

114TH CONGRESS
2D SESSION

S. 3431

To coordinate and advance fibrosis research activities at the National Institutes of Health, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28, 2016

Mrs. GILLIBRAND (for herself and Mr. SCHUMER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To coordinate and advance fibrosis research activities at the National Institutes of Health, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Scleroderma and Fi-
5 brosis Research Enhancement Act of 2016”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) Scleroderma, or systemic sclerosis, is a
9 chronic and potentially fatal rheumatic autoimmune
10 disease of the connective tissue.

1 (2) About 100,000 Americans have systemic
2 sclerosis, which causes fibrosis (very similar to scar-
3 ring where excess connective tissue is created). The
4 symptoms of scleroderma vary greatly for each per-
5 son, and the effects of scleroderma can range from
6 very mild to life-threatening. The seriousness of
7 scleroderma depends on the parts of the body that
8 are affected and the extent to which they are af-
9 fected.

10 (3) Nearly 45 percent of all deaths in the devel-
11 oped world are attributed to some type of chronic
12 fibroproliferative disease. As scleroderma impacts
13 multiple organ systems, systemic sclerosis can be
14 considered as a prototypical disease for study, and
15 any insights into its causes are likely to be applica-
16 ble more broadly to other forms of organ fibrosis
17 and fibrotic illnesses (such as pulmonary fibrosis
18 and liver fibrosis).

19 (4) Various institutes and centers of the Na-
20 tional Institutes of Health currently support re-
21 search into forms of fibrotic illness, but there is little
22 coordination and limited cross-cutting opportunity
23 between these research portfolios. Much scientific
24 progress will be gained by taking a broad, collabo-
25 rative, and systematic approach to studying fibrosis.

1 **SEC. 3. NATIONAL COMMISSION ON SCLERODERMA AND FI-**
2 **BROSIS RESEARCH.**

3 (a) ESTABLISHMENT.—Not later than 1 year after
4 the date of enactment of this Act, the Director of the Na-
5 tional Institute of Arthritis and Musculoskeletal and Skin
6 Diseases, acting jointly with the Director of the National
7 Institutes of Health, shall establish a National Commis-
8 sion on Scleroderma and Fibrosis Research (in this section
9 referred to as the “Commission”) to develop the long-term
10 plan under subsection (b).

11 (b) LONG-TERM PLAN.—

12 (1) IN GENERAL.—Not later than 18 months
13 after the date of establishment of the Commission,
14 the Commission shall develop and submit to Con-
15 gress a long-term plan on opportunities and chal-
16 lenges in scleroderma and fibrosis research.

17 (2) RECOMMENDATIONS ON RESEARCH OPPOR-
18 TUNITIES.—The plan under paragraph (1) shall in-
19 clude recommendations on relevant research oppor-
20 tunities over the next decade, including—

21 (A) a comprehensive research plan which
22 prioritizes fibrosis research opportunities that
23 have cross-cutting value and require coordina-
24 tion across multiple institutes and centers of
25 the National Institutes of Health;

1 (B) topic-specific research recommenda-
2 tions for each organ or system; and

3 (C) an overview of common themes and
4 specific steps for implementation of scleroderma
5 and fibrosis research.

6 (c) WORKING GROUPS.—The Commission shall es-
7 tablish working groups—

8 (1) to consider the various organs and systems
9 impacted by fibrotic illness; and

10 (2) to formulate the topic-specific research rec-
11 ommendations under subsection (b)(2)(B).

12 (d) MEMBERSHIP.—The Commission shall be com-
13 posed of—

14 (1) the Director of the National Institute of Ar-
15 thritis and Musculoskeletal and Skin Diseases (or
16 the Director's representative);

17 (2) a representative of the Office of the Direc-
18 tor of the National Institutes of Health who can pro-
19 vide input on program coordination across the insti-
20 tutes and centers of the National Institutes of
21 Health;

22 (3) staff from institutes and centers of the Na-
23 tional Institutes of Health, as determined appro-
24 priate; and

1 (4) non-Federal medical experts and patient ad-
2 vocates representing the various manifestations of
3 scleroderma and fibrosis, as determined necessary to
4 form effective working groups under subsection (c).

5 (e) TERMINATION.—The Commission shall terminate
6 not later than 2 years after the date of its establishment.

7 **SEC. 4. SCLERODERMA AND FIBROSIS WORKING GROUP.**

8 (a) ESTABLISHMENT.—Not later than 180 days after
9 the development and dissemination of the long-term plan
10 under section 3(b), the Director of the National Institute
11 of Arthritis and Musculoskeletal and Skins Diseases shall
12 create a working group, to be known as the Scleroderma
13 and Fibrosis Working Group (in this section referred to
14 as the “Working Group”).

15 (b) RESPONSIBILITIES.—The Working Group shall—

16 (1) oversee and assist with the implementation
17 of the recommendations and research opportunities
18 identified in the long-term plan under section 3(b);

19 (2) coordinate with the Office of the Director of
20 the National Institutes of Health and the various in-
21 stitutes and centers of the National Institutes of
22 Health as appropriate to oversee and assist with
23 such implementation; and

1 (3) report, as needed, to the advisory council of
2 the National Institute of Arthritis and Musculo-
3 skeletal and Skin Diseases.

4 (c) MEMBERSHIP.—The Working Group shall be
5 composed of—

6 (1) representatives of the institutes and centers
7 at the National Institutes of Health with active or
8 planned research projects in scleroderma or fibrosis,
9 particularly staff who are serving or have served on
10 the National Commission on Scleroderma and Fibro-
11 sis Research under section 3; and

12 (2) patient advocates and extramural research-
13 ers who can provide meaningful input on the rec-
14 ommendations and research opportunities identified
15 in the long-range plan under section 3(b), particu-
16 larly individuals who are serving or have served on
17 the National Commission on Scleroderma and Fibro-
18 sis Research under section 3.

19 (d) MEETINGS.—The Director of the National Insti-
20 tute of Arthritis and Musculoskeletal and Skin Diseases
21 shall convene the Working Group for a meeting at least
22 3 times each year.

23 **SEC. 5. REPORT TO CONGRESS.**

24 Not later than 2 years after the date of establishment
25 of the National Commission on Scleroderma and Fibrosis

1 Research under section 3, the Director of the National In-
2 stitute of Arthritis and Musculoskeletal and Skin Diseases
3 shall submit to Congress a report on implementation of
4 the long-range plan under section 3(b).

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