

111TH CONGRESS
1ST SESSION

S. _____

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

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on _____

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 congenial 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 of the National Heart,
20 Lung, and Blood Institute completed in 2007 sets
21 goals for congenital heart disease research, including
22 understanding the development and genetic basis of
23 congenital heart disease, improving evidence-based
24 care and treatment of children with congenital and
25 acquired pediatric heart disease, and improving evi-

1 dence-based care and treatment of adults with con-
2 genital heart disease.

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

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

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

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

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

23 “(b) ELIGIBILITY FOR GRANTS.—To be eligible to re-
24 ceive a grant under this section, an entity shall be a State
25 or private nonprofit entity and shall submit to the Sec-

1 retary an application at such time, in such manner, and
2 containing such information as the Secretary may re-
3 quire.”.

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

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

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

10 “(a) IN GENERAL.—Not later than 180 days after
11 the date of enactment of the Congenital Heart Futures
12 Act, the Secretary, acting through the Director of the Cen-
13 ters for Disease Control and Prevention, 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, which shall be known as
19 the ‘National 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 Congenital Heart Disease Reg-
23 istry shall be made available to congenital heart disease
24 researchers to facilitate further research into the types of
25 health services patients use and to identify possible areas

1 for educational outreach and prevention in accordance
2 with standard practices of the Centers for Disease Control
3 and Prevention.

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

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

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

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

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

18 “(C) causation of the disease;

19 “(D) treatment approaches; and

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

24 “(3) may ensure the collection and analysis of
25 longitudinal data related to individuals of all ages

1 with congenital heart disease, including infants,
2 young children, adolescents, and adults of all ages,
3 including the elderly.

4 “(d) COORDINATION WITH FEDERAL, STATE, AND
5 LOCAL REGISTRIES.—In establishing the National Con-
6 genital Heart Registry, the Secretary, acting through the
7 Director of the Centers for Disease Control and Preven-
8 tion may identify, build upon, expand, and coordinate
9 among existing data and surveillance systems, surveys,
10 registries, and other Federal public health infrastructure,
11 including—

12 “(1) State birth defects surveillance systems;

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

15 “(3) the Metropolitan Atlanta Congenital De-
16 fects Program; and

17 “(4) the National Birth Defects Prevention
18 Network.

19 “(e) PUBLIC ACCESS.—The Congenital Heart Dis-
20 ease Registry shall be made available to the public.

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

1 ability and Accountability Act of 1996 (Public Law 104-
2 191).

3 “(g) ELIGIBILITY FOR GRANT.—To be eligible to re-
4 ceive a grant under this section, an entity shall—

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

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

11 **SEC. 5. ADVISORY COMMITTEE ON CONGENITAL HEART**
12 **DISEASE.**

13 Title III of the Public Health Service Act (42 U.S.C.
14 241 et seq.), as amended by section 4, is further amended
15 by adding at the end the following:

16 **“SEC. 399JJ. ADVISORY COMMITTEE ON CONGENITAL**
17 **HEART DISEASE.**

18 “(a) ESTABLISHMENT.—Not later than 60 days after
19 the date of enactment of the Congenital Heart Futures
20 Act, the Secretary, acting through the Director of the Cen-
21 ters for Disease Control and Prevention, may establish an
22 advisory committee, to be known as the ‘Advisory Com-
23 mittee on Congenital Heart Disease’ (referred to in this
24 section as the ‘Advisory Committee’).

1 “(b) MEMBERSHIP.—Members of the Advisory Com-
2 mittee may be appointed by the Secretary, acting through
3 the Centers for Disease Control and Prevention, and shall
4 include—

5 “(1) at least one representative from—

6 “(A) the National Institutes of Health;

7 “(B) the Centers for Disease Control and
8 Prevention; and

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

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

14 “(3) clinicians, including—

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

17 “(B) at least one with experience using
18 medical data registries; and

19 “(4) at least one publicly- or privately-funded
20 researcher with experience researching congenital
21 heart disease.

22 “(c) DUTIES.—The Advisory Committee may review
23 information and make recommendations to the Secretary
24 concerning—

1 “(1) the development and maintenance of the
2 National Congenital Heart Disease Registry de-
3 scribed in section 399II;

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

6 “(3) the manner in which such data is to be
7 collected;

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

10 “(5) other matters, as the Secretary determines
11 to be appropriate.

12 “(d) REPORT.—Not later than 180 days after the
13 date on which the Advisory Committee is established and
14 annually thereafter, the Advisory Committee shall submit
15 a report to the Secretary concerning the information de-
16 scribed in subsection (c), including recommendations with
17 respect to the results of the Advisory Committee’s review
18 of such information.”.

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

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

23 “CONGENITAL HEART DISEASE

24 “SEC. 425.

25 “(a) IN GENERAL.—The Director of the Institute
26 may expand, intensify, and coordinate research and re-

1 lated activities of the Institute with respect to congenital
2 heart disease, which may include congenital heart disease
3 research with respect to—

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

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

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

10 “(4) studies using longitudinal data and retro-
11 spective analysis to identify effective treatments and
12 outcomes for individuals with congenital heart dis-
13 ease; and

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

16 “(b) COORDINATION OF RESEARCH ACTIVITIES.—
17 The Director of the Institute may coordinate research ef-
18 forts related to congenital heart disease among multiple
19 research institutions and may develop research networks.

20 “(c) MINORITY AND MEDICALLY UNDERSERVED
21 COMMUNITIES.—In carrying out the activities described in
22 this section, the Director of the Institute shall consider
23 the application of such research and other activities to mi-
24 nority and medically underserved communities.”.

1 SEC. 7. AUTHORIZATION.

2 There is authorized to be appropriated to carry out
3 the amendments made by this Act such sums as may be
4 necessary for each of fiscal years 2010 through 2014.