

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 3005

To amend the Public Health Service Act to provide for the expansion, intensification, and coordination of the activities of the National Heart, Lung, and Blood Institute with respect to research on pulmonary hypertension.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2005

Mr. BRADY of Texas (for himself, Mr. LANTOS, Mr. BLUNT, and Mr. HOYER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to provide for the expansion, intensification, and coordination of the activities of the National Heart, Lung, and Blood Institute with respect to research on pulmonary hypertension.

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 Act of 2005”.

6       **SEC. 2. FINDINGS.**

7       The Congress finds as follows:

1           (1) In order to take full advantage of the tre-  
2           mendous potential for finding a cure or effective  
3           treatment, the Federal investment in pulmonary hy-  
4           pertension must be expanded, and coordination  
5           among the national research institutes of the Na-  
6           tional Institutes of Health must be strengthened.

7           (2) Pulmonary hypertension is a serious and  
8           often fatal condition where the blood pressure in the  
9           lungs rises to dangerously high levels. In PH pa-  
10          tients, the walls of the arteries that take blood from  
11          the right side of the heart to the lungs thicken and  
12          constrict. As a result, the right side of the heart has  
13          to pump harder to move blood into the lungs, caus-  
14          ing it to enlarge and ultimately fail.

15          (3) In the United States it has been estimated  
16          that 300 new cases of PPH are diagnosed each year,  
17          or about two persons per million population per  
18          year; the greatest number are reported in women be-  
19          tween the ages of 21 and 40. While at one time the  
20          disease was thought to occur among young women  
21          almost exclusively; we now know, however, that men  
22          and women in all age ranges, from very young chil-  
23          dren to elderly people, can develop PPH. It also af-  
24          fects people of all racial and ethnic origins with Afri-

1 can Americans suffering from a mortality rate twice  
2 as high as that affecting Caucasians.

3 (4) The low prevalence of PPH makes learning  
4 more about the disease extremely difficult. Studies  
5 of PPH also have been difficult because a good ani-  
6 mal model of the disease has not been available.

7 (5) In about 6 to 10 percent of cases, PPH is  
8 familial. The familial PPH gene is located on chro-  
9 mosome 2 and was discovered in July 2000. This  
10 discovery provided new insights for determining the  
11 molecular basis of PPH and opened new avenues of  
12 study for understanding the fundamental nature of  
13 the disease.

14 (6) In the more advanced stages of PPH, the  
15 patient is able to perform only minimal activity and  
16 has symptoms even when resting. The disease may  
17 worsen to the point where the patient is completely  
18 bedridden.

19 (7) PPH remains a diagnosis of exclusion and  
20 is rarely picked up in a routine medical examination.  
21 Even in its later stages, the signs of the disease can  
22 be confused with other conditions affecting the heart  
23 and lungs. The use of new diagnostic standards has  
24 been positively related to the rates of diagnosis.

1           (8) In 1981, the National Heart, Lung, and  
2           Blood Institute established the first PPH-patient  
3           registry in the world. The registry followed 194 peo-  
4           ple with PPH over a period of at least 1 year and,  
5           in some cases, for as long as 7.5 years. Much of  
6           what we know about the illness today stems from  
7           this study.

8           (9) As research progresses, so do treatments for  
9           PH. Currently, there are four FDA-approved medi-  
10          cations for PH and three more in trials. However,  
11          all medications not are affective on all patients.  
12          Lung transplantation is often considered a treat-  
13          ment of last resort for PH.

14          (10) Because we still do not understand the  
15          cause or have a cure for PPH, basic research studies  
16          are focusing on the possible involvement of  
17          immunologic and genetic factors in the cause and  
18          progression of PPH, looking at agents that cause  
19          narrowing of the pulmonary blood vessels, and iden-  
20          tifying factors that cause growth of smooth muscle  
21          and formation of scar tissue in the vessel walls.

22          (11) Secondary pulmonary hypertension  
23          (“SPH”) means the cause is known. Common  
24          causes of SPH are the breathing disorders emphy-  
25          sema and bronchitis. Other less frequent causes are

1 the inflammatory or collagen vascular diseases such  
2 as scleroderma, CREST syndrome or systemic lupus  
3 erythematosus (“SLE”). Other causes include con-  
4 genital heart diseases that cause shunting of extra  
5 blood through the lungs like ventricular and atrial  
6 septal defects, chronic pulmonary thromboembolism,  
7 HIV infection, and liver disease. Sickle cell anemia  
8 is also linked to SPH with preliminary studies sug-  
9 gesting that approximately one third of sickle cell  
10 patients develop SPH.

11 **SEC. 3. EXPANSION, INTENSIFICATION, AND COORDINA-**  
12 **TION OF ACTIVITIES OF NATIONAL HEART,**  
13 **LUNG, AND BLOOD INSTITUTE WITH RESPECT**  
14 **TO RESEARCH ON PULMONARY HYPER-**  
15 **TENSION.**

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

19 “PULMONARY HYPERTENSION

20 “SEC. 424C. (a) IN GENERAL.—

21 “(1) EXPANSION OF ACTIVITIES.—The Director  
22 of the Institute shall expand, intensify, and coordi-  
23 nate the activities of the Institute with respect to re-  
24 search on pulmonary hypertension.

25 “(2) COORDINATION WITH OTHER INSTI-  
26 TUTES.—The Director of the Institute shall coordi-

1 nate the activities of the Director under paragraph  
2 (1) with similar activities conducted by other na-  
3 tional research institutes and agencies of the Na-  
4 tional Institutes of Health to the extent that such  
5 Institutes and agencies have responsibilities that are  
6 related to pulmonary hypertension.

7 “(b) CENTERS OF EXCELLENCE.—

8 “(1) IN GENERAL.—In carrying out subsection  
9 (a), the Director of the Institute shall make grants  
10 to, or enter into contracts with, public or nonprofit  
11 private entities for the development and operation of  
12 centers to conduct research on pulmonary hyper-  
13 tension.

14 “(2) RESEARCH, TRAINING, AND INFORMATION  
15 AND EDUCATION.—

16 “(A) IN GENERAL.—With respect to pul-  
17 monary hypertension, each center assisted  
18 under paragraph (1) shall—

19 “(i) conduct basic and clinical re-  
20 search into the cause, diagnosis, early de-  
21 tection, prevention, control, and treatment  
22 of such disease;

23 “(ii) conduct training programs for  
24 scientists and health professionals;

1                   “(iii) conduct programs to provide in-  
2                   formation and continuing education to  
3                   health professionals; and

4                   “(iv) conduct programs for the dis-  
5                   semination of information to the public.

6                   “(B) STIPENDS FOR TRAINING OF HEALTH  
7                   PROFESSIONALS.—A center under paragraph  
8                   (1) may use funds under such paragraph to  
9                   provide stipends for scientists and health pro-  
10                  fessionals enrolled in programs described in  
11                  subparagraph (A)(ii).

12                  “(3) COORDINATION OF CENTERS; REPORTS.—  
13                  The Director shall, as appropriate, provide for the  
14                  coordination of information among centers under  
15                  paragraph (1) and ensure regular communication  
16                  between such centers, and may require the periodic  
17                  preparation of reports on the activities of the centers  
18                  and the submission of the reports to the Director.

19                  “(4) ORGANIZATION OF CENTERS.—Each cen-  
20                  ter under paragraph (1) shall use the facilities of a  
21                  single institution, or be formed from a consortium of  
22                  cooperating institutions, meeting such requirements  
23                  as may be prescribed by the Director.

24                  “(5) NUMBER OF CENTERS; DURATION OF SUP-  
25                  PORT.—The Director shall, subject to the extent of

1 amounts made available in appropriations Acts, pro-  
2 vide for the establishment of not less than three cen-  
3 ters under paragraph (1). Support of such a center  
4 may be for a period not exceeding 5 years. Such pe-  
5 riod may be extended for one or more additional pe-  
6 riods not exceeding 5 years if the operations of such  
7 center have been reviewed by an appropriate tech-  
8 nical and scientific peer review group established by  
9 the Director and if such group has recommended to  
10 the Director that such period should be extended.

11 “(c) DATA SYSTEM; CLEARINGHOUSE.—

12 “(1) DATA SYSTEM.—The Director of the Insti-  
13 tute shall establish a data system for the collection,  
14 storage, analysis, retrieval, and dissemination of  
15 data derived from patient populations with pul-  
16 monary hypertension, including where possible, data  
17 involving general populations for the purpose of  
18 identifying individuals at risk of developing such  
19 condition.

20 “(2) CLEARINGHOUSE.—The Director of the  
21 Institute shall establish an information clearinghouse  
22 to facilitate and enhance, through the effective dis-  
23 semination of information, knowledge and under-  
24 standing of pulmonary hypertension by health pro-  
25 fessionals, patients, industry, and the public.

1       “(d) PUBLIC INPUT.—In carrying out subsection (a),  
2 the Director of the Institute shall provide for means  
3 through which the public can obtain information on the  
4 existing and planned programs and activities of the Na-  
5 tional Institutes of Health with respect to primary hyper-  
6 tension and through which the Director can receive com-  
7 ments from the public regarding such programs and ac-  
8 tivities.

9       “(e) REPORTS.—The Director of the Institute shall  
10 prepare biennial reports on the activities conducted and  
11 supported under this section, and shall include such re-  
12 ports in the biennial reports prepared by the Director  
13 under section 407.

14       “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
15 purpose of carrying out this section, there is authorized  
16 to be appropriated \$50,000,000 for each of the fiscal years  
17 2006 through 2010.”.

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