

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 partner-

ships 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.

§ 284o. Activities of the National Institutes of Health with respect to research on paralysis

(a) Coordination

The Director of the National Institutes of Health (referred to in this section and sections 280g-9 and 284p of this title as the “Director”), pursuant to the general authority of the Director, may develop mechanisms to coordinate the paralysis research and rehabilitation activities of the Institutes and Centers of the National Institutes of Health in order to further advance such activities and avoid duplication of activities.

(b) Christopher and Dana Reeve Paralysis Research Consortia

(1) In general

The Director may make awards of grants to public or private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for consortia in paralysis research. The Director shall designate each consortium funded through such grants as a Christopher and Dana Reeve Paralysis Research Consortium.

(2) Research

Each consortium under paragraph (1)—

- (A) may conduct basic, translational, and clinical paralysis research;
- (B) may focus on advancing treatments and developing therapies in paralysis research;

(C) may focus on one or more forms of paralysis that result from central nervous system trauma or stroke;

(D) may facilitate and enhance the dissemination of clinical and scientific findings; and

(E) may replicate the findings of consortia members or other researchers for scientific and translational purposes.

(3) Coordination of consortia; reports

The Director may, as appropriate, provide for the coordination of information among consortia under paragraph (1) and ensure regular communication among members of the consortia, and may require the periodic preparation of reports on the activities of the consortia and the submission of the reports to the Director.

(4) Organization of consortia

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

(c) Public input

The Director may provide for a mechanism to educate and disseminate information on the existing and planned programs and research activities of the National Institutes of Health with respect to paralysis and through which the Director can receive comments from the public regarding such programs and activities.

(Pub. L. 111-11, title XIV, §14101, Mar. 30, 2009, 123 Stat. 1452.)

CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

§ 284p. Activities of the National Institutes of Health with respect to research with implications for enhancing daily function for persons with paralysis

(a) In general

The Director, pursuant to the general authority of the Director, may make awards of grants to public or private entities to pay all or part of the costs of planning, establishing, improving, and providing basic operating support to multicenter networks of clinical sites that will collaborate to design clinical rehabilitation intervention protocols and measures of outcomes on one or more forms of paralysis that result from central nervous system trauma, disorders, or stroke, or any combination of such conditions.

(b) Research

A multicenter network of clinical sites funded through this section may—

(1) focus on areas of key scientific concern, including—

- (A) improving functional mobility;
- (B) promoting behavioral adaptation to functional losses, especially to prevent secondary complications;
- (C) assessing the efficacy and outcomes of medical rehabilitation therapies and practices and assisting technologies;