(3) Chair

(A) In general

With respect to autoimmune diseases, the Chair of the Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and other relevant agencies.

(B) Director of NIH

The Chair of the Committee shall be directly responsible to the Director of NIH.

(c) Plan for NIH activities

(1) In general

Not later than 1 year after October 17, 2000, the Coordinating Committee shall develop a plan for conducting and supporting research and education on autoimmune diseases through the national research institutes and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, psychosocial, and rehabilitative issues, including studies of the disproportionate impact of such diseases on women;

(B) identify priorities among the programs and activities of the National Institutes of Health regarding such diseases; and

(C) reflect input from a broad range of scientists, patients, and advocacy groups.

(2) Certain elements of plan

The plan under paragraph (1) shall, with respect to autoimmune diseases, provide for the following as appropriate:

(A) Research to determine the reasons underlying the incidence and prevalence of the diseases.

(B) Basic research concerning the etiology and causes of the diseases.

(C) Epidemiological studies to address the frequency and natural history of the diseases, including any differences among the sexes and among racial and ethnic groups.

(D) The development of improved screening techniques.

(E) Clinical research for the development and evaluation of new treatments, including new biological agents.

(F) Information and education programs for health care professionals and the public.

(3) Implementation of plan

The Director of NIH shall ensure that programs and activities of the National Institutes of Health regarding autoimmune diseases are implemented in accordance with the plan under paragraph (1).

(July 1, 1944, ch. 373, title IV, § 409E, as added Pub. L. 106–310, div. A, title XIX, § 1901, Oct. 17, 2000, 114 Stat. 1153; amended Pub. L. 109–482, title I, §§ 103(b)(11), 104(b)(1)(E), Jan. 15, 2007, 120 Stat. 3687, 3693.)

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482, § 104(b)(1)(E), struck out heading and text of subsec. (d). Text read as follows: ''The Coordinating Committee under subsection (b)(1) of this section shall biennially submit to the Committee on Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate, a report that describes the research, education, and other activities on autoimmune diseases being conducted or supported through the national research institutes, and that in addition includes the following:

''(1) The plan under subsection (c)(1) of this section (or revisions to the plan, as the case may be).

''(2) Provisions specifying the amounts expended by the National Institutes of Health with respect to each of the autoimmune diseases included in the plan.

''(3) Provisions identifying particular projects or types of projects that should in the future be considered by the national research institutes or other entities in the field of research on autoimmune diseases.''

Subsec. (e). Pub. L. 109–482, § 103(b)(11), struck out heading and text of subsec. (e). Text read as follows: ''For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to autoimmune diseases.''

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§ 284j. Muscular dystrophy research

(a) Coordination of activities

The Director of NIH shall expand and increase coordination in the activities of the National Institutes of Health with respect to research on muscular dystrophies, including Duchenne muscular dystrophy.

(b) Administration of program; collaboration among agencies

The Director of NIH shall carry out this section through the appropriate institutes, including the National Institute of Neurological Disorders and Stroke and in collaboration with any other agencies that the Director determines appropriate.

(July 1, 1944, ch. 373, title IV, § 409F, as added Pub. L. 106–310, div. A, title XXII, § 2201, Oct. 17, 2000, 114 Stat. 1157; amended Pub. L. 109–482, title I, § 103(b)(12), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (c). Pub. L. 109–482 struck out heading and text of subsec. (c). Text read as follows: ''There are authorized to be appropriated such sums as may be necessary to carry out this section for each of the fiscal years 2001 through 2005. Amounts appropriated under this subsection shall be in addition to any other amounts appropriated for such purpose.''

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§ 284k. 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 284*l* of this title. Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research training and research grant proposals.

(July 1, 1944, ch. 373, title IV, § 409G, formerly § 409C, as added Pub. L. 106–505, title II, § 203, Nov. 13, 2000, 114 Stat. 2326; renumbered § 409G, Pub. L. 107–109, § 3(1), Jan. 4, 2002, 115 Stat. 1408.)

REFERENCES IN TEXT

Section 284*l* of this title, referred to in subsec. (d), was in the original ''section 409D'', and was translated as meaning section 409D of act July 1, 1944, ch. 373, as added by section 204(b) of Pub. L. 106–505. Such section 409D was renumbered section 409H of act July 1, 1944, ch. 373, by Pub. L. 107–109, § 3(2), Jan. 4, 2002, 115 Stat. 1408. Another section 409D of act July 1, 1944, ch. 373, as added by section 1001 of Pub. L. 106–310, is classified to section 284h of this title.

FINDINGS AND PURPOSE

Pub. L. 106–505, title II, § 202, Nov. 13, 2000, 114 Stat. 2325, provided that:

''(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 research 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 title [see Short Title of 2000 Amendments note set out under section 201 of this title] to provide additional support for and to expand clinical research programs.''

OVERSIGHT BY GAO

Pub. L. 106–505, title II, § 207, Nov. 13, 2000, 114 Stat. 2330, provided that, not later than 18 months after Nov. 13, 2000, the Comptroller General was to submit to Congress a report describing the extent to which the Na-

tional Institutes of Health had complied with the amendments made by title II of Pub. L. 106–505.

§ 284*l*. 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 resources 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.

(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.

(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.

(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 one such application.

(3) Limitations

Grants under this subsection shall be for terms of up to 5 years and may be renewable.

(July 1, 1944, ch. 373, title IV, § 409H, formerly § 409D, as added Pub. L. 106–505, title II, § 204(b), Nov. 13, 2000, 114 Stat. 2327; renumbered § 409H, Pub. L. 107–109, § 3(2), Jan. 4, 2002, 115 Stat. 1408; Pub. L. 109–482, title I, § 103(b)(13), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (a)(3). Pub. L. 109–482, § 103(b)(13)(A), struck out heading and text of par. (3). Text read as follows: ''For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.''

Subsec. (b)(3). Pub. L. 109–482, § 103(b)(13)(B), struck out heading and text of par. (3). Text read as follows: ''For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.''