

(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