

# Union Calendar No. 585

106<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 1798

[Report No. 106–1002]

To amend the Public Health Service Act to provide additional support for and to expand clinical research programs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 13, 1999

Mr. GREENWOOD (for himself, Mrs. LOWEY, Mrs. JOHNSON of Connecticut, Mr. BROWN of Ohio, Mr. BURR of North Carolina, Mr. WAXMAN, Mr. PICKERING, Mr. DEAL of Georgia, Mrs. MORELLA, Mr. FRANK of Massachusetts, Ms. DELAURO, Mr. NETHERCUTT, Mr. LEACH, Mr. ENGLISH, Mr. TOWNS, Mr. COYNE, Mr. LEWIS of Georgia, Mr. NADLER, Mr. WICKER, Mr. FILNER, and Ms. PELOSI) introduced the following bill; which was referred to the Committee on Commerce

OCTOBER 25, 2000

Additional sponsors: Ms. SLAUGHTER, Mr. CAPUANO, Mr. MCGOVERN, Mr. FROST, Mr. UPTON, Mr. WYNN, Mr. HOYER, Mr. McNULTY, Mr. GONZALEZ, Mr. SANDLIN, Mr. NORWOOD, Mr. DEUTSCH, Ms. ESHOO, Mrs. THURMAN, Mr. BARRETT of Wisconsin, Mr. EHRLICH, Mr. PRICE of North Carolina, Mr. MARTINEZ, Mrs. MALONEY of New York, Mr. DIXON, Ms. STABENOW, Mr. BILBRAY, Mr. MARKEY, Ms. DEGETTE, Mr. SANDERS, Mr. STARK, Mr. GORDON, Mr. RODRIGUEZ, Mr. TAUZIN, Mr. HILLIARD, Mr. ROGAN, and Mr. BOEHLERT

OCTOBER 25, 2000

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

# A BILL

To amend the Public Health Service Act to provide additional support for and to expand clinical research programs, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Clinical Research En-  
5 hancement Act of 1999”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7       (a) FINDINGS.—Congress makes the following find-  
8 ings:

9           (1) Clinical research is critical to the advance-  
10 ment of scientific knowledge and to the development  
11 of cures and improved treatment for disease.

12           (2) Tremendous advances in biology are open-  
13 ing doors to new insights into human physiology,  
14 pathophysiology and disease, creating extraordinary  
15 opportunities for clinical research.

16           (3) Clinical research includes translational re-  
17 search which is an integral part of the research  
18 process leading to general human applications. It is  
19 the bridge between the laboratory and new methods  
20 of diagnosis, treatment, and prevention and is thus

1 essential to progress against cancer and other dis-  
2 eases.

3 (4) The United States will spend more than \$1  
4 trillion on health care in 1997, but the Federal  
5 budget for health research at the National Institutes  
6 of Health was \$12.7 billion, only 1 percent of that  
7 total.

8 (5) Studies at the Institute of Medicine, the  
9 National Research Council, and the National Acad-  
10 emy of Sciences have all addressed the current prob-  
11 lems in clinical research.

12 (6) The Director of the National Institutes of  
13 Health has recognized the current problems in clin-  
14 ical research and appointed a special advisory com-  
15 mittee, which recommended expanded support for  
16 existing NIH clinical research programs and the cre-  
17 ation of new initiatives to recruit and retain clinical  
18 investigators.

19 (7) The current level of training and support  
20 for health professionals in clinical research is frag-  
21 mented, frequently undervalued, and potentially un-  
22 derfunded.

23 (8) Young investigators are not only appren-  
24 tices for future positions but a crucial source of en-  
25 ergy, enthusiasm, and ideas in the day-to-day re-

1 search that constitutes the scientific enterprise. Seri-  
2 ous questions about the future of life-science re-  
3 search are raised by the following:

4 (A) The number of young investigators ap-  
5 plying for grants dropped by 54 percent be-  
6 tween 1985 and 1993.

7 (B) The number of physicians applying for  
8 first-time NIH research project grants fell from  
9 838 in 1994 to 575 in 1997, a 31 percent re-  
10 duction.

11 (C) Newly independent life-scientists are  
12 expected to raise funds to support their new re-  
13 search programs and a substantial proportion  
14 of their own salaries.

15 (9) The following have been cited as reasons for  
16 the decline in the number of active clinical research-  
17 ers, and those choosing this career path:

18 (A) A medical school graduate incurs an  
19 average debt of \$85,619, as reported in the  
20 Medical School Graduation Questionnaire by  
21 the American Association of Medical Colleges  
22 (AAMC).

23 (B) The prolonged period of clinical train-  
24 ing required increases the accumulated debt  
25 burden.

1 (C) The decreasing number of mentors and  
2 role models.

3 (D) The perceived instability of funding  
4 from the National Institutes of Health and  
5 other Federal agencies.

6 (E) The almost complete absence of clin-  
7 ical research training in the curriculum of  
8 training grant awardees.

9 (F) Academic Medical Centers are experi-  
10 encing difficulties in maintaining a proper envi-  
11 ronment for research in a highly competitive  
12 health care marketplace, which are compounded  
13 by the decreased willingness of third party pay-  
14 ers to cover health care costs for patients en-  
15 gaged in research studies and research proce-  
16 dures.

17 (10) In 1960, general clinical research centers  
18 were established under the Office of the Director of  
19 the National Institutes of Health with an initial ap-  
20 propriation of \$3,000,000.

21 (11) Appropriations for general clinical research  
22 centers in fiscal year 1998 equaled \$167,000,000.  
23 Since the late 1960s, spending for general clinical  
24 research centers has declined from approximately 3  
25 percent to 1 percent of the NIH budget.

1           (12) In fiscal year 1998, there were 75 general  
2           clinical research centers in operation, supplying pa-  
3           tients in the areas in which such centers operate  
4           with access to the most modern clinical research and  
5           clinical research facilities and technologies.

6           (b) PURPOSE.—It is the purpose of this Act to pro-  
7           vide additional support for and to expand clinical research  
8           programs.

9           **SEC. 3. INCREASING THE INVOLVEMENT OF THE NATIONAL**  
10                           **INSTITUTES OF HEALTH IN CLINICAL RE-**  
11                           **SEARCH.**

12           Section 402 of the Public Health Service Act (42  
13           U.S.C. 282) is amended by adding at the end the fol-  
14           lowing:

15           “(m)(1) The Director of NIH shall undertake activi-  
16           ties to support and expand the involvement of the National  
17           Institutes of Health in clinical research.

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

20                   “(A) implement the recommendations of the Di-  
21           vision of Research Grants Clinical Research Study  
22           Group and other recommendations for enhancing  
23           clinical research, where applicable; and

1           “(B) establish an intramural clinical research  
2           fellowship program and a continuing education clin-  
3           ical research training program at NIH.

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

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

12                 “(A) Mentored Patient-Oriented Research Ca-  
13                 reer Development Awards;

14                 “(B) Mid-Career Investigator Awards in Pa-  
15                 tient-Oriented Research;

16                 “(C) graduate training in clinical investigation  
17                 awards;

18                 “(D) intramural clinical research fellowships.

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

22          **SEC. 4. GENERAL CLINICAL RESEARCH CENTERS.**

23          Part B of title IV of the Public Health Service Act  
24          (42 U.S.C. 284 et seq.) is further amended by adding at  
25          the end the following:

1 **“SEC. 409C. GENERAL CLINICAL RESEARCH CENTERS.**

2       “(a) GRANTS.—The Director of the National Center  
3 for Research Resources shall award grants for the estab-  
4 lishment of general clinical research centers to provide the  
5 infrastructure for clinical research including clinical re-  
6 search training and career enhancement. Such centers  
7 shall support clinical studies and career development in  
8 all settings of the hospital or academic medical center in-  
9 volved.

10       “(b) ACTIVITIES.—In carrying out subsection (a), the  
11 Director of NIH shall expand the activities of the general  
12 clinical research centers through the increased use of tele-  
13 communications and telemedicine initiatives.

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

18 **“SEC. 409D. ENHANCEMENT AWARDS.**

19       “(a) MENTORED PATIENT-ORIENTED RESEARCH CA-  
20 REER DEVELOPMENT AWARDS.—

21               “(1) IN GENERAL.—The Director of the Na-  
22 tional Center for Research Resources shall make  
23 grants (to be referred to as ‘Mentored Patient-Ori-  
24 ented Research Career Development Awards’) to  
25 support individual careers in clinical research at gen-  
26 eral clinical research centers or at other institutions

1 that have the infrastructure and resources deemed  
2 appropriate for conducting patient-oriented clinical  
3 research. The Director of the National Center for  
4 Research Resources shall, where practicable, collabo-  
5 rate or consult with other Institute Directors in  
6 making awards under this subsection.

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

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

15 “(b) MID-CAREER INVESTIGATOR AWARDS IN PA-  
16 TIENT-ORIENTED RESEARCH.—

17 “(1) IN GENERAL.—The Director of the Na-  
18 tional Center for Research Resources shall make  
19 grants (to be referred to as ‘Mid-Career Investigator  
20 Awards in Patient-Oriented Research’) to support  
21 individual clinical research projects at general clin-  
22 ical research centers or at other institutions that  
23 have the infrastructure and resources deemed appro-  
24 priate for conducting patient-oriented clinical re-  
25 search. The Director of the National Center for Re-

1 search Resources shall, where practicable, collabo-  
2 rate or consult with other Institute Directors in  
3 making awards under this subsection.

4 “(2) APPLICATIONS.—An application for a  
5 grant under this subsection shall be submitted by an  
6 individual scientist at such time as the Director re-  
7 quires.

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

12 “(c) GRADUATE TRAINING IN CLINICAL INVESTIGA-  
13 TION AWARD.—

14 “(1) IN GENERAL.—The Director of the Na-  
15 tional Center for Research Resources shall make  
16 grants (to be referred to as ‘graduate training in  
17 clinical investigation awards’) to support individuals  
18 pursuing master’s or doctoral degrees in clinical in-  
19 vestigation.

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

24 “(3) LIMITATIONS.—Grants shall be for terms  
25 of 2 years or more and will provide stipend, tuition,

1 and institutional support for individual advanced de-  
2 gree programs in clinical investigation.

3 “(4) DEFINITION.—As used in this subsection,  
4 the term ‘advanced degree programs in clinical in-  
5 vestigation’ means programs that award a master’s  
6 or Ph.D. degree after 2 or more years of training  
7 in areas such as the following:

8 “(A) Analytical methods, biostatistics, and  
9 study design.

10 “(B) Principles of clinical pharmacology  
11 and pharmacokinetics.

12 “(C) Clinical epidemiology.

13 “(D) Computer data management and  
14 medical informatics.

15 “(E) Ethical and regulatory issues.

16 “(F) Biomedical writing.

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

21 **SEC. 5. CLINICAL RESEARCH ASSISTANCE.**

22 (a) NATIONAL RESEARCH SERVICE AWARDS.—Sec-  
23 tion 487(a)(1)(C) of the Public Health Service Act (42  
24 U.S.C. 288(a)(1)(C)) is amended by striking “50 such”  
25 and inserting “100 such”.

1 (b) LOAN REPAYMENT PROGRAM.—Section 487E of  
2 the Public Health Service Act (42 U.S.C. 288–5) is  
3 amended—

4 (1) in the section heading, by striking “FROM  
5 DISADVANTAGED BACKGROUNDS”;

6 (2) in subsection (a)(1)—

7 (A) by striking “who are from disadvan-  
8 taged backgrounds”; and

9 (B) by striking “as employees of the Na-  
10 tional Institutes of Health” and inserting “as  
11 part of a clinical research training position”;

12 (3) in subsection (a), by striking paragraph (3)  
13 and inserting the following:

14 “(3) APPLICABILITY OF CERTAIN PROVISIONS  
15 REGARDING OBLIGATED SERVICE.—With respect to  
16 the National Health Service Corps Loan Repayment  
17 Program established under subpart III of part D of  
18 title III, the provisions of such subpart shall, except  
19 as inconsistent with this section, apply to the pro-  
20 gram established in this section in the same manner  
21 and to the same extent as such provisions apply to  
22 such loan repayment program.”;

23 (4) in subsection (b)—

24 (A) by striking “Amounts” and inserting  
25 the following:

1 “(1) IN GENERAL.—Amounts”; and

2 (B) by adding at the end the following:

3 “(2) DISADVANTAGED BACKGROUNDS SET-  
4 ASIDE.—In carrying out this section, the Secretary  
5 shall ensure that not less than 50 percent of the  
6 contracts involve those appropriately qualified health  
7 professionals who are from disadvantaged back-  
8 grounds.”; and

9 (5) by adding at the end the following:

10 “(c) DEFINITION.—As used in subsection (a)(1), the  
11 term ‘clinical research training position’ means an indi-  
12 vidual serving in a general clinical research center or in  
13 clinical research at the National Institutes of Health, or  
14 a physician receiving a clinical research career enhance-  
15 ment award, or a graduate training in clinical investiga-  
16 tion award.

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

21 **SEC. 6. DEFINITION.**

22 Section 409 of the Public Health Service Act (42  
23 U.S.C. 284d) is amended—

1           (1) by striking “For purposes” and inserting  
2           “(a) HEALTH SERVICE RESEARCH.—For purposes”;  
3           and

4           (2) by adding at the end the following:

5           “(b) CLINICAL RESEARCH.—As used in this title, the  
6 term ‘clinical research’ means patient oriented clinical re-  
7 search conducted with human subjects, or research on the  
8 causes and consequences of disease in human populations  
9 involving material of human origin (such as tissue speci-  
10 mens and cognitive phenomena) for which an investigator  
11 or colleague directly interacts with human subjects in an  
12 outpatient or inpatient setting to clarify a problem in  
13 human physiology, pathophysiology, or disease; or epi-  
14 demiologic or behavioral studies, outcomes research, or  
15 health services research, or developing new technologies or  
16 therapeutic interventions.”.

17 **SEC. 7. OVERSIGHT BY GENERAL ACCOUNTING OFFICE.**

18           Not later than 18 months after the date of the enact-  
19 ment of this Act, the Comptroller General of the United  
20 States shall submit to the Congress a reporting describing  
21 the extent to which the National Institutes of Health has  
22 complied with the amendments made by this Act.



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