106TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
106–1002

CLINICAL RESEARCH ENHANCEMENT ACT OF 1999

OCTOBER 25, 2000.—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

R E P O R T

[To accompany H.R. 1798]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 1798) to amend the Public Health Service Act to provide additional support for and to expand clinical research programs, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

H.R. 1798, the Clinical Research Enhancement Act, requires the Director of the National Institutes of Health (NIH) to support and expand programs to revitalize the Nation's clinical research capacity. The bill accomplishes this objective by: establishing new career

development awards for clinical investigators; establishing awards for mid-career investigators who are studying the potential clinical application of a basic scientific discovery; expanding the existing intramural loan repayment program so that it will be available to clinical investigators in academic medical centers around the country; establishing tuition/stipend grants for individuals participating in advanced degree programs in clinical investigation; authorizing the underfunded NIH General Clinical Research Centers program in law; and, improving the peer review process for clinical research grants.

BACKGROUND AND NEED FOR LEGISLATION

The Nation's medical research enterprise seems poised to make even greater contributions to humanity's health and well-being in the coming years. However, there appears to be a defect in the structure of the country's medical research edifice which must be repaired. This defect is evidenced by the decline in the market of physicians dedicated to clinical research.

The gradual decline in the Nation's clinical research capacity is not a new phenomenon. Former National Institutes of Health Director James Wyngaarden first called attention to it some 20 years ago in a paper entitled, "The Clinical Investigator as an Endangered Species." In recent years, the problem has also been highlighted by the Institute of Medicine of the National Academy of Sciences, the NIH Director's Advisory Panel on Clinical Research, the Association of American Medical Colleges, and the American Medical Association. These organizations have all concluded that the Nation's clinical research capacity is in decline and recommended, in several reports, immediate action to correct this problem.

In the past, the Nation's academic medical centers were able to more adequately support clinical research from patient care revenues. However, due to various cost containment pressures, this internal funding has been severely curtailed and often eliminated. Despite substantial increases in NIH spending, the number of young physicians applying for their first NIH grant decreased by 30 percent over the past five years.

Obstacles to clinical research slow progress in medicine, thereby delaying discoveries of new approaches to the prevention or treatment of disease. Furthermore, a weakened clinical research effort also delays the development of new products and erodes the United States' international competitive edge in biomedical science.

HEARINGS

The Committee on Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On September 26, 2000, the Subcommittee on Health and Environment was discharged from the further consideration of H.R. 1798. On September 26, 2000, the Full Committee met in open markup session and approved H.R. 1798, without amendment, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 1798 reported.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII 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 OVERSIGHT FINDINGS

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1798, the Clinical Research Enhancement Act of 1999, 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 3(c)(3) of rule XIII 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, October 19, 2000.

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. 1798, the Clinical Research Enhancement Act of 2000.

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

Sincerely,

BARRY B. ANDERSON
(For Dan L. Crippen, Director).

Enclosure.

H.R. 1798—Clinical Research Enhancement Act of 1999

Summary: H.R. 1798 would authorize the National Institutes of Health (NIH) to provide grants to establish clinical research centers, fund clinical researchers and clinical research projects, and support students pursuing master's doctoral degrees in clinical research.

The bill also would increase the numbers of scholarships under the Public Health Service Act, and would modify a loan repayment program. Under the current program, health professionals from disadvantaged backgrounds working at the NIH agree to conduct clinical research in return for an agreement that the federal government will repay up to $35,000 of the principal and interest of educational loans for each year of service. The bill would expand the eligibility of who could qualify for loans and the sites at which these individuals could be employed. It would also require that at least half of the loan repayment contracts involve individuals from disadvantaged backgrounds. The program is currently paid out of appropriated funds and would continue to be operated in such a way under H.R. 1798.

Assuming the appropriation of the necessary amounts, CBO estimates that implementing H.R. 1798 would cost $53 million in 2001 and $814 million over the 2001–2005 period, assuming annual adjustments for inflation for the activities without specified authorization levels. The five-year total would be $783 million if such inflation adjustments are not made. The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

H.R. 1798 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). To the extent that public and university hospital conduct clinical research eligible for grant assistance under the bill, those entities may receive additional funding.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 1798 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2000	2001	2002	2003	2004	2005
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law:						
Estimated Authorization Level[1]	229	0	0	0	0	0
Estimated Outlays	201	156	90	23	11	11
Proposed Changes[2]:						
Estimated Authorization Level	0	230	236	242	249	256
Estimated Outlays	0	53	123	196	212	230
Spending Under H.R. 3250:						
Estimated Authorization Level	229	230	236	242	249	256
Estimated Outlays	201	209	214	218	224	240

[1] The 2000 level is the amount appropriated for that year for the agencies that would be affected by H.R. 1798.

[2] The amounts shown reflect adjustments for anticipated inflation for those activities for which the bill would authorize such sums as necessary. Without such inflation adjustments, the five-year changes in authorization levels would total $1.15 billion (instead of $1.21 billion) and the changes in outlays would total $783 million (instead of $814 million).

Basis of estimate: The bill authorizes several grant programs to support clinical research that NIH already operates. It also increases the number of national research service awards under section 487(a)(1)(C) of the Public Health Service Act form 50 to 100 awards. The bill would also expand the criteria under which an in-

dividual could enter into a loan repayment contract with the federal government under section 487E of the Public Health Service Act. Under current law, only individuals from disadvantaged backgrounds employed by the NIH may qualify for loan repayment. The bill would expand the program to all individuals in a clinical research training position, with a requirement that half of the contracts must be to individuals from disadvantaged backgrounds.

Many of the grants, scholarships, and loan repayment contracts that would be authorized by H.R. 1798 are currently conducted within the NIH, and are reflected in the estimated changes to both budget authority and outlays. The estimates of changes in budget authority and outlays of the proposal reflect the incremental cost of the increase in National Service Awards and the expansion of the loan repayment program.

Pay-as-you-go considerations: None.

Intergovernmental and private-sector impact: H.R. 1798 contains no intergovernmental or private-sector mandates as defined in the UMRA. To the extent that public and university hospital conduct clinical research eligible for grant assistance under the bill, those entities may receive additional funding.

Estimate prepared by: Federal Costs: Christopher J. Topoleski. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Jennifer Bullard Bowman.

Estimate approved by: Peter H. Fontaine, Deputy 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 3(d)(1) of rule XIII 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

This section provides the short title of the bill, the "Clinical Research Enhancement Act."

Section 2. Findings and purpose

Section 2 describes the role of clinical research in medical discovery, summarizes the factors that have weakened clinical research programs in recent years, and highlights the extent to which the National Institutes of Health has reduced funding for the General Clinical Research Centers as a percentage of overall NIH spending.

Section 3. Increasing the involvement of the NIH in clinical research

Section 3 requires the NIH Director to undertake activities to enhance clinical research including: (1) implementing the recommendations of an NIH study group on peer review; (2) establishing an intramural clinical research fellowship program and a continuing education program at NIH; (3) working in cooperation with Institute/Center/Division directors at NIH to expand resources available to meet the needs of the clinical research community; and, (4) establishing peer review mechanisms for the new awards and the intramural fellowship authorized by the bill.

Section 4. General clinical research centers

Section 4 amends part B of title IV of the Public Health Service Act to add two new sections. Section 409C authorizes the General Clinical Research Centers in law and authorizes such sums as may be necessary for each fiscal year.

Section 409D authorizes the Director of the National Center for Research Resources (NCRR) within NIH to provide support for three clinical research awards: (1) the Mentored Patient-Oriented Research Career Development Awards; (2) the Mid-Career Investigator Award in Patient-Oriented Research; and, (3) the Graduate Training in Clinical Investigation Award. Section 409D also requires the NCRR director to: (1) make these awards to support career development and research projects "at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented research"; and, (2) collaborate or consult with other NIH Institute Directors in making these awards. This section also authorizes such sums as may be necessary for the three awards.

Section 5. Clinical research assistance

Section 5 modifies section 487(a)(1)(C) of the Public Health Service Act, a program to provide loan repayment for clinical researchers from disadvantaged backgrounds who serve as employees of the National Institutes of Health. Section 5 eliminates the statutory requirement that all loan repayment recipients must be from disadvantaged backgrounds and substitutes language requiring that not less than 50% of recipients have such backgrounds. Section 5 also eliminates the statutory requirement that recipients must be NIH employees and substitutes language qualifying individuals in a "clinical research training position," defined as "an individual serving in a general clinical research center or in clinical research at the National Institutes of Health or a physician receiving a clinical research career enhancement award, or a graduate training in clinical investigation award." Finally, section 5 also authorizes such sums as may be necessary for the loan repayment program.

Section 6. Definition

This section defines clinical research as patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology, or disease; or epidemiologic or behavioral studies, outcomes research, or health services research, or developing new technologies or therapeutic interventions.

Section 7. Oversight by General Accounting Office

Section 7 requires the Comptroller General of the United States to submit to Congress within 18 months of the date of enactment of the bill a report describing the extent to which the NIH has complied with the provisions of the legislation.

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 italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

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APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

SEC. 402. (a) * * *

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(m)(1) The Director of NIH shall undertake activities to support and expand the involvement of the National Institutes of Health in clinical research.

(2) In carrying out paragraph (1), the Director of NIH shall—

(A) implement the recommendations of the Division of Research Grants Clinical Research Study Group and other recommendations for enhancing clinical research, where applicable; and

(B) establish an intramural clinical research fellowship program and a continuing education clinical research training program at NIH.

(3) The Director of NIH, in cooperation with the Directors of the Institutes, Centers, and Divisions of the National Institutes of Health, shall support and expand the resources available for the diverse needs of the clinical research community, including inpatient, outpatient, and critical care clinical research.

(4) The Director of NIH shall establish peer review mechanisms to evaluate applications for—

(A) Mentored Patient-Oriented Research Career Development Awards;

(B) Mid-Career Investigator Awards in Patient-Oriented Research;

(C) graduate training in clinical investigation awards;

(D) intramural clinical research fellowships.

Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research training and research grant proposals.

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PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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DEFINITIONS

SEC. 409. [For purposes] *(a) HEALTH SERVICE RESEARCH.—For purposes* of this title, the term "health services research" means research endeavors that study the impact of the organization, financing and management of health services on the quality, cost, access to and outcomes of care. Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.

(b) CLINICAL RESEARCH.—As used in this title, the term "clinical research" means patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology, or disease; or epidemiologic or behavioral studies, outcomes research, or health services research, or developing new technologies or therapeutic interventions.

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SEC. 409C. GENERAL CLINICAL RESEARCH CENTERS.

(a) GRANTS.—The Director of the National Center for Research Resources shall award grants for the establishment of general clinical research centers to provide the infrastructure for clinical research including clinical research training and career enhancement. Such centers shall support clinical studies and career development in all settings of the hospital or academic medical center involved.

(b) ACTIVITIES.—In carrying out subsection (a), the Director of NIH shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

SEC. 409D. ENHANCEMENT AWARDS.

(a) MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARDS.—

(1) IN GENERAL.—The Director of the National Center for Research Resources shall make grants (to be referred to as "Mentored Patient-Oriented Research Career Development Awards") to support individual careers in clinical research at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research. The Director of the National Center for Research Resources shall, where practicable, collaborate or consult with other Institute Directors in making awards under this subsection.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(b) MID-CAREER INVESTIGATOR AWARDS IN PATIENT-ORIENTED RESEARCH.—

(1) IN GENERAL.—The Director of the National Center for Research Resources shall make grants (to be referred to as "Mid-Career Investigator Awards in Patient-Oriented Research") to support individual clinical research projects at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research. The Director of the National Center for Research Resources shall, where practicable, collaborate or consult with other Institute Directors in making awards under this subsection.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director requires.

(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(c) GRADUATE TRAINING IN CLINICAL INVESTIGATION AWARD.—

(1) IN GENERAL.—The Director of the National Center for Research Resources shall make grants (to be referred to as "graduate training in clinical investigation awards") to support individuals pursuing master's or doctoral degrees in clinical investigation.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(3) LIMITATIONS.—Grants shall be for terms of 2 years or more and will provide stipend, tuition, and institutional support for individual advanced degree programs in clinical investigation.

(4) DEFINITION.—As used in this subsection, the term "advanced degree programs in clinical investigation" means programs that award a master's or Ph.D. degree after 2 or more years of training in areas such as the following:

(A) Analytical methods, biostatistics, and study design.

(B) Principles of clinical pharmacology and pharmacokinetics.

(C) Clinical epidemiology.

(D) Computer data management and medical informatics.

(E) Ethical and regulatory issues.

(F) Biomedical writing.

(5) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

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PART G—AWARDS AND TRAINING

NATIONAL RESEARCH SERVICE AWARDS

SEC. 487. (a)(1) The Secretary shall—

(A) * * *

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(C) provide contracts for scholarships and loan repayments in accordance with sections 487D and 487E, subject to providing not more than an aggregate [50] *100* such contracts during the fiscal years 1994 through 1996.

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LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS [FROM DISADVANTAGED BACKGROUNDS]

SEC. 487E.(a) IMPLEMENTATION OF PROGRAM.—

(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals [who are from disadvantaged backgrounds] under which such health professionals agree to conduct clinical research [as employees of the National Institutes of Health] *as part of a clinical research training position* in consideration of the Federal Government agreeing to pay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of the health professionals.

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[(3) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338B, 338C and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.]

(3) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—With respect to the National Health Service Corps Loan Repayment Program established under subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with this section, apply to the program established in this section in the same manner and to the same extent as such provisions apply to such loan repayment program.

(b) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—[Amounts]

(1) IN GENERAL.—Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

(2) DISADVANTAGED BACKGROUNDS SET-ASIDE.—In carrying out this section, the Secretary shall ensure that not less than 50 percent of the contracts involve those appropriately qualified health professionals who are from disadvantaged backgrounds.

(c) DEFINITION.—As used in subsection (a)(1), the term "clinical research training position" means an individual serving in a general clinical research center or in clinical research at the National Institutes of Health, or a physician receiving a clinical research career enhancement award, or a graduate training in clinical investigation award.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

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