

110TH CONGRESS
1ST SESSION

H. R. 3368

To amend the Public Health Service Act to establish a pulmonary hypertension clinical research network, to expand pulmonary hypertension research and training, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 3, 2007

Mr. LANTOS (for himself and Mr. BRADY of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act to establish a pulmonary hypertension clinical research network, to expand pulmonary hypertension research and training, 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 Hyper-
5 tension Research and Education Act of 2007”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) Pulmonary hypertension is a serious and
2 often fatal condition where the blood pressure in the
3 lungs rises to dangerously high levels. In pulmonary
4 hypertension patients, the walls of the arteries that
5 take blood from the right side of the heart to the
6 lungs thicken and constrict. As a result, the right
7 side of the heart has to pump harder to move blood
8 into the lungs, causing it to enlarge and ultimately
9 fail.

10 (2) In order to take full advantage of the tre-
11 mendous potential for finding a cure or effective
12 treatment, the Federal investment in pulmonary hy-
13 pertension must be expanded, and collaboration
14 among top pulmonary hypertension research centers
15 must be increased.

16 (3) Pulmonary hypertension remains a difficult
17 diagnosis and is rarely picked up in a routine med-
18 ical examination. Even in its later stages, the signs
19 of the disease can be confused with other conditions
20 affecting the heart and lungs. The use of new diag-
21 nostic standards has been positively related to the
22 rates of diagnosis.

23 (4) In the more advanced stages of pulmonary
24 hypertension, the patient is able to perform only
25 minimal activity and has symptoms even when rest-

1 ing, resulting in considerable disability. The disease
2 may worsen to the point where the patient is com-
3 pletely bedridden.

4 (5) In 1981, the National Heart, Lung, and
5 Blood Institute established the first pulmonary hy-
6 pertension patient registry in the world. The registry
7 followed 194 people with pulmonary hypertension
8 over a period of at least one year and, in some cases,
9 more than seven years. Much of what is known
10 about the illness today stems from this study.

11 (6) Because the cause of pulmonary hyper-
12 tension is still not fully understood and there is still
13 not a cure for pulmonary hypertension, basic re-
14 search studies are focusing on the possible involve-
15 ment of immunologic and genetic factors in the
16 cause and progression of pulmonary hypertension,
17 looking at agents that cause narrowing of the pul-
18 monary blood vessels, and identifying factors that
19 cause growth of endothelial and smooth muscle cells,
20 and formation of scar tissue in the vessel walls.

21 (7) As research progresses, so do treatments for
22 pulmonary hypertension. Currently, there are six
23 FDA-approved medications for pulmonary hyper-
24 tension and several more in trials. However, not all
25 medications are effective in all patients. In addition,

1 all pulmonary hypertension treatments have signifi-
2 cant negative side effects that impact patients' qual-
3 ity of life. Lung transplantation is often considered
4 a treatment of last resort for pulmonary hyper-
5 tension.

6 (8) The number of physicians who treat pul-
7 monary hypertension, and the number of pulmonary
8 hypertension patients receiving treatment, has grown
9 exponentially over the past decade, leading to the
10 need for increased education of medical profes-
11 sionals. In 2001, there were 100 identified physi-
12 cians treating pulmonary hypertension, and 3,000
13 patients receiving treatment. In 2006, there were an
14 estimated 3,000 such physicians and 30,000 such
15 patients. While pulmonary hypertension treatment
16 now includes the option of relatively easy to admin-
17 ister oral therapies, effective management of pul-
18 monary hypertension remains complicated. Given the
19 increase in the number of physicians treating pul-
20 monary hypertension, education of medical profes-
21 sionals about pulmonary hypertension management
22 is critical to ensure optimal patient care.

23 (9) In December 2006, the National Heart,
24 Lung, and Blood Institute hosted a landmark meet-
25 ing of pulmonary hypertension researchers and clini-

1 cians throughout the world. Over 500 individuals at-
 2 tended, making this the largest such meeting orga-
 3 nized by a Federal department for this disease. Dur-
 4 ing the meeting, there was clear consensus that com-
 5 munication among researchers is key to future ad-
 6 vancement in the fight against this devastating and
 7 expensive disease.

8 **SEC. 3. PULMONARY HYPERTENSION CLINICAL RESEARCH**
 9 **NETWORK; EXPANSION OF PULMONARY HY-**
 10 **PERTENSION RESEARCH AND TRAINING.**

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

14 “PULMONARY HYPERTENSION
 15 “SEC. 424C.

16 “(a) IN GENERAL.—The Director of the Institute
 17 shall expand, intensify, and coordinate the activities of the
 18 Institute with respect to research on pulmonary hyper-
 19 tension.

20 “(b) ESTABLISHMENT OF PULMONARY HYPER-
 21 TENSION CLINICAL RESEARCH NETWORK.—

22 “(1) Not later than one year after the date of
 23 the enactment of this section, the Director of the In-
 24 stitute shall establish a Pulmonary Hypertension
 25 Clinical Research Network (in this section referred
 26 to as the ‘network’). The purpose of the network

1 shall be to conduct multiple clinical trials to evaluate
2 new treatment approaches for pulmonary hyper-
3 tension and facilitate collaboration among investiga-
4 tors with expertise in pulmonary hypertension. The
5 network shall consist of the following:

6 “(A) No fewer than 15 clinical centers des-
7 ignated by the Director.

8 “(B) An institute project scientist, as de-
9 fined and appointed by the Director.

10 “(C) A data and coordinating center, as
11 defined and appointed by the Director.

12 “(D) A data and safety monitoring board,
13 as defined and appointed by the Director.

14 “(E) A steering committee comprised of
15 the principal investigators from each clinical
16 center described under subparagraph (A), the
17 data and coordinating center described in sub-
18 paragraph (C), and the institute project sci-
19 entist described in subparagraph (B).

20 “(F) An independent protocol review com-
21 mittee, as defined and appointed by the Direc-
22 tor.

23 “(2) STEERING COMMITTEE.—The steering
24 committee described in paragraph (1)(E) shall deter-
25 mine the specific clinical trials to be performed

1 under this section, establish standards for subject
2 selection and characterization for such trials, develop
3 detailed protocols for such trials, and analyze and
4 publish the results of such trials. Possible clinical
5 trials shall include:

6 “(A) Combination therapies for pulmonary
7 hypertension.

8 “(B) New avenues of drug therapy based
9 on recognized cellular defects in pulmonary hy-
10 pertension that are not impacted by current
11 treatment.

12 “(C) Use of endothelial progenitor cells for
13 replacement of abnormal pulmonary vascular
14 cells in pulmonary hypertension.

15 “(D) Discovery of treatment effects which
16 are most predictive of long-term outcome.

17 “(3) PROGRAM MANAGEMENT; APPOINT-
18 MENTS.—

19 “(A) IN GENERAL.—The Institute shall be
20 responsible for organizing and providing sup-
21 port for the network.

22 “(B) INSTITUTE PROJECT SCIENTIST.—
23 The institute project scientist appointed under
24 paragraph (1)(B) shall—

1 “(i) monitor the recruitment of sub-
2 jects for the trials and the progress of the
3 trials;

4 “(ii) ensure disclosure of conflicts of
5 interest and adherence of the conduct of
6 the clinical trials to the policies of the In-
7 stitute; and

8 “(iii) conduct, with the institute
9 grants management specialist described in
10 subparagraph (C), the fiscal management
11 of the network.

12 “(C) INSTITUTE MANAGEMENT SPE-
13 CIALIST.—An institute grants management spe-
14 cialist (as defined and appointed by the Direc-
15 tor) shall assist the institute project scientist in
16 conducting the fiscal management of the net-
17 work under subparagraph (B)(iii).

18 “(D) ADDITIONAL APPOINTMENTS.—The
19 Director shall appoint the Chair of the steering
20 committee described in paragraph (1)(E) and
21 all members of the protocol review committee
22 under paragraph (1)(F) and the data safety
23 monitoring board under paragraph (1)(D).

24 “(c) PULMONARY HYPERTENSION PRECEPTORSHIP
25 AND TRAINING PROGRAM.—

1 “(1) IN GENERAL.—Not later than one year
2 after the date of the enactment of this section, the
3 Director of the Institute shall carry out a grant pro-
4 gram under which the Director makes a grant to (or
5 enters into a contract with) a national nonprofit en-
6 tity with expertise in pulmonary hypertension to es-
7 tablish and administer a national Pulmonary Hyper-
8 tension Preceptorship and Training Program (in this
9 section referred to as the ‘program’).

10 “(2) PURPOSE.—The program shall facilitate
11 the direct education and training of medical profes-
12 sionals (including cardiologists, pulmonologists,
13 rheumatologists, and primary care physicians) by ex-
14 perienced pulmonary hypertension specialists in clin-
15 ical settings. The purpose of the program is to in-
16 crease the number of physicians in the United States
17 trained to effectively diagnosis, treat, and manage
18 pulmonary hypertension.

19 “(3) REGIONAL TRAINING SITES.—To carry out
20 the purpose of the program described in paragraph
21 (2), the entity awarded the grant (or contract) under
22 paragraph (1) shall under the program facilitate the
23 creation of no fewer than five regional training sites
24 across the United States at academic health centers,

1 hospitals, or private medical practices recognized for
2 their expertise in pulmonary hypertension.

3 “(4) REGIONAL SITE CONTACTS.—Under the
4 program—

5 “(A) each regional training site shall iden-
6 tify a site contact; and

7 “(B) the Director shall specify a percent-
8 age of the grant funds required to be allocated
9 for purposes of providing each such site contact
10 with a stipend.

11 “(5) PARTICIPANT RECRUITMENT AND PRO-
12 GRAM GUIDELINES.—The nonprofit entity awarded
13 the grant (or contract) under paragraph (1) shall es-
14 tablish mechanisms for identifying and enrolling in-
15 terested health professionals in the program. The
16 nonprofit entity shall also work with the regional
17 training sites under paragraph (3) and the Institute
18 to establish model guidelines for the program.

19 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
20 purpose of carrying out this section, there are authorized
21 to be appropriated such sums as may be necessary for
22 each of the fiscal years 2009 through 2012.”.

1 **SEC. 4. INCREASING PUBLIC AWARENESS OF PULMONARY**
2 **HYPERTENSION.**

3 (a) PULMONARY HYPERTENSION EDUCATION PRO-
4 GRAM.—The Secretary of Health and Human Services,
5 acting through the Director of the Centers for Disease
6 Control and Prevention, shall develop and disseminate to
7 the public information regarding pulmonary hypertension,
8 including materials on—

9 (1) basic information on pulmonary hyper-
10 tension and its symptoms;

11 (2) the incidence and prevalence of pulmonary
12 hypertension;

13 (3) diseases and conditions that can lead to pul-
14 monary hypertension as a secondary diagnosis;

15 (4) the importance of early diagnosis; and

16 (5) the availability, as medically appropriate, of
17 a range of treatment options and pulmonary hyper-
18 tension.

19 (b) DISSEMINATION OF INFORMATION.—The Sec-
20 retary of Health and Human Services shall disseminate
21 information under subsection (a) through arrangements
22 with a national non-profit entity with expertise in pul-
23 monary hypertension.

24 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
25 purpose of carrying out this section, there are authorized

1 to be appropriated such sums as may be necessary for
2 each of the fiscal years 2009 through 2012.

3 **SEC. 5. DISSEMINATION OF INFORMATION TO HEALTH**
4 **PROFESSIONALS ON PULMONARY HYPER-**
5 **TENSION.**

6 (a) DISSEMINATION OF INFORMATION.—The Sec-
7 retary of Health and Human Services, acting through the
8 Administrator of the Health Resources and Services Ad-
9 ministration and the Director of the Centers for Disease
10 Control and Prevention, shall develop and disseminate to
11 health care providers information on pulmonary hyper-
12 tension for the purpose of ensuring that providers remain
13 informed about the disease, its presenting symptoms, and
14 current treatment options. Such information shall include
15 material on the warning signs of pulmonary hypertension,
16 the importance of early diagnosis, diagnostic criteria, and
17 therapies approved by the Food and Drug Administration
18 for the disease. Such health care providers shall include
19 cardiologists, pulmonologists, rheumatologists, primary
20 care physicians, pediatricians, and nurse practitioners.

21 (b) DISSEMINATION OF INFORMATION.—The Sec-
22 retary of Health and Human Services shall disseminate
23 information under subsection (a) through arrangements
24 with a national non-profit entity with expertise in pul-
25 monary hypertension.

1 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated such sums as may be necessary for
4 each of the fiscal years 2009 through 2012.

5 **SEC. 6 STUDY BY GOVERNMENT ACCOUNTABILITY OFFICE**
6 **ON MEDICARE AND MEDICAID COVERAGE**
7 **STANDARDS.**

8 (a) IN GENERAL.—The Comptroller General of the
9 United States shall conduct a study on the coverage stand-
10 ards that, under the Medicare program under title XVIII
11 of the Social Security Act and the Medicaid program
12 under title XIX of such Act, apply to individuals with pul-
13 monary hypertension. The study shall detail coverage
14 standards under such programs for all therapies approved
15 by the Food and Drug Administration for the treatment
16 of pulmonary hypertension. The study shall take into ac-
17 count appropriate outpatient or home health care delivery
18 settings for delivery of such services.

19 (b) REPORT.—Not later than six months after the
20 date of the enactment of this Act, the Comptroller General
21 shall submit to Congress a report describing the findings
22 of the study under subsection (a).

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