105TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
105–538

NATIONAL BONE MARROW REGISTRY REAUTHORIZATION ACT OF 1998

MAY 18, 1998.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

REPORT

[To accompany H.R. 2202]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 2202) to amend the Public Health Service Act to revise and extend the bone marrow donor program, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Bone Marrow Registry Reauthorization Act of 1998".

SEC. 2. REAUTHORIZATION.

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

(1) by striking "(referred to in this part as the 'Registry') that meets" and inserting "(referred to in this part as the 'Registry') that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow, and that meets";

(2) by striking "under the direction of a board of directors that shall include representatives of" and all that follows and inserting the following: "under the direction of a board of directors meeting the following requirements:

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

"(2) A member of the board may continue to serve after the expiration of the term of such member until a successor is appointed.

"(3) In order to ensure the continuity of the board, the board shall be appointed so that each year the terms of approximately ⅓ of the members of the board expire.

"(4) The membership of the board shall include representatives of marrow donor centers and marrow transplant centers; recipients of a bone marrow transplant; persons who require or have required such a transplant; family members of such a recipient or family members of a patient who has requested the assistance of the Registry in searching for an unrelated donor of bone marrow; persons with expertise in the social sciences; and members of the general public; and in addition nonvoting representatives from the Naval Medical Research and Development Command and from the Division of Organ Transplantation of the Health Resources and Services Administration.".

(b) PROGRAM FOR UNRELATED MARROW TRANSPLANTS.—

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

"(2) carry out a program for the recruitment of bone marrow donors in accordance with subsection (c), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Registry;

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

"(4) annually update information to account for changes in the status of individuals as potential donors of bone marrow;

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

"(6) provide case management services for any potential donor of bone marrow to whom the Registry has provided a notice that the potential donor may be suitably matched to a particular patient (which services shall be provided through a mechanism other than the system of patient advocacy under subsection (d)), and conduct surveys of donors and potential donors to determine the extent of satisfaction with such services and to identify ways in which the services can be improved;

"(7) with respect to searches for unrelated donors of bone marrow that are conducted through the system under paragraph (1), collect and analyze and publish data on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached; the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances; and comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers; and".

(2) REPORT OF INSPECTOR GENERAL; PLAN REGARDING RELATIONSHIP BETWEEN REGISTRY AND DONOR CENTERS.—The Secretary of Health and Human Services shall ensure that, not later than one year after the date of the enactment of this Act, the National Bone Marrow Donor Registry (under section 379 of the Public Health Service Act) develops, evaluates, and implements a plan to effectuate efficiencies in the relationship between such Registry and donor centers. The plan shall incorporate, to the extent practicable, the findings and rec-

ommendations made in the inspection conducted by the Office of the Inspector General (Department of Health and Human Services) as of January 1997 and known as the Bone Marrow Program Inspection.

(c) PROGRAM FOR INFORMATION AND EDUCATION.—Section 379 of the Public Health Service Act (42 U.S.C. 274k) is amended by striking subsection (j), by redesignating subsections (c) through (i) as subsections (e) through (k), respectively, and by inserting after subsection (b) the following subsection:

"(c) RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

"(1) RECRUITMENT; PRIORITIES.—The Registry shall carry out a program for the recruitment of bone marrow donors. Such program shall identify populations that are underrepresented among potential donors enrolled with the Registry. In the case of populations that are identified under the preceding sentence:

"(A) The Registry shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

"(B) The Registry shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

"(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

"(A) IN GENERAL.—In carrying out the program under paragraph (1), the Registry shall carry out informational and educational activities for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Registry potential donors. Such information and educational activities shall include the following:

"(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

"(ii) Educating and providing information to individuals who are willing to serve as potential donors, including providing updates.

"(iii) Training individuals in requesting individuals to serve as potential donors.

"(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Registry shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

"(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding the availability, as a potential treatment option, of receiving a transplant of bone marrow from an unrelated donor.".

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

"(d) PATIENT ADVOCACY; CASE MANAGEMENT.—

"(1) IN GENERAL.—The Registry shall establish and maintain an office of patient advocacy (in this subsection referred to as the 'Office').

"(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

"(A) The Office shall be headed by a director.

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

"(C) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under subsection (b)(1) to conduct an ongoing search for a donor.

"(D) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine whether the search needs of the patient involved are being met, including with respect to the following:

"(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding donors who are suitability

matched to the patient, and other information regarding the progress being made in the search.

"(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

"(iii) Identifying and resolving problems in the search, to the extent practicable.

"(E) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine whether the Registry, donor centers, transplant centers, and other entities participating in the Registry program are complying with standards issued under subsection (e)(4) for the system for patient advocacy under this subsection.

"(F) The Office shall ensure that the following data are made available to patients:

"(i) The resources available through the Registry.

"(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

"(iii) A list of donor registries, transplant centers, and other entities that meet the applicable standards, criteria, and procedures under subsection (e).

"(iv) The posttransplant outcomes for individual transplant centers.

"(v) Such other information as the Registry determines to be appropriate.

"(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved.

"(3) CASE MANAGEMENT.—

"(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

"(i) individualized case assessment; and

"(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

"(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office may, on behalf of patients who have completed the search for an unrelated donor, provide information and education on the process of receiving a transplant of bone marrow, including the posttransplant process.".

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

"(4) standards for the system for patient advocacy operated under subsection (d), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;".

(f) REPORT.—Section 379 of the Public Health Service Act, as amended by subsection (c) of this section, is amended by adding at the end the following subsection:

"(l) ANNUAL REPORT REGARDING PRETRANSPLANT COSTS.—The Registry shall annually submit to the Secretary the data collected under subsection (b)(7) on comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers. The data shall be submitted to the Secretary through inclusion in the annual report required in section 379A(c).".

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

(1) in subsection (f), by striking "subsection (c)" and inserting "subsection (e)"; and

(2) in subsection (k), by striking "subsection (c)(5)(A)" and inserting "subsection (e)(5)(A)" and by striking "subsection (c)(5)(B)" and inserting "subsection (e)(5)(B)".

SEC. 3. RECIPIENT REGISTRY.

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

"SEC. 379A. BONE MARROW SCIENTIFIC REGISTRY.

"(a) ESTABLISHMENT OF RECIPIENT REGISTRY.—The Secretary, acting through the Registry under section 379 (in this section referred to as the 'Registry'), shall establish and maintain a scientific registry of information relating to patients who have been recipients of a transplant of bone marrow from a biologically unrelated donor.

"(b) INFORMATION.—The scientific registry under subsection (a) shall include information with respect to patients described in subsection (a), transplant procedures, and such other information as the Secretary determines to be appropriate to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of bone marrow from biologically unrelated donors.

"(c) ANNUAL REPORT ON PATIENT OUTCOMES.—The Registry shall annually submit to the Secretary a report concerning patient outcomes with respect to each transplant center. Each such report shall use data collected and maintained by the scientific registry under subsection (a). Each such report shall in addition include the data required in section 379(l) (relating to pretransplant costs).".

SEC. 4. AUTHORIZATION OF APPROPRIATIONS.

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

(1) by transferring section 378 from the current placement of the section and inserting the section after section 377; and

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

"SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

"For the purpose of carrying out this part, there are authorized to be appropriated $18,000,000 for fiscal year 1999, and such sums as may be necessary for each of the fiscal years 2000 through 2003.".

SEC. 5. STUDY BY GENERAL ACCOUNTING OFFICE.

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

(1) The extent to which, relative to the effective date of this Act, such Registry has increased the representation of racial and ethnic minority groups (including persons of mixed ancestry) among potential donors of bone marrow who are enrolled with the Registry, and whether the extent of increase results in a level of representation that meets the standard established in subsection (c)(1)(A) of such section 379 (as added by section 2(c) of this Act).

(2) The extent to which patients in need of a transplant of bone marrow from a biologically unrelated donor, and the physicians of such patients, have been utilizing the Registry in the search for such a donor.

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

(4) The extent to which the plan required in section 2(b)(2) of this Act (relating to the relationship between the Registry and donor centers) has been implemented.

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

(b) REPORT.—A report describing the findings of the study under subsection (a) shall be submitted to the Congress not later than October 1, 2001. The report may not be submitted before January 1, 2001.

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

With respect to requirements for the office of patient advocacy under section 379(d) of the Public Health Service Act, the Secretary of Health and Human Services shall ensure that, not later than 180 days after the effective date of this Act, such office is in compliance with all requirements (established pursuant to the amendment made by section 2(d)) that are additional to the requirements that under section 379 of such Act were in effect with respect to patient advocacy on the day before the date of the enactment of this Act.

SEC. 7. EFFECTIVE DATE.

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

PURPOSE AND SUMMARY

H.R. 2202, the National Bone Marrow Registry Reauthorization Act of 1998, amends Section 379 of the Public Health Service Act (42 U.S.C. 274k) to reauthorize the National Bone Marrow Donor Registry.

BACKGROUND AND NEED FOR LEGISLATION

More than 30,000 children and adults in the U.S. are diagnosed each year with leukemia, aplastic anemia, or other life-threatening diseases. For many, the only hope for survival is a marrow transplant.

The National Marrow Donor Program (NMDP) was designed to coordinate the national matching of allogeneic unrelated donors and recipients. Under the Public Health Service Act, the program is charged with the following: (1) to establish a national registry of voluntary bone marrow donors; and (2) to increase the representation of individuals from racial and ethnic minority groups in the pool of potential donors.

The NMDP maintains a Registry of nearly 3 million volunteers willing to become marrow donors if matched. To date, the NMDP has facilitated more than 6,000 bone marrow transplants. Of these, nearly 25 percent have involved transplants between donors and patients from different countries.

A preliminary search automatically looks at more than 2.4 million volunteer donors in the United States and international registries including the Netherlands, Germany, Sweden, and Israel. In addition, the patient's antigens are run through a worldwide donor database called the Bone Marrow Donors Worldwide (BMDW) which includes the national registry. This database searches 37 registries in 29 countries. Through BMDW, the NMDP has direct access to over 4 million volunteer donors worldwide who have registered to save the lives of people they have never met.

NMDP has created a coordinated network of donor centers and collection and transplant centers. The functions of the NMDP are: (1) to develop a large, centrally organized file of potential marrow donors; (2) to coordinate searches for unrelated marrow donors involving donor and transplant centers throughout the United States (and with registries in seven other countries); (3) to facilitate the donor matching, work-up, and collection and transport of marrow to increase the number of marrow transplants from unrelated donors; and (4) to evaluate the outcomes of marrow transplants from unrelated marrow donors.

The genesis of the NMDP was in 1986, when Congressional appropriators directed the U.S. Navy to establish a national registry of bone marrow donors. The National Marrow Donor Program began accepting requests for donors in 1987. The following year, the Health Omnibus Programs Extension Act (P.L. 100–607) amended the National Organ Transplantation Act (NOTA) (P.L. 98–507) to include establishment of a registry of bone marrow donors within the Department of Health and Human Services (HHS).

In 1989, HHS assumed responsibility of the NMDP, first under the authority of National Heart, Lung, and Blood Institute (NHLBI) within NIH. The administration of the program was

transferred again in 1994 to the Health Resources and Services Administration (HRSA).

The Transplant Amendments Act of 1990 (P. L. 101–616) further amended NOTA by establishing the National Bone Marrow Donor Registry in law, reauthorizing it for three years, and requiring HHS to increase the representation of racial and ethnic minorities in the data base.

In 1996, the Senate passed S. 1324, which among other things, proposed reauthorization of the National Bone Marrow Donor Program. S. 1324 was referred to the House Committee on Commerce on September 10, 1996, but no action was taken prior to the adjournment of the 104th Congress.

In June 1997, HHS/HRSA sponsored a policy forum to address the needs of the Registry, including ways to (1) increase the number of bone marrow transplants and (2) resolve the new problems that might arise if the number of bone marrow transplants increased. A broad range of participants, including scientists, physicians, patients, ethicists, and educators attended the forum, which was funded by Amgen. The six core recommendations of the forum addressed costs, insurance coverage, donor recruitment and retention, the matching process, and the psychological needs of donors and recipients. Many of the concerns raised at the June 1997 HHS/HRSA policy forum are addressed in H.R. 2202, as reported.

HEARINGS

On April 23, 1998, the Subcommittee on Health and Environment held a joint hearing with the Senate Labor and Human Resources Committee Subcommittee on Public Health and Safety on "The Gift of Life: Increasing Bone Marrow Donation and Transplantation". Testimony was received from the following witnesses: The Honorable C.W. Bill Young, Representative of the 10th Congressional District, State of Florida; Dr. Claude Earl Fox, Acting Administrator, Health Resources and Services Administration, Department of Health and Human Services; Admiral Elmo Russell Zumwalt, Jr., USN (Retired), Chairman, National Public Policy Committee, National Marrow Donor Program; Dr. Craig W.S. Howe, Chief Executive Officer, National Marrow Donor Program; Mr. Robert Wedge, patient; Mr. Angel Hernandez, father of patient; Dr. Clive O. Callender, Founder and Principal Investigator, Minority Organ and Tissue Transplant Education Program; Dr. Claude J.M. Lenfant, Director, National Heart, Lung, and Blood Institute, National Institutes of Health, Department of Health and Human Services; and Dr. Edward L. Snyder, President, American Association of Blood Banks.

COMMITTEE CONSIDERATION

On May 12, 1998, the Subcommittee on Health and Environment met in open markup session to consider H.R. 2202 and approved the bill for Full Committee consideration, amended, by a voice vote.

On May 14, 1998, the Full Committee met in open markup session to consider H.R. 2202 and ordered the bill reported to the House, as amended, by a voice vote.

ROLLCALL VOTES

Clause 2(l)(2)(B) of rule XI of the Rules of the House requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. There were no recorded votes taken in connection with ordering H.R. 2202 reported. A motion by Mr. Bliley to order H.R. 2202 reported to the House, as amended, was agreed to by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee held an oversight hearing and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee finds that H.R. 2202, the National Bone Marrow Registry Reauthorization Act of 1998, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 18, 1998.

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2202, National Bone Marrow Donor Program Reauthorization Act of 1998.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Cyndi Dudzinski.

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

H.R. 2202—National Bone Marrow Registry Reauthorization Act of 1998

Summary: H.R. 2202 would reauthorize and amend the National Bone Marrow Donor Registry (Registry) operated by the Health Resources and Services Administration. The Registry operates a system for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation. The legislation would authorize appropriations for fiscal years 1999 through 2003.

Assuming appropriation of the authorized amounts, CBO estimates that enacting H.R. 2202 would result in additional discretionary spending of $94 million during the 1999–2003 period. The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply. The legislation does not contain any intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act of 1995.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2202 is shown in the following table. For the purposes of this estimate, CBO assumes that all amounts authorized in H.R. 2202 would be appropriated by the start of each fiscal year and that outlays would follow the historical spending patterns for the National Bone Marrow Donor Registry.

	By fiscal years, in millions of dollars—					
	1998	1999	2000	2001	2202	2203
SPENDING SUBJECT TOP APPROPRIATIONS						
Spending Under Current Law:						
Budget Authority [1]	15	0	0	0	0	0
Estimated Outlays	15	0	0	0	0	0
WITH ADJUSTMENT FOR INFLATION						
Proposed Changes:						
Authorization Level	0	18	18	19	19	20
Estimated Outlays	0	18	18	19	19	20
Spending Under H.R. 2202:						
Authorization Level [1]	15	18	18	19	19	20
Estimated Outlays	15	18	18	19	19	20
WITHOUT ADJUSTMENTS FOR INFLATION						
Proposed Changes:						
Authorization Level	0	18	18	18	18	18
Estimated Outlays	0	18	18	18	18	18
Spending Under H.R. 2202:						
Authorization Level [1]	15	18	18	18	18	18
Estimated Outlays	15	18	18	18	18	18

[1] The 1998 level is the amount appropriated for that year.

The costs of this legislation fall within budget function 550 (health).

Basic of Estimate: The bill would authorize appropriations of $18 million for 1999 and such sums as may be necessary for 2000–2003. CBO's estimates of the authorizations for 2000–2003 are based on the 1999 amount, with or without adjustments for inflation.

Pay-as-you-go considerations: None.

Intergovernmental and private-section impact: The legislation does not contain any intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act of 1995.

Estimate prepared by: Federal Costs: Cyndi Dudzinski. Impact on State, Local Tribal Governments; Marc Nicole. Impact on the Private Sector: Bruce Vavrichek.

Estimate approval by: Paul N. Van de Water, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates the short title as the "National Bone Marrow Registry Reauthorization Act of 1998".

Section 2. Reauthorization

Section 2 reauthorizes the National Bone Marrow Registry and establishes procedures for rotating its board of directors. It establishes two-year terms of office, with a maximum of three consecutive terms; permits service to continue until a successor is appointed; and provides that approximately one-third of the board members" terms expire each year. Furthermore, the characteristics of the Board of Directors are mandated to broaden representation (e.g., representatives of marrow donor centers, recipients of bone marrow transplants, persons who require such a transplant.)

Section 2 also amends the National Bone Marrow Registry to carry out a program to: recruit potential donors; include educational activities to support potential donor recruitment; include annual updates of status change for potential donors; include a system of patient advocacy; conduct case management services for

those potential donors notified of a match; and collect and analyze data, including cost comparisons among transplant centers.

Within a year after passage, the registry is mandated to develop and implement a plan to increase the efficiencies of working with donor centers.

This section directs the registry to carry out a program for the recruitment of bone marrow donors. Due to larger varieties of human leukocyte antigens (HLA) in minority populations, special attention to under represented minority groups will be given such that their probability of finding a match will be comparable to the probability of finding a match for someone not from an under represented group.

Section 2 directs the registry to carry out informational and educational activity for the purposes of recruitment of donors; priority is given to those who are from under represented groups. Information is also to be provided to physicians and the public regarding transplantation as an option.

Section 2 creates an office of patient advocacy and case management for those whom the registry is searching for an unrelated donor of bone marrow. The office will provide information periodically to the patients concerning the status of the search and work to resolve difficulties. The office will also provide consumer data comparing costs of transplant centers (required in an annual report), post-transplant outcomes, survey data measuring patient satisfaction, and other information as deemed appropriate.

Section 3. Recipient registry

Section 3 establishes a "Bone Marrow Scientific Registry," which shall serve as a repository of information relating to patients who have received bone marrow transplants from an unrelated donor; such information will include transplant procedures and other data deemed appropriate by the Secretary of HHS. The Registry will also annually publish a report comparing transplant center costs and patient outcomes to better inform the public.

Section 4. Authorization of appropriations

Section 4 authorizes the National Bone Marrow Registry for $18,000,000 for Fiscal Year 1999, and such sums as may be necessary for Fiscal Years 2000 through 2003.

Section 5. Studies by General Accounting Office

Section 5 commissions a General Accounting Office study measuring the: (1) registry effectiveness of increasing minority representation; (2) registry utilization rates; (3) reasons preliminary searches in the registry were not completed; (4) and effectiveness of the program generally.

As a result of objections raised by the Administration and others to the inclusion of cord blood in the Registry, the Committee removed provisions contained in H.R. 2202 as introduced relating to cord blood. It is the Committee's intent, however, that if ongoing research on the safety and efficacy of cord blood confirms the initial promise of cord blood as an effective treatment for diseases presently treated by bone marrow transplants, that cord blood be included in the Registry. The Committee directs the Secretary of

HHS to regularly report in writing to the House Committee on Commerce and the House Committee on Appropriations Subcommittee on Labor, Health and Human Services, and Education as to the status of ongoing research on the safety, efficacy, collection, storage and confidentiality of cord blood and its viability and desirability for inclusion in the Registry, so that the Committee could consider an appropriate amendment for including cord blood in the Registry.

Section 6. Compliance with new requirements for Office of Patient Advocacy

Section 6 stipulates that any additional duties due to the provisions for patient advocacy are to be implemented within 180 days.

Section 7. Effective date

Section 7 provides that this legislation takes effect on October 1, 1998, or upon the date of enactment, whichever occurs later.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH

* * * * * * *

PART H—ORGAN TRANSPLANTS

ORGAN PROCUREMENT ORGANIZATIONS

SEC. 371. * * *

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SEC. 378. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated $8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

PART I—NATIONAL BONE MARROW DONOR REGISTRY

SEC. 379. NATIONAL REGISTRY.

(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a National Bone Marrow Donor Registry [(referred to in this part as the "Registry") that meets] *(referred to in this*

part as the "Registry") that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow, and that meets the requirements of this section. The Registry shall be under the general supervision of the Secretary, and [under the direction of a board of directors that shall include representatives of marrow donor centers, marrow transplant centers, persons with expertise in the social science, and the general public.] *under the direction of a board of directors meeting the following requirements:*

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

(2) A member of the board may continue to serve after the expiration of the term of such member until a successor is appointed.

(3) In order to ensure the continuity of the board, the board shall be appointed so that each year the terms of approximately 1/3 of the members of the board expire.

(4) The membership of the board shall include representatives of marrow donor centers and marrow transplant centers; recipients of a bone marrow transplant; persons who require or have required such a transplant; family members of such a recipient or family members of a patient who has requested the assistance of the Registry in searching for an unrelated donor of bone marrow; persons with expertise in the social sciences; and members of the general public; and in addition nonvoting representatives from the Naval Medical Research and Development Command and from the Division of Organ Transplantation of the Health Resources and Services Administration.

(b) FUNCTIONS.—The Registry shall—

(1) establish a system for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation;

[(2) establish a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists patients, their families, and their physicians in the search for an unrelated marrow donor;

[(3) increase the representation of individuals from racial and ethnic minority groups in the pool of potential donors for the Registry in order to enable an individual in a minority group, to the extent practicable, to have a comparable chance of finding a suitable unrelated donor as would an individual not in a minority group;

[(4) provide information to physicians, other health care professionals, and the public regarding bone marrow transplantation;

[(5) recruit potential bone marrow donors;

[(6) collect, analyze, and publish data concerning bone marrow donation and transplantation; and]

(2) carry out a program for the recruitment of bone marrow donors in accordance with subsection (c), including with respect to increasing the representation of racial and ethnic minority

groups (including persons of mixed ancestry) in the enrollment of the Registry;

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

(4) annually update information to account for changes in the status of individuals as potential donors of bone marrow;

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

(6) provide case management services for any potential donor of bone marrow to whom the Registry has provided a notice that the potential donor may be suitably matched to a particular patient (which services shall be provided through a mechanism other than the system of patient advocacy under subsection (d)), and conduct surveys of donors and potential donors to determine the extent of satisfaction with such services and to identify ways in which the services can be improved;

(7) with respect to searches for unrelated donors of bone marrow that are conducted through the system under paragraph (1), collect and analyze and publish data on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached; the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances; and comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers; and

[(7)**]** *(8)* support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be marrow donors.

(c) RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Registry shall carry out a program for the recruitment of bone marrow donors. Such program shall identify populations that are underrepresented among potential donors enrolled with the Registry. In the case of populations that are identified under the preceding sentence:

(A) The Registry shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Registry shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

(A) IN GENERAL.—In carrying out the program under paragraph (1), the Registry shall carry out informational and educational activities for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Registry potential donors. Such infor-

mation and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

(ii) Educating and providing information to individuals who are willing to serve as potential donors, including providing updates.

(iii) Training individuals in requesting individuals to serve as potential donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Registry shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding the availability, as a potential treatment option, of receiving a transplant of bone marrow from an unrelated donor.

(d) PATIENT ADVOCACY; CASE MANAGEMENT.—

(1) IN GENERAL.—The Registry shall establish and maintain an office of patient advocacy (in this subsection referred to as the "Office").

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

(A) The Office shall be headed by a director.

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

(C) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under subsection (b)(1) to conduct an ongoing search for a donor.

(D) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine whether the search needs of the patient involved are being met, including with respect to the following:

(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding donors who are suitability matched to the patient, and other information regarding the progress being made in the search.

(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

(iii) Identifying and resolving problems in the search, to the extent practicable.

(E) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine

whether the Registry, donor centers, transplant centers, and other entities participating in the Registry program are complying with standards issued under subsection (e)(4) for the system for patient advocacy under this subsection.

(F) The Office shall ensure that the following data are made available to patients:

(i) The resources available through the Registry.

(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

(iii) A list of donor registries, transplant centers, and other entities that meet the applicable standards, criteria, and procedures under subsection (e).

(iv) The posttransplant outcomes for individual transplant centers.

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

(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved.

(3) CASE MANAGEMENT.—

(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

(i) individualized case assessment; and

(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office may, on behalf of patients who have completed the search for an unrelated donor, provide information and education on the process of receiving a transplant of bone marrow, including the posttransplant process.

[(c)**]** *(e)* CRITERIA, STANDARDS, AND PROCEDURES.—Not later than 180 days after the date of enactment of this part, the Secretary shall establish and enforce, for entities participating in the program, including the Registry, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

[(4) standards that require the provision of information to patients, their families, and their physicians at the start of the search process concerning—

[(A) the resources available through the Registry;

[(B) all other marrow donor registries meeting the standards described in this paragraph; and

[(C) in the case of the Registry—

[(i) the comparative costs of all charges by marrow transplant centers incurred by patients prior to transplantation; and

[(ii) the success rates of individual marrow transplant centers;]

(4) standards for the system for patient advocacy operated under subsection (d), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;

(5) standards that—

(A) require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Registry.

[(d)] *(f)* COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures, which may include establishment of a policy advisory committee, under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Registry is carrying out the duties of the Registry under subsection (b) and complying with the criteria, standards, and procedures described in subsection [(c)] *(e)*.

[(e)] *(g)* CONSULTATION.—The Secretary shall consult with the board of directors of the Registry and the bone marrow donor program of the Department of the Navy in developing policies affecting the Registry.

[(f)] *(h)* APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

[(g)] *(i)* ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

[(h)] *(j)* RECORDS.—

(1) RECORDKEEPING.—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of

the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

[(i)] *(k)* PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection [(c)(5)(A)] *(e)(5)(A)* without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection [(c)(5)(B)] *(e)(5)(B)*, shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.

[(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $15,000,000 for fiscal year 1991 and such sums as may be necessary for each of fiscal years 1992 and 1993.]

(l) ANNUAL REPORT REGARDING PRETRANSPLANT COSTS.—The Registry shall annually submit to the Secretary the data collected under subsection (b)(7) on comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers. The data shall be submitted to the Secretary through inclusion in the annual report required in section 379A(c).

[SEC. 379A. STUDY BY THE GENERAL ACCOUNTING OFFICE.

[(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study that evaluates—

[(1) the costs and benefits of the search process for an unrelated bone marrow donor among different marrow donor registries;

[(2) the extent to which marrow donor registries protect donor confidentiality;

[(3) the relationship between the Registry, individual marow donor centers, and other marrow donor registries;

[(4) the effectiveness and appropriateness of policies and procedures of marrow donor centers, marrow transplant centers, and marrow donor registries, including—

[(A) the process of donor recruitment, including the policy of asking each donor whether the donor would want to donate more than one time;

[(B) the maintenance and updating of donor files; and

[(C) the policy of initially typing donors for A/B antigens only instead of initially typing for both A/B and D/R antigens;

[(5) the ability of the marrow donor registries to incorporate changes in medical research and clinical practice; and

[(6) the costs associated with tissue typing.

[(b) REPORT.—Not later than 1 year after the date of enactment of this part, the Comptroller General shall complete the study required under subsection (a) and submit to the Committee on En-

ergy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the findings made by the study and recommendations for legislative reform.]

SEC. 379A. BONE MARROW SCIENTIFIC REGISTRY.

(a) ESTABLISHMENT OF RECIPIENT REGISTRY.—The Secretary, acting through the Registry under section 379 (in this section referred to as the 'Registry'), shall establish and maintain a scientific registry of information relating to patients who have been recipients of a transplant of bone marrow from a biologically unrelated donor.

(b) INFORMATION.—The scientific registry under subsection (a) shall include information with respect to patients described in subsection (a), transplant procedures, and such other information as the Secretary determines to be appropriate to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of bone marrow from biologically unrelated donors.

(c) ANNUAL REPORT ON PATIENT OUTCOMES.—The Registry shall annually submit to the Secretary a report concerning patient outcomes with respect to each transplant center. Each such report shall use data collected and maintained by the scientific registry under subsection (a). Each such report shall in addition include the data required in section 379(l) (relating to pretransplant costs).

SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

"For the purpose of carrying out this part, there are authorized to be appropriated $18,000,000 for fiscal year 1999, and such sums as may be necessary for each of the fiscal years 2000 through 2003.

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