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(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R.

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

Mr. ROYCE introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to improve the diagnosis and treatment of hereditary hemorrhagic telangiectasia, 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 “Hereditary Hemor-
5 rhagic Telangiectasia Diagnosis and Treatment Act of
6 2015”.

7 **SEC. 2. FINDINGS.**

8 The Congress finds as follows:

1 (1) Hereditary hemorrhagic telangiectasia
2 (HHT) is a largely undiagnosed or misdiagnosed
3 vascular genetic bleeding disorder resulting in ar-
4 tery-vein malformations (AVMs) which lead to pre-
5 ventable catastrophic and disabling consequences.
6 HHT can cause sudden death at any age, unless de-
7 tected and treated. Early detection, screening, and
8 use of readily available treatment can prevent pre-
9 mature deaths and long-term health complications
10 resulting from HHT. A person with HHT has the
11 tendency to form blood vessels that lack the cap-
12 illaries between an artery and vein. HHT often re-
13 sults in spontaneous hemorrhage or stroke from
14 brain or lung AVMs. In addition to hemorrhagic
15 stroke, embolic stroke and brain abscess occur in ap-
16 proximately 30 percent of persons with HHT artery-
17 vein malformations in the lung (due to lack of cap-
18 illaries between the arterial and venous systems
19 which normally filter out clots and bacteria).

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

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

1 (4) Due to the widespread lack of knowledge,
2 accurate diagnosis, and appropriate intervention, 90
3 percent of HHT-affected families are at risk for pre-
4 ventable, life-threatening, and disabling medical inci-
5 dents such as stroke.

6 (5) Early detection, screening, and treatment
7 can prevent premature deaths, spontaneous hemor-
8 rhage, hemorrhagic stroke, embolic stroke, brain ab-
9 scess, and other long-term health care complications
10 resulting from HHT.

11 (6) HHT is an important health condition with
12 serious health consequences which are amenable to
13 early identification and diagnosis with suitable tests,
14 and acceptable and available treatments in estab-
15 lished treatment centers.

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

1 “(1) The conduct of surveillance of the preva-
2 lence and incidence of HHT as described in sub-
3 section (c).

4 “(2) The identification and conduct of inves-
5 tigations to further develop and support guidelines
6 for diagnosis of, and intervention for, HHT, includ-
7 ing cost-benefit studies.

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

10 “(4) The establishment, in collaboration with a
11 voluntary health organization representing HHT
12 families, of an HHT resource center within the Cen-
13 ters for Disease Control and Prevention to provide
14 comprehensive education on, and disseminate infor-
15 mation about, HHT to health professionals, pa-
16 tients, industry, and the public.

17 “(5) The conduct or support of public aware-
18 ness programs in collaboration with medical, genetic,
19 and professional organizations to improve the edu-
20 cation of health professionals about HHT.

21 “(b) COLLABORATIVE APPROACHES.—The Director
22 shall carry out this section through collaborative ap-
23 proaches within the National Center on Birth Defects and
24 Developmental Disabilities and the Division for Heart Dis-
25 ease and Stroke Prevention of the Centers for Disease

1 Control and Prevention for clotting and bleeding dis-
2 orders.

3 “(c) RELATED ACTIVITIES.—In carrying out sub-
4 section (a), the Director shall—

5 “(1) designate and provide funding for a suffi-
6 cient number of HHT Treatment Centers of Excel-
7 lence—

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

10 “(B) to improve patient access to informa-
11 tion, diagnosis, early intervention, and treat-
12 ment of HHT;

13 “(2) provide data collected under paragraph (1)
14 to the Paul Coverdell National Acute Stroke Reg-
15 istry to facilitate—

16 “(A) analyses of the natural history of
17 hemorrhagic and embolic stroke in HHT; and

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

21 “(3) develop and implement programs, targeted
22 for physicians and health care professional groups
23 likely to be accessed by families with HHT, to in-
24 crease HHT diagnosis and treatment rates through
25 the—

1 “(A) establishment of a partnership with
2 HHT Treatment Centers of Excellence des-
3 ignated under paragraph (1) through the cre-
4 ation of a database of patients assessed at such
5 HHT Treatment Centers of Excellence (includ-
6 ing with respect to phenotype information, gen-
7 otype information, transfusion dependence, and
8 radiological findings); and

9 “(B) inclusion of other medical providers
10 who treat HHT patients.

11 “(d) ELIGIBILITY FOR DESIGNATION AS AN HHT
12 TREATMENT CENTER OF EXCELLENCE.—In carrying out
13 subsection (c)(1), the Director may designate, as an HHT
14 Treatment Center of Excellence, only academic health cen-
15 ters demonstrated to have each of the following:

16 “(1) A team of medical experts capable of pro-
17 viding comprehensive evaluation, treatment, and
18 education to individuals with known or suspected
19 HHT and their health care providers.

20 “(2) Administrative staff with sufficient knowl-
21 edge to respond to patient inquiries and coordinate
22 patient care in a timely fashion.”.

1 **SEC. 5. ADDITIONAL HEALTH AND HUMAN SERVICES AC-**
2 **TIVITIES.**

3 With respect to hereditary hemorrhagic telangiectasia
4 (in this section referred to as “HHT”), the Secretary of
5 Health and Human Services, acting through the Adminis-
6 trator of the Centers for Medicare & Medicaid Services,
7 shall award grants on a competitive basis—

8 (1) for an analysis by grantees of the Medicare
9 Provider Analysis and Review (MEDPAR) file to de-
10 velop preliminary estimates from the Medicare pro-
11 gram under title XVIII of the Social Security Act
12 for preventable costs of annual health care expendi-
13 tures including items, services, and treatments asso-
14 ciated with untreated HHT furnished to individuals
15 with HHT, as well as socioeconomic costs such as
16 disability expenditures associated with preventable
17 medical events in this population, who are entitled to
18 benefits under part A of title XVIII of the Social Se-
19 curity Act or enrolled under part B of such title; and

20 (2) to make recommendations regarding an en-
21 hanced data collection protocol to permit a more
22 precise determination of the total costs described in
23 paragraph (1).

1 **SEC. 6. NATIONAL INSTITUTES OF HEALTH.**

2 Part B of title IV of the Public Health Service Act
3 (42 U.S.C. 284 et seq.) is amended by adding at the end
4 the following:

5 **“SEC. 409K. HEREDITARY HEMORRHAGIC TELANGIECTASIA.**

6 “(a) HHT INITIATIVE.—

7 “(1) ESTABLISHMENT.—The Secretary shall es-
8 tablish and implement an HHT initiative to assist in
9 coordinating activities to improve early detection,
10 screening, and treatment of people who suffer from
11 HHT. Such initiative shall focus on—

12 “(A) advancing research on the causes, di-
13 agnosis, and treatment of HHT, including
14 through the conduct or support of such re-
15 search; and

16 “(B) increasing physician and public
17 awareness of HHT.

18 “(2) CONSULTATION.—In carrying out this sub-
19 section, the Secretary shall consult with the Director
20 of the National Institutes of Health and the Director
21 of the Centers for Disease Control and Prevention.

22 “(b) HHT COORDINATING COMMITTEE.—

23 “(1) ESTABLISHMENT.—Not later than 60 days
24 after the date of enactment of this section, the Sec-
25 retary, in consultation with the Director of the Na-
26 tional Institutes of Health, shall establish a com-

1 mittee to be known as the HHT Coordinating Com-
2 mittee.

3 “(2) MEMBERSHIP.—

4 “(A) IN GENERAL.—The members of the
5 Committee shall be appointed by the Secretary,
6 in consultation with the Director of the Na-
7 tional Institutes of Health, and shall consist of
8 12 individuals who are experts in HHT or
9 arteriovenous malformation (AVM) as follows:

10 “(i) Four representatives of HHT
11 Treatment Centers of Excellence des-
12 ignated under section 317U(c)(1).

13 “(ii) Four experts in vascular, molec-
14 ular, or basic science.

15 “(iii) Four representatives of the Na-
16 tional Institutes of Health.

17 “(B) CHAIR.—The Secretary shall des-
18 ignate the Chair of the Committee from among
19 its members.

20 “(C) INTERIM MEMBERS.—In place of the
21 4 members otherwise required to be appointed
22 under subparagraph (A)(i), the Secretary may
23 appoint 4 experts in vascular, molecular, or
24 basic science to serve as members of the Com-
25 mittee during the period preceding designation

1 and establishment of HHT Treatment Centers
2 of Excellence under section 317U.

3 “(D) PUBLICATION OF NAMES.—Not later
4 than 30 days after the establishment of the
5 Committee, the Secretary shall publish the
6 names of the Chair and members of the Com-
7 mittee on the public website of the Department
8 of Health and Human Services.

9 “(E) TERMS.—The members of the Com-
10 mittee shall each be appointed for a 3-year term
11 and, at the end of each such term, may be re-
12 appointed.

13 “(F) VACANCIES.—A vacancy on the Com-
14 mittee shall be filled by the Secretary in the
15 same manner in which the original appointment
16 was made.

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

20 “(A) conducting or supporting basic,
21 translational, and clinical research on HHT
22 across the relevant national research institutes,
23 national centers, and offices of the National In-
24 stitutes of Health, including the National
25 Heart, Lung, and Blood Institute; the National

1 Institute of Neurological Disorders and Stroke;
2 the National Institutes of Diabetes and Digestive
3 and Kidney Diseases; the Eunice Kennedy
4 Shriver National Institute of Child Health and
5 Human Development; the National Cancer In-
6 stitute; the National Human Genome Research
7 Institute; the National Center for Advancing
8 Translational Sciences (including the Office of
9 Rare Diseases Research); and the National In-
10 stitute of Biomedical Imaging and Bio-
11 engineering; and

12 “(B) conducting evaluations and making
13 recommendations to the Secretary, the Director
14 of the National Institutes of Health, and the
15 Director of the National Cancer Institute re-
16 garding the prioritization and award of Na-
17 tional Institutes of Health research grants re-
18 lating to HHT, including with respect to grants
19 for—

20 “(i) expanding understanding of HHT
21 through basic, translational, and clinical
22 research on the cause, diagnosis, preven-
23 tion, control, and treatment of HHT;

24 “(ii) training programs on HHT for
25 scientists and health professionals; and

1 “(iii) HHT genetic testing research to
2 improve the accuracy of genetic testing.

3 “(c) DEFINITIONS.—In this section:

4 “(1) The term ‘Committee’ means the HHT
5 Coordinating Committee established under sub-
6 section (b).

7 “(2) The term ‘HHT’ means hereditary hemor-
8 rhagic telangiectasia.”.

9 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

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

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

22 (c) OFFSET.—There is authorized to be appropriated
23 to the Department of Health and Human Services for sal-
24 aries and expenses of the Department for each of fiscal
25 years 2016 through 2020 the amount that is \$5,000,000

- 1 less than the amount appropriated for such salaries and
- 2 expenses for fiscal year 2015.