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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

To expand the research, prevention, and awareness activities of the Centers for Disease Control and Prevention and the National Institutes of Health with respect to pulmonary fibrosis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. PAULSEN (for himself and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on _____

A BILL

To expand the research, prevention, and awareness activities of the Centers for Disease Control and Prevention and the National Institutes of Health with respect to pulmonary fibrosis, 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 “Pulmonary Fibrosis
5 Research Enhancement Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1 (1) Pulmonary fibrosis (in this section referred
2 to as “PF”) is a relentlessly progressive, ultimately
3 fatal disease that affects the lungs, gradually rob-
4 bing a person of the ability to breathe.

5 (2) More than 200,000 individuals may be liv-
6 ing with PF in the United States, 48,000 individuals
7 in the United States are diagnosed with PF annu-
8 ally, and as many as 40,000 die annually.

9 (3) Prevalence of PF has increased more than
10 150 percent since 2001, and is expected to continue
11 rising.

12 (4) The median survival rate for a person with
13 PF is 2.8 years.

14 (5) The cause of PF is not well understood, and
15 in most cases is unknown, though there is growing
16 evidence that one cause of PF may be environmental
17 or occupational exposure to pollutants.

18 (6) There is no Food and Drug Administration-
19 approved treatment or cure for PF.

20 (7) Public awareness of PF remains low com-
21 pared to rare diseases of lesser prevalence, despite
22 PF’s increasing prevalence.

23 (8) There has been no federally funded national
24 awareness or educational effort to improve under-
25 standing of PF in the public or medical commu-

1 nities, though nonprofit patient education and re-
2 search groups have begun to increase awareness.
3 The first Federal legislation expressing Congress's
4 support for PF research, H. Con. Res. 182, was
5 agreed to by both Houses of Congress in 2007.

6 **SEC. 3. PULMONARY FIBROSIS ADVISORY BOARD AND REG-**
7 **ISTRY.**

8 Part B of title III of the Public Health Service Act
9 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
10 tion 317T the following:

11 **“SEC. 317U. PULMONARY FIBROSIS ADVISORY BOARD AND**
12 **REGISTRY.**

13 “(a) ADVISORY BOARD.—

14 “(1) ESTABLISHMENT.—Not later than 90 days
15 after the date of the enactment of this section, the
16 Secretary, acting through the Director of the Cen-
17 ters for Disease Control and Prevention, shall estab-
18 lish a board to be known as the National Pulmonary
19 Fibrosis Advisory Board (in this section referred to
20 as the ‘Advisory Board’). The Advisory Board shall
21 be composed of at least one member, to be appointed
22 by the Secretary, acting through the Director of the
23 Centers for Disease Control and Prevention, rep-
24 resenting each of the following:

25 “(A) The National Institutes of Health.

1 “(B) The National Institute of Environ-
2 mental Health Sciences.

3 “(C) The Department of Veterans Affairs.

4 “(D) The Agency for Toxic Substances
5 and Disease Registry.

6 “(E) The Centers for Disease Control and
7 Prevention.

8 “(F) Patients with PF or their family
9 members and other individuals with an interest
10 in developing and maintaining the National PF
11 Registry.

12 “(G) Patient advocates, including organi-
13 zations representing such advocates.

14 “(H) Clinicians with expertise on PF and
15 related diseases.

16 “(I) Epidemiologists with experience work-
17 ing with data registries.

18 “(J) Geneticists or experts in genetics who
19 have experience with the genetics of PF or
20 other interstitial lung diseases.

21 “(2) DUTIES.—The Advisory Board shall—

22 “(A) review information and make rec-
23 ommendations to the Secretary concerning—

24 “(i) the development and maintenance
25 of the National PF Registry;

1 “(ii) the type of information to be col-
2 lected and stored in the National PF Reg-
3 istry;

4 “(iii) the manner in which such data
5 is to be collected;

6 “(iv) the use and availability of such
7 data, including guidelines for such use; and

8 “(v) the collection of information
9 about diseases and disorders that primarily
10 affect the lungs that are considered essen-
11 tial to furthering the study and cure of
12 PF; and

13 “(B) consult with the Director of the Cen-
14 ters for Disease Control and Prevention regard-
15 ing preparation of the National Pulmonary Fi-
16 brosis Education and Awareness Plan under
17 section 4(a) of the Pulmonary Fibrosis Re-
18 search Enhancement Act.

19 “(3) REPORT.—Not later than 1 year after the
20 date of enactment of this section, the Advisory
21 Board shall submit to the Secretary, the Committee
22 on Energy and Commerce of the House of Rep-
23 resentatives, and the Health, Education, Labor, and
24 Pensions Committee of the Senate a report on the
25 review conducted under paragraph (2), including the

1 recommendations of the Advisory Board resulting
2 from such review.

3 “(b) ESTABLISHMENT OF REGISTRY.—

4 “(1) IN GENERAL.—Not later than 1 year after
5 the receipt of the report required by subsection
6 (a)(3), the Secretary, acting through the Director of
7 the Centers for Disease Control and Prevention and
8 in consultation with patients, patient advocates, and
9 others with expertise in research and care of pul-
10 monary fibrosis (referred to in this section as ‘PF’),
11 shall—

12 “(A) develop a system to collect data on
13 PF and other interstitial lung diseases that are
14 related to PF, including information with re-
15 spect to the incidence and prevalence of the dis-
16 ease in the United States; and

17 “(B) establish a national registry (in this
18 section referred to as the ‘National PF Reg-
19 istry’) that—

20 “(i) is used for the collection and stor-
21 age of data described in subparagraph (A);
22 and

23 “(ii) includes a population-based reg-
24 istry of cases in the United States of PF

1 and other interstitial lung diseases that are
2 related to PF.

3 “(2) PURPOSE.—The purpose of the National
4 PF Registry shall be to gather available data con-
5 cerning—

6 “(A) PF, including the incidence and prev-
7 alence of PF in the United States;

8 “(B) environmental and occupational fac-
9 tors that may be associated with the disease;

10 “(C) age, race or ethnicity, gender, and
11 family history of individuals who are diagnosed
12 with the disease;

13 “(D) pathogenesis of PF; and

14 “(E) other matters as determined appro-
15 priate by the Secretary.

16 “(c) COORDINATION WITH STATE, LOCAL, AND FED-
17 ERAL REGISTRIES.—

18 “(1) IN GENERAL.—In establishing the Na-
19 tional PF Registry under subsection (b), the Sec-
20 retary shall—

21 “(A) identify, build upon, expand, and co-
22 ordinate among existing data and surveillance
23 systems, surveys, registries, and other Federal
24 public health and environmental infrastructure
25 wherever possible, including—

1 “(i) existing systems in place at uni-
2 versities, medical centers, and government
3 agencies;

4 “(ii) State-based PF registries, Na-
5 tional Institutes of Health registries, and
6 Department of Veterans Affairs registries,
7 as available; and

8 “(iii) any other relevant databases
9 that collect or maintain information on in-
10 terstitial lung diseases; and

11 “(B) provide for research access to PF
12 data in accordance with applicable statutes and
13 regulations, including those protecting personal
14 privacy.

15 “(2) COORDINATION WITH NIH AND DEPART-
16 MENT OF VETERANS AFFAIRS.—Consistent with ap-
17 plicable privacy statutes and regulations, the Sec-
18 retary shall ensure that epidemiological and other
19 types of information obtained under subsection (b) is
20 made available to the National Institutes of Health
21 and the Department of Veterans Affairs.”.

22 **SEC. 4. NATIONAL PULMONARY FIBROSIS EDUCATION AND**
23 **AWARENESS PLAN.**

24 (a) IN GENERAL.—

1 (1) PREPARATION OF PLAN.—The Director of
2 the Centers for Disease Control and Prevention, in
3 consultation with the National Pulmonary Fibrosis
4 Advisory Board established under section 317U of
5 the Public Health Service Act, as added by section
6 3 of this Act, shall prepare a comprehensive plan (in
7 this section referred to as the “National Pulmonary
8 Fibrosis Education and Awareness Plan”).

9 (2) REPORT TO CONGRESS.—Not later than one
10 year after the date of the enactment of this Act, and
11 at the same time as the report is submitted under
12 section 317U(a)(3) of the Public Health Service Act,
13 the Director of the Centers for Disease Control and
14 Prevention shall submit the National Pulmonary Fi-
15 brosis Education and Awareness Plan to the Com-
16 mittee on Energy and Commerce and the Committee
17 on Appropriations of the House of Representatives
18 and to the Committee on Health, Education, Labor,
19 and Pensions and the Committee on Appropriations
20 of the Senate.

21 (b) CONTENT.—The National Pulmonary Fibrosis
22 Education and Awareness Plan shall—

23 (1) focus on strategies to increase public edu-
24 cation and awareness of pulmonary fibrosis;

1 (2) accelerate patient education strategies, with
2 respect to pulmonary fibrosis, nationwide;

3 (3) address the need for new physician edu-
4 cation strategies to improve diagnosis and treatment
5 standards with respect to pulmonary fibrosis;

6 (4) assess and monitor the costs of pulmonary
7 fibrosis and its burden on patients and families; and

8 (5) develop such strategies in partnership with
9 patients, patient advocates, and others with exper-
10 tise in research and care of pulmonary fibrosis.

11 **SEC. 5. PULMONARY FIBROSIS RESEARCH EXPANSION.**

12 Subpart 2 of part C of title IV of the Public Health
13 Service Act (42 U.S.C. 285b et seq.) is amended by insert-
14 ing after section 424C the following:

15 **“SEC. 424D. PULMONARY FIBROSIS RESEARCH EXPANSION.**

16 “The Director of the Institute is encouraged to ex-
17 pand, intensify, and coordinate the activities of the Insti-
18 tute with respect to research on pulmonary fibrosis, as ap-
19 propriate.”.