

106<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1813

---

## AN ACT

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”.

1 **SEC. 2. FINDINGS AND PURPOSE.**

2 (a) FINDINGS.—Congress makes the following find-  
3 ings:

4 (1) Clinical research is critical to the advance-  
5 ment of scientific knowledge and to the development  
6 of cures and improved treatment for disease.

7 (2) Tremendous advances in biology are open-  
8 ing doors to new insights into human physiology,  
9 pathophysiology and disease, creating extraordinary  
10 opportunities for clinical research.

11 (3) Clinical research includes translational re-  
12 search which is an integral part of the research  
13 process leading to general human applications. It is  
14 the bridge between the laboratory and new methods  
15 of diagnosis, treatment, and prevention and is thus  
16 essential to progress against cancer and other dis-  
17 eases.

18 (4) The United States will spend more than  
19 \$1,200,000,000,000 on health care in 1999, but the  
20 Federal budget for health research at the National  
21 Institutes of Health was \$15,600,000,000 only 1  
22 percent of that total.

23 (5) Studies at the Institute of Medicine, the  
24 National Research Council, and the National Acad-  
25 emy of Sciences have all addressed the current prob-  
26 lems in clinical research.

1           (6) The Director of the National Institutes of  
2           Health has recognized the current problems in clin-  
3           ical research and appointed a special panel, which  
4           recommended expanded support for existing Na-  
5           tional Institutes of Health clinical research programs  
6           and the creation of new initiatives to recruit and re-  
7           tain clinical investigators.

8           (7) The current level of training and support  
9           for health professionals in clinical research is frag-  
10          mented, undervalued, and underfunded.

11          (8) Young investigators are not only appren-  
12          tices for future positions but a crucial source of en-  
13          ergy, enthusiasm, and ideas in the day-to-day re-  
14          search that constitutes the scientific enterprise. Seri-  
15          ous questions about the future of life-science re-  
16          search are raised by the following:

17                (A) The number of young investigators ap-  
18                plying for grants dropped by 54 percent be-  
19                tween 1985 and 1993.

20                (B) The number of physicians applying for  
21                first-time National Institutes of Health research  
22                project grants fell from 1226 in 1994 to 963 in  
23                1998, a 21 percent reduction.

24                (C) Newly independent life-scientists are  
25                expected to raise funds to support their new re-

1 search programs and a substantial proportion  
2 of their own salaries.

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

6 (A) A medical school graduate incurs an  
7 average debt of \$85,619, as reported in the  
8 Medical School Graduation Questionnaire by  
9 the Association of American Medical Colleges  
10 (AAMC).

11 (B) The prolonged period of clinical train-  
12 ing required increases the accumulated debt  
13 burden.

14 (C) The decreasing number of mentors and  
15 role models.

16 (D) The perceived instability of funding  
17 from the National Institutes of Health and  
18 other Federal agencies.

19 (E) The almost complete absence of clin-  
20 ical research training in the curriculum of  
21 training grant awardees.

22 (F) Academic Medical Centers are experi-  
23 encing difficulties in maintaining a proper envi-  
24 ronment for research in a highly competitive  
25 health care marketplace, which are compounded

1 by the decreased willingness of third party pay-  
2 ers to cover health care costs for patients en-  
3 gaged in research studies and research proce-  
4 dures.

5 (10) In 1960, general clinical research centers  
6 were established under the Office of the Director of  
7 the National Institutes of Health with an initial ap-  
8 propriation of \$3,000,000.

9 (11) Appropriations for general clinical research  
10 centers in fiscal year 1999 equaled \$200,500,000.

11 (12) Since the late 1960s, spending for general  
12 clinical research centers has declined from approxi-  
13 mately 3 percent to 1 percent of the National Insti-  
14 tutes of Health budget.

15 (13) In fiscal year 1999, there were 77 general  
16 clinical research centers in operation, supplying pa-  
17 tients in the areas in which such centers operate  
18 with access to the most modern clinical research and  
19 clinical research facilities and technologies.

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

1 **SEC. 3. INCREASING THE INVOLVEMENT OF THE NATIONAL**  
2 **INSTITUTES OF HEALTH IN CLINICAL RE-**  
3 **SEARCH.**

4 Part B of title IV of the Public Health Service Act  
5 (42 U.S.C. 284 et seq.) is amended by adding at the end  
6 the following:

7 **“SEC. 409C. CLINICAL RESEARCH.**

8 “(a) IN GENERAL.—The Director of National Insti-  
9 tutes of Health shall undertake activities to support and  
10 expand the involvement of the National Institutes of  
11 Health in clinical research.

12 “(b) REQUIREMENTS.—In carrying out subsection  
13 (a), the Director of National Institutes of Health shall—

14 “(1) consider the recommendations of the Divi-  
15 sion of Research Grants Clinical Research Study  
16 Group and other recommendations for enhancing  
17 clinical research; and

18 “(2) establish intramural and extramural clin-  
19 ical research fellowship programs directed specifi-  
20 cally at medical and dental students and a con-  
21 tinuing education clinical research training program  
22 at the National Institutes of Health.

23 “(c) SUPPORT FOR THE DIVERSE NEEDS OF CLIN-  
24 ICAL RESEARCH.—The Director of National Institutes of  
25 Health, in cooperation with the Directors of the Institutes,  
26 Centers, and Divisions of the National Institutes of

1 Health, shall support and expand the resources available  
2 for the diverse needs of the clinical research community,  
3 including inpatient, outpatient, and critical care clinical  
4 research.

5 “(d) PEER REVIEW.—The Director of National Insti-  
6 tutes of Health shall establish peer review mechanisms to  
7 evaluate applications for the awards and fellowships pro-  
8 vided for in subsection (b)(2) and section 409D. Such re-  
9 view mechanisms shall include individuals who are excep-  
10 tionally qualified to appraise the merits of potential clin-  
11 ical research training and research grant proposals.”.

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

13 (a) GRANTS.—Subpart 1 of part B of title IV of the  
14 Public Health Service Act (42 U.S.C. 287 et seq.) is  
15 amended by adding at the end the following:

16 **“SEC. 481C. GENERAL CLINICAL RESEARCH CENTERS.**

17 “(a) GRANTS.—The Director of the National Center  
18 for Research Resources shall award grants for the estab-  
19 lishment of general clinical research centers to provide the  
20 infrastructure for clinical research including clinical re-  
21 search training and career enhancement. Such centers  
22 shall support clinical studies and career development in  
23 all settings of the hospital or academic medical center in-  
24 volved.

1           “(b) ACTIVITIES.—In carrying out subsection (a), the  
2 Director of National Institutes of Health shall expand the  
3 activities of the general clinical research centers through  
4 the increased use of telecommunications and telemedicine  
5 initiatives.

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

10          (b) ENHANCEMENT AWARDS.—Part B of title IV of  
11 the Public Health Service Act (42 U.S.C. 284 et seq.),  
12 as amended by section 3, is further amended by adding  
13 at the end the following:

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

15           “(a) MENTORED PATIENT-ORIENTED RESEARCH CA-  
16 REER DEVELOPMENT AWARDS.—

17                   “(1) GRANTS.—

18                           “(A) IN GENERAL.—The Director of the  
19 National Institutes of Health shall make grants  
20 (to be referred to as ‘Mentored Patient-Ori-  
21 ented Research Career Development Awards’)  
22 to support individual careers in clinical research  
23 at general clinical research centers or at other  
24 institutions that have the infrastructure and re-



1 sources deemed appropriate for conducting pa-  
2 tient-oriented clinical research.

3 “(B) USE.—Grants under subparagraph  
4 (A) shall be used to support clinical investiga-  
5 tors in the early phases of their independent ca-  
6 reers by providing salary and such other sup-  
7 port for a period of supervised study.

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

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

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

18 “(1) GRANTS.—

19 “(A) IN GENERAL.—The Director of the  
20 National Institutes of Health shall make grants  
21 (to be referred to as ‘Mid-Career Investigator  
22 Awards in Patient-Oriented Research’) to sup-  
23 port individual clinical research projects at gen-  
24 eral clinical research centers or at other institu-  
25 tions that have the infrastructure and resources

1           deemed appropriate for conducting patient-ori-  
2           ented clinical research.

3           “(B) USE.—Grants under subparagraph  
4           (A) shall be used to provide support for mid-ca-  
5           reer level clinicians to allow such clinicians to  
6           devote time to clinical research and to act as  
7           mentors for beginning clinical investigators.

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

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

16          “(c) GRADUATE TRAINING IN CLINICAL INVESTIGA-  
17          TION AWARD.—

18          “(1) IN GENERAL.—The Director of the Na-  
19          tional Institutes of Health shall make grants (to be  
20          referred to as ‘Graduate Training in Clinical Inves-  
21          tigation Awards’) to support individuals pursuing  
22          master’s or doctoral degrees in clinical investigation.

23          “(2) APPLICATIONS.—An application for a  
24          grant under this subsection shall be submitted by an

1 individual scientist at such time as the Director may  
2 require.

3 “(3) LIMITATIONS.—Grants under this sub-  
4 section shall be for terms of 2 years or more and  
5 shall provide stipend, tuition, and institutional sup-  
6 port for individual advanced degree programs in  
7 clinical investigation.

8 “(4) DEFINITION.—As used in this subsection,  
9 the term ‘advanced degree programs in clinical in-  
10 vestigation’ means programs that award a master’s  
11 or Ph.D. degree in clinical investigation after 2 or  
12 more years of training in areas such as the fol-  
13 lowing:

14 “(A) Analytical methods, biostatistics, and  
15 study design.

16 “(B) Principles of clinical pharmacology  
17 and pharmacokinetics.

18 “(C) Clinical epidemiology.

19 “(D) Computer data management and  
20 medical informatics.

21 “(E) Ethical and regulatory issues.

22 “(F) Biomedical writing.

23 “(5) AUTHORIZATION OF APPROPRIATIONS.—  
24 For the purpose of carrying out this subsection,

1 there are authorized to be appropriated such sums  
2 as may be necessary for each fiscal year.

3 “(d) CLINICAL RESEARCH CURRICULUM AWARDS.—

4 “(1) IN GENERAL.—The Director of the Na-  
5 tional Institutes of Health shall make grants (to be  
6 referred to as ‘Clinical Research Curriculum  
7 Awards’) to institutions for the development and  
8 support of programs of core curricula for training  
9 clinical investigators, including medical students.  
10 Such core curricula may include training in areas  
11 such as the following:

12 “(A) Analytical methods, biostatistics, and  
13 study design.

14 “(B) Principles of clinical pharmacology  
15 and pharmacokinetics.

16 “(C) Clinical epidemiology.

17 “(D) Computer data management and  
18 medical informatics.

19 “(E) Ethical and regulatory issues.

20 “(F) Biomedical writing.

21 “(2) APPLICATIONS.—An application for a  
22 grant under this subsection shall be submitted by an  
23 individual institution or a consortium of institutions  
24 at such time as the Director may require. An insti-  
25 tution may submit only 1 such application.

1           “(3) LIMITATIONS.—Grants under this sub-  
2           section shall be for terms of up to 5 years and may  
3           be renewable.

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

8   **SEC. 5. LOAN REPAYMENT PROGRAM REGARDING CLIN-**  
9                                   **ICAL RESEARCHERS.**

10          Part G of title IV of the Public Health Service Act  
11 is amended by inserting after section 487E (42 U.S.C.  
12 288–5) the following:

13   **“SEC. 487F. LOAN REPAYMENT PROGRAM REGARDING**  
14                                   **CLINICAL RESEARCHERS.**

15          “(a) IN GENERAL.—The Secretary, acting through  
16 the Director of the National Institutes of Health, shall es-  
17 tablish a program to enter into contracts with qualified  
18 health professionals under which such health professionals  
19 agree to conduct clinical research, in consideration of the  
20 Federal Government agreeing to repay, for each year of  
21 service conducting such research, not more than \$35,000  
22 of the principal and interest of the educational loans of  
23 such health professionals.

24          “(b) APPLICATION OF PROVISIONS.—The provisions  
25 of sections 338B, 338C, and 338E shall, except as incon-

1 sistent with subsection (a) of this section, apply to the pro-  
2 gram established under subsection (a) to the same extent  
3 and in the same manner as such provisions apply to the  
4 National Health Service Corps Loan Repayment Program  
5 established in subpart III of part D of title III.

6 “(c) FUNDING.—

7 “(1) AUTHORIZATION OF APPROPRIATIONS.—

8 For the purpose of carrying out this section, there  
9 are authorized to be appropriated such sums as may  
10 be necessary for each fiscal year.

11 “(2) AVAILABILITY.—Amounts appropriated for  
12 carrying out this section shall remain available until  
13 the expiration of the second fiscal year beginning  
14 after the fiscal year for which the amounts were  
15 made available.”.

16 **SEC. 6. DEFINITION.**

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

19 (1) by striking “For purposes” and inserting

20 “(a) HEALTH SERVICE RESEARCH.—For purposes”;

21 and

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

23 “(b) CLINICAL RESEARCH.—As used in this title, the  
24 term ‘clinical research’ means patient oriented clinical re-  
25 search conducted with human subjects, or research on the

1 causes and consequences of disease in human populations  
2 involving material of human origin (such as tissue speci-  
3 mens and cognitive phenomena) for which an investigator  
4 or colleague directly interacts with human subjects in an  
5 outpatient or inpatient setting to clarify a problem in  
6 human physiology, pathophysiology or disease, or epi-  
7 demiologic or behavioral studies, outcomes research or  
8 health services research, or developing new technologies,  
9 therapeutic interventions, or clinical trials.”.

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

11 Not later than 18 months after the date of enactment  
12 of this Act, the Comptroller General of the United States  
13 shall submit to the Congress a reporting describing the  
14 extent to which the National Institutes of Health has com-  
15 plied with the amendments made by this Act.

Passed the Senate November 19, 1999.

Attest:

*Secretary.*

106TH CONGRESS  
1ST SESSION

**S. 1813**

---

---

**AN ACT**

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



S 1813 ES—2

S 1813 ES—3

S 1813 ES—4

S 1813 ES—5