

104TH CONGRESS
2D SESSION

S. 1534

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

IN THE SENATE OF THE UNITED STATES

JANUARY 26, 1996

Mr. HATFIELD (for himself and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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 1996”.

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

7 (a) FINDINGS.—Congress finds the following:

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

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

8 (3) The United States spent more than \$1 tril-
9 lion on health care in 1994, but the Federal budget
10 for health research at the National Institutes of
11 Health was \$10 billion, only 1 percent of that total.

12 (4) Studies at the Institute of Medicine, the
13 National Research Council, and the National Acad-
14 emy of Sciences have all addressed the current prob-
15 lems in clinical research.

16 (5) The Director of the National Institutes of
17 Health has recognized the current problems in clini-
18 cal research and has through the use of an advisory
19 committee begun to evaluate these problems.

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

24 (7) Young investigators are not only appren-
25 tices for future positions but a crucial source of en-

1 ergy, enthusiasm, and ideas in the day-to-day re-
2 search that constitutes the scientific enterprise. Seri-
3 ous questions about the future of life-science re-
4 search are raised by the following:

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

8 (B) The number of federally funded re-
9 search (R01) grants awarded to persons under
10 the age of 36 have decreased by 70 percent
11 from 1985 to 1993.

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

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

19 (A) A medical school graduate incurs an
20 average debt of \$63,000, as reported in the
21 Medical School Graduation Questionnaire by
22 the American Association of Medical Colleges
23 (AAMC).

1 (B) The prolonged period of clinical train-
2 ing required increases the accumulated debt
3 burden.

4 (C) The decreasing number of mentors and
5 role models.

6 (D) The perceived instability of funding
7 from the National Institutes of Health and
8 other Federal agencies.

9 (E) The almost complete absence of clini-
10 cal research training in the curriculum of train-
11 ing grant awardees.

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

20 (9) In 1960, general clinical research centers
21 were established under the Office of the Director of
22 the National Institutes of Health with an initial ap-
23 propriation of \$3,000,000.

24 (10) Appropriations for general clinical research
25 centers in fiscal year 1995 equal \$136,640,000.

1 (11) In fiscal year 1995, there are 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 (12) The average annual amount allocated for
7 each general clinical research center is \$1,000,000,
8 establishing a current funding level of 75 percent of
9 the amounts approved by the Advisory Council of
10 the National Center for Research Resources.

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

14 **SEC. 3. PRESIDENT'S CLINICAL RESEARCH PANEL.**

15 Part H of title IV of the Public Health Service Act
16 (42 U.S.C. 289 et seq.) is amended by adding at the end
17 thereof the following new section:

18 **“SEC. 498C. PRESIDENT'S CLINICAL RESEARCH PANEL.**

19 “(a) ESTABLISHMENT.—The President shall estab-
20 lish a panel to be known as the ‘President’s Clinical Re-
21 search Panel’ (hereafter referred to in this section as the
22 ‘Panel’) as a part of the Office of Science and Technology
23 Policy, to carry out the duties described in this section.

24 “(b) MEMBERSHIP.—

1 “(1) IN GENERAL.—The Panel shall be com-
2 posed of 12 individuals appointed by the President
3 and selected from recommendations submitted by
4 the President of the Institute of Medicine of the Na-
5 tional Academy of Sciences.

6 “(2) QUALIFICATIONS.—Individuals appointed
7 to the panel under paragraph (1) shall, by virtue of
8 their training, experience and background, be excep-
9 tionally qualified to appraise the status of clinical re-
10 search both within and outside of the Federal Gov-
11 ernment, and should represent distinguished re-
12 search scientists and physicians, insurance compa-
13 nies, pharmaceutical companies, health maintenance
14 organizations, accreditation and certification organi-
15 zations and academic research administrators, and
16 patients.

17 “(3) EXCLUSION AND ADVISORS.—Officers or
18 employees of the Federal Government shall not be
19 eligible to be appointed to the Panel. The Secretary
20 of Health and Human Services, the Secretary of De-
21 fense, the Secretary of Veterans Affairs, the Assist-
22 ant to the President for Science and Technology,
23 and other Cabinet officers as the President deter-
24 mines to be appropriate may serve as advisors to the
25 Panel.

1 “(c) TERMS AND VACANCIES.—

2 “(1) TERMS.—Members of the Panel shall be
3 appointed for 3-year terms, except that—

4 “(A) any member appointed to fill a va-
5 cancy occurring on the Panel prior to the expi-
6 ration of the term for which the member’s pred-
7 ecessor was appointed, shall be appointed for
8 the remainder of such term; and

9 “(B) a member may serve until the mem-
10 ber’s successor has taken office.

11 “(2) VACANCIES.—If a vacancy on the Panel
12 occurs, the President shall make an appointment to
13 fill the vacancy not later than 90 days after the date
14 on which the vacancy occurred.

15 “(3) REAPPOINTMENTS.—A member of the
16 Panel may be reappointed but may not serve more
17 than 2 consecutive terms.

18 “(d) DATE OF APPOINTMENT.—The initial members
19 of the Panel shall be appointed not later than 120 days
20 after the date of enactment of this section.

21 “(e) CHAIRPERSON AND VICE CHAIRPERSON.—The
22 President shall designate one of the members of the Panel
23 to serve as the chairperson of the Panel and one member
24 to serve as the vice chairperson of the Panel, each to serve
25 for a term of 1 year.

1 “(f) MEETINGS.—The Panel shall meet at the call of
2 the chairperson, but in no event less than 4 times each
3 year. A transcript shall be kept of the proceedings of each
4 such meeting of the Panel, and the chairperson shall make
5 such transcripts available to the public. Not later than 30
6 days after the date on which all members of the Panel
7 have been appointed, the Panel shall hold its first meeting.

8 “(g) DUTIES.—The Panel shall evaluate the status
9 of the clinical research environment throughout the United
10 States, and prepare and submit periodic progress reports
11 to the President. The Panel shall submit to the President,
12 the Secretary of Health and Human Services, the Sec-
13 retary of Defense, the Secretary of Veterans Affairs, and
14 the Congress an annual evaluation of the clinical research
15 environment in the United States and recommendations
16 for improvements and shall submit such other reports as
17 the President shall direct.

18 “(h) PERSONNEL MATTERS.—

19 “(1) COMPENSATION.—Each member of the
20 Panel shall be compensated at a rate equal to the
21 daily equivalent of the annual rate of basic pay pre-
22 scribed for level IV of the Executive Schedule under
23 section 5315 of title 5, United States Code, for each
24 day (including travel time) during which such mem-

1 ber is engaged in the performance of the duties of
2 the Panel.

3 “(2) TRAVEL EXPENSES.—The members of the
4 Panel shall be allowed travel expenses, including per
5 diem in lieu of subsistence, at rates authorized for
6 employees of agencies under subchapter I of chapter
7 57 of title 5, United States Code, while away from
8 their homes or regular places of business in the per-
9 formance of services for the Panel.

10 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
11 are authorized to be appropriated such sums as may be
12 necessary to enable the Panel to carry out this section.”.

13 **SEC. 4. ADVISORY COMMITTEE TO THE DIRECTOR ON CLIN-**
14 **ICAL RESEARCH.**

15 Part H of title IV of the Public Health Service Act
16 (42 U.S.C. 289 et seq.), as amended by section 3, is fur-
17 ther amended by adding at the end thereof the following
18 new section:

19 **“SEC. 498D. ADVISORY COMMITTEE TO THE DIRECTOR ON**
20 **CLINICAL RESEARCH.**

21 “(a) IN GENERAL.—The advisory committee estab-
22 lished by the Director of the National Institutes of Health
23 and known as the Advisory Committee to the Director on
24 Clinical Research (hereafter referred to in this section as
25 the ‘Advisory Committee’) shall report to such Director

1 and to the President’s Clinical Research Panel established
2 under section 498C and shall implement recommendations
3 as determined necessary by the Advisory Committee to
4 remedy deficiencies in clinical research within the National
5 Institutes of Health.

6 “(b) TERMINATION.—The Advisory Committee shall
7 terminate on the date that occurs 5 years after the date
8 of enactment of this Act.”.

9 **SEC. 5. STUDY SECTION REVIEW.**

10 Part B of title IV of the Public Health Service Act
11 (42 U.S.C. 284 et seq.) is amended by adding at the end
12 thereof the following new section:

13 **“SEC. 409B. STUDY SECTION REVIEW.**

14 “(a) IN GENERAL.—The President’s Clinical Re-
15 search Panel shall direct the Office of Science and Tech-
16 nology Policy to conduct a review of the compositions,
17 functions, and outcomes of study section activities at all
18 Federal agencies which conduct or fund such activities as
19 such activities relate to clinical research proposals for in-
20 vestigator-initiated support.

21 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
22 are authorized to be appropriated such sums as may be
23 necessary to carry out this section.”.

1 **SEC. 6. INCREASE THE INVOLVEMENT OF THE NATIONAL**
2 **INSTITUTES OF HEALTH IN CLINICAL**
3 **RESEARCH.**

4 Section 402 of the Public Health Service Act (42
5 U.S.C. 282) is amended by adding at the end thereof the
6 following new subsection:

7 “(1)(1) The Director of NIH shall undertake activi-
8 ties to support and expand the involvement of the National
9 Institutes of Health in clinical research.

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

12 “(A) increase the number of FIRST grants
13 (R29) for young clinical investigators;

14 “(B) design test pilot projects and implement
15 the recommendations of the Division of Research
16 Grants Clinical Research Study Group; and

17 “(C) establish an intramural clinical research
18 fellowship program (similar to the program estab-
19 lished under section 738(b)) and a continuing edu-
20 cation clinical research training program at NIH.

21 “(3) The Director of NIH, in cooperation with the
22 Director of the National Institutes of Health and the Di-
23 rectors of the Institutes, Centers, and Divisions of the Na-
24 tional Institutes of Health, shall support and expand the
25 resources available for the diverse needs of the clinical re-

1 search community, including inpatient, outpatient, and
2 critical care clinical research.

3 “(4) The Director of NIH, in cooperation with the
4 Director of the National Center for Research Resources,
5 shall establish peer review mechanisms to evaluate applica-
6 tions for intramural clinical research fellowships, clinical
7 research career enhancement awards, and innovative med-
8 ical science award programs. Such review mechanisms
9 shall include individuals who are exceptionally qualified to
10 appraise the merits of potential clinical research train-
11 ees.”.

12 **SEC. 7. GENERAL CLINICAL RESEARCH CENTERS.**

13 Part B of title IV of the Public Health Service Act
14 (42 U.S.C. 284 et seq.) as amended by section 5, is fur-
15 ther amended by adding at the end thereof the following
16 new sections:

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

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

1 “(b) ACTIVITIES.—In carrying out subsection (b), the
2 Director of NIH shall expand the activities of the general
3 clinical research centers through the increased use of tele-
4 communications and telemedicine initiatives.

5 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated to make grants under
7 subsection (a), \$200,000,000 for fiscal year 1997, and
8 such sums as may be necessary for each subsequent fiscal
9 year.

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

11 “(a) CLINICAL RESEARCH CAREER ENHANCEMENT
12 AWARD.—

13 “(1) IN GENERAL.—The Director of the Na-
14 tional Center for Research Resources shall make
15 grants (to be referred to as ‘clinical research career
16 enhancement awards’) to support individual careers
17 in clinical research.

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

22 “(3) LIMITATIONS.—The amount of a grant
23 under this subsection shall not exceed \$130,000 per
24 year per grant. Grants shall be for terms of 5 years.
25 The Director shall award not more than 20 grants

1 in the first fiscal year, and not more than 40 grants
2 in the second fiscal year, in which grants are award-
3 ed under this subsection.

4 “(4) AUTHORIZATION OF APPROPRIATIONS.—
5 There are authorized to be appropriated to make
6 grants under paragraph (1), \$300,000,000 for fiscal
7 year 1997, and such sums as may be necessary for
8 each subsequent fiscal year.

9 “(b) INNOVATIVE MEDICAL SCIENCE AWARD.—

10 “(1) IN GENERAL.—The Director of the Na-
11 tional Center for Research Resources shall make
12 grants (to be referred to as ‘innovative medical
13 science awards’) to support individual clinical re-
14 search projects.

15 “(2) APPLICATIONS.—An application for a
16 grant under this subsection shall be submitted by an
17 individual scientist at such time as the Director re-
18 quires.

19 “(3) LIMITATIONS.—The amount of a grant
20 under this subsection shall not exceed \$100,000 per
21 year per grant.

22 “(4) AUTHORIZATION OF APPROPRIATIONS.—
23 There are authorized to be appropriated to make
24 grants under paragraph (1), \$30,000,000 for fiscal

1 year 1997, and such sums as may be necessary for
2 each subsequent fiscal year.”.

3 **SEC. 8. CLINICAL RESEARCH ASSISTANCE.**

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

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

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

13 (2) in subsection (a)(1), by striking “who are
14 from disadvantaged backgrounds”;

15 (3) in subsection (b)—

16 (A) by striking “Amounts” and inserting
17 the following:

18 “(1) IN GENERAL.—Amounts”; and

19 (B) by adding at the end thereof the fol-
20 lowing new paragraph:

21 “(2) DISADVANTAGED BACKGROUNDS SET-
22 ASIDE.—In carrying out this section, the Secretary
23 shall ensure that not less than 50 percent of the
24 amounts appropriated for a fiscal year are used for
25 contracts involving those appropriately qualified

1 health professionals who are from disadvantaged
2 backgrounds.”; and

3 (4) by adding at the end thereof the following
4 new subsections:

5 “(c) DEFINITION.—As used in subsection (a)(1), the
6 term ‘clinical research training position’ means an individ-
7 ual serving in a general clinical research center, or a physi-
8 cian receiving a clinical research career enhancement
9 award or NIH intramural research fellowship.

10 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
11 are authorized to be appropriated to carry out this section
12 such sums as may be necessary for each fiscal year.”.

13 **SEC. 9. INSURANCE COVERAGE OF INVESTIGATIONAL**
14 **TREATMENTS.**

15 (a) PARTICIPATION.—A health plan shall allow indi-
16 viduals, when medically appropriate, to participate in an
17 investigational therapy, and shall cover the patient care
18 provided pursuant to investigational treatments as de-
19 scribed in subsection (b). The plan shall permit an individ-
20 ual to participate in an investigational treatment, subject
21 to the limitations and cost sharing requirements applicable
22 to the item or service, when the item or service is provided
23 to an individual in the course of an investigational treat-
24 ment, if—

1 (1) the treatment is a qualifying investigational
2 treatment; and

3 (2) the item or service is required to provide
4 patient care pursuant to the design of an approved
5 clinical research trial, except those services normally
6 paid for by other funding sources such as the cost
7 of the investigational agent or device itself, and the
8 costs of managing the research.

9 A plan may not discriminate against or refuse plan partici-
10 pation by an individual participating in an investigational
11 treatment.

12 (b) DEFINITIONS.—For purposes of subsection (a):

13 (1) QUALIFYING INVESTIGATIONAL TREAT-
14 MENT.—The term “qualifying investigational treat-
15 ment” means a treatment—

16 (A) the effectiveness of which has not been
17 determined; and

18 (B) that is under clinical investigation as
19 part of an approved research trial.

20 (2) APPROVED RESEARCH TRIAL.—The term
21 “approved research trial” means—

22 (A) a research trial approved by the Sec-
23 retary of Health and Human Services, the Di-
24 rector of the National Institutes of Health, the
25 Commissioner of the Food and Drug Adminis-

1 tration, the Secretary of Veterans Affairs, the
2 Secretary of Defense, or a qualified nongovern-
3 mental research entity as defined in guidelines
4 of the National Institutes of Health; or

5 (B) a peer-reviewed and approved research
6 program, as defined by the Secretary of Health
7 and Human Services, conducted for the primary
8 purpose of determining whether or not a treat-
9 ment is safe, efficacious, or having any other
10 characteristic of a treatment which must be
11 demonstrated in order for the treatment to be
12 medically necessary or appropriate.

13 **SEC. 10. DEFINITION.**

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

16 (1) by striking “For purposes” and inserting
17 “(a) HEALTH SERVICE RESEARCH.—For purposes”;
18 and

19 (2) by adding at the end thereof the following
20 new subsection:

21 “(b) CLINICAL RESEARCH.—As used in this title, the
22 term ‘clinical research’ means patient oriented clinical re-
23 search conducted with human subjects, or research on the
24 causes and consequences of disease in human populations,
25 or on material of human origin (such as tissue specimens

1 and cognitive phenomena) for which an investigator or col-
2 league directly interacts with human subjects in an out-
3 patient or inpatient setting to clarify a problem in human
4 physiology, pathophysiology, or disease.”.

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