

S.621 -- Congenital Heart Futures Act (Introduced in Senate - IS)

S 621 IS

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Congenital Heart Futures Act'.

SEC. 2. FINDINGS.

Congress finds the following:

- (1) 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.
- (2) 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.

- (3) 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.
- (4) 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.
- (5) 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 require 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 for the Division of Cardiovascular Diseases at the National Heart, Lung and Blood Institute, completed in 2008, set 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 evidence-based care and treatment of adults with congenital heart disease.

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

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

‘PART S--PROGRAMS RELATING TO CONGENITAL HEART DISEASE

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

‘(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.

`(b) Eligibility for Grants- To be eligible to receive a grant, cooperative agreement, or contract under this section, an entity shall be a State or private nonprofit entity and shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.'

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 REGISTRY.

`(a) In General- The Secretary, acting through the Director of the Centers 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 comprehensive, nationwide registry of actual occurrences of congenital heart disease, to be known as the `National Congenital Heart Disease Registry'; or

`(2) award a grant to one eligible entity to undertake the activities described in paragraph (1).

`(b) Purpose- The purpose of the Congenital Heart Disease Registry shall be 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 Registry--

`(1) may include information concerning the incidence 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 concerning--

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

`(B) risk factors associated with the disease;

`(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 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, including congenital heart disease researchers.

`(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 Portability and Accountability Act of 1996.

`(g) Eligibility for Grant- To be eligible to receive a grant under subsection (a)(2), 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- 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- The 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 established under 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:

`SEC. 425. CONGENITAL HEART DISEASE.

- `(a) In General- The Director of the Institute may expand, intensify, and coordinate research and related 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 OF APPROPRIATIONS.

There are 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.