

108TH CONGRESS
1ST SESSION

H. R. 1316

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.

IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 2003

Mr. BRADY of Texas introduced the following bill; which was referred to the Committee on Energy and Commerce

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 2003”.

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) Primary, or unexplained, pulmonary hyper-
8 tension (“PPH”) is a rare lung disorder which oc-
9 curs for no apparent reason. It has been historically
10 chronic and incurable with a poor survival rate.

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

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

1 (5) In about 6 to 10 percent of cases, PPH is
2 familial.

3 (6) In the more advanced stages of PPH, the
4 patient is able to perform only minimal activity and
5 has symptoms even when resting. The disease may
6 worsen to the point where the patient is completely
7 bedridden.

8 (7) PPH remains a diagnosis of exclusion and
9 is rarely picked up in a routine medical examination.
10 Even in its later stages, the signs of the disease can
11 be confused with other conditions affecting the heart
12 and lungs.

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

20 (9) Because we still do not understand the
21 cause or have a cure for PPH, basic research studies
22 are focusing on the possible involvement of
23 immunologic and genetic factors in the cause and
24 progression of PPH, looking at agents that cause
25 narrowing of the pulmonary blood vessels, and iden-

1 tifying factors that cause growth of smooth muscle
2 and formation of scar tissue in the vessel walls.

3 (10) During the period January 1996 through
4 December 1997 almost 6,000,000 Americans took
5 anorexic drugs, which can cause PPH in some peo-
6 ple. Thousands now have PPH and are in terminal
7 stages or have already succumbed to the disease. It
8 is anticipated that many more cases of PPH from
9 diet drugs will be diagnosed within the coming years.

10 (11) Secondary pulmonary hypertension
11 (“SPH”) means the cause is known. Common
12 causes of SPH are the breathing disorders emphy-
13 sema and bronchitis. Other less frequent causes are
14 the inflammatory or collagen vascular diseases such
15 as scleroderma, CREST syndrome or systemic lupus
16 erythematosus (“SLE”). Other causes include con-
17 genital heart diseases that cause shunting of extra
18 blood through the lungs like ventricular and atrial
19 septal defects, chronic pulmonary thromboembolism,
20 HIV infection, liver disease and certain diet drugs.

1 **SEC. 3. EXPANSION, INTENSIFICATION, AND COORDINA-**
2 **TION OF ACTIVITIES OF NATIONAL HEART,**
3 **LUNG, AND BLOOD INSTITUTE WITH RESPECT**
4 **TO RESEARCH ON PULMONARY HYPER-**
5 **TENSION.**

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

9 “PULMONARY HYPERTENSION

10 “SEC. 424C. (a) IN GENERAL.—

11 “(1) EXPANSION OF ACTIVITIES.—The Director
12 of the Institute shall expand, intensify, and coordi-
13 nate the activities of the Institute with respect to re-
14 search on pulmonary hypertension.

15 “(2) COORDINATION WITH OTHER INSTI-
16 TUTES.—The Director of the Institute shall coordi-
17 nate the activities of the Director under paragraph
18 (1) with similar activities conducted by other na-
19 tional research institutes and agencies of the Na-
20 tional Institutes of Health to the extent that such
21 Institutes and agencies have responsibilities that are
22 related to pulmonary hypertension.

23 “(b) CENTERS OF EXCELLENCE.—

24 “(1) IN GENERAL.—In carrying out subsection
25 (a), the Director of the Institute shall make grants
26 to, or enter into contracts with, public or nonprofit

1 private entities for the development and operation of
2 centers to conduct research on pulmonary hyper-
3 tension.

4 “(2) RESEARCH, TRAINING, AND INFORMATION
5 AND EDUCATION.—

6 “(A) IN GENERAL.—With respect to pul-
7 monary hypertension, each center assisted
8 under paragraph (1) shall—

9 “(i) conduct basic and clinical re-
10 search into the cause, diagnosis, early de-
11 tection, prevention, control, and treatment
12 of such disease;

13 “(ii) conduct training programs for
14 scientists and health professionals;

15 “(iii) conduct programs to provide in-
16 formation and continuing education to
17 health professionals; and

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

20 “(B) STIPENDS FOR TRAINING OF HEALTH
21 PROFESSIONALS.—A center under paragraph
22 (1) may use funds under such paragraph to
23 provide stipends for scientists and health pro-
24 fessionals enrolled in programs described in
25 subparagraph (A)(ii).

1 “(3) COORDINATION OF CENTERS; REPORTS.—

2 The Director shall, as appropriate, provide for the
3 coordination of information among centers under
4 paragraph (1) and ensure regular communication
5 between such centers, and may require the periodic
6 preparation of reports on the activities of the centers
7 and the submission of the reports to the Director.

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

13 “(5) NUMBER OF CENTERS; DURATION OF SUP-
14 PORT.—The Director shall, subject to the extent of
15 amounts made available in appropriations Acts, pro-
16 vide for the establishment of not less than three cen-
17 ters under paragraph (1). Support of such a center
18 may be for a period not exceeding 5 years. Such pe-
19 riod may be extended for one or more additional pe-
20 riods not exceeding 5 years if the operations of such
21 center have been reviewed by an appropriate tech-
22 nical and scientific peer review group established by
23 the Director and if such group has recommended to
24 the Director that such period should be extended.

25 “(c) DATA SYSTEM; CLEARINGHOUSE.—

1 “(1) DATA SYSTEM.—The Director of the Insti-
2 tute shall establish a data system for the collection,
3 storage, analysis, retrieval, and dissemination of
4 data derived from patient populations with pul-
5 monary hypertension, including where possible, data
6 involving general populations for the purpose of
7 identifying individuals at risk of developing such
8 condition.

9 “(2) CLEARINGHOUSE.—The Director of the
10 Institute shall establish an information clearinghouse
11 to facilitate and enhance, through the effective dis-
12 semination of information, knowledge and under-
13 standing of pulmonary hypertension by health pro-
14 fessionals, patients, industry, and the public.

15 “(d) PUBLIC INPUT.—In carrying out subsection (a),
16 the Director of the Institute shall provide for means
17 through which the public can obtain information on the
18 existing and planned programs and activities of the Na-
19 tional Institutes of Health with respect to primary hyper-
20 tension and through which the Director can receive com-
21 ments from the public regarding such programs and ac-
22 tivities.

23 “(e) REPORTS.—The Director of the Institute shall
24 prepare biennial reports on the activities conducted and
25 supported under this section, and shall include such re-

1 ports in the biennial reports prepared by the Director
2 under section 407.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated such sums as may be necessary up to
6 \$25,000,000 for each of the fiscal years 2004 through
7 2008. Such authorizations of appropriations are in addi-
8 tion to any other authorization of appropriations that is
9 available for such purpose.”.

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