(iii) on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

(6) Report

The Secretary shall ensure that recommendations and actions taken by the Director with respect to the topics discussed at the meetings described in paragraph (4) are included in appropriate reports to Congress.

(7) Review

The Secretary shall review the necessity of the Committee at least once every 2 years.

(July 1, 1944, ch. 373, title IV, § 409J, as added Pub. L. 111–148, title IV, § 4305(b), Mar. 23, 2010, 124 Stat. 585; amended Pub. L. 115–271, title VII, § 7042, Oct. 24, 2018, 132 Stat. 4016.)

AMENDMENTS

2018—Subsec. (b)(5)(A). Pub. L. 115–271, § 7042(1)(A), substituted ''treatment, and management of pain and diseases and disorders associated with pain, including information on best practices for the utilization of nonpharmacologic treatments, non-addictive medical products, and other drugs or devices approved or cleared by the Food and Drug Administration'' for ''and treatment of pain and diseases and disorders associated with pain''.

Subsec. (b)(5)(B). Pub. L. 115–271, § 7042(1)(B), substituted ''on—'' and cls. (i) to (iii) for ''on the symptoms and causes of pain;''.

Subsec. (b)(5)(C) to (E). Pub. L. 115–271, § 7042(1)(C), added subpar. (C) and struck out former subpars. (C) to (E) which read as follows:

''(C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

''(D) make recommendations on how best to disseminate information on pain care; and

''(E) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.''

Subsec. (b)(6), (7). Pub. L. 115–271, § 7042(2), (3), added par. (6) and redesignated former par. (6) as (7).

§ 284q–1. NIH opioid research

(a) In general

The Director of the National Institutes of Health (referred to in this section as the ''NIH'') may intensify and coordinate fundamental, translational, and clinical research of the NIH with respect to—

(1) the understanding of pain;

(2) the discovery and development of therapies for chronic pain; and

(3) the development of alternatives to opioids for effective pain treatments.

(b) Priority and direction

The prioritization and direction of the Federally funded portfolio of pain research studies shall consider recommendations made by the Interagency Pain Research Coordinating Committee in concert with the Pain Management Best Practices Inter-Agency Task Force, and in accordance with the National Pain Strategy, the Federal Pain Research Strategy, and the NIH-Wide Strategic Plan for Fiscal Years 2016–2020, the latter of which calls for the relative burdens of individual diseases and medical disorders to be regarded as crucial considerations in balancing the priorities of the Federal research portfolio.

(Pub. L. 114–198, title I, § 108, July 22, 2016, 130 Stat. 705.)

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Public Health Service Act which comprises this chapter.

§ 284r. Basic research

(1) Developing policies

Not later than 2 years after December 13, 2016, the Director of the National Institutes of Health (referred to in this section as the ''Director of the National Institutes of Health''), taking into consideration the recommendations developed under section 2039,[1] shall develop policies for projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

(2) Revising policies

The Director of the National Institutes of Health may update or revise the policies developed under paragraph (1) as appropriate.

(3) Consultation and outreach

In developing, updating, or revising the policies under this section, the Director of the National Institutes of Health shall—

(A) consult with—

(i) the Office of Research on Women's Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback on when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

(4) Additional requirements

The Director of the National Institutes of Health shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(Pub. L. 114–255, div. A, title II, § 2038(g), Dec. 13, 2016, 130 Stat. 1066.)

REFERENCES IN TEXT

Section 2039, referred to in par. (1), is section 2039 of Pub. L. 114–255, which is set out as a note under section 282 of this title.

[1] See References in Text note below.

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 284s. Tick-borne diseases

(a) In general

The Secretary of Health and Human Services (referred to in this section as ''the Secretary'') shall continue to conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases.

(b) Reports

The Secretary shall ensure that each triennial report under section 283 of this title (as amended by section 2032) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to tick-borne diseases.

(c) Tick-Borne Diseases Working Group

(1) Establishment

The Secretary shall establish a working group, to be known as the Tick-Borne Disease Working Group (referred to in this section as the ''Working Group''), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

(2) Responsibilities

The working group shall—

(A) not later than 2 years after December 13, 2016, develop or update a summary of—

(i) ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;

(ii) advances made pursuant to such research;

(iii) Federal activities related to tick-borne diseases, including—

(I) epidemiological activities related to tick-borne diseases; and

(II) basic, clinical, and translational tick-borne disease research related to the pathogenesis, prevention, diagnosis, and treatment of tick-borne diseases;

(iv) gaps in tick-borne disease research described in clause (iii)(II);

(v) the Working Group's meetings required under paragraph (4); and

(vi) the comments received by the Working Group;

(B) make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and

(C) solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

(3) Membership

The members of the working group shall represent a diversity of scientific disciplines and views and shall be composed of the following members:

(A) Federal members

Seven Federal members, consisting of one or more representatives of each of the following:

(i) The Office of the Assistant Secretary for Health.

(ii) The Food and Drug Administration.

(iii) The Centers for Disease Control and Prevention.

(iv) The National Institutes of Health.

(v) Such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

(B) Non–Federal public members

Seven non–Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

(4) Meetings

The Working Group shall meet not less than twice each year.

(5) Reporting

Not later than 2 years after December 13, 2016, and every 2 years thereafter until termination of the Working Group pursuant to paragraph (7), the Working Group shall—

(A) submit a report on its activities under paragraph (2)(A) and any recommendations under paragraph (2)(B) to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) make such report publicly available on the Internet website of the Department of Health and Human Services.

(6) Applicability of FACA

The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(7) Sunset

The Working Group under this section shall terminate 6 years after December 13, 2016.

(Pub. L. 114–255, div. A, title II, § 2062, Dec. 13, 2016, 130 Stat. 1079.)

REFERENCES IN TEXT

Section 2032, referred to in subsec. (b), means section 2032 of Pub. L. 114–255.