

May 12, 2021

The Honorable Andy Barr
U.S. House of Representatives
2430 Rayburn House Office Building
Washington, DC 20515

The Honorable Mitch McConnell
U.S. Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Kyrsten Sinema
U.S. Senate
317 Hart Senate Office Building
Washington, DC 20510

Dear Representative Barr, Leader McConnell and Senator Sinema,

We are writing to express our support for the Cardiovascular Advances in Research and Opportunities Legacy (CAROL) Act (HR 1193/ S 1133). As organizations that represent and advocate for patients living with heart disease, we thank you for sponsoring this legislation to advance our understanding and awareness of heart valve disease, a condition that kills approximately 25,000 people each year.

The CAROL Act authorizes funding for the National Heart, Lung and Blood Institute (NHLBI) at the NIH to conduct life-saving research on valve disease and to convene a workshop on mitral valve prolapse. This investment will help address gaps in our understanding of heart valve disease, including what causes sudden cardiac death in a small number of people, predominantly women.

The bill also invests in education efforts to broaden awareness of the risk factors and symptoms of heart valve disease and in efforts to increase screening, detection, and diagnosis of heart valve disease. According to an awareness survey, 3 out of 4 Americans report knowing little to nothing about heart valve disease. Many people living with heart valve disease, particularly women, are never diagnosed or they are diagnosed later in the course of the disease, leading to missed opportunities for treatment. Currently, there is no heart valve disease screening recommendation from the U.S. Preventive Services Task Force (USPSTF) nor is screening part of the "Welcome to Medicare" preventive visit or the yearly "Wellness" visit. It is important for both the public and clinicians to be aware of patients' risk for valve disease, to recognize the symptoms, and to have accurate and timely diagnosis. Earlier detection and diagnosis can lead to earlier treatment, before the onset of worse symptoms.

Thank you for recognizing the impact of heart valve disease on millions of people across the country, and for your leadership in advancing solutions that will improve heart health. We look forward to working with you to pass this legislation.

Sincerely,

WomenHeart: The National Coalition for Women with Heart Disease
Alliance for Aging Research
Heart Valve Voice - US
American Heart Association (AHA)
American College of Cardiology

American College of Emergency Physicians
American Association of Cardiovascular and Pulmonary Rehabilitation
Association of Black Cardiologists
Baton Rouge General Medical Center
CardioStart International Inc.
CardioVisual: Heart Health App by MedicalVisual, Inc
Caregiver Action Network
HealthyWomen
Lymphatic Education & Research Network
Medical Management Associates, Inc.
Preventive Cardiovascular Nurses Association
Scandic health LLC
StopAfib.org, American Foundation for Women's Health
Sustainable Cardiovascular Health Equity Development Alliance
The Pediatric & Congenital Interventional Cardiovascular Society (PICS)

.....
(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R.

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 make grants for valvular disease research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

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, shall establish a program under which the Director of the National Institutes of Health shall make grants for valvular disease research, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Cardiovascular Ad-
3 vances in Research and Opportunities Legacy Act”.

4 **SEC. 2. GRANTS FOR VALVULAR HEART DISEASE RE-**
5 **SEARCH.**

6 Subpart 2 of part C of title IV of the Public Health
7 Service Act (42 U.S.C. 285b et seq.) is amended by insert-
8 ing after section 424C (42 U.S.C. 285b–7c) the following:

9 **“SEC. 424D. GRANTS FOR VALVULAR HEART DISEASE RE-**
10 **SEARCH.**

11 “(a) IN GENERAL.—The Director of the National In-
12 stitutes of Health, in consultation with the Director of the
13 Institute, shall make grants or contracts for the conduct
14 of research regarding valvular heart disease.

15 “(b) GRANT GUIDELINES.—The distribution of fund-
16 ing authorized in subsection (a) may be used to pursue
17 the following outcomes—

18 “(1) using precision medicine and advanced
19 technological imaging to generate data on individ-
20 uals with valvular heart disease;

21 “(2) identifying and developing a cohort of indi-
22 viduals with valvular heart disease and available
23 data;

24 “(3) corroborating data generated through clin-
25 ical trials to develop a prediction model to distin-
26 guish individuals at high risk for sudden cardiac ar-

1 rest or sudden cardiac death from valvular heart dis-
2 ease; or

3 “(4) for other outcomes needed to acquire nec-
4 essary data on valvular heart disease.

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

12 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
13 purpose of carrying out this section, there is authorized
14 to be appropriated \$20,000,000 for each of fiscal years
15 2022 through 2026.”.

16 **SEC. 3. PROGRAMS OF CENTERS FOR DISEASE CONTROL**
17 **AND PREVENTION.**

18 Part J of title III of the Public Health Service Act
19 (42 U.S.C. 2 et seq.) is amended by inserting after section
20 393 the following section:

21 **“SEC. 393A. PREVENTION OF SUDDEN CARDIAC DEATH AS A**
22 **RESULT OF VALVULAR HEART DISEASE.**

23 “(a) IN GENERAL.—The Secretary, acting through
24 the Director of the Centers for Disease Control and Pre-
25 vention, may carry out projects to increase education,

1 awareness or diagnosis of valvular heart disease and to
2 reduce the incidence of sudden cardiac death caused by
3 valvular heart disease. Such projects may be carried out
4 by the Secretary directly or through awards of grants or
5 contracts to public or nonprofit private entities. The Sec-
6 retary may directly (or through such awards) provide tech-
7 nical assistance with respect to the planning, development,
8 and operation of such projects.

9 “(b) CERTAIN ACTIVITIES.—Projects carried out
10 under subsection (a) may include—

11 “(1) the implementation of public information
12 and education programs for—

13 “(A) the prevention of sudden cardiac
14 death from valvular heart disease;

15 “(B) broadening the awareness of the pub-
16 lic concerning the risk factors for, the symp-
17 toms of, and the public health consequences of
18 valvular heart disease; and

19 “(C) increasing screening, detection, and
20 diagnosis of valvular heart disease; and

21 “(2) surveillance of out of hospital cardiac ar-
22 rests to improve patient outcomes.

23 “(c) GRANT PRIORITIZATION.—The Secretary may,
24 in awarding grants or entering into contracts pursuant to
25 subsection (a), give priority to nonprofit entities seeking

1 to carry out projects that target populations most im-
2 pacted by valvular heart disease.

3 “(d) COORDINATION OF ACTIVITIES.—The Secretary
4 shall ensure that activities under this section are coordi-
5 nated, as appropriate, with other agencies of the Public
6 Health Service that carry out activities regarding valvular
7 heart disease.

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

11 “(1) collect and analyze the findings of research
12 conducted pursuant to this section; and

13 “(2) taking into account such findings, publish
14 on the website of the Centers for Disease Control
15 and Prevention best practices for physicians and
16 other health care providers who provide care to indi-
17 viduals with valvular heart disease.

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
19 purpose of carrying out this section, there is authorized
20 to be appropriated such sums as may be necessary for
21 each of fiscal years 2022 through 2026.”.



Congress of the United States
House of Representatives
Washington, DC 20515

February 24, 2021

Dear Colleague:

As many of you know, on June 16th of last year, I tragically lost my beloved wife Carol to sudden cardiac arrest. She was only 39 years old. Carol's greatest legacy is our two beautiful daughters, Eleanor (age 9) and Mary Clay (age 7). She was the best wife, mother, daughter, sister, and friend anyone could ever have.

The medical examiner and Carol's doctors told us that her fatal heart attack was likely brought on by a ventricular arrhythmia. At a young age, Carol had been diagnosed with an underlying condition called mitral valve prolapse (MVP), or floppy valve syndrome—a typically benign condition that results in sudden cardiac death (SCD) in only .2% of cases. The American Heart Association reports that isolated MVP and SCD predominantly affects young females with redundant bileaflet prolapse, with cardiac arrest usually occurring as a result of ventricular arrhythmias.

According to the National Heart, Lung, and Blood Institute (NHLBI), heart valve disease occurs if one or more of your heart valves do not work well. Many people in the United States have heart valve defects or disease but do not have symptoms. For some, the condition remains the same throughout their lives and does not cause significant or life-threatening problems. Unfortunately, over 25,000 people die each year in the United States from heart valve disease, primarily due to underdiagnosis and undertreatment of the condition.

The specific condition that Carol was diagnosed with, MVP, is a common heart valve disease that has an estimated 2.4% prevalence in the general population. Though most cases are thought to be benign, reported complications such as severe mitral regurgitation can result in SCD. Medical research has found an association between MVP and SCD. Predictors of this outcome, however, are not readily available, underlying mechanisms are poorly understood, and indicators of high-risk individuals are lacking. Despite several studies, there is not sufficient data to generate prescriptive guidelines for care of patients with valvular heart disease, including MVP.

That is why, inspired by the extraordinary life of my wife Carol, I introduced H.R. 1193, the Cardiovascular Advances in Research and Opportunities Legacy Act (CAROL Act). This legislation will address the gaps in understanding about what risk factors make valvular heart disease a potentially life-threatening condition.

More specifically, the bill will authorize a grant program, administered by the NHLBI, to support research on valvular heart disease, including MVP. In particular, the research will advance technological imaging and precision medicine to generate data on individuals with valvular heart disease, identify a cohort of individuals who are at high risk of sudden cardiac death, and develop prediction models for high-risk patients, enabling interventions and treatment plans to help keep these patients healthy throughout their lives.

Additionally, the legislation will convene a working group of subject matter experts to identify research needs and opportunities to develop prescriptive guidelines for treatment of patients with MVP. It will also instruct the Centers for Disease Control and Prevention (CDC) to increase public awareness regarding symptoms of valvular heart disease and effective strategies for preventing sudden cardiac death.

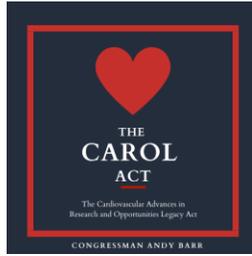
I am so grateful to so many of you, my colleagues on both sides of the aisle, for reaching out to me in the wake of Carol's passing, to share expressions of sympathy. Your friendship and support means the world to me. Now, I would be grateful if you would join me in supporting this legislative effort to help other families avoid the tragedy that has so profoundly impacted mine.

To cosponsor the CAROL Act please contact my Senior Legislative Assistant, Claire Osborn, at Claire.Osborn@mail.house.gov or 202-225-4706.

Sincerely,

A handwritten signature in blue ink that reads "Andy Barr". The signature is written in a cursive style with a long horizontal line extending to the right.

Andy Barr
Member of Congress



The CAROL Act Section by Section

Section 1 – Short Title: The Cardiovascular Advances in Research and Opportunities Legacy Act (the CAROL Act).

Section 2-- Grants for Valvular Heart Disease: Directs the Director of the National Institutes of Health in coordination with the National Heart Lung and Blood Institute to make grants or contracts for conducting research on valvular heart disease. The distribution of this funding may be used to pursue several outcomes including but not limited to:

- using precision medicine and advanced technological imaging to generate data on individuals with valvular disease.
- identifying and developing a cohort of individuals with valvular heart disease and available data.
- corroborating data generated 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.

Authorizes the convening of a workshop of subject matter experts and stakeholders to identify research needs and opportunities to develop prescriptive guidelines for treatment of patients with mitral valve prolapse.

Section 3 – Programs of Centers of Disease Control and Prevention: Instructs the Centers for Disease Control (CDC) or others so authorized to carry out projects to reduce the incidence of sudden cardiac death caused by valvular heart disease. These programs may include, but are not limited to:

- implementation of public information and education programs for the prevention of sudden cardiac death and for broadening the awareness of the public concerning the symptoms and public health consequences of valvular heart disease.
- Surveillance of out of hospital cardiac arrest to improve patient outcomes and help the medical community establish who is most at risk for SCA.

Requires that entities collecting the information and research outlined above shall submit their findings to CDC, which upon receipt shall publish best practices for physicians and other health care providers who provide care to individuals with valvular disease.

117TH CONGRESS
1ST SESSION

H. R. 1956

To amend title XVIII of the Social Security Act and the Bipartisan Budget Act of 2018 to expand and expedite access to cardiac rehabilitation programs and pulmonary rehabilitation programs under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 2021

Ms. BLUNT ROCHESTER (for herself, Mr. SMITH of Nebraska, Mr. KILMER, Mr. FITZPATRICK, and Mr. WELCH) 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

A BILL

To amend title XVIII of the Social Security Act and the Bipartisan Budget Act of 2018 to expand and expedite access to cardiac rehabilitation programs and pulmonary rehabilitation programs under the Medicare program, 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 “Increasing Access to
5 Quality Cardiac Rehabilitation Care Act of 2021”.

1 **SEC. 2. EXPANDING ACCESS TO CARDIAC REHABILITATION**
2 **PROGRAMS AND PULMONARY REHABILITA-**
3 **TION PROGRAMS UNDER MEDICARE PRO-**
4 **GRAM.**

5 (a) **CARDIAC REHABILITATION PROGRAMS.**—Section
6 1861(eee) of the Social Security Act (42 U.S.C.
7 1395x(eee)) is amended—

8 (1) in paragraph (2)—

9 (A) in subparagraph (A)(i), by striking “a
10 physician’s office” and inserting “the office of
11 a physician (as defined in subsection (r)(1)) or
12 the office of a physician assistant, nurse practi-
13 tioner, or clinical nurse specialist (as those
14 terms are defined in subsection (aa)(5))”; and

15 (B) in subparagraph (C), by inserting after
16 “physician” the following: “(as defined in sub-
17 section (r)(1)) or a physician assistant, nurse
18 practitioner, or clinical nurse specialist (as
19 those terms are defined in subsection (aa)(5))”;

20 (2) in paragraph (3)(A), by striking “physician-
21 prescribed exercise” and inserting “exercise pre-
22 scribed by a physician (as defined in subsection
23 (r)(1)) or a physician assistant, nurse practitioner,
24 or clinical nurse specialist (as those terms are de-
25 fined in subsection (aa)(5))”; and

1 (3) in paragraph (5), by inserting after “physi-
2 cian” the following: “(as defined in subsection
3 (r)(1)) or a physician assistant, nurse practitioner,
4 or clinical nurse specialist (as those terms are de-
5 fined in subsection (aa)(5))”.

6 (b) PULMONARY REHABILITATION PROGRAMS.—Sec-
7 tion 1861(fff) of the Social Security Act (42 U.S.C.
8 1395x(fff)) is amended—

9 (1) in paragraph (2)(A), by striking “physician-
10 prescribed exercise” and inserting “exercise pre-
11 scribed by a physician (as defined in subsection
12 (r)(1)) or a physician assistant, nurse practitioner,
13 or clinical nurse specialist (as those terms are de-
14 fined in subsection (aa)(5))”; and

15 (2) in paragraph (3), by inserting after “physi-
16 cian” the following: “(as defined in subsection
17 (r)(1)) or a physician assistant, nurse practitioner,
18 or clinical nurse specialist (as those terms are de-
19 fined in subsection (aa)(5))”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall apply with respect to items and services
22 furnished on or after January 1, 2022.

1 **SEC. 3. EXPEDITING ACCESS TO CARDIAC REHABILITATION**
2 **PROGRAMS AND PULMONARY REHABILITA-**
3 **TION PROGRAMS UNDER MEDICARE PRO-**
4 **GRAM.**

5 Section 51008(c) of the Bipartisan Budget Act of
6 2018 (Public Law 115–123; 42 U.S.C. 1395x note) is
7 amended by striking “January 1, 2024” and inserting
8 “January 1, 2022”.

○

The Increasing Access to Quality Cardiac Rehabilitation Care Act of 2021 (H.R. 1956/S. 1986)

This House version was introduced by the Reps. Lisa Blunt Rochester, Adrian Smith (R-NE), Derek Kilmer (D-WA), Brian Fitzpatrick (R-PA), and Peter Welch (D-VT). It currently has 22 co-sponsors, 14 Democrats and 8 Republicans.

The Senate version was introduced by Sen. Shelly Moore Capito (R-WV) and Sen. Amy Klobuchar (D-MN). It has 8 co-sponsors, 5 Democrats and 3 Republicans.

It has been endorsed by the American Academy of Pas, American Association for Respiratory Care, American Association of Cardiovascular and Pulmonary Rehabilitation, American Association of Nurse Practitioners, American Heart Association, American Nurses Association, Preventive Cardiovascular Nurses Association, and WomenHeart: The National Coalition for Women with Heart Disease

- Authorize physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs), referred to as advanced practice providers (APPs), to begin supervising patients' day-to-day cardiac and pulmonary rehabilitation care
- Would allow APP supervision and provision of CV rehabilitation services to begin in 2022 – rather than 2024 (current law).