

108TH CONGRESS
2D SESSION

S. 2922

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

OCTOBER 7, 2004

Mr. CORNYN 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 2004”.

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-

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

(10) Secondary pulmonary hypertension (“SPH”) means the cause is known. Common causes of SPH are the breathing disorders emphysema and bronchitis. Other less frequent causes are the inflammatory or collagen vascular diseases such as scleroderma, CREST syndrome or systemic lupus erythematosus (“SLE”). Other causes include congenital heart diseases that cause shunting of extra blood through the lungs like ventricular and atrial septal defects, chronic pulmonary thromboembolism, HIV infection, liver disease and certain diet drugs.

SEC. 3. EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES OF NATIONAL HEART, LUNG, AND BLOOD INSTITUTE WITH RESPECT TO RESEARCH ON PULMONARY HYPERTENSION.

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

“PULMONARY HYPERTENSION

“SEC. 424C. (a) IN GENERAL.—

“(1) EXPANSION OF ACTIVITIES.—The Director of the Institute shall expand, intensify, and coordi-

1 nate the activities of the Institute with respect to re-
2 search on pulmonary hypertension.

3 “(2) COORDINATION WITH OTHER INSTI-
4 TUTES.—The Director of the Institute shall coordi-
5 nate the activities of the Director under paragraph
6 (1) with similar activities conducted by other na-
7 tional research institutes and agencies of the Na-
8 tional Institutes of Health to the extent that such
9 Institutes and agencies have responsibilities that are
10 related to pulmonary hypertension.

11 “(b) CENTERS OF EXCELLENCE.—

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

18 “(2) RESEARCH, TRAINING, AND INFORMATION
19 AND EDUCATION.—

20 “(A) IN GENERAL.—With respect to pul-
21 monary hypertension, each center assisted
22 under paragraph (1) shall—

23 “(i) conduct basic and clinical re-
24 search into the cause, diagnosis, early de-

tection, prevention, control, and treatment
of such disease;

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

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

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

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

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

“(4) ORGANIZATION OF CENTERS.—Each cen-
ter under paragraph (1) shall use the facilities of a
single institution, or be formed from a consortium of

1 cooperating institutions, meeting such requirements
2 as may be prescribed by the Director.

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

15 “(c) DATA SYSTEM; CLEARINGHOUSE.—

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

24 “(2) CLEARINGHOUSE.—The Director of the
25 Institute shall establish an information clearinghouse

1 to facilitate and enhance, through the effective dis-
2 semination of information, knowledge and under-
3 standing of pulmonary hypertension by health pro-
4 fessionals, patients, industry, and the public.

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

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

18 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
19 purpose of carrying out this section, there are authorized
20 to be appropriated such sums as may be necessary up to
21 \$25,000,000 for each of the fiscal years 2005 through
22 2009. Such authorizations of appropriations are in addi-
23 tion to any other authorization of appropriations that is
24 available for such purpose.”.

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