

105TH CONGRESS
1ST SESSION

S. 1421

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

NOVEMBER 7, 1997

Mr. KENNEDY (for himself, Mr. COCHRAN, Mr. DURBIN, Mr. FAIRCLOTH, and
Ms. MIKULSKI) 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 1997”.

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

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

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

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

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

24 (6) The Director of the National Institutes of
25 Health has recognized the current problems in clini-

1 cal research and has through the use of an advisory
2 committee begun to evaluate these problems.

3 (7) The current level of training and support
4 for health professionals in clinical research is frag-
5 mented, frequently undervalued, and potentially un-
6 derfunded.

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

13 (A) The number of young investigators ap-
14 plying for grants dropped by 54 percent be-
15 tween 1985 and 1993.

16 (B) The number of federally funded re-
17 search (R01) grants awarded to persons under
18 the age of 36 have decreased by 70 percent
19 from 1985 to 1993.

20 (C) Newly independent life-scientists are
21 expected to raise funds to support their new re-
22 search programs and a substantial proportion
23 of their own salaries.

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

4 (A) A medical school graduate incurs an
5 average debt of \$80,000, as reported in the
6 Medical School Graduation Questionnaire by
7 the American Association of Medical Colleges
8 (AAMC).

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

12 (C) The decreasing number of mentors and
13 role models.

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

17 (E) The almost complete absence of clini-
18 cal research training in the curriculum of train-
19 ing grant awardees.

20 (F) Academic Medical Centers are experi-
21 encing difficulties in maintaining a proper envi-
22 ronment for research in a highly competitive
23 health care marketplace, which are compounded
24 by the decreased willingness of third party pay-
25 ers to cover health care costs for patients en-

1 gaged in research studies and research proce-
2 dures.

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

7 (11) Appropriations for general clinical research
8 centers in fiscal year 1997 equaled \$153,000,000.

9 (12) In fiscal year 1997, there were 74 general
10 clinical research centers in operation, supplying pa-
11 tients in the areas in which such centers operate
12 with access to the most modern clinical research and
13 clinical research facilities and technologies.

14 (13) The average annual amount allocated for
15 each general clinical research center is \$1,900,000,
16 establishing a current funding level of 75 percent of
17 the amounts approved by the Advisory Council of
18 the National Center for Research Resources.

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

1 **SEC. 3. INCREASING 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 the follow-
6 ing:

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) design test pilot projects and implement
13 the recommendations of the Division of Research
14 Grants Clinical Research Study Group and other
15 recommendations for enhancing clinical research,
16 where applicable; and

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

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

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

3 “(A) clinical research career enhancement
4 awards;

5 “(B) innovative medical science awards;

6 “(C) graduate training in clinical investigation
7 awards;

8 “(D) intramural clinical research fellowships.

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

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

13 Part B of title IV of the Public Health Service Act
14 (42 U.S.C. 284 et seq.) is further amended by adding at
15 the end the following:

16 **“SEC. 409B. 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 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 carry out this section,
7 such sums as may be necessary.

8 **“SEC. 409C. ENHANCEMENT AWARDS.**

9 “(a) CLINICAL RESEARCH CAREER ENHANCEMENT
10 AWARD.—

11 “(1) IN GENERAL.—The Director of the Na-
12 tional Center for Research Resources shall make
13 grants (to be referred to as ‘clinical research career
14 enhancement awards’) to support individual careers
15 in clinical research at general clinical research cen-
16 ters or at other institutions that have the infrastruc-
17 ture and resources deemed appropriate for conduct-
18 ing patient-oriented clinical research. The Director
19 of the National Center for Research Resources shall,
20 where practicable, collaborate or consult with other
21 Institute Directors in making awards under this
22 subsection.

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.—The amount of a grant
 4 under this subsection shall not exceed \$125,000 per
 5 year per grant. Grants shall be for terms of 5 years.
 6 The Director shall award not more than 20 grants
 7 in the first fiscal year, and not more than 40 grants
 8 in the second fiscal year, in which grants are award-
 9 ed under this subsection.

10 “(4) AUTHORIZATION OF APPROPRIATIONS.—
 11 There is authorized to be appropriated to make
 12 grants under paragraph (1), \$3,000,000 for fiscal
 13 year 1998, and such sums as may be necessary for
 14 each subsequent fiscal year.

15 “(b) INNOVATIVE MEDICAL SCIENCE AWARD.—

16 “(1) IN GENERAL.—The Director of the Na-
 17 tional Center for Research Resources shall make
 18 grants (to be referred to as ‘innovative medical
 19 science awards’) to support individual clinical re-
 20 search projects at general clinical research centers or
 21 at other institutions that have the infrastructure and
 22 resources deemed appropriate for conducting pa-
 23 tient-oriented clinical research. The Director of the
 24 National Center for Research Resources shall, where
 25 practicable, collaborate or consult with other Insti-

1 tute Directors in making awards under this sub-
2 section.

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

7 “(3) LIMITATIONS.—The amount of a grant
8 under this subsection shall not exceed \$175,000 per
9 year per grant.

10 “(4) AUTHORIZATION OF APPROPRIATIONS.—
11 There is authorized to be appropriated to make
12 grants under this subsection, \$52,500,000 for fiscal
13 year 1998, and such sums as may be necessary for
14 each subsequent fiscal year.

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

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

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.—The amount of a grant
4 under this subsection shall not exceed \$75,000 per
5 year per grant. Grants shall be for terms of 2 years
6 or more and will provide stipend, tuition, and insti-
7 tutional support for individual advanced degree pro-
8 grams in clinical investigation.

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

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 There is authorized to be appropriated to make
25 grants under this subsection, \$3,000,000 for fiscal

1 year 1998, and such sums as may be necessary for
 2 each subsequent fiscal year.”.

3 **SEC. 5. 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)—

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

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

19 (3) in subsection (a), by striking paragraph (3)
 20 and inserting the following:

21 “(3) APPLICABILITY OF CERTAIN PROVISIONS
 22 REGARDING OBLIGATED SERVICE.—With respect to
 23 the National Health Service Corps Loan Repayment
 24 Program established under subpart III of part D of
 25 title III, the provisions of such subpart shall, except

1 as inconsistent with this section, apply to the pro-
 2 gram established in this section in the same manner
 3 and to the same extent as such provisions apply to
 4 such loan repayment program.”;

5 (4) in subsection (b)—

6 (A) by striking “Amounts” and inserting
 7 the following:

8 “(1) IN GENERAL.—Amounts”; and

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

10 “(2) DISADVANTAGED BACKGROUNDS SET-
 11 ASIDE.—In carrying out this section, the Secretary
 12 shall ensure that not less than 50 percent of the
 13 contracts involve those appropriately qualified health
 14 professionals who are from disadvantaged back-
 15 grounds.”; and

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

17 “(c) DEFINITION.—As used in subsection (a)(1), the
 18 term ‘clinical research training position’ means an individ-
 19 ual serving in a general clinical research center or in clini-
 20 cal research at the National Institutes of Health, or a phy-
 21 sician receiving a clinical research career enhancement
 22 award, an innovative medical science award, or a graduate
 23 training in clinical investigation award.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
 2 is authorized to be appropriated to carry out this section
 3 such sums as may be necessary for each fiscal year.”.

4 **SEC. 6. DEFINITION.**

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

7 (1) by striking “For purposes” and inserting
 8 “(a) HEALTH SERVICE RESEARCH.—For purposes”;
 9 and

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

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

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