

105TH CONGRESS
1ST SESSION

H. R. 2202

To amend the Public Health Service Act to revise and extend the bone marrow donor program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 17, 1997

Mr. YOUNG of Florida (for himself, Mr. BLILEY, Mr. SAXTON, Mr. STOKES, Mr. HOYER, Mr. HALL of Ohio, Mr. McDADE, Mr. SHAW, Mr. WATTS of Oklahoma, Mr. WAXMAN, Mr. HEFLEY, Mr. MOAKLEY, Mr. DELLUMS, Mr. HILLEARY, Mr. BORSKI, Ms. GRANGER, Mr. HORN, Mr. COBURN, Mr. HASTINGS of Florida, Mr. THOMPSON, Mr. PICKETT, Mr. MASCARA, Mr. PETERSON of Minnesota, Mr. THORNBERRY, Mr. GORDON, Mr. BLUNT, Mr. McNULTY, Mr. PASTOR, Mr. MORAN of Virginia, Ms. ROSLEHTINEN, Mrs. MINK of Hawaii, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. DUNN, Mr. FALDOMAVAEGA, Mr. CONDIT, Mr. DUNCAN, Mr. GREENWOOD, Mr. GUTIERREZ, Mr. SHIMKUS, Mr. CLAY, Mr. BOB SCHAFFER of Colorado, Mr. BOEHLERT, Mr. DEFazio, Mr. QUINN, Ms. NORTON, Mr. CALVERT, Mr. WISE, Ms. PELOSI, Mr. FRELINGHUYSEN, Mr. FROST, Mrs. LOWEY, Mr. BARTON of Texas, Ms. DELAURO, Mr. LATHAM, Mr. FOLEY, Mr. SPENCE, Mr. CANADY of Florida, Mr. HINCHEY, Ms. KILPATRICK, Mr. BOYD, Ms. SLAUGHTER, Mr. BONILLA, Mr. ABERCROMBIE, Mrs. THURMAN, and Mr. PORTER) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Public Health Service Act to revise and extend the bone marrow donor program, 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 “National Marrow
3 Donor Program Reauthorization Act of 1997”.

4 **SEC. 2. REVISION AND EXTENSION OF NATIONAL BONE**
5 **MARROW DONOR PROGRAM.**

6 Title III of the Public Health Service Act (42 U.S.C.
7 241 et seq.) is amended—

8 (1) by transferring section 378 from the cur-
9 rent placement of the section and inserting the sec-
10 tion after section 377; and

11 (2) by amending part I to read as follows:

12 **“PART I—NATIONAL BONE MARROW AND BLOOD**
13 **STEM CELL DONOR PROGRAM**

14 **“SEC. 379. ESTABLISHMENT OF NATIONAL PROGRAM.**

15 “(a) IN GENERAL.—The Secretary shall by contract
16 establish a program whose purpose is to carry out in ac-
17 cordance with this part a system to assist patients who
18 are in need of a transplant of blood stem cells in searching
19 for individuals who are biologically unrelated to the pa-
20 tients and willing to be donors of such cells.

21 “(b) ADMINISTRATION OF PROGRAM.—

22 “(1) IN GENERAL.—The program under sub-
23 section (a) (referred to in this part as the ‘Pro-
24 gram’) shall be under the general supervision of the
25 Secretary, and under the direction of a board of di-
26 rectors meeting the requirements of section 379C(a).

1 “(2) CONSULTATIONS.—In developing policies
2 affecting the Program, the Secretary shall consult
3 with the board of directors of the Program and with
4 the bone marrow donor program of the Department
5 of the Navy.

6 “(c) BLOOD STEM CELLS; RELATION TO BONE MAR-
7 ROW.—For purposes of subsection (a), the term ‘blood
8 stem cells’ (referred to in this part as ‘stem cells’) means
9 hematopoietic cells found in bone marrow, umbilical-cord
10 blood, peripheral blood, and such other sources as may
11 be identified.

12 **“SEC. 379A. FUNCTIONS OF NATIONAL PROGRAM.**

13 “(a) IN GENERAL.—In providing for the system
14 under section 379(a), the Program shall carry out the fol-
15 lowing:

16 “(1) Establish the system through coordinating
17 with entities that operate programs relevant to the
18 purpose described in such section, including the op-
19 eration of donor and recipient registries, donor cen-
20 ters, collection centers, and transplant centers.

21 “(2) Maintain registries in accordance with sub-
22 section (b).

23 “(3) Recruit potential donors of stem cells, and
24 carry out educational activities, in accordance with
25 subsection (c).

1 “(4) Carry out activities for patient advocacy
2 and case management in accordance with subsection
3 (d).

4 “(5) Collect, analyze, and publish data concern-
5 ing the donation and transplantation of stem cells.

6 “(6) With respect to searches for a biologically
7 unrelated donor of stem cells that are conducted
8 through the system, collect and analyze and publish
9 data on the number and percentage of patients at
10 each of the various stages of the search process, in-
11 cluding data regarding the furthest stage reached;
12 the number and percentage of patients who are un-
13 able to complete the search process; and the com-
14 parative search costs of transplant centers incurred
15 by patients prior to transplantation.

16 “(7) Support studies and demonstration
17 projects for the purpose of increasing the number of
18 individuals, especially individuals who are members
19 of racial or ethnic minority groups, who are willing
20 to be donors of stem cells.

21 “(b) REGISTRIES.—

22 “(1) DONOR REGISTRY.—

23 “(A) IN GENERAL.—The Program shall
24 under subsection (a)(2) maintain one or more
25 registries containing information relating to in-

1 individuals who are willing to be donors of stem
2 cells to biologically unrelated recipients.

3 “(B) BONE MARROW; CORD BLOOD.—In-
4 formation regarding bone marrow, and informa-
5 tion regarding umbilical-cord blood, shall be in-
6 cluded for purposes of subparagraph (A).

7 “(C) MONITORING OF SCIENTIFIC DATA.—
8 In carrying out subparagraph (A), the Program
9 shall monitor the available scientific data on the
10 use as a source of stem cells of bone marrow,
11 umbilical-cord blood, peripheral blood, and such
12 other sources as may be identified, and shall
13 consider such data in carrying out subpara-
14 graph (A).

15 “(D) PRIORITY FOR UNDERREPRESENTED
16 POPULATIONS.—The Program shall identify
17 populations that are underrepresented with re-
18 spect to the information maintained under sub-
19 paragraph (A). In the case of populations that
20 are identified under the preceding sentence:

21 “(i) The Program shall give priority
22 to carrying out activities under this part to
23 increase representation for such popu-
24 lations in order to enable a member of
25 such a population, to the extent prac-

1 ticable, to have a probability of finding a
2 suitable unrelated donor that is com-
3 parable to the probability that an individ-
4 ual who is not a member of an underrep-
5 resented population would have.

6 “(ii) The Program shall consider ra-
7 cial and ethnic minority groups to be popu-
8 lations that have been identified for pur-
9 poses of this subparagraph, and shall carry
10 out clause (i) with respect to such popu-
11 lations.

12 “(E) ANNUAL UPDATING.—The Program
13 shall annually update information under sub-
14 paragraph (A) to account for changes in the
15 status of individuals as potential donors of stem
16 cells.

17 “(2) RECIPIENT REGISTRY.—

18 “(A) IN GENERAL.—The Program shall
19 under subsection (a)(2) maintain one or more
20 registries containing—

21 “(i) information relating to individuals
22 who have been a recipient of a stem-cell
23 transplant from a biologically unrelated
24 donor; and

1 “(ii) to the extent practicable, infor-
2 mation relating to individuals who have
3 been a recipient of such a transplant from
4 an autologous donation or from a bio-
5 logically related donor.

6 “(B) PATIENT OUTCOMES; ANNUAL RE-
7 PORT.—Information under subparagraph (A)
8 shall include information regarding medical out-
9 comes for patients who have been a recipient of
10 a stem-cell transplant. Such information shall
11 be categorized according to the diseases that
12 necessitated the transplants and according to
13 the transplant centers involved. The Program
14 shall annually submit to the Secretary a report
15 on such medical outcomes.

16 “(3) ADDITIONAL INFORMATION.—In addition
17 to the information required in paragraphs (1) and
18 (2) to be included in the registries under such para-
19 graphs, the Program may include in the registries
20 such information as may be appropriate with respect
21 to the purpose described in section 379(a) (including
22 information necessary to conduct an ongoing evalua-
23 tion of the scientific and clinical status of individuals
24 who have been a recipient of a stem-cell transplant
25 from a biologically unrelated donor of such cells).

1 “(c) EDUCATIONAL ACTIVITIES.—

2 “(1) RECRUITMENT OF DONORS.—

3 “(A) IN GENERAL.—The Program shall
4 under subsection (a)(3) carry out activities, in-
5 cluding providing information, for purposes of
6 recruiting individuals to serve as donors of stem
7 cells. Such activities shall include testing poten-
8 tial donors, and providing information to up-
9 date potential donors.

10 “(B) PRIORITY FOR UNDERREPRESENTED
11 POPULATIONS.—In carrying out subparagraph
12 (A), the Program shall give priority to recruit-
13 ing individuals to serve as donors of stem cells
14 for populations that are identified under sub-
15 section (b)(1)(D).

16 “(2) TRANSPLANTATION AS TREATMENT OP-
17 TION.—The Program shall under subsection (a)(3)
18 provide information to physicians, other health care
19 professionals, and the public regarding the availabil-
20 ity as a potential treatment option of receiving a
21 stem-cell transplant from a biologically unrelated
22 donor.

23 “(3) CONTRACTS FOR EDUCATIONAL ACTIVI-
24 TIES.—The Program may enter into contracts with
25 public and nonprofit private entities for the purpose

1 of assisting the Program in carrying out paragraphs
2 (1) and (2).

3 “(d) OFFICE OF PATIENT ADVOCACY AND CASE
4 MANAGEMENT.—

5 “(1) IN GENERAL.—The Program shall under
6 subsection (a)(4) establish within the Program an
7 office to be known as the Office of Patient Advocacy
8 and Case Management (referred to in this subsection
9 as the ‘Office’), which shall be headed by a director
10 appointed by the Program.

11 “(2) FUNCTIONS.—With respect to utilizing the
12 system under section 379(a) to conduct on behalf of
13 patients searches for a biologically unrelated donor
14 of stem cells, the Office shall carry out the following:

15 “(A) Through coordinating with donor reg-
16 istries, transplant centers, and other entities,
17 carry out under the Program a system for pa-
18 tient advocacy and case management (separate
19 from mechanisms for donor advocacy).

20 “(B) In the case of patients who (directly
21 or through family members, physicians, or other
22 individuals) request the assistance of the Pro-
23 gram, directly provide individualized services
24 with respect to efficiently utilizing the system
25 under section 379(a) to conduct an ongoing

1 search (including individualized services regard-
2 ing each stage of the search process).

3 “(C) In carrying out subparagraph (B)
4 with respect to a patient—

5 “(i) serve as an advocate on behalf of
6 the patient; and

7 “(ii) provide individualized case man-
8 agement services on behalf of the patient.

9 “(D) In carrying out subparagraph (B),
10 monitor the system under section 379(a) to de-
11 termine—

12 “(i) whether the search needs of pa-
13 tients are being met (including the periodic
14 provision to the patient of information re-
15 garding donors who are suitability matched
16 to the patient, and of other information re-
17 garding the progress being made in the
18 search; informing the patient if the search
19 has been interrupted or discontinued; and
20 identifying and resolving problems in the
21 search, to the extent practicable); and

22 “(ii) whether donor registries, trans-
23 plant centers, and other entities are com-
24 plying with standards issued under section
25 379B(a)(4) for the system for patient ad-

1 vocacy and case management under this
2 subsection.

3 “(E) Provide for patients the following
4 data:

5 “(i) The resources available through
6 the Program.

7 “(ii) The comparative search costs of
8 transplant centers incurred by patients
9 prior to transplantation.

10 “(iii) A list of donor registries, trans-
11 plant centers, and other entities that meet
12 the applicable standards, criteria, and pro-
13 cedures under section 379B.

14 “(iv) The posttransplant outcomes for
15 individual transplant centers.

16 “(v) Such other information as the
17 Program determines to be appropriate.

18 “(F) Conduct surveys of patients and their
19 families and physicians to determine the extent
20 of satisfaction with the system for patient advo-
21 cacy and case management under this sub-
22 section, and to identify ways in which the sys-
23 tem can be improved.

24 “(3) ADDITIONAL FUNCTIONS.—In addition to
25 the functions established in paragraph (2) for the

1 Office, the Office may, on behalf of patients who
2 have completed the search described in such para-
3 graph, provide information and education on the
4 process of receiving a stem-cell transplant, including
5 the posttransplant process.

6 **“SEC. 379B. CRITERIA, STANDARDS, AND PROCEDURES.**

7 “(a) IN GENERAL.—For the Program and for entities
8 participating in the system established under section
9 379(a) (including individual donor centers, donor and re-
10 cipient registries, collection centers, and transplant cen-
11 ters), the Secretary shall with respect to such system es-
12 tablish and enforce the following:

13 “(1) Quality standards and standards for tissue
14 typing, obtaining the informed consent of donors,
15 and providing patient advocaacy.

16 “(2) Donor selection criteria, based on estab-
17 lished medical criteria, to protect both the donor and
18 the recipient and to prevent the transmission of po-
19 tentially harmful infectious diseases such as the vi-
20 ruses that cause hepatitis and such as the human
21 immunodeficiency virus (commonly known as HIV).

22 “(3) Procedures to ensure the proper collection
23 and transportation of stem cells.

24 “(4) Standards for the system for patient advo-
25 cacy and case management carried out under section

1 379A(d), including standards requiring the provision
2 of appropriate information (at the start of the
3 search process and throughout the process) to pa-
4 tients and their families and physicians.

5 “(5) Standards that accomplish the following:

6 “(A) Require the establishment of a sys-
7 tem of strict confidentiality of records relating
8 to the identity, address, HLA type, and manag-
9 ing donor center for donors and potential do-
10 nors, including such records that are electroni-
11 cally maintained.

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

16 “(6) In the case of donor registries and donor
17 centers participating in the system under section
18 379(a), procedures to ensure the establishment of a
19 method for integrating with the Program the donor
20 files, searches, and general procedures of such reg-
21 istries and centers.

22 “(b) PENALTIES FOR VIOLATION OF CONFIDENTIAL-
23 ITY PROVISIONS.—Any person who discloses the content
24 of any record referred to in subparagraph (A) of sub-
25 section (a)(5) without the prior written consent of the

1 donor or potential donor with respect to whom the record
2 is maintained, or in violation of the standards described
3 in subparagraph (B) of such subsection, shall be fined in
4 accordance with title 18, United States Code, or impris-
5 oned for not more than 2 years, or both.

6 **“SEC. 379C. GENERAL PROVISIONS.**

7 “(a) BOARD OF DIRECTORS.—The Program shall
8 under section 379(b)(1) appoint a board of directors and
9 shall provide for such board in accordance with the follow-
10 ing:

11 “(1) The membership of the board shall include
12 representatives of donor centers, transplant centers,
13 and blood banks; recipients of a stem-cell transplant;
14 family members of such a recipient or family mem-
15 bers of a patient who has requested the assistance
16 of the Program in searching for a biologically unre-
17 lated donor of such cells; persons with expertise in
18 the social sciences; and members of the general pub-
19 lic.

20 “(2) The Program shall select a member of the
21 board to serve as the Chair of the board.

22 “(3) The term for a member of the board shall
23 be two years, and a member shall not serve for more
24 than three consecutive terms, except that such limi-
25 tations shall not apply to the Chair of the board (or

1 the Chair-elect) or to the member of the board who
2 most recently served as the Chair.

3 “(4) Appointments to the board shall be made
4 such that each year the terms of approximately $\frac{1}{3}$
5 of the members of the board expire.

6 “(5) A member of the board may continue to
7 serve after the expiration of the term of the member
8 until a successor is appointed.

9 “(b) PROCEDURES REGARDING PUBLIC COMMENT
10 ON PROGRAM.—The Secretary shall establish and provide
11 information to the public on procedures, which may in-
12 clude establishment of a policy advisory committee, under
13 which the Secretary shall receive and consider comments
14 from interested persons relating to the manner in which
15 the Program is carrying out the functions of the Program
16 under section 379A and complying with the criteria,
17 standards, and procedures under section 379B.

18 “(c) PROVISIONS REGARDING CONTRACT FOR PRO-
19 GRAM.—

20 “(1) RECORDS.—

21 “(A) RECORDKEEPING.—Each recipient of
22 a contract or subcontract under section 379(a)
23 shall keep such records as the Secretary shall
24 prescribe, including records that fully disclose
25 the amount and disposition by the recipient of

1 the proceeds of the contract; the total cost of
2 the undertaking in connection with which the
3 contract was made; and the amount of the por-
4 tion of the cost of the undertaking supplied by
5 other sources; and such other records as will fa-
6 cilitate an effective audit.

7 “(B) EXAMINATION OF RECORDS.—The
8 Secretary and the Comptroller General of the
9 United States shall have access to any books,
10 documents, papers, and records of the recipient
11 of a contract or subcontract entered into under
12 section 379(a) that are pertinent to the con-
13 tract, for the purpose of conducting audits and
14 examinations.

15 “(2) AWARDING OF CONTRACT.—

16 “(A) ELIGIBILITY.—Entities eligible to re-
17 ceive a contract under section 379(a) include
18 nonprofit private entities.

19 “(B) APPLICATION FOR CONTRACT.—To
20 be eligible to enter into a contract under section
21 379(a), an entity shall submit to the Secretary
22 and obtain approval of an application submitted
23 at such time and in such manner, and contain-
24 ing such information, as the Secretary shall by
25 regulation prescribe.

1 **“SEC. 379D. AUTHORIZATION OF APPROPRIATIONS.**

2 For the purpose of carrying out this part, there are
3 authorized to be appropriated \$18,000,000 for fiscal year
4 1998, and such sums as may be necessary for each of the
5 fiscal years 1999 through 2002.”.

6 **SEC. 3. MISCELLANEOUS PROVISIONS REGARDING NA-**
7 **TIONAL BONE MARROW AND BLOOD STEM**
8 **CELL DONOR PROGRAM.**

9 (a) COMPLIANCE WITH NEW REQUIREMENTS FOR
10 OFFICE OF PATIENT ADVOCACY AND CASE MANAGE-
11 MENT.—With respect to requirements for the Office of Pa-
12 tient Advocacy and Case Management under part I of title
13 III of the Public Health Service Act, the Secretary of
14 Health and Human Services shall ensure that, not later
15 than 180 days after the date of the enactment of this Act,
16 such Office is in compliance with all requirements (estab-
17 lished pursuant to the amendment made by section 2(2))
18 that are additional to the requirements that under such
19 part were in effect for the Office on the day before the
20 date of the enactment of this Act.

21 (b) PLAN REGARDING RELATIONSHIP BETWEEN NA-
22 TIONAL PROGRAM AND DONOR CENTERS.—The Secretary
23 of Health and Human Services shall ensure that, not later
24 than one year after the date of the enactment of this Act,
25 the Program develops, evaluates, and implements a plan
26 to effectuate efficiencies in the relationship between the

1 Program and donor centers. The plan shall incorporate,
2 to the extent practicable, the findings and recommenda-
3 tions made in the inspection conducted by the Office of
4 the Inspector General (Department of Health and Human
5 Services) as of January 1997 and known as the Bone Mar-
6 row Program Inspection. For purposes of this subsection,
7 the terms “Program” and “donor center” have the mean-
8 ings applicable to such terms under part I of title III of
9 the Public Health Service Act.

10 (c) **RULE OF CONSTRUCTION REGARDING NATIONAL**
11 **HEART, LUNG, AND BLOOD INSTITUTE.**—The provisions
12 of part I of title III of the Public Health Service Act may
13 not be construed as having any legal effect on any pro-
14 gram of research carried out by the National Heart, Lung
15 and Blood Institute with respect to blood stem cells (in-
16 cluding such cells found in umbilical-cord blood).

17 **SEC. 4. EFFECTIVE DATE.**

18 This Act takes effect October 1, 1997, or upon the
19 date of the enactment of this Act, whichever occurs later.

○