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SENATE

{ REPORT
109-75

FOUNDATION FOR THE NATIONAL INSTITUTES OF
HEALTH IMPROVEMENT ACT

MAY 26, 2005.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and
Pensions, submitted the following

R E P O R T

[To accompany S. 302]

The Committee on Health, Education, Labor, and Pensions, to
which was referred the bill (S. 302) to make improvements in the
Foundation for the National Institutes of Health, having considered
the same, reports favorably thereon with an amendment and rec-
ommends that the bill, as amended, do pass.

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I. PURPOSE AND SUMMARY OF THE BILL

The purpose of S. 302, the Foundation for the National Institutes
of Health Improvement Act, is to make technical corrections and
improvements to Section 499 of the Public Health Service Act
(PHSA), which established the Foundation for the National Insti-
tutes of Health (the Foundation). Most significantly, these correc-
tions clarify membership in the Foundation’s board of directors and
assure that the Foundation receives funds from the National Insti-
tutes of Health (NIH) to support the Foundation’s administrative
and operating expenses.

II. BACKGROUND AND NEED FOR LEGISLATION

The Foundation is a private, not-for-profit foundation established by Congress to raise private funds to support the work of the NIH. Authorized in 1990 and incorporated as a nonprofit organization in Maryland 9 years ago, the Foundation in 2003 raised \$426 in private funds for every \$1 that the Foundation received from the NIH, and 85 percent of the money the Foundation spent in 2003 directly supported the programs and initiatives of the NIH, with 15 percent used for administration and fundraising. Since its inception, the Foundation has raised \$276.5 million or \$66 in private support for every appropriated dollar received.

The Foundation is currently managing 38 programs that are supported by \$276.5 million generated from private contributions. In 2003, Bill Gates announced a gift to the Foundation for NIH of \$200 million to establish the Grand Challenges in Global Health initiative, supporting research on global health priorities. When the Congress passed the Best Pharmaceuticals for Children Act in 2001 (P.L. 107-109), it charged the Foundation with collecting private funds to study drugs in children. The Foundation's role with the NIH is expected to continue to grow productively in the coming years.

One current project is the construction of the Edmond J. Safra Family Lodge on the NIH campus. Families of patients receiving in-patient treatment at the NIH Clinical Center will have the Lodge as a place to stay, at no cost to them. The project is funded completely by private funds donated through the Foundation, with services and land donated by the NIH. In addition, the Foundation currently has partnerships with the NIH that include helping develop new cancer treatments, two initiatives identifying biomarkers for Osteoarthritis and Alzheimer's Disease, and others that highlight the great promise of genomics. Through a public-private partnership, the Foundation helped accelerate the sequencing of the mouse genome.

The operating costs for the Foundation climbed from the \$0.944 million in 2002 to \$3.09 million in 2005. The Bill & Melinda Gates Foundation provides an additional \$2.25 million in funding to cover the direct costs associated with the Grand Challenges initiative; however, the Foundation will also expand its staffing for media relations and communications functions, as well as staffing for its public-private partnerships.

III. LEGISLATIVE HISTORY AND COMMITTEE ACTION

On February 7, 2005, Senator Kennedy, for himself and Senator Gregg, Senator Frist, Senator Enzi, and Senator Bingaman, introduced S. 302, to amend Section 499 of the PHSA to improve the Foundation for the National Institutes of Health. On February 9, 2005, the committee held an executive session to consider S. 302. After accepting a manager's amendment, the committee approved S. 302 by unanimous voice vote.

IV. EXPLANATION OF BILL AND COMMITTEE VIEWS

In the past, the Foundation has been provided \$500,000 through the NIH appropriation to help defray its operating and administrative costs. The legislation will correct the current need for a yearly

line appropriation of \$500,000 for the Foundation in the NIH appropriation bill, and will allow the Foundation to continue its effective support for the work and the mission of the NIH. The legislation permits the NIH to support the work of the Foundation beyond the \$500,000 baseline if, in the judgment of the NIH Director, an occasion were to arise that would warrant it.

In addition, when Congress charged the Foundation with collecting private funds to study drugs in children in the BPCA, it added the Commissioner of Food and Drugs as an ex officio member of the board of the Foundation. This addition failed to take account of the fact that, under Section 499(d)(1)(D)(ii) of the PHSA, the terms of service of the original ex officio members of the board (the chair and ranking minority member of the Subcommittee on Health and the Environment of the House Energy and Commerce Committee, the chair and ranking minority member of the Senate Committee on Labor and Human Resources, and the Director of NIH) terminated on appointment of the initial board. The legislation maintains the policy that the terms of service of the congressional members of the board terminated upon initial appointment of the board, but clarifies that the NIH Director and the FDA Commissioner remain as ex officio members of the board.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, February 14, 2005.

Hon. MIKE B. ENZI,
*Chairman, Committee on Health, Education, Labor, and Pensions,
U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 302, the Foundation for the National Institutes of Health Improvement Act.

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

ELIZABETH M. ROBINSON,
(For Douglas Holtz-Eakin, Director).

Enclosure.

S. 302—Foundation for the National Institutes of Health Improvement Act

S. 302 would modify the Public Health Service Act to change the law that governs the Foundation for the National Institutes of Health (NIH), a private, not-for-profit entity that raises private funds to support the work of NIH. It would specify that the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration remain as ex officio members of the board, make provisions for the continued operation of the board when vacancies occur, and correct an incorrect cross-reference in the statute. The bill also would require that \$500,000 out of funds appropriated for NIH be transferred to the foundation each year. Such annual payments are authorized under current law but are not required.

CBO estimates that implementing S. 302 would have no significant budgetary effect in any individual year. Enacting the bill would not affect receipts or direct spending.

S. 302 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact is Christopher Topoleski. This estimate was approved by Peter H. Fontaine, Deputy Assistance Director for Budget Analysis.

VI. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

S. 302 amends Section 499 of the PHSA to make improvements to the functioning of the Foundation for the National Institutes of Health, a non-profit corporation in the State of Maryland that supports the work of the NIH. As such, it has no application to the legislative branch.

VII. REGULATORY IMPACT STATEMENT

The committee has determined that there will be de minimus changes to the regulatory burden due to this bill.

VIII. SECTION-BY-SECTION ANALYSIS

Sec. 1. Short title

Sec. 2. National Institutes of Health establishment and duties

Paragraph (1)(A) makes a technical amendment to clarify that the NIH Director and the FDA Commissioner will serve as ex officio members of the board of the Foundation.

Paragraph (1)(B) clarifies an ambiguous provision of current law and codifies current policy under which new members of the Foundation's board are appointed under the bylaws of the Foundation.

Paragraph (1)(C) makes a conforming amendment.

Paragraph (2)(A) corrects an incorrect cross-reference in section 499 of the PHSA.

Paragraph (2)(B) requires the Foundation's annual reports to include an accounting of the use of funds transferred from the NIH to the Foundation for its operating expenses and that these reports be provided to the appropriate committees in Congress.

Paragraph (2)(C) makes a technical correction to clarify that the NIH may accept transfers of funds from the Foundation.

Paragraph (3) makes a change to require the NIH Director to transfer no less than \$500,000 and no more than \$1,250,000 to the Foundation for operating expenses.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (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

* * * * *

PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

SEC. 499. ESTABLISHMENT AND DUTIES OF FOUNDATION.

(a) IN GENERAL.—* * *

* * * * *

(d) BOARD OF DIRECTORS.—

(1) COMPOSITION.—

(A) * * *

* * * * *

(D)(i) * * *

* * * * *

[(ii) Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.]

(ii) Upon the appointment of the appointed members of the Board under clause (i)(II), the terms of service as members of the Board of the ex officio members of the Board described in clauses (i) and (ii) of subparagraph (B) shall terminate. The ex officio members of the Board described in clauses (iii) and (iv) of subparagraph (B) shall continue to serve as ex officio members of the Board.

* * * * *

(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of *appointed* members of the Board shall be greater than the number specified in subparagraph (C).

* * * * *

(3) TERMS AND VACANCIES.—

(A) * * *

[(B) Any vacancy in the membership of the Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining members to execute the duties of the Board.]

(B) Any vacancy in the membership of the appointed members of the Board shall be filled in accordance with the bylaws of the Foundation established in accordance with paragraph (6), and shall not affect the power of the remaining appointed members to execute the duties of the Board.

* * * * *

(5) MEETINGS AND QUORUM.—A majority of the *appointed* members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

* * * * *

(j) GENERAL PROVISIONS.—

(1) FOUNDATION INTEGRITY.—* * *

(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection **[(d)(2)(B)(i)(II)]** *(d)(6)*) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

* * * * *

(4) REPORTS.—

(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, *including an accounting of the use of amounts transferred under subsection (l)*.

* * * * *

[(C) The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.]

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge that shall not exceed the cost of providing the copy; and
(i) to the appropriate committees of Congress.

* * * * *

(10) TRANSFER OF FUNDS.—The Foundation may transfer funds to the National Institutes **[of Health.]** *of Health and the National Institutes of Health may accept transfers of funds from the Foundation.*

* * * * *

[(1) FUNDING.—

[(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there is authorized to be appropriated an aggregate \$500,000 for each fiscal year.

[(2) LIMITATION REGARDING OTHER FUNDS.—Amounts appropriated under any provision of law other than paragraph (1) may not be expended to establish or operate the Foundation.]

(l) FUNDING.—From amounts appropriated to the National Institutes of Health, for each fiscal year, the Director of NIH shall trans-

*fer not less than \$500,000 and not more than \$1,250,000 to the
Foundation.*

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