

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 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 “(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.

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