(B) Research

The Director of NIH shall, as appropriate, ensure that—

(i) each consortium receiving an award under subparagraph (A) conducts or supports at least one category of research described in subparagraph (A)(i) and collectively such consortia conduct or support such categories of research; and

(ii) one or more such consortia provide training described in subparagraph (A)(ii).

(C) Organization of consortium

Each consortium receiving an award under subparagraph (A) shall—

(i) be formed from a collaboration of cooperating institutions;

(ii) be coordinated by a lead institution or institutions;

(iii) agree to disseminate scientific findings, including from clinical trials, rapidly and efficiently, as appropriate, to—

(I) other consortia;

(II) the National Institutes of Health;

(III) the Food and Drug Administration;

(IV) and[1] other relevant agencies; and

(iv) meet such requirements as may be prescribed by the Director of NIH.

(D) Supplement, not supplant

Any support received by a consortium under subparagraph (A) shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported under this paragraph.

(E) Duration of support

Support of a consortium under subparagraph (A) may be for a period of not to exceed 5 years. Such period may be extended at the discretion of the Director of NIH.

(3) Coordination of consortia activities

The Director of NIH shall, as appropriate—

(A) provide for the coordination of activities (including the exchange of information and regular communication) among the consortia established pursuant to paragraph (2); and

(B) require the periodic preparation and submission to the Director of reports on the activities of each such consortium.

(4) Assistance with registries

Each consortium receiving an award under paragraph (2)(A) may provide assistance, as appropriate, to the Centers for Disease Control and Prevention for activities related to patient registries and other surveillance systems upon request by the Director of the Centers for Disease Control and Prevention.

(e) Research on pediatric rare diseases or conditions

In making awards under subsection (d)(2) for pediatric research consortia, the Director of NIH shall ensure that an appropriate number of such awards are awarded to such consortia that agree to—

(1) consider pediatric rare diseases or conditions, or those related to birth defects; and

(2) conduct or coordinate one or more multisite clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of one or more pediatric rare diseases or conditions.

(f) Transfer of funds

The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

(July 1, 1944, ch. 373, title IV, § 409D, as added Pub. L. 106–310, div. A, title X, § 1001, Oct. 17, 2000, 114 Stat. 1127; amended Pub. L. 109–482, title I, § 103(b)(10), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110–154, § 1(b)(4), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 113–55, title II, § 202, Nov. 27, 2013, 127 Stat. 644.)

CODIFICATION

Another section 409D of act July 1, 1944, was renumbered section 409H and is classified to section 284*l* of this title.

AMENDMENTS

2013—Subsecs. (d) to (f). Pub. L. 113–55 added subsecs. (d) and (e) and redesignated former subsec. (d) as (f).

2007—Subsec. (c)(1). Pub. L. 110–154 substituted ''Eunice Kennedy Shriver National Institute of Child Health and Human Development'' for ''National Institute of Child Health and Human Development''.

Subsecs. (d), (e). Pub. L. 109–482 redesignated subsec. (e) as (d) and struck out heading and text of former subsec. (d). Text read as follows: ''For the purpose of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.''

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.

§ 284i. Autoimmune diseases

(a) Expansion, intensification, and coordination of activities

(1) In general

The Director of NIH shall expand, intensify, and coordinate research and other activities of the National Institutes of Health with respect to autoimmune diseases.

(2) Allocations by Director of NIH

With respect to amounts appropriated to carry out this section for a fiscal year, the Director of NIH shall allocate the amounts among the national research institutes that are carrying out paragraph (1).

(3) Definition

The term ''autoimmune disease'' includes, for purposes of this section such diseases or disorders with evidence of autoimmune pathogensis[1] as the Secretary determines to be appropriate.

(b) Coordinating Committee

(1) In general

The Secretary shall ensure that the Autoimmune Diseases Coordinating Committee (re-

[1] So in original. The word ''and'' probably should appear at end of subcl. (III).

[1] So in original. Probably should be ''pathogenesis''.

ferred to in this section as the ''Coordinating Committee'') coordinates activities across the National Institutes and with other Federal health programs and activities relating to such diseases.

(2) Composition

The Coordinating Committee shall be composed of the directors or their designees of each of the national research institutes involved in research with respect to autoimmune diseases and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention and the Food and Drug Administration.

(3) Chair

(A) In general

With respect to autoimmune diseases, the Chair of the Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and other relevant agencies.

(B) Director of NIH

The Chair of the Committee shall be directly responsible to the Director of NIH.

(c) Plan for NIH activities

(1) In general

Not later than 1 year after October 17, 2000, the Coordinating Committee shall develop a plan for conducting and supporting research and education on autoimmune diseases through the national research institutes and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, psychosocial, and rehabilitative issues, including studies of the disproportionate impact of such diseases on women;

(B) identify priorities among the programs and activities of the National Institutes of Health regarding such diseases; and

(C) reflect input from a broad range of scientists, patients, and advocacy groups.

(2) Certain elements of plan

The plan under paragraph (1) shall, with respect to autoimmune diseases, provide for the following as appropriate:

(A) Research to determine the reasons underlying the incidence and prevalence of the diseases.

(B) Basic research concerning the etiology and causes of the diseases.

(C) Epidemiological studies to address the frequency and natural history of the diseases, including any differences among the sexes and among racial and ethnic groups.

(D) The development of improved screening techniques.

(E) Clinical research for the development and evaluation of new treatments, including new biological agents.

(F) Information and education programs for health care professionals and the public.

(3) Implementation of plan

The Director of NIH shall ensure that programs and activities of the National Institutes of Health regarding autoimmune diseases are implemented in accordance with the plan under paragraph (1).

(July 1, 1944, ch. 373, title IV, § 409E, as added Pub. L. 106–310, div. A, title XIX, § 1901, Oct. 17, 2000, 114 Stat. 1153; amended Pub. L. 109–482, title I, §§ 103(b)(11), 104(b)(1)(E), Jan. 15, 2007, 120 Stat. 3687, 3693.)

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482, § 104(b)(1)(E), struck out heading and text of subsec. (d). Text read as follows: ''The Coordinating Committee under subsection (b)(1) of this section shall biennially submit to the Committee on Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate, a report that describes the research, education, and other activities on autoimmune diseases being conducted or supported through the national research institutes, and that in addition includes the following:

''(1) The plan under subsection (c)(1) of this section (or revisions to the plan, as the case may be).

''(2) Provisions specifying the amounts expended by the National Institutes of Health with respect to each of the autoimmune diseases included in the plan.

''(3) Provisions identifying particular projects or types of projects that should in the future be considered by the national research institutes or other entities in the field of research on autoimmune diseases.''

Subsec. (e). Pub. L. 109–482, § 103(b)(11), 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 may be necessary for each of the fiscal years 2001 through 2005. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to autoimmune diseases.''

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.

§ 284j. Muscular dystrophy research

(a) Coordination of activities

The Director of NIH shall expand and increase coordination in the activities of the National Institutes of Health with respect to research on muscular dystrophies, including Duchenne muscular dystrophy.

(b) Administration of program; collaboration among agencies

The Director of NIH shall carry out this section through the appropriate institutes, including the National Institute of Neurological Disorders and Stroke and in collaboration with any other agencies that the Director determines appropriate.

(July 1, 1944, ch. 373, title IV, § 409F, as added Pub. L. 106–310, div. A, title XXII, § 2201, Oct. 17, 2000, 114 Stat. 1157; amended Pub. L. 109–482, title I, § 103(b)(12), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (c). Pub. L. 109–482 struck out heading and text of subsec. (c). Text read as follows: ''There are