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104TH CONGRESS
2D SESSION

# H. R. 3904

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

JULY 25, 1996

Mrs. LOWEY (for herself, Mrs. JOHNSON of Connecticut, Mr. DURBIN, Mr. HOYER, Mrs. MORELLA, Mr. LEACH, Ms. PELOSI, Mr. NADLER, and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Commerce

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# A BILL

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

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Clinical Research Enhancement Act of 1996''.

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

(a) FINDINGS.—Congress finds the following:

(1) Clinical research is critical to the advancement of scientific knowledge and to the development of cures and improved treatment for disease.

(2) Tremendous advances in biology are opening doors to new insights into human physiology, pathophysiology and disease, creating extraordinary opportunities for clinical research.

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

(4) Studies at the Institute of Medicine, the National Research Council, and the National Academy of Sciences have all addressed the current problems in clinical research.

(5) The Director of the National Institutes of Health has recognized the current problems in clinical research and has through the use of an advisory committee begun to evaluate these problems.

(6) The current level of training and support for health professionals in clinical research is fragmented, frequently undervalued, and potentially underfunded.

(7) Young investigators are not only apprentices for future positions but a crucial source of en-

ergy, enthusiasm, and ideas in the day-to-day research that constitutes the scientific enterprise. Serious questions about the future of life-science research are raised by the following:

(A) The number of young investigators applying for grants dropped by 54 percent between 1985 and 1993.

(B) The number of federally funded research (R01) grants awarded to persons under the age of 36 have decreased by 70 percent from 1985 to 1993.

(C) Newly independent life-scientists are expected to raise funds to support their new research programs and a substantial proportion of their own salaries.

(8) The following have been cited as reasons for the decline in the number of active clinical researchers, and those choosing this career path:

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

(B) The prolonged period of clinical training required increases the accumulated debt burden.

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

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

(E) The almost complete absence of clinical research training in the curriculum of training grant awardees.

(F) Academic Medical Centers are experiencing difficulties in maintaining a proper environment for research in a highly competitive health care marketplace, which are compounded by the decreased willingness of third party payers to cover health care costs for patients engaged in research studies and research procedures.

(9) In 1960, general clinical research centers were established under the Office of the Director of the National Institutes of Health with an initial appropriation of $3,000,000.

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

(11) In fiscal year 1995, there are 75 general clinical research centers in operation, supplying patients in the areas in which such centers operate with access to the most modern clinical research and clinical research facilities and technologies.

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

(b) PURPOSE.—It is the purpose of this Act to provide additional support for and to expand clinical research programs.

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

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

**"SEC. 498C. PRESIDENT'S CLINICAL RESEARCH PANEL.**

''(a) ESTABLISHMENT.—The President shall establish a panel to be known as the 'President's Clinical Research Panel' (hereafter referred to in this section as the 'Panel') as a part of the Office of Science and Technology Policy, to carry out the duties described in this section.

''(b) MEMBERSHIP.—

''(1) IN GENERAL.—The Panel shall be composed of 12 individuals appointed by the President and selected from recommendations submitted by the President of the Institute of Medicine of the National Academy of Sciences.

''(2) QUALIFICATIONS.—Individuals appointed to the panel under paragraph (1) shall, by virtue of their training, experience and background, be exceptionally qualified to appraise the status of clinical research both within and outside of the Federal Government, and should represent distinguished research scientists and physicians, insurance companies, pharmaceutical companies, health maintenance organizations, accreditation and certification organizations and academic research administrators, and patients.

''(3) EXCLUSION AND ADVISORS.—Officers or employees of the Federal Government shall not be eligible to be appointed to the Panel. The Secretary of Health and Human Services, the Secretary of Defense, the Secretary of Veterans Affairs, the Assistant to the President for Science and Technology, and other Cabinet officers as the President determines to be appropriate may serve as advisors to the Panel.

''(c) TERMS AND VACANCIES.—

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

''(A) any member appointed to fill a vacancy occurring on the Panel prior to the expiration of the term for which the member's predecessor was appointed, shall be appointed for the remainder of such term; and

''(B) a member may serve until the member's successor has taken office.

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

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

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

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

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

''(g) DUTIES.—The Panel shall evaluate the status of the clinical research environment throughout the United States, and prepare and submit periodic progress reports to the President. The Panel shall submit to the President, the Secretary of Health and Human Services, the Secretary of Defense, the Secretary of Veterans Affairs, and the Congress an annual evaluation of the clinical research environment in the United States and recommendations for improvements and shall submit such other reports as the President shall direct.

''(h) PERSONNEL MATTERS.—

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

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

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

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

**SEC. 4. ADVISORY COMMITTEE TO THE DIRECTOR ON CLINICAL RESEARCH.**

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

**''SEC. 498D. ADVISORY COMMITTEE TO THE DIRECTOR ON CLINICAL RESEARCH.**

''(a) IN GENERAL.—The advisory committee established by the Director of the National Institutes of Health and known as the Advisory Committee to the Director on Clinical Research (hereafter referred to in this section as the 'Advisory Committee') shall report to such Director

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

''(b) TERMINATION.—The Advisory Committee shall terminate on the date that occurs 5 years after the date of enactment of this Act.''.

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

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

**''SEC. 409B. STUDY SECTION REVIEW.**

''(a) IN GENERAL.—The President's Clinical Research Panel shall direct the Office of Science and Technology Policy to conduct a review of the compositions, functions, and outcomes of study section activities at all Federal agencies which conduct or fund such activities as such activities relate to clinical research proposals for investigator-initiated support.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.''.

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

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

''(l)(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) increase the number of FIRST grants (R29) for young clinical investigators;

''(B) design test pilot projects and implement the recommendations of the Division of Research Grants Clinical Research Study Group; and

''(C) establish an intramural clinical research fellowship program (similar to the program established under section 738(b)) and a continuing education clinical research training program at NIH.

''(3) The Director of NIH, in cooperation with the Director of the National Institutes of Health and 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 re-

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

''(4) The Director of NIH, in cooperation with the Director of the National Center for Research Resources, shall establish peer review mechanisms to evaluate applications for intramural clinical research fellowships, clinical research career enhancement awards, and innovative medical science award programs. Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research trainees.''.

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

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

**''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 (b), 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.—There are authorized to be appropriated to make grants under subsection (a), $200,000,000 for fiscal year 1997, and such sums as may be necessary for each subsequent fiscal year.

**''SEC. 409D. ENHANCEMENT AWARDS.**

''(a) CLINICAL RESEARCH CAREER ENHANCEMENT AWARD.—

''(1) IN GENERAL.—The Director of the National Center for Research Resources shall make grants (to be referred to as 'clinical research career enhancement awards') to support individual careers in clinical research.

''(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.—The amount of a grant under this subsection shall not exceed $130,000 per year per grant. Grants shall be for terms of 5 years. The Director shall award not more than 20 grants

in the first fiscal year, and not more than 40 grants in the second fiscal year, in which grants are awarded under this subsection.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to make grants under paragraph (1), $3,000,000 for fiscal year 1997, and such sums as may be necessary for each subsequent fiscal year.

''(b) INNOVATIVE MEDICAL SCIENCE AWARD.—

''(1) IN GENERAL.—The Director of the National Center for Research Resources shall make grants (to be referred to as 'innovative medical science awards') to support individual clinical research projects.

''(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) LIMITATIONS.—The amount of a grant under this subsection shall not exceed $100,000 per year per grant.

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

year 1997, and such sums as may be necessary for each subsequent fiscal year.''.

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

(a) NATIONAL RESEARCH SERVICE AWARDS.—Section 487(a)(1)(C) of the Public Health Service Act (42 U.S.C. 288(a)(1)(C)) is amended by striking ''50 such'' and inserting ''100 such''.

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

(1) in the section heading, by striking ''FROM DISADVANTAGED BACKGROUNDS'';

(2) in subsection (a)(1), by striking ''who are from disadvantaged backgrounds'';

(3) in subsection (b)—

(A) by striking ''Amounts'' and inserting the following:

''(1) IN GENERAL.—Amounts''; and

(B) by adding at the end thereof the following new paragraph:

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

health professionals who are from disadvantaged backgrounds.''; and

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

''(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 a physician receiving a clinical research career enhancement award or NIH intramural research fellowship.

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

**SEC. 9. DEFINITION.**

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

(1) by striking ''For purposes'' and inserting ''(a) HEALTH SERVICE RESEARCH.—For purposes''; and

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

''(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, or on 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.''.

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