

to promote the development of drugs and devices for rare diseases or disorders.

“(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act [Jan. 4, 1983], more than 220 new orphan drugs have been approved and marketed in the United States and more than 800 additional drugs are in the research pipeline.

“(6) Despite the tremendous success of the Orphan Drug Act, rare diseases and disorders deserve greater emphasis in the national biomedical research enterprise. The Office of Rare Diseases at the National Institutes of Health was created in 1993, but lacks a statutory authorization.

“(7) The National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research.

“(8) Notwithstanding such increases, funding for rare diseases and disorders at the National Institutes of Health has not increased appreciably.

“(9) To redress this oversight, the Department of Health and Human Services has proposed the establishment of a network of regional centers of excellence for research on rare diseases.

“(b) PURPOSES.—The purposes of this Act [see Short Title of 2002 Amendments note set out under section 201 of this title] are to—

“(1) amend the Public Health Service Act [42 U.S.C. 201 et seq.] to establish an Office of Rare Diseases at the National Institutes of Health; and

“(2) increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders.”

§ 287a-2. Rare disease regional centers of excellence

(a) Cooperative agreements and grants

(1) In general

The Director of the Office of Rare Diseases (in this section referred to as the “Director”), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

(2) Policies

A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

(b) Coordination with other institutes

The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

(c) Uses for Federal payments under cooperative agreements or grants

Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

(3) clinical research and demonstration programs.

(d) Period of support; additional periods

Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 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.

(July 1, 1944, ch. 373, title IV, § 481A, formerly § 404G, as added Pub. L. 107-280, § 4, Nov. 6, 2002, 116 Stat. 1990; amended Pub. L. 109-482, title I, § 103(b)(6), Jan. 15, 2007, 120 Stat. 3687; renumbered § 481A, Pub. L. 112-74, div. F, title II, § 221(c)(3), Dec. 23, 2011, 125 Stat. 1089.)

CODIFICATION

Section was formerly classified to section 283i of this title.

PRIOR PROVISIONS

A prior section 481A of act July 1, 1944, was renumbered section 404I, and is classified to section 283k of this title.

AMENDMENTS

2007—Subsec. (e). Pub. L. 109-482 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 already have been appropriated for fiscal year 2002, and \$20,000,000 for each of the fiscal years 2003 through 2006.”

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.

§§ 287a-3, 287a-3a. Transferred

CODIFICATION

Section 287a-3, act July 1, 1944, ch. 373, title IV, § 481B, as added Pub. L. 103-43, title XV, § 1503, June 10, 1993, 107 Stat. 178; amended Pub. L. 105-392, title IV, § 411, Nov. 13, 1998, 112 Stat. 3590; Pub. L. 106-505, title III, § 304, Nov. 13, 2000, 114 Stat. 2335; Pub. L. 109-482, title I, § 103(b)(41), Jan. 15, 2007, 120 Stat. 3688, which related to construction of regional centers for research on primates, was renumbered section 404J of act July 1, 1944, by Pub. L. 112-74, div. F, title II, § 221(b)(2)(A), Dec. 23, 2011, 125 Stat. 1088, and transferred to section 283l of this title.

Section 287a-3a, July 1, 1944, ch. 373, title IV, § 481C, as added Pub. L. 106-551, § 2, Dec. 20, 2000, 114 Stat. 2752; amended Pub. L. 110-170, § 2(a), Dec. 26, 2007, 121 Stat. 2465, which related to sanctuary system for surplus chimpanzees, was renumbered section 404K of act July 1, 1944, by Pub. L. 112-74, div. F, title II, § 221(b)(3)(A), Dec. 23, 2011, 125 Stat. 1088, and transferred to section 283m of this title.

A prior section 481C of act July 1, 1944, was renumbered section 481B of act July 1, 1944, and is classified to section 287a-4 of this title.