117TH CONGRESS
*1st Session*
HOUSE OF REPRESENTATIVES
REPORT
117–183

# SUPPORTING THE FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH AND THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION ACT

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NOVEMBER 30, 2021.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

# R E P O R T

[To accompany H.R. 3743]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3743) to increase funding for the Reagan-Udall Foundation for the Food and Drug Administration and for 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



## I. PURPOSE AND SUMMARY

H.R. 3743, the "Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food

and Drug Administration Act," amends Section 770(n) of the Federal Food, Drug and Cosmetic Act and Section 499(l) of the Public Health Service Act to authorize increased transfer authorities from the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) to the Reagan-Udall Foundation for the Food and Drug Administration and the Foundation for the National Institutes of Health, respectively.

H.R. 3743 increases the transfer authority for both foundations from "$500,000 and not more than $1,250,000" to "$1,250,000 and not more than $5,000,000."

## II. Background and Need for Legislation

The Reagan-Udall Foundation for the FDA is an independent non-profit organization established by Congress in 2007 to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.[1] The foundation was required to: (1) identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness of such products; (2) establish goals and priorities; (3) identify federal research and development programs and minimize duplication; (4) award grants to scientists and entities to efficiently and effectively advance such goals and priorities; and (5) provide objective clinical and scientific information to FDA and other federal agencies.[2]

Originally named the National Foundation for Biomedical Research, the Foundation for the NIH is an independent non-profit organization established by Congress in 1990 to develop private-public partnerships that advance biomedical research at the NIH and worldwide.[3] [4] As part of its mission, the Foundation for the NIH organizes and administers research projects; supports the education and development of new researchers; hosts educational campaigns and symposiums; and manages funding to support a wide range of health issues.[5]

Both foundations receive funding from transfers from federal agencies, as mandated by law. In addition to these transfers, the foundations are authorized to solicit and accept gifts from private entities.

H.R. 3743 would increase the statutory authorization for the transferring of funds from the FDA and NIH to their respective foundations for the first time since 2007.[6] Increased federal funding will allow the Reagan-Udall Foundation and the Foundation for the NIH to carry out more authorized projects in service of their respective missions.

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[1] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85.
[2] *Id.*
[3] National Institutes of Health Amendment Act of 1990, Pub. L. No. 101–613.
[4] Foundation for the National Institutes of Health, *About Us* (https://fnih.org/about).
[5] *Id.*
[6] Office of Congressman Richard Hudson, *Hudson Introduces Bill to Expand Future Vaccine Development* (June 10, 2021) (https://hudson.house.gov/press-releases/hudson-introduces-bill-to-expand-future-vaccine-development) (press release).

## III. COMMITTEE HEARINGS

For the purposes of section 3(c) of rule XIII of the Rules of the House of Representatives, the following hearing was used to develop or consider H.R. 3743:

The Subcommittee on Health held a legislative hearing on Tuesday, June 15, 2021, entitled, "Booster Shot: Enhancing Public Health through Vaccine Legislation." The Subcommittee received testimony form the following witnesses:

- Phyllis Arthur, Vice President, Infectious Diseases and Diagnostic Policy, Biotechnology Innovation Organization;
- Rebecca Coyle, Executive Director, American Immunization Registry Association;
- Yvonne Maldonado, M.D., Chair, Committee on Infectious Diseases, American Academy of Pediatrics, Professor of Pediatrics and of Epidemiology and Public Health, Stanford University, Stanford University Center for Academic Medicine, Pediatric Infectious Diseases; and
- Lijen (L.J.) Tan, Ph.D., Chief Strategy Officer, Immunization Action Coalition.

## IV. COMMITTEE CONSIDERATION

Representatives Richard Hudson (R–NC) and Anna G. Eshoo (D–CA) introduced H.R. 3743, the "Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act," on June 8, 2021, which was referred to the Committee on Energy and Commerce. Subsequently, on June 9, 2021, H.R. 3743 was referred to the Subcommittee on Health. A legislative hearing was held on the bill on June 15, 2021.

On July 15, 2021, the Subcommittee on Health met in open markup session, pursuant to notice, to consider H.R. 3743 and 18 other bills. No amendments were offered during consideration of the bill. Upon conclusion of consideration of the bill, the Subcommittee on Health agreed to report the bill favorably to the full Committee, without amendment, by a voice vote.

On July 21, 2021, the full Committee met in open markup session, pursuant to notice, to consider H.R. 3743 and 23 other bills. No amendments were offered during consideration of the bill. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage offered by Representative Pallone (D–NJ), Chairman of the Committee, to order H.R. 3743 reported favorably to the House, without amendment, by a voice vote.

## V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 3743, including a motion by Mr. Pallone ordering H.R. 3743 favorably reported to the House, without amendment.

## VI. Oversight Findings

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

## VII. New Budget Authority, Entitlement Authority, and Tax Expenditures

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

## VIII. Congressional Budget Office Estimate

U.S. Congress,
Congressional Budget Office,
*Washington, DC, October 25, 2021.*

Hon. Frank Pallone, Jr.,
*Chairman, Committee on Energy and Commerce,*
*House of Representatives, Washington, DC.*

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3743, the Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act.

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

Sincerely,

Phillip L. Swagel,
*Director.*

Enclosure.

**H.R. 3743, Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act**
**As ordered reported by the House Committee on Energy and Commerce on July 21, 2021**

| By Fiscal Year, Millions of Dollars | 2022 | 2022-2026 | 2022-2031 |
|---|---|---|---|
| Direct Spending (Outlays) | 0 | 0 | 0 |
| Revenues | 0 | 0 | 0 |
| Increase or Decrease (-) in the Deficit | 0 | 0 | 0 |
| Spending Subject to Appropriation (Outlays) | 2 | 29 | not estimated |

| | | Mandate Effects | |
|---|---|---|---|
| Statutory pay-as-you-go procedures apply? | No | | |
| Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2032? | No | Contains intergovernmental mandate? | No |
| | | Contains private-sector mandate? | No |

H.R. 3743 would authorize the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) to increase

funding transfers to the Reagan-Udall Foundation and the Foundation for the National Institutes of Health, respectively, up to an annual cap of $5 million each. The foundations are 501(c)(3) organizations created by the Congress to support the missions of FDA and NIH. CBO anticipates that the agencies would transfer the maximum authorized amounts to the foundations each year, about $38 million more than authorized under current law over the 2022–2026 period. CBO estimates that costs associated with the increased transfers would total $29 million over the 2022–2026 period; any spending would be subject to the availability of appropriated funds.

On June 22, 2021, CBO transmitted a cost estimate for S. 1662, the Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on May 25, 2021. H.R. 3743 is identical to S. 1662, and CBO's estimates of their budgetary effects are nearly identical after adjusting for a later projected enactment date.

The CBO staff contact for this estimate is Ryan Greenfield. The estimate was reviewed by Leo Lex, Deputy Director of Budget Analysis.

## IX. 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.

## X. Statement of General Performance Goals and Objectives

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to authorize increased transfer authority to the FDA and NIH for the Reagan-Udall Foundation for the Food and Drug Administration and the Foundation for the National Institutes of Health, respectively, to advance public health and biomedical research.

## XI. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 3743 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

## XII. Committee Cost Estimate

Pursuant to clause 3(d)(1) of rule XIII, 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.

## XIII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 4743 contains no earmarks, limited tax benefits, or limited tariff benefits.

## XIV. Advisory Committee Statement

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

## XV. 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.

## XVI. Section-by-Section Analysis of the Legislation

*Section 1. Short title*

Section 1 designates that the short title may be cited as the "Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act."

*Sec. 2. Reagan-Udall Foundation and Foundation for the National Institutes of Health.*

Section 2(a) amends Section 770(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(n)) by striking "$500,000 and not more than $1,250,000" and inserting "$1,250,000 and not more than $5,000,000".

Section 2(b) amends Section 499(l) of the Public Health Service Act (42 U.S.C. 290b(l)) by striking "$500,000 and not more than $1,250,000" and inserting "$1,250,000 and not more than $5,000,000".

## XVII. Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) 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 italics, and existing law in which no change is proposed is shown in roman):

## FEDERAL FOOD, DRUG, AND COSMETIC ACT

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### CHAPTER VII—GENERAL AUTHORITY

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## Subchapter I—Reagan-Udall Foundation for the Food and Drug Administration

**SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION.**

(a) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this subchapter as the "Foundation") shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

(c) DUTIES OF THE FOUNDATION.—The Foundation shall—

(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including post-approval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics, and including the incorporation of more sensitive and predictive tools and devices to measure safety;

(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code (and exempt from tax under section 501(a) of such Code), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

(7) ensure that—

(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);

(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

(d) BOARD OF DIRECTORS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subchapter as the "Board"), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

(i) The Commissioner.

(ii) The Director of the National Institutes of Health.

(iii) The Director of the Centers for Disease Control and Prevention.

(iv) The Director of the Agency for Healthcare Research and Quality.

(C) APPOINTED MEMBERS.—

(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 14 individuals, of which 9 shall be from a list of candidates to be provided by the National Academy of Sciences and 5 shall be from lists of candidates provided by patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations. Of such appointed members—

(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;

(II) 3 shall be representatives of academic research organizations;

(III) 2 shall be representatives of patient or consumer advocacy organizations;

(IV) 1 shall be a representative of health care providers; and

(V) 4 shall be at-large members with expertise or experience relevant to the purpose of the Foundation.

(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries.

(iii) REQUIREMENTS.—

(I) EXPERTISE.—The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

(II) FEDERAL EMPLOYEES.—No employee of the Federal Government shall be appointed as a member of the Board under this subparagraph or under paragraph (3)(B). For purposes of this section, the term "employee of the Federal Government" does not include a special Government employee, as that term is defined in section 202(a) of title 18, United States Code.

(D) INITIAL MEETING.—

(i) IN GENERAL.—Not later than 30 days after the date of the enactment of this subchapter, the Secretary shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation; and

(II) appoint the members of the Board in accordance with subparagraph (C).

(ii) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II)—

(I) the terms of service of the Director of the Centers for Disease Control and Prevention and of the Director of the Agency for Healthcare Research and Quality as ex officio members of the Board shall terminate; and

(II) the Commissioner and the Director of the National Institutes of Health shall continue to serve as ex officio members of the Board, but shall be nonvoting members.

(iii) CHAIR.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

(2) DUTIES OF BOARD.—The Board shall—

(A) establish bylaws for the Foundation that—

(i) are published in the Federal Register and available for public comment;

(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;

(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code;

(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;

(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;

(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;

(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

(x) specify a process for annual Board review of the operations of the Foundation; and

(xi) establish specific duties of the Executive Director;

(B) prioritize and provide overall direction to the activities of the Foundation;

(C) evaluate the performance of the Executive Director; and

(D) carry out any other necessary activities regarding the functioning of the Foundation.

(3) TERMS AND VACANCIES.—

(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.

(B) VACANCY.—Any vacancy in the membership of the Board—

(i) shall not affect the power of the remaining members to execute the duties of the Board; and

(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

(f) NONPROFIT STATUS.—In carrying out subsection (b), the Board shall establish such policies and bylaws under subsection (d), and the Executive Director shall carry out such activities under subsection (g), as may be necessary to ensure that the Foundation maintains status as an organization that—

(1) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

(2) is, under subsection (a) of such section, exempt from taxation.

(g) EXECUTIVE DIRECTOR.—

(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board.

(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

(3) prescribe the manner in which—

(A) real or personal property of the Foundation is acquired, held, and transferred;

(B) general operations of the Foundation are to be conducted; and

(C) the privileges granted to the Board by law are exercised and enjoyed;

(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subchapter.

(i) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may solicit and accept on behalf of the Foundation,

any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

(j) SERVICE OF FEDERAL EMPLOYEES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

(k) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

(B) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

(l) ANNUAL REPORTS.—

(1) REPORTS TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

(2) REPORT TO CONGRESS AND THE FDA.—Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

(m) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treasury are managed as indi-

vidual programmatic funds under subsection (i), according to best accounting practices.

(n) FUNDING.—From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than [$500,000 and not more than $1,250,000] *$1,250,000 and not more than $5,000,000*, to the Foundation to carry out subsections (a), (b), and (d) through (m).

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## PUBLIC HEALTH SERVICE ACT

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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# PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

**SEC. 499. ESTABLISHMENT AND DUTIES OF FOUNDATION.**

(a) IN GENERAL.—The Secretary shall, acting through the Director of NIH, establish a nonprofit corporation to be known as the Foundation for the National Institutes of Health (hereafter in this section referred to as the "Foundation"). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to support the National Institutes of Health in its mission (including collection of funds for pediatric pharmacologic research), and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

(c) CERTAIN ACTIVITIES OF FOUNDATION.—

(1) IN GENERAL.—In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement

of the Director of the National Institutes of Health and the Executive Director of the Foundation.

(C) A program to collect funds for pediatric pharmacologic research and studies.

(D) Supplementary programs to provide for—

(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health officials in the United States to serve in such capacities in other countries, or both;

(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

(E) The Cures Acceleration Network described in section 480.

(2) FEES.—The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

(3) AUTHORITY OF FOUNDATION.—The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

(d) BOARD OF DIRECTORS.—

(1) COMPOSITION.—

(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the "Board"), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) The ex officio members of the Board shall be—

(i) the Chairman and ranking minority member of the Subcommittee on Health and the Environment (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

(ii) the Chairman and ranking minority member of the Committee on Labor and Human Resources or their designees, in the case of the Senate;

(iii) the Director of the National Institutes of Health; and

(iv) the Commissioner of Food and Drugs.

(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include—

(i) representatives of the general biomedical field;

(ii) representatives of experts in pediatric medicine and research;

(iii) representatives of the general biobehavioral field, which may include experts in biomedical ethics; and

(iv) representatives of the general public, which may include representatives of affected industries.

(D)(i) Not later than 30 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the Foundation; and

(II) appoint the members of the Board in accordance with subparagraph (C).

(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.

(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

(F) No employee of the National Institutes of Health shall be appointed as a member 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).

(2) CHAIR.—

(A) The ex officio members of the Board under paragraph (1)(B) shall designate an individual to serve as the initial Chair of the Board.

(B) Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the

Board shall elect a member of the Board to serve as the Chair of the Board.

(3) TERMS AND VACANCIES.—

(A) The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years, except that the terms of offices for the initial appointed members of the Board shall expire as determined by the ex officio members and the Chair.

(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.

(C) If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by 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.

(6) CERTAIN BYLAWS.—

(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation or the National Institutes of Health to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.

(e) INCORPORATION.—The initial members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

(g) EXECUTIVE DIRECTOR.—

(1) IN GENERAL.—The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) COMPENSATION.—The rate of compensation of the Executive Director shall be fixed by the Board.

(h) POWERS.—In carrying out subsection (b), the Foundation may—

(1) operate under the direction of its Board;

(2) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(3) provide for 1 or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;

(4) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;

(5) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

(6) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(7) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;

(8) establish a process for the selection of candidates for positions under subsection (c);

(9) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(10) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(11) solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

(12) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;

(13) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation;

(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and

(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

(i) ADMINISTRATIVE CONTROL.—No participant in the program established under this part shall exercise any administrative control over any Federal employee.

(j) GENERAL PROVISIONS.—

(1) FOUNDATION INTEGRITY.—The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct, financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

(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)(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.

(3) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

(A) provide for annual audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(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).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

(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

(ii) to the appropriate committees of Congress.

(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

(5) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

(6) RELATIONSHIP WITH EXISTING ENTITIES.—The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation, such as the Foundation for Advanced Education in the Sciences.

(7) INTELLECTUAL PROPERTY RIGHTS.—The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

(8) NATIONAL INSTITUTES OF HEALTH AMENDMENTS OF 1990.—The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101–613), and the amendments made by such Act, shall not be nullified by the enactment of this section.

(9) LIMITATION OF ACTIVITIES.—

(A) IN GENERAL.—The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

(B) GIFTS, GRANTS, AND OTHER DONATIONS.—

(i) IN GENERAL.—Gifts, grants, and other donations to the Foundation may be designated for pediatric research and studies on drugs, and funds so designated shall be used solely for grants for research and studies under subsection (c)(1)(C).

(ii) OTHER GIFTS.—Other gifts, grants, or donations received by the Foundation and not described in clause (i) may also be used to support such pediatric research and studies.

(iii) REPORT.—The recipient of a grant for research and studies shall agree to provide the Director of the National Institutes of Health and the Commissioner of Food and Drugs, at the conclusion of the research and studies—

(I) a report describing the results of the research and studies; and

(II) all data generated in connection with the research and studies.

(iv) ACTION BY THE COMMISSIONER OF FOOD AND DRUGS.—The Commissioner of Food and Drugs shall take appropriate action in response to a report received under clause (iii) in accordance with paragraphs (7) through (12) of section 409I(c), including negotiating with the holders of approved applications for the drugs studied for any labeling changes that the Commissioner determines to be appropriate and requests the holders to make.

(C) APPLICABILITY.—Subparagraph (A) does not apply to the program described in subsection (c)(1)(C).

(10) TRANSFER OF FUNDS.—The Foundation may transfer funds to the National Institutes 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.

(k) 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 not less than [$500,000 and not more than $1,250,000] *$1,250,000 and not more than $5,000,000* to the Foundation.

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