

111TH CONGRESS  
1ST SESSION

# S. 621

To amend the Public Health Service Act to coordinate Federal congenital heart disease research efforts and to improve public education and awareness of congenital heart disease, and for other purposes.

---

## IN THE SENATE OF THE UNITED STATES

MARCH 17, 2009

Mr. DURBIN (for himself and Mr. COCHRAN) 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 coordinate Federal congenital heart disease research efforts and to improve public education and awareness of congenital heart disease, 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 “Congenital Heart Fu-  
5       tures Act”.

6       **SEC. 2. FINDINGS.**

7       Congress finds the following:

1           (1) Congenital heart defects are the most com-  
2           mon and most deadly group of birth defects and af-  
3           fect nearly 1 percent of all live births, approximately  
4           36,000 births a year. A child is born with a con-  
5           genital heart defect every 15 minutes.

6           (2) Congenital heart disease is a rapidly grow-  
7           ing national health problem. Childhood survival has  
8           risen from below 20 percent in 1950 to more than  
9           90 percent today. Due to the increase in childhood  
10          survival, the congenital heart disease population in-  
11          creases by an estimated 5 percent every year.

12          (3) Approximately 800,000 children and  
13          1,000,000 adults in the United States are now living  
14          with congenital heart disease and require highly spe-  
15          cialized life-long cardiac care.

16          (4) There is no cure for congenital heart dis-  
17          ease. Even survivors of successful childhood treat-  
18          ment can face life-long risks from congenital heart  
19          disease, including heart failure, rhythmic disorders,  
20          stroke, renal dysfunction, and neurocognitive dys-  
21          function.

22          (5) Less than 10 percent of adults living with  
23          complex congenital heart disease currently receive  
24          recommended cardiac care. Many individuals with  
25          congenital heart disease are unaware that they re-

1       quire life-long specialized health surveillance. Delays  
2       in care can result in premature death and disability.

3           (6) The estimated life expectancy for those with  
4       congenital heart disease is significantly lower than  
5       for the general population. The life expectancy for  
6       those born with moderately complex heart defects is  
7       55, while the estimated life expectancy for those  
8       born with highly complex defects is between 35 and  
9       40.

10          (7) Despite the prevalence and seriousness of  
11       the disease, Federal research, data collection, edu-  
12       cation, and awareness activities are limited.

13          (8) The strategic plan of the National Heart,  
14       Lung, and Blood Institute completed in 2007 notes  
15       that “successes over several decades have enabled  
16       people with congenital heart diseases to live beyond  
17       childhood, but too often inadequate data are avail-  
18       able to guide their treatment as adults”.

19          (9) The strategic plan for the Division of Car-  
20       diovascular Diseases at the National Heart, Lung  
21       and Blood Institute, completed in 2008, set goals for  
22       congenital heart disease research, including under-  
23       standing the development and genetic basis of con-  
24       genital heart disease, improving evidence-based care  
25       and treatment of children with congenital and ac-

1       quired pediatric heart disease, and improving evi-  
 2       dence-based care and treatment of adults with con-  
 3       genital heart disease.

4   **SEC. 3. PUBLIC EDUCATION AND AWARENESS OF CON-**  
 5       **GENITAL HEART DISEASE.**

6       Title III of the Public Health Service Act (42 U.S.C.  
 7   241 et seq.) is amended by adding at the end the fol-  
 8   lowing:

9   **“PART S—PROGRAMS RELATING TO CONGENITAL**  
 10       **HEART DISEASE**

11   **“SEC. 399HH. PUBLIC EDUCATION AND AWARENESS OF**  
 12       **CONGENITAL HEART DISEASE.**

13       “(a) IN GENERAL.—The Secretary, acting through  
 14   the Director of the Centers for Disease Control and Pre-  
 15   vention and in collaboration with appropriate congenital  
 16   heart disease patient organizations and professional orga-  
 17   nizations, may directly or through grants, cooperative  
 18   agreements, or contracts to eligible entities conduct, sup-  
 19   port, and promote a comprehensive public education and  
 20   awareness campaign to increase public and medical com-  
 21   munity awareness regarding congenital heart disease, in-  
 22   cluding the need for life-long treatment of congenital heart  
 23   disease survivors.

24       “(b) ELIGIBILITY FOR GRANTS.—To be eligible to re-  
 25   ceive a grant, cooperative agreement, or contract under

1 this section, an entity shall be a State or private nonprofit  
 2 entity and shall submit to the Secretary an application at  
 3 such time, in such manner, and containing such informa-  
 4 tion as the Secretary may require.”.

5 **SEC. 4. NATIONAL CONGENITAL HEART DISEASE REGISTRY.**

6 Title III of the Public Health Service Act (42 U.S.C.  
 7 241 et seq.), as amended by section 3, is further amended  
 8 by adding at the end the following:

9 **“SEC. 399II. NATIONAL CONGENITAL HEART DISEASE REG-**  
 10 **ISTRY.**

11 “(a) IN GENERAL.—The Secretary, acting through  
 12 the Director of the Centers for Disease Control and Pre-  
 13 vention, may—

14 “(1) enhance and expand infrastructure to  
 15 track the epidemiology of congenital heart disease  
 16 and to organize such information into a comprehen-  
 17 sive, nationwide registry of actual occurrences of  
 18 congenital heart disease, to be known as the ‘Na-  
 19 tional Congenital Heart Disease Registry’; or

20 “(2) award a grant to one eligible entity to un-  
 21 dertake the activities described in paragraph (1).

22 “(b) PURPOSE.—The purpose of the Congenital  
 23 Heart Disease Registry shall be to facilitate further re-  
 24 search into the types of health services patients use and  
 25 to identify possible areas for educational outreach and pre-

1 vention in accordance with standard practices of the Cen-  
 2 ters for Disease Control and Prevention.

3 “(c) CONTENT.—The Congenital Heart Disease Reg-  
 4 istry—

5 “(1) may include information concerning the in-  
 6 cidence and prevalence of congenital heart disease in  
 7 the United States;

8 “(2) may be used to collect and store data on  
 9 congenital heart disease, including data con-  
 10 cerning—

11 “(A) demographic factors associated with  
 12 congenital heart disease, such as age, race, eth-  
 13 nicity, sex, and family history of individuals  
 14 who are diagnosed with the disease;

15 “(B) risk factors associated with the dis-  
 16 ease;

17 “(C) causation of the disease;

18 “(D) treatment approaches; and

19 “(E) outcome measures, such that analysis  
 20 of the outcome measures will allow derivation of  
 21 evidence-based best practices and guidelines for  
 22 congenital heart disease patients; and

23 “(3) may ensure the collection and analysis of  
 24 longitudinal data related to individuals of all ages  
 25 with congenital heart disease, including infants,

1       young children, adolescents, and adults of all ages,  
2       including the elderly.

3       “(d) COORDINATION WITH FEDERAL, STATE, AND  
4 LOCAL REGISTRIES.—In establishing the National Con-  
5 genital Heart Registry, the Secretary may identify, build  
6 upon, expand, and coordinate among existing data and  
7 surveillance systems, surveys, registries, and other Federal  
8 public health infrastructure, including—

9               “(1) State birth defects surveillance systems;

10              “(2) the State birth defects tracking systems of  
11 the Centers for Disease Control and Prevention;

12              “(3) the Metropolitan Atlanta Congenital De-  
13 fects Program; and

14              “(4) the National Birth Defects Prevention  
15 Network.

16       “(e) PUBLIC ACCESS.—The Congenital Heart Dis-  
17 ease Registry shall be made available to the public, includ-  
18 ing congenital heart disease researchers.

19       “(f) PATIENT PRIVACY.—The Secretary shall ensure  
20 that the Congenital Heart Disease Registry is maintained  
21 in a manner that complies with the regulations promul-  
22 gated under section 264 of the Health Insurance Port-  
23 ability and Accountability Act of 1996.

24       “(g) ELIGIBILITY FOR GRANT.—To be eligible to re-  
25 ceive a grant under subsection (a)(2), an entity shall—

1 “(1) be a public or private nonprofit entity with  
 2 specialized experience in congenital heart disease;  
 3 and

4 “(2) submit to the Secretary an application at  
 5 such time, in such manner, and containing such in-  
 6 formation as the Secretary may require.”.

7 **SEC. 5. ADVISORY COMMITTEE ON CONGENITAL HEART**  
 8 **DISEASE.**

9 Title III of the Public Health Service Act (42 U.S.C.  
 10 241 et seq.), as amended by section 4, is further amended  
 11 by adding at the end the following:

12 **“SEC. 399JJ. ADVISORY COMMITTEE ON CONGENITAL**  
 13 **HEART DISEASE.**

14 “(a) ESTABLISHMENT.—The Secretary, acting  
 15 through the Director of the Centers for Disease Control  
 16 and Prevention, may establish an advisory committee, to  
 17 be known as the ‘Advisory Committee on Congenital Heart  
 18 Disease’ (referred to in this section as the ‘Advisory Com-  
 19 mittee’).

20 “(b) MEMBERSHIP.—The members of the Advisory  
 21 Committee may be appointed by the Secretary, acting  
 22 through the Centers for Disease Control and Prevention,  
 23 and shall include—

24 “(1) at least one representative from—

25 “(A) the National Institutes of Health;



1           “(B) the Centers for Disease Control and  
2           Prevention; and

3           “(C) a national patient advocacy organiza-  
4           tion with experience advocating on behalf of pa-  
5           tients living with congenital heart disease;

6           “(2) at least one epidemiologist who has experi-  
7           ence working with data registries;

8           “(3) clinicians, including—

9           “(A) at least one with experience diag-  
10          nosing or treating congenital heart disease; and

11          “(B) at least one with experience using  
12          medical data registries; and

13          “(4) at least one publicly or privately funded re-  
14          searcher with experience researching congenital  
15          heart disease.

16          “(c) DUTIES.—The Advisory Committee may review  
17          information and make recommendations to the Secretary  
18          concerning—

19          “(1) the development and maintenance of the  
20          National Congenital Heart Disease Registry estab-  
21          lished under section 399II;

22          “(2) the type of data to be collected and stored  
23          in the National Congenital Heart Disease Registry;

24          “(3) the manner in which such data is to be  
25          collected;

1           “(4) the use and availability of such data, in-  
2           cluding guidelines for such use; and

3           “(5) other matters, as the Secretary determines  
4           to be appropriate.

5           “(d) REPORT.—Not later than 180 days after the  
6           date on which the Advisory Committee is established and  
7           annually thereafter, the Advisory Committee shall submit  
8           a report to the Secretary concerning the information de-  
9           scribed in subsection (c), including recommendations with  
10          respect to the results of the Advisory Committee’s review  
11          of such information.”.

12   **SEC. 6. CONGENITAL HEART DISEASE RESEARCH.**

13          Subpart 2 of part C of title IV of the Public Health  
14          Service Act (42 U.S.C. 285b et seq.) is amended by adding  
15          at the end the following:

16   **“SEC. 425. CONGENITAL HEART DISEASE.**

17          “(a) IN GENERAL.—The Director of the Institute  
18          may expand, intensify, and coordinate research and re-  
19          lated activities of the Institute with respect to congenital  
20          heart disease, which may include congenital heart disease  
21          research with respect to—

22                 “(1) causation of congenital heart disease, in-  
23                 cluding genetic causes;

1           “(2) long-term outcomes in individuals with  
 2           congenital heart disease, including infants, children,  
 3           teenagers, adults, and elderly individuals;

4           “(3) diagnosis, treatment, and prevention;

5           “(4) studies using longitudinal data and retro-  
 6           spective analysis to identify effective treatments and  
 7           outcomes for individuals with congenital heart dis-  
 8           ease; and

9           “(5) identifying barriers to life-long care for in-  
 10          dividuals with congenital heart disease.

11          “(b) COORDINATION OF RESEARCH ACTIVITIES.—

12       The Director of the Institute may coordinate research ef-  
 13       forts related to congenital heart disease among multiple  
 14       research institutions and may develop research networks.

15          “(c) MINORITY AND MEDICALLY UNDERSERVED  
 16       COMMUNITIES.—In carrying out the activities described in  
 17       this section, the Director of the Institute shall consider  
 18       the application of such research and other activities to mi-  
 19       nority and medically underserved communities.”.

20       **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

21       There are authorized to be appropriated to carry out  
 22       the amendments made by this Act such sums as may be  
 23       necessary for each of fiscal years 2010 through 2014.

