

111TH CONGRESS  
1ST SESSION

# H. R. 1079

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.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2009

Mr. BAIRD (for himself, Mr. CASTLE, Mr. DEAL of Georgia, Mr. DICKS, Mr. GERLACH, Ms. HARMAN, Ms. KAPTUR, Mr. KIRK, Mr. LATOURETTE, Ms. ZOE LOFGREN of California, Mr. SPACE, Mr. TIERNEY, and Mr. YOUNG of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 128,000 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 as the population of the United States ages.

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

14          (5) More than 50 percent of PF cases are ini-  
15          tially misdiagnosed as other forms of respiratory ill-  
16          ness before being correctly diagnosed as PF, and  
17          more than 58 percent of patients go more than a  
18          year with symptoms before being diagnosed cor-  
19          rectly.

20          (6) The cause of most forms of PF is not well  
21          understood, and in most cases is unknown, though  
22          there is growing evidence that one cause of PF may  
23          be environmental or occupational exposure to pollut-  
24          ants.

1           (7) There is no Food and Drug Administration-  
2           approved treatment or cure for PF.

3           (8) Public awareness of PF remains low com-  
4           pared to rare diseases of lesser prevalence, despite  
5           PF's increasing prevalence.

6           (9) There has been no federally funded national  
7           awareness or educational effort to improve under-  
8           standing of PF in the public or medical commu-  
9           nities, though nonprofit patient education and re-  
10          search groups have begun to increase awareness.  
11          The first Federal legislation expressing Congress'  
12          support for PF research, H. Con. Res. 182, was  
13          agreed to by both Houses of Congress in 2007.

14   **SEC. 3. PULMONARY FIBROSIS REGISTRY.**

15          Part B of title III of the Public Health Service Act  
16   (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
17   tion 317T the following:

18   **“SEC. 317U. PULMONARY FIBROSIS REGISTRY.**

19          “(a) ESTABLISHMENT.—

20               “(1) IN GENERAL.—Not later than 1 year after  
21   the receipt of the report required by subsection  
22   (b)(3), the Secretary, acting through the Director of  
23   the Centers for Disease Control and Prevention and  
24   in consultation with patients, patient advocates, and  
25   others with expertise in research and care of pul-

1 monary fibrosis (referred to in this section as ‘PF’),  
2 shall—

3 “(A) develop a system to collect data on  
4 PF and other interstitial lung diseases that are  
5 related to PF, including information with re-  
6 spect to the incidence and prevalence of the dis-  
7 ease in the United States; and

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

11 “(i) is used for the collection and stor-  
12 age of data described in subparagraph (A);  
13 and

14 “(ii) includes a population-based reg-  
15 istry of cases in the United States of PF  
16 and other interstitial lung diseases that are  
17 related to PF.

18 “(2) PURPOSE.—The purpose of the National  
19 PF Registry shall be to gather available data con-  
20 cerning—

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

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

1           “(C) age, race or ethnicity, gender, and  
2           family history of individuals who are diagnosed  
3           with the disease;

4           “(D) pathogenesis of PF; and

5           “(E) other matters as determined appro-  
6           priate by the Secretary.

7           “(3) IMPLEMENTATION.—Implementation of  
8           the National PF Registry shall begin not later than  
9           180 days after the date of the enactment of this sec-  
10          tion.

11          “(b) ADVISORY BOARD.—

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

23           “(A) The National Institutes of Health.

24           “(B) The National Institute of Environ-  
25           mental Health Sciences.

1 “(C) The Department of Veterans Affairs.

2 “(D) The Agency for Toxic Substances  
3 and Disease Registry.

4 “(E) The Centers for Disease Control and  
5 Prevention.

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

10 “(G) Patient Advocates.

11 “(H) Clinicians with expertise on PF and  
12 related diseases.

13 “(I) Epidemiologists with experience work-  
14 ing with data registries.

15 “(J) Geneticists or experts in genetics who  
16 have experience with the genetics of PF or  
17 other neurological diseases.

18 “(K) Others with expertise in research and  
19 care of PF.

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

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

23 “(i) the development and maintenance  
24 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 Action Plan under section 5(a) of the  
17 Pulmonary Fibrosis Research Enhancement  
18 Act.

19 “(3) REPORT.—Not later than 1 year after the  
20 date on which the Advisory Board is established, the  
21 Advisory Board shall submit to the Secretary, the  
22 Committee on Energy and Commerce of the House  
23 of Representatives, and the Health, Education,  
24 Labor, and Pensions Committee of the Senate a re-  
25 port on the review conducted under paragraph (2),

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

3 “(c) GRANTS.—The Secretary, acting through the  
4 Director of the Centers for Disease Control and Preven-  
5 tion, may award grants to, and enter into contracts and  
6 cooperative agreements with, public or private nonprofit  
7 entities for the collection, analysis, and reporting of data  
8 on PF and other interstitial lung diseases that can be con-  
9 fused with PF, be misdiagnosed as PF, and in some cases  
10 progress to PF.

11 “(d) COORDINATION WITH STATE, LOCAL, AND FED-  
12 ERAL REGISTRIES.—

13 “(1) IN GENERAL.—In establishing the Na-  
14 tional PF Registry under subsection (a), the Sec-  
15 retary shall—

16 “(A) identify, build upon, expand, and co-  
17 ordinate among existing data and surveillance  
18 systems, surveys, registries, and other Federal  
19 public health and environmental infrastructure  
20 wherever possible, including—

21 “(i) existing systems in place at uni-  
22 versities, medical centers, and government  
23 agencies;

24 “(ii) State-based PF registries, Na-  
25 tional Institutes of Health registries, and



1 Department of Veterans Affairs registries,  
2 as available; and

3 “(iii) any other relevant databases  
4 that collect or maintain information on in-  
5 terstitial lung diseases; and

6 “(B) provide for research access to PF  
7 data in accordance with applicable statutes and  
8 regulations, including those protecting personal  
9 privacy.

10 “(2) COORDINATION WITH NIH AND DEPART-  
11 MENT OF VETERANS AFFAIRS.—Consistent with ap-  
12 plicable privacy statutes and regulations, the Sec-  
13 retary shall ensure that epidemiological and other  
14 types of information obtained under subsection (a) is  
15 made available to the National Institutes of Health  
16 and the Department of Veterans Affairs.

17 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
18 are authorized to be appropriated to carry out this section  
19 \$5,000,000 for fiscal year 2010 and \$2,500,000 for each  
20 of the fiscal years 2011 through 2014.”.

21 **SEC. 4. PULMONARY FIBROSIS RESEARCH EXPANSION.**

22 Subpart 2 of part C of title IV of the Public Health  
23 Service Act (42 U.S.C. 285b et seq.) is amended by adding  
24 at the end the following:

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

2       “The Director of the Institute is encouraged to ex-  
3 pand, intensify, and coordinate the activities of the Insti-  
4 tute with respect to research on pulmonary fibrosis, as ap-  
5 propriate.”.

6 **SEC. 5. NATIONAL PULMONARY FIBROSIS ACTION PLAN.**

7       (a) IN GENERAL.—

8           (1) PREPARATION OF PLAN.—The Director of  
9 the Centers for Disease Control and Prevention, in  
10 consultation with the National Pulmonary Fibrosis  
11 Advisory Board established under section 317U of  
12 the Public Health Service Act, as added by section  
13 3 of this Act, shall prepare a comprehensive plan (in  
14 this section referred to as the “National Pulmonary  
15 Fibrosis Action Plan”).

16           (2) REPORT TO CONGRESS.—Not later than one  
17 year after the date of the enactment of this Act, the  
18 Director of the Centers for Disease Control and Pre-  
19 vention shall submit the National Pulmonary Fibro-  
20 sis Action Plan to the Committee on Energy and  
21 Commerce and the Committee on Appropriations of  
22 the House of Representatives and to the Committee  
23 on Health, Education, Labor, and Pensions and the  
24 Committee on Appropriations of the Senate.

25       (b) CONTENT.—The National Pulmonary Fibrosis  
26 Action Plan shall—

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

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

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

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

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

13          (c) AUTHORIZATION OF APPROPRIATIONS.—There  
14          are authorized to be appropriated to carry out this section  
15          \$1,000,000 for fiscal year 2010.

16          **SEC. 6. NATIONAL SUMMIT.**

17          (a) IN GENERAL.—Not later than one year after the  
18          date of the enactment of this Act, and every three years  
19          thereafter, the Secretary of Health and Human Services  
20          shall convene a summit of researchers, representatives of  
21          academic institutions, Federal and State policymakers,  
22          public health professionals, and patients, patient advo-  
23          cates, and others with expertise in research and care of  
24          pulmonary fibrosis to provide a detailed overview of cur-  
25          rent research activities at the National Institutes of

1 Health, as well as to discuss and solicit input related to  
2 potential areas of collaboration between the National In-  
3 stitutes of Health and other Federal health agencies, in-  
4 cluding the Centers for Disease Control and Prevention,  
5 related to research, prevention, and treatment of pul-  
6 monary fibrosis.

7 (b) FOCUS AREAS.—The summit convened under  
8 subsection (a) shall focus on—

9 (1) a broad range of research activities relating  
10 to the epidemiology and pathogenesis of pulmonary  
11 fibrosis;

12 (2) clinical research for the development and  
13 evaluation of treatments for pulmonary fibrosis;

14 (3) translational research on evidence-based and  
15 cost-effective best practices in the treatment, preven-  
16 tion, and management of pulmonary fibrosis;

17 (4) information and education programs on pul-  
18 monary fibrosis for health care professionals and the  
19 public;

20 (5) priorities among the programs and activities  
21 of the various Federal agencies regarding pulmonary  
22 fibrosis; and

23 (6) challenges and opportunities relating to pul-  
24 monary fibrosis for scientists, clinicians, patients,  
25 and patient advocates.

1       (c) REPORT TO CONGRESS.—Not later than 180 days  
2 after the first day that the summit convenes under this  
3 section, the Director of the National Institutes of Health  
4 shall prepare and submit to the Committee on Energy and  
5 Commerce of the House of Representatives and the Com-  
6 mittee on Health, Education, Labor, and Pensions of the  
7 Senate a report that includes a summary of the pro-  
8 ceedings of the summit and a description of pulmonary  
9 fibrosis research, education, and other activities that are  
10 conducted or supported through the national research in-  
11 stitutes of the National Institutes of Health.

12       (d) PUBLIC INFORMATION.—The Secretary of Health  
13 and Human Services shall make readily available to the  
14 public information about the research, education, and  
15 other activities relating to pulmonary fibrosis and other  
16 related diseases conducted or supported by the National  
17 Institutes of Health.

