

CARDIOVASCULAR ADVANCES IN RESEARCH AND
OPPORTUNITIES LEGACY ACT

DECEMBER 8, 2021.—Committed to the Committee of the Whole House on the State
of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 1193]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1193) to amend title IV of the Public Health Service Act to direct the Director of the National Institutes of Health, in consultation with the Director of the National Heart, Lung, and Blood Institute, shall establish a program under which the Director of the National Institutes of Health shall support or conduct research on valvular heart disease, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

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The amendments are as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Cardiovascular Advances in Research and Opportunities Legacy Act”.

SEC. 2. GRANTS FOR VALVULAR 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 inserting after section 424C (42 U.S.C. 285b–7c) the following:

“SEC. 424D. GRANTS FOR VALVULAR HEART DISEASE RESEARCH.

“(a) **IN GENERAL.**—The Director of the National Institutes of Health, in consultation with the Director of the Institute, shall support or conduct research regarding valvular heart disease.

“(b) **SUPPORT GUIDELINES.**—The distribution of funding authorized under subsection (a) may be used to pursue the following outcomes:

“(1) Using precision medicine and advanced technological imaging to generate data on individuals with valvular heart disease.

“(2) Identifying and developing a cohort of individuals with valvular heart disease and available data.

“(3) Corroborating data generated through clinical trials to develop a prediction model to distinguish individuals at high risk for sudden cardiac arrest or sudden cardiac death from valvular heart disease.

“(4) For other outcomes needed to acquire necessary data on valvular heart disease.

“(c) **MITRAL VALVE PROLAPSE WORKSHOP.**—Not later than one year after the date of the enactment of this section, the Director of the Institute shall convene a workshop composed of subject matter experts and stakeholders to identify research needs and opportunities to develop prescriptive guidelines for treatment of individuals with mitral valve prolapse.

“(d) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there is authorized to be appropriated \$20,000,000 for each of fiscal years 2022 through 2026.”.

SEC. 3. PROGRAMS OF 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 312 the following section:

“SEC. 312A. PREVENTION OF SUDDEN CARDIAC DEATH AS A RESULT OF VALVULAR HEART DISEASE.

“(a) **IN GENERAL.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out projects to increase education, awareness, or diagnosis of valvular heart disease and to reduce the incidence of sudden cardiac death caused by valvular heart disease. Such projects may be carried out by the Secretary directly or through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly (or through such awards) provide technical assistance with respect to the planning, development, and operation of such projects.

“(b) **CERTAIN ACTIVITIES.**—Upon availability of applicable data, projects carried out under subsection (a) may include—

“(1) continuing the activities at the Division for Heart Disease and Stroke Prevention, including those related to valvular heart disease;

“(2) broadening the awareness of the public concerning the risk factors for, the symptoms of, and the public health consequences of valvular heart disease; and

“(3) enhancing surveillance of out-of-hospital cardiac arrests to improve patient outcomes.

“(c) **GRANT PRIORITIZATION.**—The Secretary may, in awarding grants or entering into contracts pursuant to subsection (a), give priority to entities seeking to carry out projects that target populations most impacted by valvular heart disease.

“(d) **COORDINATION OF ACTIVITIES.**—The Secretary shall ensure that activities under this section are coordinated, as appropriate, with other agencies of the Public Health Service that carry out activities regarding valvular heart disease.

“(e) **BEST PRACTICES.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

“(1) collect and analyze the findings of research conducted with respect to valvular heart disease; and

“(2) taking into account such findings, publish on the website of the Centers for Disease Control and Prevention best practices for physicians and other health care providers who provide care to individuals with valvular heart disease.”.

Amend the title so as to read:

A bill to amend title IV of the Public Health Service Act to direct the Director of the National Institutes of Health, in consultation with the Director of the National Heart, Lung, and Blood Institute, to establish a program under which the Director of the National Institutes of Health shall support or conduct research on valvular heart disease, and for other purposes.

I. PURPOSE AND SUMMARY

H.R. 1193, the “Cardiovascular Advances in Research and Opportunities Legacy Act” or the “CAROL Act,” authorizes the National Institutes of Health (NIH) in collaboration with the National Heart, Lung, and Blood Institute (NHLBI) to support research on valvular heart disease and to convene a workshop of subject matter experts and stakeholders to identify research needs and treatment guidelines for individuals diagnosed with mitral valve prolapse, a type of valvular heart disease (VHD). The bill also requires the Centers for Disease Control and Prevention (CDC) to carry out projects to increase education, awareness, or diagnosis of valvular heart disease, and to carry out initiatives to help reduce cardiac deaths caused by valvular heart disease.

II. BACKGROUND AND NEED FOR LEGISLATION

VHD is caused by damage or disease affecting the valves of the heart that regulate blood flow into the heart.¹ VHD affects 2.5 percent of the general United States population and 13 percent of the elderly population.² It is the cause of approximately 27,000 deaths in the United States each year, predominantly in women, and it is on the rise, accounting for more than five million diagnoses each year.^{3,4} Despite the rising incidence of VHD, low awareness and the often-asymptomatic nature of the disease contribute to the underdiagnosis and undertreatment of these potentially fatal conditions.⁵

Some known causes of VHD include congenital conditions, infections, generative conditions, and conditions linked to other types of heart disease.⁶ VHD can develop quickly or over a long period of time. When the disease develops more slowly, there may be no symptoms until the condition is quite advanced.⁷ However, there is a gap in understanding about what makes valvular heart disease life-threatening since there has been little research on the condition and its treatment.⁸

H.R. 1193 aims to expand research on VHD and its treatment by authorizing a grant program at NIH to support research on the condition and to convene a workshop of subject matter experts to

¹Centers for Disease Control and Prevention, Valvular Heart Disease (www.cdc.gov/heartdisease/valvular_disease.htm) (accessed Nov. 29, 2021).

²*Id.*

³*Id.*

⁴American College of Cardiology, Succeed in Managing Heart Valve Disease Initiative (www.acc.org/tools-and-practice-support/quality-programs/valvular-heart-disease-initiatives) (accessed Nov. 29, 2021).

⁵Patient-Centered Outcomes Research Institute, Building and Educating a Heart Valve Disease Network Prepared to Engage in Research (www.pcori.org/research-results/2019/building-and-educating-heart-valve-disease-network-prepared-engage-research) (accessed Nov. 29, 2021).

⁶Centers for Disease Control and Prevention, Valvular Heart Disease (www.cdc.gov/heartdisease/valvular_disease.htm) (accessed Nov. 29, 2021).

⁷*Id.*

⁸Stecker, E. & Nazer, B., *The Shadows of Sudden Cardiac Death*, Journal of the American College of Cardiology (www.jacc.org/doi/10.1016/j.jacc.2021.03.321) (accessed Nov. 29, 2021).

identify research needs and treatment guidelines for mitral valve prolapse. In order to create awareness about VHD, the bill would support increasing public awareness on the risk factors and symptoms of VHD and enhancing surveillance around cardiac deaths. These initiatives will help address the gaps in our understanding of what causes sudden cardiac death, particularly in young women.

III. COMMITTEE HEARINGS

For the purposes of section 3(c) of rule XIII of the Rules of the House of Representatives, the following hearing was used to develop or consider H.R. 1193:

The Subcommittee on Health held a legislative hearing on October 20, 2021, entitled “Enhancing Public Health: Legislation to Protect Children and Families.” The Subcommittee received testimony from the following witnesses:

- Bruce L. Cassis, D.D.S., President, Academy of General Dentistry;
- Raymond DuBois, M.D., Ph.D., Former President, American Association for Cancer Research;
- Donald M. Lloyd-Jones, M.D., Sc.M., President, American Heart Association;
- Ellyn Miller, President and Founder, Smashing Walnuts Foundation;
- Rick Nolan, Former U.S. Representative (MN);
- Jenny Radesky, M.D., Assistant Professor of Pediatrics, University of Michigan Medical School; and
- Stacey Stewart, President and CEO, March of Dimes.

IV. COMMITTEE CONSIDERATION

H.R. 1193, the “Cardiovascular Advances in Research and Opportunities Legacy Act” or the “CAROL Act,” was introduced on February 22, 2021, by Representative Andy Barr (R-KY) and referred to the Committee on Energy and Commerce. Subsequently, on February 23, 2021, the bill was referred to the Subcommittee on Health.

On November 4, 2021, the Subcommittee on Health met in open markup session, pursuant to notice, to consider H.R. 1193 and eight other bills. During consideration of the bill, an amendment in the nature of a substitute (AINS) offered by Representative Guthrie (R-KY) was agreed to by a voice vote. Upon conclusion of consideration of the bill, the Subcommittee on Health agreed to report the bill favorably to the full Committee, amended, by a voice vote.

On November 17, 2021, the full Committee met in open markup session, pursuant to notice, to consider H.R. 1193 and 11 other bills. No amendments were offered during consideration of the bill. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage offered by Representative Pallone (D-NJ), Chairman of the Committee, to order H.R. 1193 reported favorably to the House, as amended, by a voice vote.

V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee ad-

vises that there were no record votes taken on H.R. 1193, including a motion by Mr. Pallone ordering H.R. 1193 favorably reported to the House, as amended.

VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to expand research on VHD and its treatment, and increase awareness and education around cardiac deaths caused by VHD.

X. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 1193 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

XI. COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 1193 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the Act may be cited as the “Cardiovascular Advances in Research and Opportunities Legacy Act.”

Sec. 2. Grants for valvular heart disease research

Section 2 amends the Public Health Service Act (PHSA) to direct the Director of NIH, in consultation with the Director of NHLBI to support or conduct valvular heart disease research. The funding authorized under this section may be used to pursue the use of precision medicine and advanced technological imaging to generate data on individuals with VHD; the identification and development of a cohort of individuals with VHD and available data; and the generation of data through clinical trials to develop a prediction model to identify patients at high risk for sudden cardiac arrest or sudden cardiac death from valvular disease.

Section 2 further instructs the Director of NHLBI to convene a workshop of subject matter experts and stakeholders within one year of enactment to identify research needs and opportunities to develop prescriptive guidelines for treatment of individuals with mitral valve prolapse.

This section authorizes \$20 million for each of fiscal years 2022 through 2026 for these activities.

Sec. 3. Programs of Centers for Disease Control and Prevention

Section 3 amends the PHSA to direct the Secretary, acting through the Director of the Centers for Disease Control and Prevention (CDC), to carry out projects to increase education, awareness, or diagnosis of VHD in order to reduce the incidence of sudden cardiac death caused by VHD. Such projects may be carried out by CDC or through grants or contracts to public or nonprofit organizations.

Upon availability of applicable data, Section 3 also authorizes the continuations of projects and activities at the Division of Heart and Stroke at CDC, including broadening public awareness activities concerning risk factors for, symptoms of, and the public health con-

sequences of VHD; and enhancing hospital surveillance data related to cardiac arrests.

Section 3 provides discretion to the Secretary of Health and Human Services (HHS), acting through the Director of CDC, to give priority for grants or contracts to entities seeking to carry out projects that target populations most impacted by VHD.

Section 3 requires the HHS Secretary to ensure that activities under this section are coordinated, as appropriate, with other agencies of the Public Health Service that carry out activities regarding VHD, and instructs the Secretary, acting through the Director of CDC, to collect and analyze the findings of valvular heart disease research and publish best practices on the CDC website for physicians and other health care providers who provide care to individuals with valvular heart disease.

XVI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART B—FEDERAL-STATE COOPERATION

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SEC. 312A. PREVENTION OF SUDDEN CARDIAC DEATH AS A RESULT OF VALVULAR HEART DISEASE.

(a) *IN GENERAL.*—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out projects to increase education, awareness, or diagnosis of valvular heart disease and to reduce the incidence of sudden cardiac death caused by valvular heart disease. Such projects may be carried out by the Secretary directly or through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly (or through such awards) provide technical assistance with respect to the planning, development, and operation of such projects.

(b) *CERTAIN ACTIVITIES.*—Upon availability of applicable data, projects carried out under subsection (a) may include—

(1) continuing the activities at the Division for Heart Disease and Stroke Prevention, including those related to valvular heart disease;

(2) broadening the awareness of the public concerning the risk factors for, the symptoms of, and the public health consequences of valvular heart disease; and

(3) enhancing surveillance of out-of-hospital cardiac arrests to improve patient outcomes.

(c) *GRANT PRIORITIZATION.*—The Secretary may, in awarding grants or entering into contracts pursuant to subsection (a), give priority to entities seeking to carry out projects that target populations most impacted by valvular heart disease.

(d) *COORDINATION OF ACTIVITIES.*—The Secretary shall ensure that activities under this section are coordinated, as appropriate, with other agencies of the Public Health Service that carry out activities regarding valvular heart disease.

(e) *BEST PRACTICES.*—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(1) collect and analyze the findings of research conducted with respect to valvular heart disease; and

(2) taking into account such findings, publish on the website of the Centers for Disease Control and Prevention best practices for physicians and other health care providers who provide care to individuals with valvular heart disease.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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Subpart 2—National Heart, Lung, and Blood Institute

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SEC. 424D. GRANTS FOR VALVULAR HEART DISEASE RESEARCH.

(a) *IN GENERAL.*—The Director of the National Institutes of Health, in consultation with the Director of the Institute, shall support or conduct research regarding valvular heart disease.

(b) *SUPPORT GUIDELINES.*—The distribution of funding authorized under subsection (a) may be used to pursue the following outcomes:

(1) Using precision medicine and advanced technological imaging to generate data on individuals with valvular heart disease.

(2) Identifying and developing a cohort of individuals with valvular heart disease and available data.

(3) Corroborating data generated through clinical trials to develop a prediction model to distinguish individuals at high risk for sudden cardiac arrest or sudden cardiac death from valvular heart disease.

(4) For other outcomes needed to acquire necessary data on valvular heart disease.

(c) *MITRAL VALVE PROLAPSE WORKSHOP.*—Not later than one year after the date of the enactment of this section, the Director of the Institute shall convene a workshop composed of subject matter experts and stakeholders to identify research needs and opportunities to develop prescriptive guidelines for treatment of individuals with mitral valve prolapse.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$20,000,000 for each of fiscal years 2022 through 2026.

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