

110TH CONGRESS
2D SESSION

H. R. 6567

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

JULY 22, 2008

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

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 317S the following:

18 **“SEC. 317T. 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 2009 and \$2,500,000 for each
20 of the fiscal years 2010 through 2013.”.

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. 424C. 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 317T 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 2009.

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.

