114TH CONGRESS
1ST SESSION

H. R. 1849

To amend the Public Health Service Act to improve the diagnosis and treatment of hereditary hemorrhagic telangiectasia, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 16, 2015

Mr. ROYCE (for himself and Mr. HIMES) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Public Health Service Act to improve the diagnosis and treatment of hereditary hemorrhagic telangiectasia, 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 "Hereditary Hemorrhagic Telangiectasia Diagnosis and Treatment Act of 2015".

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Hereditary hemorrhagic telangiectasia (HHT) is a largely undiagnosed or misdiagnosed vascular genetic bleeding disorder resulting in artery-vein malformations (AVMs) which lead to preventable catastrophic and disabling consequences. HHT can cause sudden death at any age, unless detected and treated. Early detection, screening, and use of readily available treatment can prevent premature deaths and long-term health complications resulting from HHT. A person with HHT has the tendency to form blood vessels that lack the capillaries between an artery and vein. HHT often results in spontaneous hemorrhage or stroke from brain or lung AVMs. In addition to hemorrhagic stroke, embolic stroke and brain abscess occur in approximately 30 percent of persons with HHT artery-vein malformations in the lung (due to lack of capillaries between the arterial and venous systems which normally filter out clots and bacteria).

(2) One in 5,000 American children and adults suffer from HHT.

(3) Studies have found an increase in morbidity and mortality rates for individuals who suffer from HHT.

(4) Due to the widespread lack of knowledge, accurate diagnosis, and appropriate intervention, 90 percent of HHT-affected families are at risk for preventable, life-threatening, and disabling medical incidents such as stroke.

(5) Early detection, screening, and treatment can prevent premature deaths, spontaneous hemorrhage, hemorrhagic stroke, embolic stroke, brain abscess, and other long-term health care complications resulting from HHT.

(6) HHT is an important health condition with serious health consequences which are amenable to early identification and diagnosis with suitable tests, and acceptable and available treatments in established treatment centers.

(7) Timely identification and management of HHT cases is an important public health objective because it will save lives, prevent disability, and reduce direct and indirect health care costs. A recent study found that use of a genetic testing model for HHT diagnosis saves $9.9 million in that screening can be limited to those persons within the family groups who actually have the gene defect, leading to early intervention in those found to have treatable AVMs.

(8) Without a new program for early detection, screening, and treatment, 14,000 children and adults who suffer from HHT in the population today will suffer premature death and disability.

SEC. 3. PURPOSE.

The purpose of this Act is to create a federally led and financed initiative for early diagnosis and appropriate treatment of hereditary hemorrhagic telangiectasia that will—

(1) reduce the suffering of families;

(2) prevent premature death and disability; and

(3) lower health care costs through proven treatment interventions.

SEC. 4. CENTERS FOR DISEASE CONTROL AND PREVENTION.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317T the following:

“SEC. 317U. HEREDITARY HEMORRHAGIC TELANGIECTASIA.

‘‘(a) IN GENERAL.—With respect to hereditary hemorrhagic telangiectasia (in this section referred to as ‘HHT’), the Director of the Centers for Disease Control and Prevention (in this section referred to as the ‘Director’) shall carry out the following activities:

“(1) The conduct of surveillance of the prevalence and incidence of HHT as described in subsection (c).

“(2) The identification and conduct of investigations to further develop and support guidelines for diagnosis of, and intervention for, HHT, including cost-benefit studies.

“(3) The development of a standardized survey and screening tool on family history.

“(4) The establishment, in collaboration with a voluntary health organization representing HHT families, of an HHT resource center within the Centers for Disease Control and Prevention to provide comprehensive education on, and disseminate information about, HHT to health professionals, patients, industry, and the public.

“(5) The conduct or support of public awareness programs in collaboration with medical, genetic, and professional organizations to improve the education of health professionals about HHT.

“(b) COLLABORATIVE APPROACHES.—The Director shall carry out this section through collaborative approaches within the National Center on Birth Defects and Developmental Disabilities and the Division for Heart Disease and Stroke Prevention of the Centers for Disease

Control and Prevention for clotting and bleeding disorders.

"(c) RELATED ACTIVITIES.—In carrying out subsection (a), the Director shall—

"(1) designate and provide funding for a sufficient number of HHT Treatment Centers of Excellence—

"(A) to collect data on the prevalence of, and stroke incidence associated with, HHT; and

"(B) to improve patient access to information, diagnosis, early intervention, and treatment of HHT;

"(2) provide data collected under paragraph (1) to the Paul Coverdell National Acute Stroke Registry to facilitate—

"(A) analyses of the natural history of hemorrhagic and embolic stroke in HHT; and

"(B) development of screening and artery-vein malformation treatment guidelines specific to prevention of complications from HHT; and

"(3) develop and implement programs, targeted for physicians and health care professional groups likely to be accessed by families with HHT, to increase HHT diagnosis and treatment rates through the—

''(A) establishment of a partnership with HHT Treatment Centers of Excellence designated under paragraph (1) through the creation of a database of patients assessed at such HHT Treatment Centers of Excellence (including with respect to phenotype information, genotype information, transfusion dependence, and radiological findings); and

''(B) inclusion of other medical providers who treat HHT patients.

''(d) ELIGIBILITY FOR DESIGNATION AS AN HHT TREATMENT CENTER OF EXCELLENCE.—In carrying out subsection (c)(1), the Director may designate, as an HHT Treatment Center of Excellence, only academic health centers demonstrated to have each of the following:

''(1) A team of medical experts capable of providing comprehensive evaluation, treatment, and education to individuals with known or suspected HHT and their health care providers.

''(2) Administrative staff with sufficient knowledge to respond to patient inquiries and coordinate patient care in a timely fashion.''.

SEC. 5. ADDITIONAL HEALTH AND HUMAN SERVICES ACTIVITIES.

With respect to hereditary hemorrhagic telangiectasia (in this section referred to as ''HHT''), the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall award grants on a competitive basis—

(1) for an analysis by grantees of the Medicare Provider Analysis and Review (MEDPAR) file to develop preliminary estimates from the Medicare program under title XVIII of the Social Security Act for preventable costs of annual health care expenditures including items, services, and treatments associated with untreated HHT furnished to individuals with HHT, as well as socioeconomic costs such as disability expenditures associated with preventable medical events in this population, who are entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title; and

(2) to make recommendations regarding an enhanced data collection protocol to permit a more precise determination of the total costs described in paragraph (1).

SEC. 6. NATIONAL INSTITUTES OF HEALTH.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409K. HEREDITARY HEMORRHAGIC TELANGIECTASIA.

"(a) HHT INITIATIVE.—

"(1) ESTABLISHMENT.—The Secretary shall establish and implement an HHT initiative to assist in coordinating activities to improve early detection, screening, and treatment of people who suffer from HHT. Such initiative shall focus on—

"(A) advancing research on the causes, diagnosis, and treatment of HHT, including through the conduct or support of such research; and

"(B) increasing physician and public awareness of HHT.

"(2) CONSULTATION.—In carrying out this subsection, the Secretary shall consult with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention.

"(b) HHT COORDINATING COMMITTEE.—

"(1) ESTABLISHMENT.—Not later than 60 days after the date of enactment of this section, the Secretary, in consultation with the Director of the National Institutes of Health, shall establish a committee to be known as the HHT Coordinating Committee.

"(2) MEMBERSHIP.—

"(A) IN GENERAL.—The members of the Committee shall be appointed by the Secretary, in consultation with the Director of the National Institutes of Health, and shall consist of 12 individuals who are experts in HHT or arteriovenous malformation (AVM) as follows:

"(i) Four representatives of HHT Treatment Centers of Excellence designated under section 317U(c)(1).

"(ii) Four experts in vascular, molecular, or basic science.

"(iii) Four representatives of the National Institutes of Health.

"(B) CHAIR.—The Secretary shall designate the Chair of the Committee from among its members.

"(C) INTERIM MEMBERS.—In place of the 4 members otherwise required to be appointed under subparagraph (A)(i), the Secretary may appoint 4 experts in vascular, molecular, or basic science to serve as members of the Committee during the period preceding designation and establishment of HHT Treatment Centers of Excellence under section 317U.

"(D) PUBLICATION OF NAMES.—Not later than 30 days after the establishment of the Committee, the Secretary shall publish the names of the Chair and members of the Committee on the public Web site of the Department of Health and Human Services.

"(E) TERMS.—The members of the Committee shall each be appointed for a 3-year term and, at the end of each such term, may be reappointed.

"(F) VACANCIES.—A vacancy on the Committee shall be filled by the Secretary in the same manner in which the original appointment was made.

"(3) RESPONSIBILITIES.—The Committee shall develop and coordinate implementation of a plan to advance research and understanding of HHT by—

"(A) conducting or supporting basic, translational, and clinical research on HHT across the relevant national research institutes, national centers, and offices of the National Institutes of Health, including the National Heart, Lung, and Blood Institute; the National

Institute of Neurological Disorders and Stroke; the National Institutes of Diabetes and Digestive and Kidney Diseases; the Eunice Kennedy Shriver National Institute of Child Health and Human Development; the National Cancer Institute; the National Human Genome Research Institute; the National Center for Advancing Translational Sciences (including the Office of Rare Diseases Research); and the National Institute of Biomedical Imaging and Bioengineering; and

"(B) conducting evaluations and making recommendations to the Secretary, the Director of the National Institutes of Health, and the Director of the National Cancer Institute regarding the prioritization and award of National Institutes of Health research grants relating to HHT, including with respect to grants for—

"(i) expanding understanding of HHT through basic, translational, and clinical research on the cause, diagnosis, prevention, control, and treatment of HHT;

"(ii) training programs on HHT for scientists and health professionals; and "(iii) HHT genetic testing research to improve the accuracy of genetic testing.

"(c) DEFINITIONS.—In this section:

"(1) The term 'Committee' means the HHT Coordinating Committee established under subsection (b).

"(2) The term 'HHT' means hereditary hemorrhagic telangiectasia.".

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—To carry out section 317U of the Public Health Service Act as added by section 4 of this Act, section 5 of this Act, and section 409K of the Public Health Service Act as added by section 6 of this Act, there is authorized to be appropriated $5,000,000 for each of fiscal years 2016 through 2020.

(b) RESOURCE CENTER.—Of the amount authorized to be appropriated under subsection (a) for each of fiscal years 2016 through 2020, $1,000,000 shall be for carrying out section 317U(a)(4) of the Public Health Service Act (providing for an HHT resource center), as added by section 4 of this Act.

(c) OFFSET.—There is authorized to be appropriated to the Department of Health and Human Services for salaries and expenses of the Department for each of fiscal years 2016 through 2020 the amount that is $5,000,000 less than the amount appropriated for such salaries and expenses for fiscal year 2015.

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