this section.

3 (f) DEFINITIONS.—In this section:

4 (1) The term “C.W. Bill Young Cell Transplan-
5 tation and Treatment Program” means the C.W.
6 Bill Young Cell Transplantation and Treatment Pro-
7 gram under section 379 of the Public Health Service
8 Act, as amended by this Act.

9 (2) The term “amniotic fluid and placental
10 stem cell donor” means a mother who has delivered
11 a baby and consents to donate the placental stem
12 cells or a mother who undergoes amniocentesis or
13 placental sampling for other diagnostic purposes and
14 consents to donate the discarded amniotic fluid and
15 placental stem cells after the diagnostic analysis is
16 completed.

17 (3) The term “amniotic fluid and placental
18 stem cell unit” means the amniotic fluid and pla-
19 cental stem cells collected from the placenta of a sin-
20 gle newborn baby or collected from the discarded
21 amniotic fluid or placenta after a diagnostic test.

22 (5) The term “qualified amniotic fluid and pla-
23 cental stem cell bank” has the meaning given to that
24 term in section 379(d)(4) of the Public Health Serv-
25 ice Act, as amended by this Act.

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

3 (g) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to the Secretary
5 \$20,000,000 for each of fiscal years 2008 through 2012,
6 to carry out this section.

7 **SEC. 3. C.W. BILL YOUNG CELL TRANSPLANTATION AND**
8 **TREATMENT PROGRAM.**

9 Part I of title III of the Public Health Service Act
10 (42 U.S.C. 274k et seq.) is amended—

11 (1) in the part heading by inserting “AND
12 TREATMENT” after “TRANSPLANTATION”;

13 (2) in section 379—

14 (A) in subsection (a)

15 (i) in paragraph (4)(A), by inserting
16 “representatives of amniotic fluid and pla-
17 cental stem cell banks and participating
18 birthing hospitals and ob/gyn offices, re-
19 cipients of an amniotic fluid and placental
20 stem cell treatment, basic scientists with
21 expertise in the biology of amniotic fluid
22 and placental stem cells,” after “adult
23 stem cells,”;

24 (ii) in paragraph (5)(A), by striking
25 “, or cord blood bank from participating in

any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank” and inserting “, cord blood bank, or amniotic fluid and placental stem cell bank from participating in any decision that materially affects the center, recruitment organization, transplant center, cord blood bank, or amniotic fluid and placental stem cell bank”; and

(iii) in paragraph (6)

(I) in subparagraph (A), by striking “and” at the end.

(II) in subparagraph (B), by striking the period and inserting “; and”; and

(III) by adding at the end the following:

“(C) not later than 6 months after the date of enactment of the Amniotic Fluid and Placental Stem Cell Banking Act of 2007, a report concerning the recommendations on the scientific factors necessary to define an amniotic fluid and placental stem cell unit as a high-quality unit.”;

(B) in subsection (b), by inserting “and amniotic fluid and placental stem cell banks” before the period;

(C) in subsection (c)—

(i) in the matter preceding paragraph (1), by striking “process, examine” and inserting the following: “process—

“(1) examine”;

(ii) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B) and indenting accordingly;

(iii) by striking the first period and inserting “; and

“(2) examine the informed consent procedures for cord blood donation and determine appropriate informed consent procedures for amniotic fluid and placental stem cell donation.”; and

(v) by adding at the end the following:

“The Secretary shall require that the standards used by the accreditation entities recognized under subsection (b) ensures that an amniotic fluid and placental stem cell unit is acquired with the informed consent of the maternal donor.”;

(D) in subsection (d)—

1 (i) by redesignating paragraphs (3)
2 and (4) as paragraphs (4) and (5), respec-
3 tively; and

4 (ii) by inserting after paragraph (2),
5 the following;

6 “(2) AMNIOTIC FLUID AND PLACENTAL STEM
7 CELL FUNCTIONS.—With respect to amniotic fluid
8 and placental stem cells, the Program shall—

9 “(A) operate a system for identifying,
10 matching, and facilitating the distribution of
11 donated amniotic fluid and placental stem cell
12 units that are suitably matched to candidate
13 patients and meet all applicable Federal and
14 State regulations from a qualified amniotic
15 fluid and placental stem cell bank;

16 “(B) consistent with paragraph (3), allow
17 treatment physicians, other appropriate health
18 care professionals, and patients to search by
19 means of electronic access all available amniotic
20 fluid and placental stem cell units made avail-
21 able through the Program;

22 “(C) allow treatment physicians and other
23 appropriate health care professionals to reserve,
24 as defined by the Secretary, an amniotic fluid
25 and placental stem cell unit for treatment;

1 “(D) support studies and demonstration
2 and outreach projects for the purpose of in-
3 creasing amniotic fluid and placental stem cell
4 donation to ensure a genetically diverse collec-
5 tion of amniotic fluid and placental stem cell
6 units;

7 “(E) provide for a system of patient advoca-
8 cacy through the office established under sub-
9 section (h);

10 “(F) coordinate with the qualified amniotic
11 fluid and placental stem cell banks to support
12 informational and educational activities in ac-
13 cordance with subsection (g); and

14 “(G) with respect to the system under sub-
15 paragraph (A), collect, analyze, and publish
16 data in a standardized electronic format, as re-
17 quired by the Secretary, on the number and
18 percentage of patients at each of the various
19 stages of the search process, including data re-
20 garding the furthest stage reached, the number
21 and percentage of patients who are unable to
22 complete the search process, and the reasons
23 underlying such circumstances.”;

24 (iii) in paragraph (4) (as so redesign-
25 nated)—

1 (I) in subparagraph (A), by strik-
 2 ing “and (2)(A), cells from bone mar-
 3 row donors and cord blood” and in-
 4 serting “, (2)(A), and (3)(A), cells
 5 from bone marrow donors, cord blood,
 6 and amniotic fluid and placental stem
 7 cells”; and

8 (II) in subparagraph (B), by
 9 striking “that enables transplant,”
 10 and inserting “. The standardization
 11 shall enable”;

12 (iv) in paragraph (5) (as so redesign-
 13 nated)—

14 (I) by redesignating subpara-
 15 graphs (A) through (F) as clauses (i)
 16 through (vi), respectively, and indent
 17 accordingly;

18 (II) by striking “The term” and
 19 inserting the following:

20 “(A) The term”; and

21 (III) by adding at the end the
 22 following:

23 “(B) The term ‘qualified amniotic fluid
 24 and placental stem cell bank’ means a qualified

1 amniotic fluid and placental stem cell bank
2 that—

3 “(i) has obtained all applicable Fed-
4 eral and State licenses, certifications, reg-
5 istrations (including pursuant to the regu-
6 lations of the Food and Drug Administra-
7 tion), and other authorizations required to
8 operate and maintain an amniotic fluid
9 and placental stem cell bank;

10 “(ii) has implemented donor screen-
11 ing, amniotic fluid and placental stem cell
12 collection practices, and processing meth-
13 ods intended to protect the health and
14 safety of donors and transplant recipients
15 to improve transplant outcomes, including
16 with respect to the transmission of poten-
17 tially harmful infections and other dis-
18 eases;

19 “(iii) is accredited by an accreditation
20 entity recognized by the Secretary under
21 subsection (b);

22 “(iv) has established a system of strict
23 confidentiality to protect the identity and
24 privacy of patients and donors in accord-
25 ance with existing Federal and State law;

1 “(v) has established a system for en-
 2 couraging donation by a genetically diverse
 3 group of donors; and

4 “(vi) has established a system to con-
 5 fidentially maintain linkage between a
 6 amniotic fluid and placental stem cell unit
 7 and a maternal donor.”;

8 (E) by redesignating subsections (h)
 9 through (n) as subsections (i) through (o), re-
 10 spectively;

11 (F) by inserting after subsection (g), the
 12 following:

13 “(h) AMNIOTIC FLUID AND PLACENTAL STEM CELL
 14 RECRUITMENT; PRIORITIES; INFORMATION AND EDU-
 15 CATION.—

16 “(1) RECRUITMENT; PRIORITIES.—The Pro-
 17 gram shall support activities, in cooperation with
 18 qualified amniotic fluid and placental stem cell
 19 banks, for the recruitment of amniotic fluid and pla-
 20 cental stem cell donors. Such recruitment program
 21 shall identify populations that are underrepresented
 22 among amniotic fluid and placental stem cell donors.
 23 In the case of populations that are identified under
 24 the preceding sentence:

1 “(A) The Program shall give priority to
2 supporting activities under this part to increase
3 representation for such populations in order to
4 enable a member of such a population, to the
5 extent practicable, to have a probability of find-
6 ing a suitable amniotic fluid and placental stem
7 cell unit that is comparable to the probability
8 that an individual who is not a member of an
9 underrepresented population would have.

10 “(B) The Program shall consider racial
11 and ethnic minority groups (including persons
12 of mixed ancestry) to be populations that have
13 been identified for purposes of this paragraph,
14 and shall support activities under subparagraph
15 (A) with respect to such populations.

16 “(2) INFORMATION AND EDUCATION REGARD-
17 ING RECRUITMENT; TESTING AND DONATION.—

18 “(A) IN GENERAL.—In carrying out the
19 recruitment program under paragraph (1), the
20 Program shall support informational and edu-
21 cational activities in coordination with qualified
22 amniotic fluid and placental stem cell banks
23 and organ donation public awareness campaigns
24 operated through the Department of Health
25 and Human Services, for purposes of recruiting

1 pregnant women to serve as donors of amniotic
2 fluid and placental stem cells. Such information
3 and educational activities shall include the fol-
4 lowing:

5 “(i) Making information available to
6 the general public, including information
7 describing the needs of patients with re-
8 spect to amniotic fluid and placental stem
9 cell units.

10 “(ii) Educating and providing infor-
11 mation to pregnant women who are willing
12 to donate amniotic fluid and placental
13 stem cell units.

14 “(iii) Training individuals in request-
15 ing pregnant women to serve as amniotic
16 fluid and placental stem cell donors.

17 “(B) PRIORITIES.—In carrying out infor-
18 mational and educational activities under sub-
19 paragraph (A), the Program shall give priority
20 to supporting the recruitment of pregnant
21 women to serve as donors of amniotic fluid and
22 placental stem cell for populations that are
23 identified under paragraph (1).

24 “(3) TRANSPLANTATION AS TREATMENT OP-
25 TION.—In addition to activities regarding recruit-

1 ment, the recruitment program under paragraph (1)
 2 shall provide information to physicians, other health
 3 care professionals, and the public regarding amniotic
 4 fluid and placental stem cell treatments as a treat-
 5 ment option.

6 “(4) IMPLEMENTATION OF SUBSECTION.—The
 7 requirements of this subsection shall be carried out
 8 by the entity that has been awarded a contract by
 9 the Secretary under subsection (a) to carry out the
 10 functions described in subsection (d)(3).”;

11 (G) in subsection (i) (as so redesignated)—

12 (i) in the subsection heading by strik-
 13 ing “AND CORD BLOOD” and inserting “,
 14 CORD BLOOD, AND AMNIOTIC FLUID AND
 15 PLACENTAL STEM CELLS”;

16 (ii) in paragraph (2)—

17 (I) in subparagraph (B), by
 18 striking “and cord blood therapy” and
 19 inserting “, cord blood, and amniotic
 20 fluid and placental stem cell therapy
 21 and treatment”;

22 (II) in subparagraph (C), by
 23 striking “or cord blood unit” and in-
 24 serting “, cord blood unit, or amniotic
 25 fluid and placental stem cell unit”;

1 (III) in subparagraph (D), by
 2 striking “and (2) of subsection (d) to
 3 conduct an ongoing search for a bone
 4 marrow donor or cord blood unit” and
 5 inserting “, (2), and (3) of subsection
 6 (d) to conduct an ongoing search for
 7 a bone marrow donor, cord blood unit,
 8 or amniotic fluid and placental stem
 9 cell unit”;

10 (IV) in subparagraph (E)—

11 (aa) in the matter preceding
 12 clause (i), by striking “(1) and
 13 (2)” and inserting “(1), (2), and
 14 (3)”; and

15 (bb) in clause (i), by striking
 16 “or cord blood units” and insert-
 17 ing “, cord blood units, or
 18 amniotic fluid and placental stem
 19 cell units”; and

20 (V) in subparagraph (F)—

21 (aa) by redesignating clause
 22 (v) as clause (viii); and

23 (bb) by inserting after
 24 clause (iv), the following:

1 “(v) A comparison of treatment cen-
 2 ters with respect to search and other costs
 3 that prior to treatment are charged to pa-
 4 tients by treatment centers.

5 “(vi) The post-treatment outcomes for
 6 individual treatment centers.

7 “(vii) Information concerning issues
 8 that patients may face after a treatment.”;
 9 and

10 (iii) in paragraph (3)(B), by inserting
 11 before the period the following: “and on
 12 behalf of patients who have completed the
 13 search for an amniotic fluid and placental
 14 stem cell unit, provide information and
 15 education on the process of receiving a
 16 treatment, including the post-treatment
 17 process”; and

18 (H) in subsection (o) (as so redesignated),
 19 by striking “(d)(4)(D)” and inserting
 20 “(d)(5)(A)(iv)”;

21 (3) in section 379A—

22 (A) in subsection (b)—

23 (i) by striking “, results” and insert-
 24 ing “, treatments, results”; and

1 (ii) by inserting “or treatment” after
 2 “transplantation”;

3 (B) in subsection (c), by inserting “or
 4 treatment” after “transplant”; and

5 (C) in subsection (d)

6 (i) by inserting “treatment centers,”
 7 after “programs,”; and

8 (ii) by striking “and cord blood
 9 banks” and inserting “cord blood banks,
 10 and amniotic fluid and placental stem cell
 11 banks”; and

12 (4) in section 379A–1, in paragraph (4), by in-
 13 serting “and Treatment” after “Transplantation”.

14 **SEC. 4. AUTHORIZATION OF APPROPRIATIONS.**

15 Section 379B of the Public Health Service Act (42
 16 U.S.C. 274m) is amended by striking “2010” and insert-
 17 ing “2012”.

○