subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§ 283j. Review of centers of excellence

(a) In general

Not later than April 1, 2008, and periodically thereafter, the Secretary, acting through the Director of NIH, shall conduct a review and submit a report to the appropriate committees of the Congress on the centers of excellence.

(b) Report contents

Each report under subsection (a) shall include the following:

(1) Evaluation of the performance and research outcomes of each center of excellence.

(2) Recommendations for promoting coordination of information among centers of excellence.

(3) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

(c) Definition

In this section, the term ''center of excellence'' means an entity receiving funding under this subchapter in its capacity as a center of excellence.

(July 1, 1944, ch. 373, title IV, § 404H, as added Pub. L. 109–416, § 2(b), Dec. 19, 2006, 120 Stat. 2821.)

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

§ 284. Directors of national research institutes

(a) Appointment

The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.

(b) Duties and authority; grants, contracts, and cooperative agreements

(1) In carrying out the purposes of section 241 of this title with respect to human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 289a(b) of this title and any advisory council review under section 284a(a)(3)(A)(i) of this title, conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) may conduct and support research training (i) for which fellowship support is not provided under section 288 of this title, and (ii) which is not residency training of physicians or other health professionals;

(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(E) may develop, conduct, and support public and professional education and information programs;

(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of $50,000, establish suitable memorials to the donor;

(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(K) may accept voluntary and uncompensated services; and

(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354 of title 10 shall apply with respect to contracts entered into under this subsection and section 282(b) of this title.

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 289a of this title;

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds $50,000, such grant or cooperative agreement

may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title and is recommended under section 284a(a)(3)(A)(ii) of this title by the advisory council for the national research institute involved; and

(C) shall, subject to section 300cc–40b(d)(2) of this title, receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

(c) Coordination with other public and private entities; cooperation with other national research institutes; appointment of additional peer review groups

In carrying out subsection (b) of this section, each Director of a national research institute—

(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute;

(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(A) establish technical and scientific peer review groups in addition to those appointed under section 282(b)(16) of this title; and

(B) appoint the members of peer review groups established under subparagraph (A); and

(4) may publish, or arrange for the publication of, information with respect to the purpose of the Institute without regard to section 501 of title 44.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (3).

(July 1, 1944, ch. 373, title IV, § 405, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 826; amended Pub. L. 100–607, title I, § 116, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 100–690, title II, § 2613(c), Nov. 18, 1988, 102 Stat. 4239; Pub. L. 103–43, title III, § 301(a)(1), (b), June 10, 1993, 107 Stat. 150; Pub. L. 109–482, title I, § 102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (c), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

2007—Subsec. (c)(3)(A). Pub. L. 109–482 substituted ''section 282(b)(16)'' for ''section 282(b)(6)''.

1993—Subsec. (b)(2)(C). Pub. L. 103–43, § 301(a)(1), added subpar. (C).

Subsec. (c). Pub. L. 103–43, § 301(b)(2), inserted concluding provisions relating to Federal Advisory Committee Act.

Subsec. (c)(3). Pub. L. 103–43, § 301(b)(1), amended par. (3) generally. Prior to amendment, par. (3) read as follows: ''may, in consultation with the advisory council for the Institute and the approval of the Director of NIH, establish and appoint technical and scientific peer review groups in addition to those established and appointed under section 282(b)(6) of this title; and''.

1988—Subsec. (b)(1). Pub. L. 100–607, § 116(1), struck out ''the'' after ''with respect to'' in introductory provisions.

Subsec. (c)(3). Pub. L. 100–690 substituted ''establish and appoint'' and ''established and appointed'' for ''establish'' and ''established'', respectively.

Pub. L. 100–607, § 116(2)(A), amended par. (3) generally. Prior to amendment, par. (3) read as follows: ''may, with the approval of the advisory council for the institute and the Director of NIH, appoint technical and scientific peer review groups in addition to those appointed under section 282(b)(6) of this title.''

Subsec. (c)(4). Pub. L. 100–607, § 116(2)(C), added par. (4).

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.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD

Pub. L. 109–482, title I, § 106, Jan. 15, 2007, 120 Stat. 3696, provided that:

''(a) IN GENERAL.—In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by—

''(1) allowing the appointment of a secondary principal investigator under a single Clinical and Translational Science Award, such that a pediatric principal investigator may be appointed with direct authority over a separate budget and infrastructure for pediatric clinical research; or

''(2) otherwise securing institutional independence of pediatric clinical research centers with respect to finances, infrastructure, resources, and research agenda.

''(b) REPORT.—As part of the biennial report under section 403 of the Public Health Service Act [section 283 of this title], the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a).

''(c) DEFINITION.—For purposes of this section, the term 'Director of NIH' has the meaning given such term in section 401 of the Public Health Service Act [section 281 of this title].''

§ 284a. Advisory councils

(a) Establishment; acceptance of conditional gifts; functions

(1) Except as provided in subsection (h) of this section, the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C of this subchapter.

(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 238 of this title, of conditional gifts for study,

investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

(3) Each advisory council for a national research institute—

(A)(i) may on the basis of the materials provided under section 289a(b)(2) of this title respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

(ii) may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 284(b)(2) of this title and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b) Membership; compensation

(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary. The ex officio members shall be nonvoting members.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Under Secretary for Health of the Department of Veterans Affairs or the Chief Dental Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

(c) Term of office; reappointment; vacancy

The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term for 180 days after the date of such expiration. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) Chairman; term of office

The chairman of an advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the national research institute for which the advisory council is established to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) Meetings

The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

(f) Appointment of executive secretary; training and orientation for new members

The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) Comments and recommendations for inclusion in biennial report; additional reports

Each advisory council may prepare, for inclusion in the biennial report made under section 284b[1] of this title, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

(h) Advisory councils in existence; application of section to National Cancer Advisory Board and advisory council to National Heart, Lung, and Blood Institute

(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on November 20, 1985. After November 20, 1985—

(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

(i) appointments to such Board shall be made by the President;

(ii) the term of office of an appointed member shall be 6 years;

(iii) of the members appointed to the Board not less than five members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

(v) the ex officio members of the Board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Under Secretary for Health of the Department of Veterans Affairs, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Science of the Department of Energy (or the designees of such officers); and

(vi) the Board shall meet at least four times each fiscal year.

(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.

(July 1, 1944, ch. 373, title IV, § 406, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 828; amended Pub. L. 100–607, title I, § 117, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 101–381, title I, § 102(1), Aug. 18, 1990, 104 Stat. 585; Pub. L. 102–405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103–43, title II, § 210(a), title XX, §§ 2008(b)(1), 2010(b)(2), June 10, 1993, 107 Stat. 149, 210, 214; Pub. L. 105–245, title III, § 309(b)(2)(C), Oct. 7, 1998, 112 Stat. 1853.)

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (g), was repealed by Pub. L. 109–482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

AMENDMENTS

1998—Subsec. (h)(2)(A)(v). Pub. L. 105–245 substituted ''Science of the Department of Energy'' for ''Energy Research of the Department of Energy''.

1993—Subsec. (a)(2). Pub. L. 103–43, § 2010(b)(2), substituted ''section 238'' for ''section 300aaa''.

Subsec. (b)(2)(A). Pub. L. 103–43, § 2008(b)(1)(A), substituted ''Department of Veterans Affairs'' for ''Veterans' Administration'' in two places.

Subsec. (c). Pub. L. 103–43, § 210(a), substituted ''for 180 days after the date of such expiration'' for ''until a successor has taken office''.

Subsec. (h)(2)(A)(v). Pub. L. 103–43, § 2008(b)(1)(B), substituted ''Department of Veterans Affairs'' for ''Veterans' Administration''.

1992—Subsecs. (b)(2)(A), (h)(2)(A)(v). Pub. L. 102–405 substituted ''Under Secretary for Health'' for ''Chief Medical Director''.

1990—Subsec. (a)(2). Pub. L. 101–381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Subsec. (b)(1). Pub. L. 100–607, § 117(a), inserted at end ''The ex officio members shall be nonvoting members.''

Subsec. (b)(3)(A). Pub. L. 100–607, § 117(b), inserted ''not less than two individuals who are leaders in the fields of'' after ''(including''.

Subsec. (h)(2)(A)(v). Pub. L. 100–607, § 117(c), inserted ''shall be nonvoting members and'' after ''Board'' and substituted ''the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy'' for ''and the Assistant Secretary of Defense for Health Affairs''.

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as

[1] See References in Text note below.

may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§ 284b. Repealed. Pub. L. 109–482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693

Section, act July 1, 1944, ch. 373, title IV, § 407, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 831, related to biennial report and its contents.

EFFECTIVE DATE OF REPEAL

Repeal 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 an Effective Date of 2007 Amendment note under section 281 of this title.

§ 284c. Certain uses of funds

(a)(1) Except as provided in paragraph (2), the sum of the amounts obligated in any fiscal year for administrative expenses of the National Institutes of Health may not exceed an amount which is 5.5 percent of the total amount appropriated for such fiscal year for the National Institutes of Health.

(2) Paragraph (1) does not apply to the National Library of Medicine, the National Center for Nursing Research, the John E. Fogarty International Center for Advanced Study in the Health Sciences, the Warren G. Magnuson Clinical Center, and the Office of Medical Applications of Research.

(3) For purposes of paragraph (1), the term ''administrative expenses'' means expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

(b) For fiscal year 1989 and subsequent fiscal years, amounts made available to the National Institutes of Health shall be available for payment of nurses and allied health professionals in accordance with payment authorities, scheduling options, benefits, and other authorities provided under chapter 73 of title 38 for nurses of the Department of Veterans Affairs.

(July 1, 1944, ch. 373, title IV, § 408, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 831; amended Pub. L. 100–607, title I, § 118, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 100–690, title II, § 2613(d), Nov. 18, 1988, 102 Stat. 4239; Pub. L. 103–43, title IV, § 403(b)(1), title XX, § 2008(b)(2), June 10, 1993, 107 Stat. 158, 211; Pub. L. 104–316, title I, § 122(a), Oct. 19, 1996, 110 Stat. 3836; Pub. L. 105–362, title VI, § 601(a)(1)(B), Nov. 10, 1998, 112 Stat. 3285.)

AMENDMENTS

1998—Subsec. (a)(4). Pub. L. 105–362 struck out par. (4) which read as follows: ''Not later than December 31, 1987, and December 31 of each succeeding year, the Secretary shall report to the Congress the amount obligated in the fiscal year preceding such date for administrative expenses of the National Institutes of Health and the total amount appropriated for the National Institutes of Health for such fiscal year. The Secretary shall consult with the Comptroller General of the United States in preparing each report.''

1996—Subsec. (a)(3). Pub. L. 104–316 struck out at end ''In identifying expenses incurred for such support and administration the Secretary shall consult with the Comptroller General of the United States.''

1993—Pub. L. 103–43 amended section catchline generally, redesignated subsec. (b) as (a) and par. (5) of subsec. (a) as (b), struck out former subsec. (a) which authorized appropriations in addition to amounts otherwise appropriated under this subchapter for the National Cancer Institute for programs other than under section 285a–1 of this title and for its program under section 285a–1 of this title and for the National Heart, Lung, and Blood Institute for programs other than under section 285b–1 of this title and for its program under section 285b–1 of this title, and substituted ''Department of Veterans Affairs'' for ''Veterans' Administration'' in subsec. (b).

1988—Subsec. (a)(1), (2). Pub. L. 100–607, § 118(a), amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

''(1)(A) For the National Cancer Institute (other than its programs under section 285a–1 of this title), there are authorized to be appropriated $1,194,000,000 for fiscal year 1986, $1,270,000,000 for fiscal year 1987, and $1,344,000,000 for fiscal year 1988.

''(B) For the programs under section 285a–1 of this title, there are authorized to be appropriated $68,000,000 for fiscal year 1986, $74,000,000 for fiscal year 1987, and $80,000,000 for fiscal year 1988.

''(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 285b–1 of this title), there are authorized to be appropriated $809,000,000 for fiscal year 1986, $871,000,000 for fiscal year 1987, and $927,000,000 for fiscal year 1988. Of the amount appropriated under this subsection for such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

''(B) For the programs under section 285b–1 of this title, there are authorized to be appropriated $82,000,000 for fiscal year 1986, $90,000,000 for fiscal year 1987, and $98,000,000 for fiscal year 1988.''

Subsec. (a)(2)(B). Pub. L. 100–690 inserted a comma after ''section 285b–1 of this title''.

Subsec. (b)(5). Pub. L. 100–607, § 118(b), added par. (5).

CHANGE OF NAME

National Center for Nursing Research changed to National Institute of Nursing Research by Pub. L. 103–43, title XV, § 1511, June 10, 1993, 107 Stat. 178.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

WARREN G. MAGNUSON CLINICAL CENTER; AVAILABILITY OF FUNDS FOR PAYMENT OF NURSES; RATE OF PAY AND OPTIONS AND BENEFITS

Pub. L. 99–349, title I, July 2, 1986, 100 Stat. 738, provided that: ''Funds made available for fiscal year 1986 and hereafter to the Warren G. Magnuson Clinical Center of the National Institutes of Health shall be available for payment of nurses at the rates of pay and with schedule options and benefits authorized for the Veterans Administration pursuant to 38 U.S.C. 4107.''

§ 284d. Definitions

(a) Health service research

For purposes of this subchapter, the term ''health services research'' means research en-

deavors that study the impact of the organization, financing and management of health services on the quality, cost, access to and outcomes of care. Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.

(b) Clinical research

As used in this subchapter, 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.

(July 1, 1944, ch. 373, title IV, § 409, as added Pub. L. 102–321, title I, § 121(b), July 10, 1992, 106 Stat. 358; amended Pub. L. 103–43, title XX, § 2016(a), June 10, 1993, 107 Stat. 218; Pub. L. 106–505, title II, § 206, Nov. 13, 2000, 114 Stat. 2329.)

AMENDMENTS

2000—Pub. L. 106–505 designated existing provisions as subsec. (a), inserted heading, and added subsec. (b).

1993—Pub. L. 103–43 inserted at end ''Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.''

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§ 284e. Research on osteoporosis, Paget's disease, and related bone disorders

(a) Establishment

The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Dental Research, and the National Institute of Diabetes and Digestive and Kidney Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

(b) Coordination

The Directors referred to in subsection (a) of this section shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

(c) Information clearinghouse

(1) In general

In order to assist in carrying out the purpose described in subsection (a) of this section, the Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information.

(2) Establishment through grant or contract

For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

(July 1, 1944, ch. 373, title IV, § 409A, as added Pub. L. 103–43, title III, § 302, June 10, 1993, 107 Stat. 151; amended Pub. L. 105–340, title I, § 102, Oct. 31, 1998, 112 Stat. 3192; Pub. L. 109–482, title I, § 103(b)(7), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out heading and text of subsec. (d). Text read as follows: ''For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003.''

1998—Subsec. (d). Pub. L. 105–340 substituted ''through 2003'' for ''and 1996''.

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.

§ 284f. Parkinson's disease

(a) In general

The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson's disease (subject to the extent of amounts appropriated to carry out this section).

(b) Inter-institute coordination

(1) In general

The Director of NIH shall provide for the coordination of the program established under subsection (a) of this section among all of the national research institutes conducting Parkinson's disease research.

(2) Conference

Coordination under paragraph (1) shall include the convening of a research planning conference not less frequently than once every 2 years. Each such conference shall prepare and submit to the Committee on Appropriations and the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations and the Committee on Commerce of the House of Representatives a report concerning the conference.

(c) Morris K. Udall research centers

(1) In general

The Director of NIH is authorized to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. The Director is authorized to award not more than 10 Core Center Grants and designate each center funded under such grants as a Morris K. Udall Center for Research on Parkinson's Disease.

(2) Requirements

(A) In general

With respect to Parkinson's disease, each center assisted under this subsection shall—

(i) use the facilities of a single institution or a consortium of cooperating institutions, and meet such qualifications as may be prescribed by the Director of the NIH; and

(ii) conduct basic and clinical research.

(B) Discretionary requirements

With respect to Parkinson's disease, each center assisted under this subsection may—

(i) conduct training programs for scientists and health professionals;

(ii) conduct programs to provide information and continuing education to health professionals;

(iii) conduct programs for the dissemination of information to the public;

(iv) separately or in collaboration with other centers, establish a nationwide data system derived from patient populations with Parkinson's disease, and where possible, comparing relevant data involving general populations;

(v) separately or in collaboration with other centers, establish a Parkinson's Disease Information Clearinghouse to facilitate and enhance knowledge and understanding of Parkinson's disease; and

(vi) separately or in collaboration with other centers, establish a national education program that fosters a national focus on Parkinson's disease and the care of those with Parkinson's disease.

(3) Stipends regarding training programs

A center may use funds provided under paragraph (1) to provide stipends for scientists and health professionals enrolled in training programs under paragraph (2)(B).

(4) Duration of support

Support of a center under this subsection may be for a period not exceeding five years. Such period may be extended by the Director of NIH for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) Morris K. Udall Awards for Excellence in Parkinson's Disease Research

The Director of NIH is authorized to establish a grant program to support investigators with a proven record of excellence and innovation in Parkinson's disease research and who demonstrate potential for significant future breakthroughs in the understanding of the pathogensis,[1] diagnosis, and treatment of Parkinson's disease. Grants under this subsection shall be available for a period of not to exceed 5 years.

(July 1, 1944, ch. 373, title IV, § 409B, as added Pub. L. 105–78, title VI, § 603(c), Nov. 13, 1997, 111 Stat. 1520; amended Pub. L. 109–482, title I, § 103(b)(8), Jan. 15, 2007, 120 Stat. 3687.)

[1] So in original. Probably should be ''pathogenesis,''.

AMENDMENTS

2007—Subsec. (a). Pub. L. 109–482, § 103(b)(8)(A), substituted ''to carry out this section'' for ''under subsection (e) of this section''.

Subsec. (e). Pub. L. 109–482, § 103(b)(8)(B), struck out heading and text of subsec. (e). Text read as follows: ''For the purpose of carrying out this section and section 241 of this title and this subchapter with respect to research focused on Parkinson's disease, there are authorized to be appropriated up to $100,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 and 2000.''

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

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.

ADDITIONAL GRANTS

Pub. L. 108–199, div. E, title II, § 217, Jan. 23, 2004, 118 Stat. 255, provided that: ''Notwithstanding section 409B(c) of the Public Health Service Act [subsec. (c) of this section] regarding a limitation on the number of such grants, funds appropriated in this Act [div. E of Pub. L. 108–199, see Tables for classification] and Acts in fiscal years thereafter may be expended by the Director of the National Institutes of Health to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. Each center funded under such grants shall be designated as a Morris K. Udall Center for Research on Parkinson's Disease.''

Similar provisions were contained in Pub. L. 108–7, div. G, title II, § 218, Feb. 20, 2003, 117 Stat. 326.

FINDING AND PURPOSE

Section 603(b) of Pub. L. 105–78 provided that:

''(1) FINDING.—Congress finds that to take full advantage of the tremendous potential for finding a cure or effective treatment, the Federal investment in Parkinson's disease must be expanded, as well as the coordination strengthened among the National Institutes of Health research institutes.

''(2) PURPOSE.—It is the purpose of this section [enacting this section] to provide for the expansion and coordination of research regarding Parkinson's disease, and to improve care and assistance for afflicted individuals and their family caregivers.''

§ 284g. Expansion, intensification, and coordination of activities of National Institutes of Health with respect to research on autism spectrum disorder

(a) In general

(1) Expansion of activities

The Director of NIH (in this section referred to as the ''Director'') shall, subject to the availability of appropriations, expand, intensify, and coordinate the activities of the Na-

tional Institutes of Health with respect to research on autism spectrum disorder, including basic and clinical research in fields including pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, and toxicology. Such research shall investigate the cause (including possible environmental causes), diagnosis or rule out, early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder.

(2) Consolidation

The Director may consolidate program activities under this section if such consolidation would improve program efficiencies and outcomes.

(3) Administration of program; collaboration among agencies

The Director shall carry out this section acting through the Director of the National Institute of Mental Health and in collaboration with any other agencies that the Director determines appropriate.

(b) Centers of excellence

(1) In general

The Director shall under subsection (a)(1) of this section make awards of grants and contracts to public or nonprofit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on autism spectrum disorder.

(2) Research

Each center under paragraph (1) shall conduct basic and clinical research into autism spectrum disorder. Such research should include investigations into the cause, diagnosis, early detection, prevention, control, and treatment of autism spectrum disorder. The centers, as a group, shall conduct research including the fields of developmental neurobiology, genetics, and psychopharmacology.

(3) Services for patients

(A) In general

A center under paragraph (1) may expend amounts provided under such paragraph to carry out a program to make individuals aware of opportunities to participate as subjects in research conducted by the centers.

(B) Referrals and costs

A program under subparagraph (A) may, in accordance with such criteria as the Director may establish, provide to the subjects described in such subparagraph, referrals for health and other services, and such patient care costs as are required for research.

(C) Availability and access

The extent to which a center can demonstrate availability and access to clinical services shall be considered by the Director in decisions about awarding grants to applicants which meet the scientific criteria for funding under this section.

(4) Organization of centers

Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director.

(5) Number of centers; duration of support

(A) In general

The Director shall provide for the establishment of not less than five centers under paragraph (1).

(B) Duration

Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(c) Facilitation of research

The Director shall under subsection (a)(1) of this section provide for a program under which samples of tissues and genetic materials that are of use in research on autism spectrum disorder are donated, collected, preserved, and made available for such research. The program shall be carried out in accordance with accepted scientific and medical standards for the donation, collection, and preservation of such samples.

(d) Public input

The Director shall under subsection (a)(1) of this section provide for means through which the public can obtain information on the existing and planned programs and activities of the National Institutes of Health with respect to autism spectrum disorder and through which the Director can receive comments from the public regarding such programs and activities.

(July 1, 1944, ch. 373, title IV, § 409C, as added Pub. L. 106–310, div. A, title I, § 101, Oct. 17, 2000, 114 Stat. 1105; amended Pub. L. 109–416, §§ 2(a), 4(b), Dec. 19, 2006, 120 Stat. 2821, 2830; Pub. L. 109–482, title I, §§ 103(b)(9), 104(b)(1)(D), Jan. 15, 2007, 120 Stat. 3687, 3693.)

PRIOR PROVISIONS

Another section 409C of act July 1, 1944, was renumbered section 409G and is classified to section 284k of this title.

AMENDMENTS

2007—Subsec. (b)(4) to (6). Pub. L. 109–482, § 104(b)(1)(D), redesignated pars. (5) and (6) as (4) and (5), respectively, and struck out heading and text of former par. (4). Text read as follows: ''The Director shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers, and may require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.''

Subsec. (e). Pub. L. 109–482, § 103(b)(9), which directed the striking of subsec. (e), could not be executed because of prior amendment by Pub. L. 109–416. See 2006 Amendment note below.

2006—Pub. L. 109–416, § 2(a)(1), substituted ''autism spectrum disorder'' for ''autism'' in section catchline.

Subsec. (a). Pub. L. 109–416, § 2(a)(3), added pars. (1) and (2), redesignated former par. (2) as (3), and struck out heading and text of former par. (1). Text read as follows: ''The Director of NIH (in this section referred to as the 'Director') shall expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism.''

Subsec. (b)(1), (2). Pub. L. 109–416, § 2(a)(2), substituted ''autism spectrum disorder'' for ''autism'' in par. (1) and in two places in par. (2).

Subsecs. (c), (d). Pub. L. 109–416, § 2(a)(2), substituted ''autism spectrum disorder'' for ''autism''.

Subsec. (e). Pub. L. 109–416, § 4(b), struck out heading and text of subsec. (e). Text read as follows: ''There are authorized to be appropriated such sums as may be necessary to carry out this section. Amounts appropriated under this subsection are 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.

§ 284h. Pediatric Research Initiative

(a) Establishment

The Secretary shall establish within the Office of the Director of NIH a Pediatric Research Initiative (referred to in this section as the ''Initiative'') to conduct and support research that is directly related to diseases, disorders, and other conditions in children. The Initiative shall be headed by the Director of NIH.

(b) Purpose

The purpose of the Initiative is to provide funds to enable the Director of NIH—

(1) to increase support for pediatric biomedical research within the National Institutes of Health to realize the expanding opportunities for advancement in scientific investigations and care for children;

(2) to enhance collaborative efforts among the Institutes to conduct and support multidisciplinary research in the areas that the Director deems most promising; and

(3) in coordination with the Food and Drug Administration, to increase the development of adequate pediatric clinical trials and pediatric use information to promote the safer and more effective use of prescription drugs in the pediatric population.

(c) Duties

In carrying out subsection (b) of this section, the Director of NIH shall—

(1) consult with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the other national research institutes, in considering their requests for new or expanded pediatric research efforts, and consult with the Administrator of the Health Resources and Services Administration and other advisors as the Director determines to be appropriate;

(2) have broad discretion in the allocation of any Initiative assistance among the Institutes, among types of grants, and between basic and clinical research so long as the assistance is directly related to the illnesses and conditions of children; and

(3) be responsible for the oversight of any newly appropriated Initiative funds and annually report to Congress and the public on the extent of the total funds obligated to conduct or support pediatric research across the National Institutes of Health, including the specific support and research awards allocated through the Initiative.

(d) Transfer of funds

The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

(July 1, 1944, ch. 373, title IV, § 409D, as added Pub. L. 106–310, div. A, title X, § 1001, Oct. 17, 2000, 114 Stat. 1127; amended Pub. L. 109–482, title I, § 103(b)(10), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110–154, § 1(b)(4), Dec. 21, 2007, 121 Stat. 1827.)

CODIFICATION

Another section 409D of act July 1, 1944, was renumbered section 409H and is classified to section 284*l* of this title.

AMENDMENTS

2007—Subsec. (c)(1). Pub. L. 110–154 substituted ''Eunice Kennedy Shriver National Institute of Child Health and Human Development'' for ''National Institute of Child Health and Human Development''.

Subsecs. (d), (e). Pub. L. 109–482 redesignated subsec. (e) as (d) and struck out heading and text of former subsec. (d). Text read as follows: ''For the purpose of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.''

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.

§ 284i. Autoimmune diseases

(a) Expansion, intensification, and coordination of activities

(1) In general

The Director of NIH shall expand, intensify, and coordinate research and other activities of the National Institutes of Health with respect to autoimmune diseases.

(2) Allocations by Director of NIH

With respect to amounts appropriated to carry out this section for a fiscal year, the Director of NIH shall allocate the amounts among the national research institutes that are carrying out paragraph (1).

(3) Definition

The term ''autoimmune disease'' includes, for purposes of this section such diseases or disorders with evidence of autoimmune pathogensis[1] as the Secretary determines to be appropriate.

(b) Coordinating Committee

(1) In general

The Secretary shall ensure that the Autoimmune Diseases Coordinating Committee (re-

[1] So in original. Probably should be ''pathogenesis''.

ferred to in this section as the ''Coordinating Committee'') coordinates activities across the National Institutes and with other Federal health programs and activities relating to such diseases.

(2) Composition

The Coordinating Committee shall be composed of the directors or their designees of each of the national research institutes involved in research with respect to autoimmune diseases and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention and the Food and Drug Administration.

(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) of this section, 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) of this section 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 National 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.''

Subsec. (c)(5). Pub. L. 109–482, § 103(b)(13)(C), struck out heading and text of par. (5). 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. (d)(4). Pub. L. 109–482, § 103(b)(13)(D), struck out heading and text of par. (4). 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.''

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.

§ 284m. Program for pediatric studies of drugs

(a) List of priority issues in pediatric therapeutics

(1) In general

Not later than one year after September 27, 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every three years.

(2) Consideration of available information

In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

(b) Pediatric studies and research

The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(c) Process for proposed pediatric study requests and labeling changes

(1) Submission of proposed pediatric study request

The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a], including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(j)]; or

(ii) there is a submitted application that could be approved under the criteria of such section; and

(B) there is no patent protection or market exclusivity protection for at least one form of the drug under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]; and

(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

(2) Written request to holders of approved applications for drugs lacking exclusivity

The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355]. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of such Act [21 U.S.C. 355a], including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

(3) Requests for proposals

If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of

the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

(4) Disqualification

A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

(5) Contracts, grants, or other funding mechanisms

A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(6) Reporting of studies

(A) In general

On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

(B) Availability of reports

Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

(C) Action by Commissioner

The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

(7) Requests for labeling change

During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

(ii) publish in the Federal Register and through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

(8) Dispute resolution

(A) Referral to Pediatric Advisory Committee

If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

(B) Action by the Pediatric Advisory Committee

Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

(9) FDA determination

Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

(10) Failure to agree

If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(11) No effect on authority

Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(d) Dissemination of pediatric information

Not later than one year after September 27, 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.

(e) Authorization of appropriations

(1) In general

There are authorized to be appropriated to carry out this section—

(A) $200,000,000 for fiscal year 2008; and

(B) such sums as are necessary for each of the four succeeding fiscal years.

(2) Availability

Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.

(July 1, 1944, ch. 373, title IV, § 409I, as added Pub. L. 107–109, § 3(3), Jan. 4, 2002, 115 Stat. 1408; amended Pub. L. 108–155, § 3(b)(6), Dec. 3, 2003, 117 Stat. 1942; Pub. L. 109–482, title I, § 103(b)(14), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110–85, title V, § 502(b), Sept. 27, 2007, 121 Stat. 886.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(1)(B), (10), (11), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

AMENDMENTS

2007—Pub. L. 110–85 amended section generally. Prior to amendment, section related to development of list of drugs for which pediatric studies are needed, award of contracts for pediatric studies, process for requesting contract proposals to conduct certain pediatric studies, reporting of completed studies, requests for labeling changes and dispute resolution, and recommendation by the Secretary for formulation changes.

Subsec. (d). Pub. L. 109–482 struck out subsec. (d) which related to authorization and availability of appropriations.

2003—Subsec. (c)(8), (9), (11). Pub. L. 108–155 struck out ''Advisory Subcommittee of the Anti-Infective Drugs'' before ''Advisory Committee'' wherever appearing.

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.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

PEDIATRIC ADVISORY COMMITTEE

Pub. L. 107–109, § 14, Jan. 4, 2002, 115 Stat. 1419, as amended by Pub. L. 108–155, § 3(b)(2), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110–85, title III, § 306(b), title V, § 502(d), Sept. 27, 2007, 121 Stat. 865, 889, provided that:

''(a) IN GENERAL.—The Secretary of Health and Human Services shall, under section 222 of the Public Health Service Act (42 U.S.C. 217a) or other appropriate authority, convene and consult an advisory committee on pediatric therapeutics (including drugs and biological products) and medical devices (referred to in this section as the 'advisory committee').

''(b) PURPOSE.—

''(1) IN GENERAL.—The advisory committee shall advise and make recommendations to the Secretary, through the Commissioner of Food and Drugs, on matters relating to pediatric therapeutics (including drugs and biological products) and medical devices.

''(2) MATTERS INCLUDED.—The matters referred to in paragraph (1) include—

''(A) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act [42 U.S.C. 262, 284m, and 290b] and sections 501, 502, 505, 505A, 505B, 510(k), 515, and 520(m) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351, 352, 355, 355a, 355c, 360(k), 360e, and 360j(m)];

''(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions; [and]

''(C) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices.

''(c) COMPOSITION.—The advisory committee shall include representatives of pediatric health organizations, pediatric researchers, relevant patient and patient-family organizations, and other experts selected by the Secretary.

''(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act [5 U.S.C. App.], the advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007 [Sept. 27, 2007].''

§ 284n. Certain demonstration projects

(a) Bridging the sciences

(1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary of Health and Human Services, acting through the Director of NIH, (in this subsection referred to as the ''Secretary'') in consultation with the Director of the National Science Foundation, the Secretary of Energy, and other agency heads when necessary, may allocate funds for the national research institutes and national centers to make grants for the purpose of improving the public health through demonstration projects for biomedical research at the interface between the biological, behavioral, and social sciences and the physical, chemical, mathematical, and computational sciences.

(2) Goals, priorities, and methods; interagency collaboration

The Secretary shall establish goals, priorities, and methods of evaluation for research under paragraph (1), and shall provide for interagency collaboration with respect to such research. In developing such goals, priorities, and methods, the Secretary shall ensure that—

(A) the research reflects the vision of innovation and higher risk with long-term payoffs; and

(B) the research includes a wide spectrum of projects, funded at various levels, with varying timeframes.

(3) Peer review

A grant may be made under paragraph (1) only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title or has been reviewed by an advisory council composed of representatives from appropriate scientific disciplines who can fully evaluate the applicant.

(b) High-risk, high-reward research

(1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary, acting through the Director of NIH, may allocate funds for the national research institutes and

national centers to make awards of grants or contracts or to engage in other transactions for demonstration projects for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders. The head of a national research institute or national center may conduct or support such high-impact, cutting-edge research (with funds allocated under the preceding sentence or otherwise available for such purpose) if the institute or center gives notice to the Director of NIH beforehand and submits a report to the Director of NIH on an annual basis on the activities of the institute or center relating to such research.

(2) Special consideration

In carrying out the program under paragraph (1), the Director of NIH shall give special consideration to coordinating activities with national research institutes whose budgets are substantial relative to a majority of the other institutes.

(3) Administration of program

Activities relating to research described in paragraph (1) shall be designed by the Director of NIH or the head of a national research institute or national center, as applicable, to enable such research to be carried out with maximum flexibility and speed.

(4) Public-private partnerships

In providing for research described in paragraph (1), the Director of NIH or the head of a national research institute or national center, as applicable, shall seek to facilitate partnerships between public and private entities and shall coordinate when appropriate with the Foundation for the National Institutes of Health.

(5) Peer review

A grant for research described in paragraph (1) may be made only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title.

(c) Report to Congress

Not later than the end of fiscal year 2009, the Secretary, acting through the Director of NIH, shall conduct an evaluation of the activities under this section and submit a report to the Congress on the results of such evaluation.

(d) Definitions

For purposes of this section, the terms ''Director of NIH'', ''national research institute'', and ''national center'' have the meanings given such terms in section 281 of this title.

(Pub. L. 109–482, title I, § 105, Jan. 15, 2007, 120 Stat. 3694.)

CODIFICATION

Section was enacted as part of the National Institutes of Health Reform Act of 2006, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section 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 an Effective Date of 2007 Amendment note under section 281 of this title.

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

SUBPART 1—NATIONAL CANCER INSTITUTE

§ 285. Purpose of Institute

The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the ''Institute'') is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

(July 1, 1944, ch. 373, title IV, § 410, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 832; amended Pub. L. 100–607, title I, § 121, Nov. 4, 1988, 102 Stat. 3054.)

AMENDMENTS

1988—Pub. L. 100–607 inserted '', rehabilitation from cancer,'' after ''treatment of cancer''.

§ 285a. National Cancer Program

The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

(July 1, 1944, ch. 373, title IV, § 411, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 832.)

§ 285a–1. Cancer control programs

The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—

(A) the detection, diagnosis, prevention, and treatment of cancer,

(B) the continuing care of cancer patients and the families of cancer patients, and

(C) rehabilitation and counseling respecting cancer,

to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of students of the health professions and health professionals in—

(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and