AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

Calendar No. 92

108TH CONGRESS, *1st Session* | SENATE | REPORT 108–45

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH IMPROVEMENT ACT

MAY 12, 2003.—Ordered to be printed

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

R E P O R T

[To accompany S. 314]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 314) to make improvements in the Foundation for the National Institutes of Health, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

CONTENTS

		Page
I.	Purpose and Summary of Legislation	1
II.	Committee Action	2
III.	Background and Need for Legislation	2
IV.	Cost Estimate	3
V.	Application of Law to the Legislative Branch	4
VI.	Regulatory Impact Statement	4
VII.	Section-by-Section Analysis	4
VIII.	Changes in Existing Law	4

I. PURPOSE AND SUMMARY OF LEGISLATION

The Foundation for the National Institutes of Health Improvement Act (S. 314) makes a number of technical corrections and improvements to section 499 of the PHSA, which established the Foundation for the National Institutes of Health (the Foundation). Most significantly, these corrections clarify membership in the Foundation's board of directors and ensure that the Foundation receives funds from the National Institutes of Health (NIH) to support the Foundation's administrative and operating expenses.

II. COMMITTEE ACTION

On February 5, 2003, Senator Kennedy, for himself and Senator Gregg, Senator Frist, and Senator Bingaman, introduced S. 314, to amend section 499 of the PHSA to improve the Foundation for the National Institutes of Health. On February 12, 2003, the Committee on Health, Education, Labor, and Pensions held an executive session to consider S. 314. The committee approved S. 314 by unanimous voice vote.

III. 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 by section 499 of the PHSA and incorporated as a nonprofit organization in Maryland 7 years ago, the Foundation has raised $13 in private funds for every $1 it has received from the NIH to support the work of the NIH.

By fall of 2002, the Foundation was managing 20 programs with multiyear revenue and funding goals of over $45 million. On January 26, 2003, the Gates Foundation announced a gift to the NIH through the Foundation of $200 million over the next 10 years to support research on global health priorities. In the Best Pharmaceuticals for Children Act (BPCA) (Pub. Law 107–109), Congress charged the Foundation with collecting private funds to study drugs in children. The Foundation's role with the NIH is expected to grow 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 cancer 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; identifying biomarkers for osteoarthritis; and highlighting the great promise of genomics. Through a public-private partnership, the Foundation helped accelerate the sequencing of the mouse genome.

The Foundation's own operating costs include the cost of raising private funds to support the work of the NIH and the cost of administering and managing the use of those private funds. The operating costs for the Foundation are expected to climb from $860,000 in 2002 to $2.2 million in 2003. The Gates Foundation is being asked to provide $1.2 million in funding to cover the majority of the costs associated with staff and office space to administer the new program on global health priorities. The Foundation will also expand its staffing for media relations and communications functions, as well as staffing for its public-private partnerships.

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 is not intended to limit the ability of 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 into account 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 terminate upon initial appointment of the board, but clarifies that the NIH Director and the FDA Commissioner remain as ex officio members of the board.

IV. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 24, 2003.

Hon. JUDD GREGG,
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. 314, 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,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

S. 314—Foundation for the National Institutes of Health Improvement Act

S. 314 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 of the appropriations for NIH be transferred to the foundation. Such annual payments are authorized under current law but are not required.

CBO estimates that implementing S. 314 would have no significant budgetary effect. Enacting the bill would not affect receipts or direct spending.

S. 314 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 Assistant Director for Budget Analysis.

V. Application of Law to the Legislative Branch

S. 314 amends section 499 of the PHSA to make improvements to the functioning of the Foundation for the National Institutes of Health, a nonprofit corporation in the State of Maryland that supports the work of the NIH. As such, it has no application to the legislative branch.

VI. Regulatory Impact Statement

The legislation amends section 499 of the PHSA to make improvements to the functioning of the Foundation for the National Institutes of Health. It includes a requirement that the Director of the NIH transfer $500,000 of the NIH's appropriated funds to the Foundation to support its costs in supporting the work of the NIH. Accordingly, S. 314 is not expected to increase costs to government or to the private sector.

VII. Section-by-Section Analysis

Sec. 1. Short title

Designates the short title and reference as the "Foundation for the National Institutes of Health Improvement Act."

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 erroneous cross reference in section 499 of the PHSA.

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

Paragraph (3) provides that the NIH Director shall transfer $500,000 annually to the Foundation for operating expenses.

VIII. 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

* * * * * * *

FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

* * * * * * *

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 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 de-

veloped 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 (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.

* * * * * * *

(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.* Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.

[(l) DUTIES OF THE DIRECTOR.—

[(1) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of the National Institutes of Health, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of the National Institutes of Health determines is appropriate.

[(2) SUPPORT SERVICES.—The Director of the National Institutes of Health may provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health.]

(l) FUNDING.—From amounts appropriated to the National Institutes of Health, for each fiscal year, the Director of NIH shall transfer $500,000 to the Foundation.

* * * * * * *

○