this section through the Center with related activities of the Director of the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IV, § 478A, as added Pub. L. 103–43, title XIV, § 1421, June 10, 1993, 107 Stat. 171; amended Pub. L. 106–129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

AMENDMENTS

1999—Subsec. (d). Pub. L. 106–129 substituted ''Director of the Agency for Healthcare Research and Quality'' for ''Administrator for Health Care Policy and Research''.

CONSTRUCTION

Pub. L. 103–43, § 1422(b), June 10, 1993, 107 Stat. 172, provided that: ''The amendments made by section 3 of Public Law 102–410 (106 Stat. 2094) [amending section 299a–1 of this title], by section 1421 of this Act [enacting this section], and by subsection (a) of this section [amending section 299a–1 of this title] may not be construed as terminating the information center on health care technologies and health care technology assessment established under section 904 of the Public Health Service Act [42 U.S.C. 299a–2], as in effect on the day before the date of the enactment of Public Law 102–410 [Oct. 13, 1992]. Such center shall be considered to be the center established in section 478A of the Public Health Service Act [42 U.S.C. 286d], as added by section 1421 of this Act, and shall be subject to the provisions of such section 478A.''

PART E—OTHER AGENCIES OF NIH

SUBPART 1—NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

CODIFICATION

Pub. L. 112–74, div. F, title II, § 221(a)(1)(A), Dec. 23, 2011, 125 Stat. 1086, substituted ''advancing translational sciences'' for ''research resources'' in subpart heading.

§ 287. National Center for Advancing Translational Sciences

(a) Purpose

The purpose of the National Center for Advancing Translational Sciences (in this subpart referred to as the ''Center'') is to advance translational sciences, including by—

(1) coordinating and developing resources that leverage basic research in support of translational science; and

(2) developing partnerships and working cooperatively to foster synergy in ways that do not create duplication, redundancy, and competition with industry activities.

(b) Clinical trial activities

(1) In general

The Center may develop and provide infrastructure and resources for all phases of clinical trials research. Except as provided in paragraph (2), the Center may support clinical trials only through the end of phase IIB.

(2) Exception

The Center may support clinical trial activities through the end of phase III for a treatment for a rare disease or condition (as defined in section 360bb of title 21) so long as—

(A) the Center gives public notice for a period of at least 120 days of the Center's intention to support the clinical trial activities in phase III;

(B) no public or private organization provides credible written intent to the Center that the organization has timely plans to further the clinical trial activities or conduct clinical trials of a similar nature beyond phase IIB; and

(C) the Center ensures that support of the clinical trial activities in phase III will not increase the Federal Government's liability beyond the award value of the Center's support.

(c) Biennial report

The Center shall publish a report on a biennial basis that, with respect to all research supported by the Center, includes a complete list of—

(1) the molecules being studied;

(2) clinical trial activities being conducted;

(3) the methods and tools in development;

(4) ongoing partnerships, including—

(A) the rationale for each partnership;

(B) the status of each partnership;

(C) the funding provided by the Center to other entities pursuant to each partnership, and

(D) the activities which have been transferred to industry pursuant to each partnership;

(5) known research activity of other entities that is or will expand upon research activity of the Center;

(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews.

(d) Inclusion of list

The first biennial report submitted under this section after December 13, 2016, shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

(e) Rule of construction

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(July 1, 1944, ch. 373, title IV, § 479, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 864; amended Pub. L. 103–43, title XV, § 1501(2)(B), June 10, 1993, 107 Stat. 172; Pub. L. 112–74, div. F, title II, § 221(a)(1)(C), Dec. 23, 2011, 125 Stat. 1086; Pub. L. 114–255, div. A, title II, §§ 2037, 2042(e), Dec. 13, 2016, 130 Stat. 1063, 1073.)

AMENDMENTS

2016—Subsec. (b)(1). Pub. L. 114–255, § 2037(a)(1), substituted ''phase IIB'' for ''phase IIA''.

Subsec. (b)(2). Pub. L. 114–255, § 2037(a)(2)(A), substituted ''phase III'' for ''phase IIB'' in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 114–255, § 2037(a)(2)(B), substituted ''phase III'' for ''phase IIB''.

Subsec. (b)(2)(B). Pub. L. 114–255, § 2037(a)(2)(C), substituted ''phase IIB'' for ''phase IIA''.

Subsec. (b)(2)(C). Pub. L. 114–255, § 2037(a)(2)(D), substituted ''phase III'' for ''phase IIB''.

Subsec. (c). Pub. L. 114–255, § 2042(e), substituted ''Biennial'' for ''Annual'' in heading and ''a report on a biennial basis'' for ''an annual report'' in introductory provisions.

Subsec. (c)(6), (7). Pub. L. 114–255, § 2037(b)(1), added pars. (6) and (7).

Subsecs. (d), (e). Pub. L. 114–255, § 2037(b)(2), added subsecs. (d) and (e).

2011—Pub. L. 112–74 amended section generally. Prior to amendment, text read as follows: ''The general purpose of the National Center for Research Resources (in this subpart referred to as the 'Center') is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources.''

1993—Pub. L. 103–43 substituted ''the National Center for Research Resources (in this subpart referred to as the 'Center')'' for ''the Division of Research Resources''.

SHARED INSTRUMENTATION GRANT PROGRAM

Pub. L. 106–505, title III, § 305, Nov. 13, 2000, 114 Stat. 2335, which was formerly set out as a note under this section, was renumbered section 404L of act July 1, 1944, ch. 373, the Public Health Service Act, by Pub. L. 112–74, div. F, title II, § 221(b)(4)(A), Dec. 23, 2011, 125 Stat. 1088, and is classified to section 283n of this title.

§ 287a. Cures Acceleration Network

(a) Definitions

In this section:

(1) Biological product

The term ''biological product'' has the meaning given such term in section 262 of this title.

(2) Drug; device

The terms ''drug'' and ''device'' have the meanings given such terms in section 321 of title 21.

(3) High need cure

The term ''high need cure'' means a drug (as that term is defined by section 321(g)(1) of title 21,[1] biological product (as that term is defined by section 262(i)[2] of this title), or device (as that term is defined by section 321(h) of title 21) that, in the determination of the Director of the Center—

(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

(4) Medical product

The term ''medical product'' means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products.

(b) Establishment of the Cures Acceleration Network

Subject to the appropriation of funds as described in subsection (g), there is established within the Center a program to be known as the Cures Acceleration Network (referred to in this section as ''CAN''), which shall—

(1) be under the direction of the Director of the Center, taking into account the recommendations of a CAN Review Board (referred to in this section as the ''Board''), described in subsection (d); and

(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of high need cures, including through the development of medical products and behavioral therapies.

(c) Functions

The functions of the CAN are to—

(1) conduct and support revolutionary advances in basic research, translating scientific discoveries from bench to bedside;

(2) award grants and contracts to eligible entities to accelerate the development of high need cures;

(3) provide the resources necessary for government agencies, independent investigators, research organizations, biotechnology companies, academic research institutions, and other entities to develop high need cures;

(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and

(5) facilitate review in the Food and Drug Administration for the high need cures funded by the CAN, through activities that may include—

(A) the facilitation of regular and ongoing communication with the Food and Drug Administration regarding the status of activities conducted under this section;

(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of countermeasures and products; and

(C) connecting interested persons with additional technical assistance made available under section 360bbb–4 of title 21.

(d) CAN Board

(1) Establishment

There is established a Cures Acceleration Network Review Board (referred to in this section as the ''Board''), which shall advise the Director of the Center on the conduct of the activities of the Cures Acceleration Network.

(2) Membership

(A) In general

(i) Appointment

The Board shall be comprised of 24 members who are appointed by the Secretary and who serve at the pleasure of the Secretary.

(ii) Chairperson and Vice Chairperson

The Secretary shall designate, from among the 24 members appointed under clause (i), one Chairperson of the Board (referred to in this section as the ''Chairperson'') and one Vice Chairperson.

(B) Terms

(i) In general

Each member shall be appointed to serve a 4-year term, except that any member ap-

[1] So in original. A closing parenthesis probably should precede the comma.

[2] See References in Text note below.