I

106TH CONGRESS
2D SESSION

S. 1813

IN THE HOUSE OF REPRESENTATIVES

JANUARY 27, 2000
Referred to the Committee on Commerce

AN ACT

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 1999''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress makes the following findings:

(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) Clinical research includes translational research which is an integral part of the research process leading to general human applications. It is the bridge between the laboratory and new methods of diagnosis, treatment, and prevention and is thus essential to progress against cancer and other diseases.

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

(5) 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.

(6) The Director of the National Institutes of Health has recognized the current problems in clinical research and appointed a special panel, which recommended expanded support for existing National Institutes of Health clinical research programs and the creation of new initiatives to recruit and retain clinical investigators.

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

(8) Young investigators are not only apprentices for future positions but a crucial source of energy, 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 physicians applying for first-time National Institutes of Health research project grants fell from 1226 in 1994 to 963 in 1998, a 21 percent reduction.

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

search programs and a substantial proportion of their own salaries.

(9) 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 $85,619, as reported in the Medical School Graduation Questionnaire by the Association of American 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.

(10) 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.

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

(12) Since the late 1960s, spending for general clinical research centers has declined from approximately 3 percent to 1 percent of the National Institutes of Health budget.

(13) In fiscal year 1999, there were 77 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.

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

SEC. 3. INCREASING THE INVOLVEMENT OF THE NATIONAL INSTITUTES OF HEALTH IN CLINICAL RESEARCH.

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 the following:

"SEC. 409C. CLINICAL RESEARCH.

''(a) IN GENERAL.—The Director of National Institutes of Health shall undertake activities to support and expand the involvement of the National Institutes of Health in clinical research.

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

''(1) consider the recommendations of the Division of Research Grants Clinical Research Study Group and other recommendations for enhancing clinical research; and

''(2) establish intramural and extramural clinical research fellowship programs directed specifically at medical and dental students and a continuing education clinical research training program at the National Institutes of Health.

''(c) SUPPORT FOR THE DIVERSE NEEDS OF CLINICAL RESEARCH.—The Director of National Institutes of Health, in cooperation with 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 research community, including inpatient, outpatient, and critical care clinical research.

''(d) PEER REVIEW.—The Director of National Institutes of Health shall establish peer review mechanisms to evaluate applications for the awards and fellowships provided for in subsection (b)(2) and section 409D. Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research training and research grant proposals.''.

SEC. 4. GENERAL CLINICAL RESEARCH CENTERS.

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

''SEC. 481C. 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 (a), the Director of National Institutes of Health shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.

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

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

''SEC. 409D. ENHANCEMENT AWARDS.

''(a) MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARDS.—

''(1) GRANTS.—

''(A) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as 'Mentored Patient-Oriented Research Career Development Awards') to support individual careers in clinical research at general clinical research centers or at other institutions that have the infrastructure and re-

sources deemed appropriate for conducting patient-oriented clinical research.

''(B) USE.—Grants under subparagraph (A) shall be used to support clinical investigators in the early phases of their independent careers by providing salary and such other support for a period of supervised study.

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

''(b) MID-CAREER INVESTIGATOR AWARDS IN PATIENT-ORIENTED RESEARCH.—

''(1) GRANTS.—

''(A) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as 'Mid-Career Investigator Awards in Patient-Oriented Research') to support individual clinical research projects at general clinical research centers or at other institutions that have the infrastructure and resources

deemed appropriate for conducting patient-oriented clinical research.

''(B) USE.—Grants under subparagraph (A) shall be used to provide support for mid-career level clinicians to allow such clinicians to devote time to clinical research and to act as mentors for beginning clinical investigators.

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

''(c) GRADUATE TRAINING IN CLINICAL INVESTIGATION AWARD.—

''(1) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as 'Graduate Training in Clinical Investigation Awards') to support individuals pursuing master's or doctoral degrees in clinical investigation.

''(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.—Grants under this subsection shall be for terms of 2 years or more and shall provide stipend, tuition, and institutional support for individual advanced degree programs in clinical investigation.

''(4) DEFINITION.—As used in this subsection, the term 'advanced degree programs in clinical investigation' means programs that award a master's or Ph.D. degree in clinical investigation after 2 or more years of training in areas such as the following:

''(A) Analytical methods, biostatistics, and study design.

''(B) Principles of clinical pharmacology and pharmacokinetics.

''(C) Clinical epidemiology.

''(D) Computer data management and medical informatics.

''(E) Ethical and regulatory issues.

''(F) Biomedical writing.

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

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

''(d) CLINICAL RESEARCH CURRICULUM AWARDS.—

''(1) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as 'Clinical Research Curriculum Awards') to institutions for the development and support of programs of core curricula for training clinical investigators, including medical students. Such core curricula may include training in areas such as the following:

''(A) Analytical methods, biostatistics, and study design.

''(B) Principles of clinical pharmacology and pharmacokinetics.

''(C) Clinical epidemiology.

''(D) Computer data management and medical informatics.

''(E) Ethical and regulatory issues.

''(F) Biomedical writing.

''(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual institution or a consortium of institutions at such time as the Director may require. An institution may submit only 1 such application.

''(3) LIMITATIONS.—Grants under this subsection shall be for terms of up to 5 years and may be renewable.

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

SEC. 5. LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS.

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

''SEC. 487F. LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, shall establish a program to enter into contracts with qualified health professionals under which such health professionals agree to conduct clinical research, in consideration of the Federal Government agreeing to repay, for each year of service conducting such research, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

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

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

''(c) FUNDING.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

''(2) AVAILABILITY.—Amounts appropriated for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.''.

SEC. 6. 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 the following:

''(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 involving 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, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.''.

SEC. 7. OVERSIGHT BY GENERAL ACCOUNTING OFFICE.

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

Passed the Senate November 19, 1999.

Attest: GARY SISCO,

Secretary.