

105TH CONGRESS
2D SESSION

S. 2150

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

IN THE SENATE OF THE UNITED STATES

JUNE 9, 1998

Mr. FRIST (for himself, Mr. KENNEDY, Mr. JEFFORDS, Mr. WELLSTONE, Ms. MIKULSKI, and Mr. TORRICELLI) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “National Bone Marrow
5 Registry Reauthorization Act of 1998”.

6 **SEC. 2. REAUTHORIZATION.**

7 (a) ESTABLISHMENT OF REGISTRY.—Section 379(a)
8 of the Public Health Service Act (42 U.S.C. 274k(a)) is
9 amended—

1 (1) by striking “(referred to in this part as the
2 ‘Registry’) that meets” and inserting “(referred to
3 in this part as the ‘Registry’) that has the purpose
4 of increasing the number of transplants for recipi-
5 ents suitably matched to biologically unrelated do-
6 nors of bone marrow, and that meets”;

7 (2) by striking “under the direction of a board
8 of directors that shall include representatives of”
9 and all that follows and inserting the following:
10 “under the direction of a board of directors meeting
11 the following requirements:

12 “(1) Each member of the board shall serve for
13 a term of two years, and each such member may
14 serve as many as three consecutive two-year terms,
15 except that such limitations shall not apply to the
16 Chair of the board (or the Chair-elect) or to the
17 member of the board who most recently served as
18 the Chair.

19 “(2) A member of the board may continue to
20 serve after the expiration of the term of such mem-
21 ber until a successor is appointed.

22 “(3) In order to ensure the continuity of the
23 board, the board shall be appointed so that each
24 year the terms of approximately $\frac{1}{3}$ of the members
25 of the board expire.

1 “(4) The membership of the board shall include
2 representatives of marrow donor centers and marrow
3 transplant centers; recipients of a bone marrow
4 transplant; persons who require or have required
5 such a transplant; family members of such a recipi-
6 ent or family members of a patient who has re-
7 quested the assistance of the Registry in searching
8 for an unrelated donor of bone marrow; persons with
9 expertise in the social sciences; and members of the
10 general public; and in addition nonvoting representa-
11 tives from the Naval Medical Research and Develop-
12 ment Command and from the Division of Organ
13 Transplantation of the Health Resources and Serv-
14 ices Administration.”.

15 (b) PROGRAM FOR UNRELATED MARROW TRANS-
16 PLANTS.—

17 (1) IN GENERAL.—Section 379(b) of the Public
18 Health Service Act (42 U.S.C. 274k(b)) is amended
19 by redesignating paragraph (7) as paragraph (8),
20 and by striking paragraphs (2) through (6) and in-
21 serting the following:

22 “(2) carry out a program for the recruitment of
23 bone marrow donors in accordance with subsection
24 (c), including with respect to increasing the rep-
25 resentation of racial and ethnic minority groups (in-

1 including persons of mixed ancestry) in the enrollment
2 of the Registry;

3 “(3) carry out informational and educational
4 activities in accordance with subsection (c);

5 “(4) annually update information to account for
6 changes in the status of individuals as potential do-
7 nors of bone marrow;

8 “(5) provide for a system of patient advocacy
9 through the office established under subsection (d);

10 “(6) provide case management services for any
11 potential donor of bone marrow to whom the Reg-
12 istry has provided a notice that the potential donor
13 may be suitably matched to a particular patient
14 (which services shall be provided through a mecha-
15 nism other than the system of patient advocacy
16 under subsection (d)), and conduct surveys of donors
17 and potential donors to determine the extent of sat-
18 isfaction with such services and to identify ways in
19 which the services can be improved;

20 “(7) with respect to searches for unrelated do-
21 nors of bone marrow that are conducted through the
22 system under paragraph (1), collect and analyze and
23 publish data on the number and percentage of pa-
24 tients at each of the various stages of the search
25 process, including data regarding the furthest stage

1 reached; the number and percentage of patients who
2 are unable to complete the search process, and the
3 reasons underlying such circumstances; and com-
4 parisons of transplant centers regarding search and
5 other costs that prior to transplantation are charged
6 to patients by transplant centers; and”.

7 (2) REPORT OF INSPECTOR GENERAL; PLAN
8 REGARDING RELATIONSHIP BETWEEN REGISTRY
9 AND DONOR CENTERS.—The Secretary of Health
10 and Human Services shall ensure that, not later
11 than one year after the date of the enactment of this
12 Act, the National Bone Marrow Donor Registry
13 (under section 379 of the Public Health Service Act)
14 develops, evaluates, and implements a plan to effec-
15 tuate efficiencies in the relationship between such
16 Registry and donor centers. The plan shall incor-
17 porate, to the extent practicable, the findings and
18 recommendations made in the inspection conducted
19 by the Office of the Inspector General (Department
20 of Health and Human Services) as of January 1997
21 and known as the Bone Marrow Program Inspec-
22 tion.

23 (c) PROGRAM FOR INFORMATION AND EDUCATION.—
24 Section 379 of the Public Health Service Act (42 U.S.C.
25 274k) is amended by striking subsection (j), by redesignig-

1 nating subsections (c) through (i) as subsections (e)
2 through (k), respectively, and by inserting after subsection
3 (b) the following subsection:

4 “(c) RECRUITMENT; PRIORITIES; INFORMATION AND
5 EDUCATION.—

6 “(1) RECRUITMENT; PRIORITIES.—The Reg-
7 istry shall carry out a program for the recruitment
8 of bone marrow donors. Such program shall identify
9 populations that are underrepresented among poten-
10 tial donors enrolled with the Registry. In the case of
11 populations that are identified under the preceding
12 sentence:

13 “(A) The Registry shall give priority to
14 carrying out activities under this part to in-
15 crease representation for such populations in
16 order to enable a member of such a population,
17 to the extent practicable, to have a probability
18 of finding a suitable unrelated donor that is
19 comparable to the probability that an individual
20 who is not a member of an underrepresented
21 population would have.

22 “(B) The Registry shall consider racial
23 and ethnic minority groups (including persons
24 of mixed ancestry) to be populations that have
25 been identified for purposes of this paragraph,

1 and shall carry out subparagraph (A) with re-
2 spect to such populations.

3 “(2) INFORMATION AND EDUCATION REGARD-
4 ING RECRUITMENT; TESTING AND ENROLLMENT.—

5 “(A) IN GENERAL.—In carrying out the
6 program under paragraph (1), the Registry
7 shall carry out informational and educational
8 activities for purposes of recruiting individuals
9 to serve as donors of bone marrow, and shall
10 test and enroll with the Registry potential do-
11 nors. Such information and educational activi-
12 ties shall include the following:

13 “(i) Making information available to
14 the general public, including information
15 describing the needs of patients with re-
16 spect to donors of bone marrow.

17 “(ii) Educating and providing infor-
18 mation to individuals who are willing to
19 serve as potential donors, including provid-
20 ing updates.

21 “(iii) Training individuals in request-
22 ing individuals to serve as potential donors.

23 “(B) PRIORITIES.—In carrying out infor-
24 mational and educational activities under sub-
25 paragraph (A), the Registry shall give priority

1 to recruiting individuals to serve as donors of
2 bone marrow for populations that are identified
3 under paragraph (1).

4 “(3) TRANSPLANTATION AS TREATMENT OP-
5 TION.—In addition to activities regarding recruit-
6 ment, the program under paragraph (1) shall pro-
7 vide information to physicians, other health care
8 professionals, and the public regarding the availabil-
9 ity, as a potential treatment option, of receiving a
10 transplant of bone marrow from an unrelated
11 donor.”.

12 (d) PATIENT ADVOCACY AND CASE MANAGEMENT.—
13 Section 379 of the Public Health Service Act (42 U.S.C.
14 274k), as amended by subsection (c) of this section, is
15 amended by inserting after subsection (c) the following
16 subsection:

17 “(d) PATIENT ADVOCACY; CASE MANAGEMENT.—

18 “(1) IN GENERAL.—The Registry shall estab-
19 lish and maintain an office of patient advocacy (in
20 this subsection referred to as the ‘Office’).

21 “(2) GENERAL FUNCTIONS.—The Office shall
22 meet the following requirements:

23 “(A) The Office shall be headed by a direc-
24 tor.

1 “(B) The Office shall operate a system for
2 patient advocacy, which shall be separate from
3 mechanisms for donor advocacy, and which
4 shall serve patients for whom the Registry is
5 conducting, or has been requested to conduct, a
6 search for an unrelated donor of bone marrow.

7 “(C) In the case of such a patient, the Of-
8 fice shall serve as an advocate for the patient
9 by directly providing to the patient (or family
10 members, physicians, or other individuals acting
11 on behalf of the patient) individualized services
12 with respect to efficiently utilizing the system
13 under subsection (b)(1) to conduct an ongoing
14 search for a donor.

15 “(D) In carrying out subparagraph (C),
16 the Office shall monitor the system under sub-
17 section (b)(1) to determine whether the search
18 needs of the patient involved are being met, in-
19 cluding with respect to the following:

20 “(i) Periodically providing to the pa-
21 tient (or an individual acting on behalf of
22 the patient) information regarding donors
23 who are suitability matched to the patient,
24 and other information regarding the
25 progress being made in the search.

1 “(ii) Informing the patient (or such
2 other individual) if the search has been in-
3 terrupted or discontinued.

4 “(iii) Identifying and resolving prob-
5 lems in the search, to the extent prac-
6 ticable.

7 “(E) In carrying out subparagraph (C),
8 the Office shall monitor the system under sub-
9 section (b)(1) to determine whether the Reg-
10 istry, donor centers, transplant centers, and
11 other entities participating in the Registry pro-
12 gram are complying with standards issued
13 under subsection (e)(4) for the system for pa-
14 tient advocacy under this subsection.

15 “(F) The Office shall ensure that the fol-
16 lowing data are made available to patients:

17 “(i) The resources available through
18 the Registry.

19 “(ii) A comparison of transplant cen-
20 ters regarding search and other costs that
21 prior to transplantation are charged to pa-
22 tients by transplant centers.

23 “(iii) A list of donor registries, trans-
24 plant centers, and other entities that meet

1 the applicable standards, criteria, and pro-
2 cedures under subsection (e).

3 “(iv) The posttransplant outcomes for
4 individual transplant centers.

5 “(v) Such other information as the
6 Registry determines to be appropriate.

7 “(G) The Office shall conduct surveys of
8 patients (or family members, physicians, or
9 other individuals acting on behalf of patients)
10 to determine the extent of satisfaction with the
11 system for patient advocacy under this sub-
12 section, and to identify ways in which the sys-
13 tem can be improved.

14 “(3) CASE MANAGEMENT.—

15 “(A) IN GENERAL.—In serving as an advo-
16 cate for a patient under paragraph (2), the Of-
17 fice shall provide individualized case manage-
18 ment services directly to the patient (or family
19 members, physicians, or other individuals acting
20 on behalf of the patient), including—

21 “(i) individualized case assessment;

22 and

23 “(ii) the functions described in para-
24 graph (2)(D) (relating to progress in the
25 search process).

1 “(B) POSTSEARCH FUNCTIONS.—In addi-
2 tion to the case management services described
3 in paragraph (1) for patients, the Office may,
4 on behalf of patients who have completed the
5 search for an unrelated donor, provide informa-
6 tion and education on the process of receiving
7 a transplant of bone marrow, including the
8 posttransplant process.”.

9 (e) CRITERIA, STANDARDS, AND PROCEDURES.—Sec-
10 tion 379(e) of the Public Health Service Act (42 U.S.C.
11 274k), as redesignated by subsection (c) of this section,
12 is amended by striking paragraph (4) and inserting the
13 following:

14 “(4) standards for the system for patient advo-
15 cacy operated under subsection (d), including stand-
16 ards requiring the provision of appropriate informa-
17 tion (at the start of the search process and through-
18 out the process) to patients and their families and
19 physicians;”.

20 (f) REPORT.—Section 379 of the Public Health Serv-
21 ice Act, as amended by subsection (c) of this section, is
22 amended by adding at the end the following subsection:

23 “(1) ANNUAL REPORT REGARDING PRETRANSPLANT
24 COSTS.—The Registry shall annually submit to the Sec-
25 retary the data collected under subsection (b)(7) on com-

1 parisons of transplant centers regarding search and other
2 costs that prior to transplantation are charged to patients
3 by transplant centers. The data shall be submitted to the
4 Secretary through inclusion in the annual report required
5 in section 379A(c).”.

6 (g) CONFORMING AMENDMENTS.—Section 379 of the
7 Public Health Service Act, as amended by subsection (c)
8 of this section, is amended—

9 (1) in subsection (f), by striking “subsection
10 (c)” and inserting “subsection (e)”; and

11 (2) in subsection (k), by striking “subsection
12 (e)(5)(A)” and inserting “subsection (e)(5)(A)” and
13 by striking “subsection (e)(5)(B)” and inserting
14 “subsection (e)(5)(B)”.

15 **SEC. 3. RECIPIENT REGISTRY.**

16 Part I of title III of the Public Health Service Act
17 (42 U.S.C. 274k et seq.) is amended by striking section
18 379A and inserting the following:

19 **“SEC. 379A. BONE MARROW SCIENTIFIC REGISTRY.**

20 “(a) ESTABLISHMENT OF RECIPIENT REGISTRY.—
21 The Secretary, acting through the Registry under section
22 379 (in this section referred to as the ‘Registry’), shall
23 establish and maintain a scientific registry of information
24 relating to patients who have been recipients of a trans-
25 plant of bone marrow from a biologically unrelated donor.

1 “(b) INFORMATION.—The scientific registry under
2 subsection (a) shall include information with respect to
3 patients described in subsection (a), transplant proce-
4 dures, and such other information as the Secretary deter-
5 mines to be appropriate to conduct an ongoing evaluation
6 of the scientific and clinical status of transplantation in-
7 volving recipients of bone marrow from biologically unre-
8 lated donors.

9 “(c) ANNUAL REPORT ON PATIENT OUTCOMES.—
10 The Registry shall annually submit to the Secretary a
11 report concerning patient outcomes with respect to each
12 transplant center. Each such report shall use data col-
13 lected and maintained by the scientific registry under sub-
14 section (a). Each such report shall in addition include the
15 data required in section 379(l) (relating to pretransplant
16 costs).”.

17 **SEC. 4. AUTHORIZATION OF APPROPRIATIONS.**

18 Title III of the Public Health Service Act (42 U.S.C.
19 241 et seq.) is amended—

20 (1) by transferring section 378 from the cur-
21 rent placement of the section and inserting the sec-
22 tion after section 377; and

23 (2) in part I, by inserting after section 379A
24 the following section:

1 **“SEC. 379B. 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 1999, and such sums as may be necessary for each of the
5 fiscal years 2000 through 2003.”.

6 **SEC. 5. STUDY BY GENERAL ACCOUNTING OFFICE.**

7 (a) IN GENERAL.—During the period indicated pur-
8 suant to subsection (b), the Comptroller General of the
9 United States shall conduct a study of the National Bone
10 Marrow Donor Registry under section 379 of the Public
11 Health Service Act for purposes of making determinations
12 of the following:

13 (1) The extent to which, relative to the effective
14 date of this Act, such Registry has increased the
15 representation of racial and ethnic minority groups
16 (including persons of mixed ancestry) among poten-
17 tial donors of bone marrow who are enrolled with
18 the Registry, and whether the extent of increase re-
19 sults in a level of representation that meets the
20 standard established in subsection (c)(1)(A) of such
21 section 379 (as added by section 2(c) of this Act).

22 (2) The extent to which patients in need of a
23 transplant of bone marrow from a biologically unre-
24 lated donor, and the physicians of such patients,
25 have been utilizing the Registry in the search for
26 such a donor.

1 (3) The number of such patients for whom the
2 Registry began a preliminary search but for whom
3 the full search process was not completed, and the
4 reasons underlying such circumstances.

5 (4) The extent to which the plan required in
6 section 2(b)(2) of this Act (relating to the relation-
7 ship between the Registry and donor centers) has
8 been implemented.

9 (5) The extent to which the Registry, donor
10 centers, donor registries, collection centers, trans-
11 plant centers, and other appropriate entities have
12 been complying with the standards, criteria, and
13 procedures under subsection (e) of such section 379
14 (as redesignated by section 2(c) of this Act).

15 (b) REPORT.—A report describing the findings of the
16 study under subsection (a) shall be submitted to the Con-
17 gress not later than October 1, 2001. The report may not
18 be submitted before January 1, 2001.

19 **SEC. 6. COMPLIANCE WITH NEW REQUIREMENTS FOR**
20 **OFFICE OF PATIENT ADVOCACY.**

21 With respect to requirements for the office of patient
22 advocacy under section 379(d) of the Public Health Serv-
23 ice Act, the Secretary of Health and Human Services shall
24 ensure that, not later than 180 days after the effective
25 date of this Act, such office is in compliance with all re-

1 requirements (established pursuant to the amendment made
2 by section 2(d)) that are additional to the requirements
3 that under section 379 of such Act were in effect with
4 respect to patient advocacy on the day before the date of
5 the enactment of this Act.

6 **SEC. 7. EFFECTIVE DATE.**

7 This Act takes effect October 1, 1998, or upon the
8 date of enactment of this Act, whichever occurs later.

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