

109TH CONGRESS
1ST SESSION

S. 1774

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 SENATE OF THE UNITED STATES

SEPTEMBER 27, 2005

Mr. CORNYN (for himself and Ms. MIKULSKI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 Congress finds the following:

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 (“PH”) is a seri-
8 ous and often fatal condition where the blood pres-
9 sure in the lungs rises to dangerously high levels. In
10 PH patients, the walls of the arteries that take
11 blood from the right side of the heart to the lungs
12 thicken and constrict. As a result, the right side of
13 the heart has to pump harder to move blood into the
14 lungs, causing 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 2 persons per million population per year;
18 the greatest number are reported in women between
19 the ages of 21 and 40. While at one time the disease
20 was thought to occur among young women almost
21 exclusively, we now know, however, that men and
22 women in all age ranges, from very young children
23 to elderly people, can develop PPH. It also affects
24 people of all racial and ethnic origins, with African

1 Americans suffering from a mortality rate twice as
2 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 4 FDA-approved medica-
 10 tions for PH and 3 more in trials. However, all
 11 medications are not effective on all patients. Lung
 12 transplantation is often considered a treatment of
 13 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. Sick 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 provided under such para-
9 graph to provide stipends for scientists and
10 health professionals enrolled in the programs
11 described in 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 3 centers
3 under paragraph (1). Support of such a center may
4 be for a period not exceeding 5 years. Such period
5 may be extended for 1 or more additional periods
6 not exceeding 5 years if—

7 “(A) the operations of such center have
8 been reviewed by an appropriate technical and
9 scientific peer review group established by the
10 Director; and

11 “(B) such group has recommended to the
12 Director that such period should be extended.

13 “(c) DATA SYSTEM; CLEARINGHOUSE.—

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

22 “(2) CLEARINGHOUSE.—The Director of the
23 Institute shall establish an information clearinghouse
24 to facilitate and enhance, through the effective dis-
25 semination of information, knowledge and under-

1 standing of pulmonary hypertension by health pro-
2 fessionals, patients, industry, and the public.

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

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

16 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
17 purpose of carrying out this section, there is authorized
18 to be appropriated \$50,000,000 for each of the fiscal years
19 2006 through 2010.”.

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