

[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 [this chapter] 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.”

### § 283i. 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) of this section 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) of this section 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, §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.)

#### 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.

### § 283j. Review of centers of excellence

#### (a) In general

Not later than April 1, 2008, and periodically thereafter, the Secretary, acting through the Director of NIH, shall conduct a review and submit a report to the appropriate committees of the Congress on the centers of excellence.

#### (b) Report contents

Each report under subsection (a) shall include the following:

(1) Evaluation of the performance and research outcomes of each center of excellence.

(2) Recommendations for promoting coordination of information among centers of excellence.

(3) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

#### (c) Definition

In this section, the term “center of excellence” means an entity receiving funding under this subchapter in its capacity as a center of excellence.

(July 1, 1944, ch. 373, title IV, §404H, as added Pub. L. 109-416, §2(b), Dec. 19, 2006, 120 Stat. 2821.)

PART B—GENERAL PROVISIONS RESPECTING  
NATIONAL RESEARCH INSTITUTES

**§ 284. Directors of national research institutes**

**(a) Appointment**

The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.

**(b) Duties and authority; grants, contracts, and cooperative agreements**

(1) In carrying out the purposes of section 241 of this title with respect to human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

- (i) the maintenance of health,
- (ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,
- (iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 289a(b) of this title and any advisory council review under section 284a(a)(3)(A)(i) of this title, conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) may conduct and support research training (i) for which fellowship support is not provided under section 288 of this title, and (ii) which is not residency training of physicians or other health professionals;

(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(E) may develop, conduct, and support public and professional education and information programs;

(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of \$50,000, establish suitable memorials to the donor;

(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(K) may accept voluntary and uncompensated services; and

(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354 of title 10 shall apply with respect to contracts entered into under this subsection and section 282(b) of this title.

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 289a of this title;

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed \$50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds \$50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title and is recommended under section 284a(a)(3)(A)(ii) of this title by the advisory council for the national research institute involved; and

(C) shall, subject to section 300cc-40c(d)(2) of this title, receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

**(c) Coordination with other public and private entities; cooperation with other national research institutes; appointment of additional peer review groups**

In carrying out subsection (b) of this section, each Director of a national research institute—

(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute;

(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—