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:
Congenital heart defects are the most common and most deadly group of birth defects and affect nearly 1 percent of all live births, approximately 36,000 births a year. A child is born with a congenital heart defect every 15 minutes.

Congenital heart disease is a rapidly-growing national health problem. Childhood survival has risen from below 20 percent in 1950 to more than 90 percent today. Due to the increase in childhood survival, the congenital heart disease population increases by an estimated 5 percent every year.

Approximately 800,000 children and 1,000,000 adults in the United States are now living with congenital heart disease and require highly-specialized life-long cardiac care.

There is no cure for congenital heart disease. Even survivors of successful childhood treatment can face life-long risks from congenital heart disease, including heart failure, rhythmic disorders, stroke, renal dysfunction, and neurocognitive dysfunction.

Less than 10 percent of adults living with complex congenital heart disease currently receive recommended cardiac care. Many individuals with congenital heart disease are unaware that they re-
quire life-long specialized health surveillance. Delays in care can result in premature death and disability.

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

(7) Despite the prevalence and seriousness of the disease, Federal research, data collection, education, and awareness activities are limited.

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

(9) The strategic plan of the National Heart, Lung, and Blood Institute completed in 2007 sets goals for congenital heart disease research, including understanding the development and genetic basis of congenital heart disease, improving evidence-based care and treatment of children with congenital and acquired pediatric heart disease, and improving evi-
1 evidence-based care and treatment of adults with congenital heart disease.

3 SEC. 3. PUBLIC EDUCATION AND AWARENESS OF CONGENITAL HEART DISEASE.

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

8 “PART S—PROGRAMS RELATING TO CONGENITAL HEART DISEASE

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

12 “(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with appropriate congenital heart disease patient organizations and professional organizations, may directly or through grants, cooperative agreements, or contracts to eligible entities conduct, support, and promote a comprehensive public education and awareness campaign to increase public and medical community awareness regarding congenital heart disease, including the need for life-long treatment of congenital heart disease survivors.

19 “(b) ELIGIBILITY FOR GRANTS.—To be eligible to receive a grant under this section, an entity shall be a State or private nonprofit entity and shall submit to the Sec-
Secretary an application at such time, in such manner, and
containing such information as the Secretary may re-
quire.”.

SEC. 4. NATIONAL CONGENITAL HEART DISEASE REGISTRY.

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

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

“(a) In General.—Not later than 180 days after
the date of enactment of the Congenital Heart Futures
Act, the Secretary, acting through the Director of the Cen-
ters for Disease Control and Prevention, may—

“(1) enhance and expand infrastructure to
track the epidemiology of congenital heart disease
and to organize such information into a comprehen-
sive, nationwide registry of actual occurrences of
congenital heart disease, which shall be known as
the ‘National Congenital Heart Disease Registry’; or

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

“(b) Purpose.—The Congenital Heart Disease Reg-
istry shall be made available to congenital heart disease
researchers to facilitate further research into the types of
health services patients use and to identify possible areas
for educational outreach and prevention in accordance
with standard practices of the Centers for Disease Control
and Prevention.

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

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

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

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

“(B) risk factors associated with the dis-
case;

“(C) causation of the disease;

“(D) treatment approaches; and

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

“(3) may ensure the collection and analysis of
longitudinal data related to individuals of all ages
with congenital heart disease, including infants, young children, adolescents, and adults of all ages, including the elderly.

“(d) COORDINATION WITH FEDERAL, STATE, AND LOCAL REGISTRIES.—In establishing the National Congenital Heart Registry, the Secretary, acting through the Director of the Centers for Disease Control and Prevention may identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, including—

“(1) State birth defects surveillance systems;
“(2) the State birth defects tracking systems of the Centers for Disease Control and Prevention;
“(3) the Metropolitan Atlanta Congenital Defects Program; and
“(4) the National Birth Defects Prevention Network.

“(e) PUBLIC ACCESS.—The Congenital Heart Disease Registry shall be made available to the public.

“(f) PATIENT PRIVACY.—The Secretary shall ensure that the Congenital Heart Disease Registry is maintained in a manner that complies with the regulations promulgated under section 264 of the Health Insurance Port-
ability and Accountability Act of 1996 (Public Law 104-191).

“(g) ELIGIBILITY FOR GRANT.—To be eligible to receive a grant under this section, an entity shall—

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

“(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.”.

SEC. 5. ADVISORY COMMITTEE ON CONGENITAL HEART DISEASE.

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

“SEC. 399JJ. ADVISORY COMMITTEE ON CONGENITAL HEART DISEASE.

“(a) ESTABLISHMENT.—Not later than 60 days after the date of enactment of the Congenital Heart Futures Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish an advisory committee, to be known as the ‘Advisory Committee on Congenital Heart Disease’ (referred to in this section as the ‘Advisory Committee’).
“(b) MEMBERSHIP.—Members of the Advisory Committee may be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, and shall include—

“(1) at least one representative from—

“(A) the National Institutes of Health;

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

“(C) a national patient advocacy organization with experience advocating on behalf of patients living with congenital heart disease;

“(2) at least one epidemiologist who has experience working with data registries;

“(3) clinicians, including—

“(A) at least one with experience diagnosing or treating congenital heart disease; and

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

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

“(c) DUTIES.—The Advisory Committee may review information and make recommendations to the Secretary concerning—
“(1) the development and maintenance of the National Congenital Heart Disease Registry described in section 399II;
“(2) the type of data to be collected and stored in the National Congenital Heart Disease Registry;
“(3) the manner in which such data is to be collected;
“(4) the use and availability of such data, including guidelines for such use; and
“(5) other matters, as the Secretary determines to be appropriate.
“(d) REPORT.—Not later than 180 days after the date on which the Advisory Committee is established and annually thereafter, the Advisory Committee shall submit a report to the Secretary concerning the information described in subsection (c), including recommendations with respect to the results of the Advisory Committee’s review of such information.”.

SEC. 6. CONGENITAL HEART DISEASE RESEARCH.

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

“CONGENITAL HEART DISEASE
“Sec. 425.
“(a) IN GENERAL.—The Director of the Institute may expand, intensify, and coordinate research and re-
lated activities of the Institute with respect to congenital heart disease, which may include congenital heart disease research with respect to—

“(1) causation of congenital heart disease, including genetic causes;

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

“(3) diagnosis, treatment, and prevention;

“(4) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with congenital heart disease; and

“(5) identifying barriers to life-long care for individuals with congenital heart disease.

“(b) Coordination of Research Activities.—
The Director of the Institute may coordinate research efforts related to congenital heart disease among multiple research institutions and may develop research networks.

“(c) Minority and Medically Underserved Communities.—In carrying out the activities described in this section, the Director of the Institute shall consider the application of such research and other activities to minority and medically underserved communities.”
SEC. 7. AUTHORIZATION.

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