(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;

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

(D) the development of countermeasures (as defined in section 360bbb–4(a) of title 21) for pediatric populations.

(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 1013 of title 5, the advisory committee shall continue to operate to carry out the advisory committee's responsibilities under sections 355a, 355c, and 360j(m) of title 21.

(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; Pub. L. 112–144, title V, §507(a), July 9, 2012, 126 Stat. 1045; Pub. L. 113–5, title III, §307(c), Mar. 13, 2013, 127 Stat. 192; Pub. L. 117–286, §4(a)(233), Dec. 27, 2022, 136 Stat. 4331.)

Editorial Notes

CODIFICATION

Section was formerly set out as a note under section 284m of this title.

Section was enacted as part of the Best Pharmaceuticals for Children Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2022—Subsec. (d). Pub. L. 117–286 substituted ''section 1013 of title 5,'' for ''section 14 of the Federal Advisory Committee Act,''.

2013—Subsec. (b)(2)(D). Pub. L. 113–5 added subpar. (D).

2012—Subsec. (d). Pub. L. 112–144 substituted ''to carry out the advisory committee's responsibilities under sections 355a, 355c, and 360j(m) of title 21'' for ''during the five-year period beginning on September 27, 2007''.

2007—Subsec. (a). Pub. L. 110–85, §306(b)(1), inserted ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

Subsec. (b)(1). Pub. L. 110–85, §306(b)(2)(A), inserted ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

Subsec. (b)(2)(A). Pub. L. 110–85, §306(b)(2)(B)(i), substituted ''355c, 360(k), 360e, and 360j(m)'' for ''and 355c''.

Subsec. (b)(2)(B). Pub. L. 110–85, §306(b)(2)(B)(ii), added subpar. (B) and struck out former subpar. (B) which read as follows: ''identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; and''.

Subsec. (b)(2)(C). Pub. L. 110–85, §306(b)(2)(B)(iii), inserted ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

Subsec. (d). Pub. L. 110–85, §502(d), added subsec. (d).

2003—Pub. L. 108–155, §3(b)(2)(A), struck out ''Pharmacology'' after ''Pediatric'' in section catchline.

Subsec. (a). Pub. L. 108–155, §3(b)(2)(D), substituted ''therapeutics'' for ''pharmacology''.

Pub. L. 108–155, §3(b)(2)(B), inserted ''or other appropriate authority'' after ''217a of this title''.

Subsec. (b)(1). Pub. L. 108–155, §3(b)(2)(D), substituted ''therapeutics'' for ''pharmacology''.

Pub. L. 108–155, §3(b)(2)(C)(i), struck out ''and in consultation with the Director of the National Institutes of Health'' after ''Commissioner of Food and Drugs''.

Subsec. (b)(2). Pub. L. 108–155, §3(b)(2)(C)(ii), substituted ''355a, and 355c'' for ''and 355a''.

Subsec. (b)(2)(B), (C). Pub. L. 108–155, §3(b)(2)(D), substituted ''therapeutics'' for ''pharmacology''.

Statutory Notes and Related Subsidiaries

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.

§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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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.

§ 284*o*. 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 ex-