

November 17, 2022

The Honorable Donald M. Payne, Jr.  
106 Cannon House Office Building  
Washington, DC 20515

Dear Representative Payne:

On behalf of the Society for Vascular Surgery (SVS), we appreciate the opportunity for engagement and stakeholder comment regarding potential improvements to the Amputation Reduction and Compassion Act, or ARC Act in anticipation of re-introduction in the 118<sup>th</sup> Congress. As you are aware, the SVS is a professional medical specialty society composed primarily of vascular surgeons, that seeks to advance excellence and innovation in vascular health through education, advocacy, research, and public awareness.

Peripheral Arterial Disease (PAD) is a relatively common, yet serious disease that affects millions of individuals each year in the United States. The SVS, on behalf of its approximately 6,000 members, commends you for your leadership and dedication to ensuring those impacted by PAD have access to critical interventions and therapies that will improve their quality of life and potentially reduce amputations relating to such disease. Our comments related to revisions to the ARC Act and other PAD-related initiatives are below.

#### **Comments on provisions in the existing ARC Act**

The SVS continues to support, in concept, the goals of the ARC Act. As written, the bill is designed to provide for coverage of peripheral artery disease screening tests without cost-sharing under Medicare, Medicaid, and private health insurance for certain at-risk individuals, while also requiring the development of certain educational programs and Medicare quality measures to reduce amputations relating to such disease.

Estimates on the number of people in the United States with PAD vary widely but are likely as high as 10 million. More than 10 percent of those suffer from chronic limb-threatening ischemia (CLTI), the most severe form of PAD, which carries the risk of amputation, lowering quality of life and increasing mortality. Globally, an estimated 200 million suffer from PAD and CLTI affects approximately 22 million. As such, the education and awareness provisions of the ARC Act represent a critical step for increasing the likelihood of early diagnosis, intervention, and mitigation of serious complications associated with untreated PAD. **However, SVS remains concerned with the disallowance of payment provision, SEC. 6. DISALLOWANCE OF PAYMENT FOR NONTRAUMATIC AMPUTATION SERVICES FURNISHED WITHOUT ANATOMICAL TESTING SERVICES, included in the current legislation (H.R. 2631, 117<sup>th</sup>).** The SVS believes physicians must be free to practice medicine and provide patient-centered care informed by medical education, experience, and scientific evidence. Therefore, we reiterate our concern that Section 6 of the ARC Act, as currently written, is too prescriptive and would prevent physicians from following the best course of treatment for individual patients. **The SVS recommends the removal of this section before the bill is reintroduced in the 118<sup>th</sup> Congress and would be happy to review a new draft of this legislation prior to its reintroduction.**

### **Examples of interventions that have demonstrated CLI reduction and may be applicable to reducing unnecessary limb amputation**

The Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia trial (BEST-CLI) was recently published (November 7, 2022) in the New England Journal of Medicine.<sup>1</sup> This landmark clinical trial compared two standard treatments for restoring blood flow to the leg: surgery with the patient's own single-segment great saphenous vein (SSGSV) or with artificial grafts or another vein, versus endovascular therapy such as angioplasty, with or without stenting. The trial enrolled 1,830 patients across 150 sites in the United States, Canada, Finland, Italy and New Zealand. Each patient underwent vein mapping of the great saphenous vein, and then was assigned to one of two cohorts in this "two trials" study:

- Cohort 1 included patients with a SSGSV (1,424 patients)
- Cohort 2 included those without a SSGSV, for whom alternative autogenous vein or a prosthetic would be used (396 patients)

Patients were then randomized one-to-one to either endovascular or surgical treatment and followed for a median of 2.7 years and up to 7 years for Cohort 1 and a median of 1.9 years for Cohort 2. The choice of specific treatment following randomization was left up to the clinician. In the group that included patients who underwent bypass surgery with a SSGSV, there was a 32 percent overall reduction in major adverse limb events or death, based on a 65 percent reduction in major re-interventions, and a 27 percent reduction in above-ankle amputation. The trial's lead Investigators characterized these findings as "statistically significant."

The second cohort included patients who had either endovascular procedures, or bypass surgery using an arm vein or artificial graft. There were no statistically significant differences in outcomes, such as additional interventions or amputations, between patients who had bypass surgery with disadvantaged conduit and those who had endovascular procedures.

The international research study, funded by the National Heart, Lung and Blood Institute at the National Institutes of Health, was created to determine "the effectiveness of the best available surgical treatment with the best endovascular treatment in adults with CLI who are eligible for both treatment options."

Completion of the BEST-CLI trial is foundational in building an evidence base to help inform both the safety and impact of available therapies in both short and long-term time frames. As noted by the trial's primary investigators, both surgical and endovascular therapies are effective and important. Other key findings include:

- Patients should have an appropriate initial assessment of their vein status. For those with a good saphenous vein, bypass surgery should be considered as an initial intervention.

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<sup>1</sup> Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia;  
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2207899>

- Mortality rates and major cardiovascular safety events were low and equal between the two study groups.
- Open surgery plays an important role as an initial revascularization strategy for certain patients with CLTI.

Another key point, which is informative in the context of changes to the ARC Act, is the necessity of flexibility in terms of treating patients with PAD, CLI, and CLTI. There is no one size fits all approach for assessing the appropriateness of available treatments for individual patients, and all interventions should be driven by joint decision-making between patients and their physician, and in consultation with collaborating specialties.

### **Conclusion**

Chronic health conditions like PAD can drastically impact a patient's quality of life. The SVS commends the leadership of those in the Congressional PAD Caucus, and we appreciate the opportunity to offer recommendations for improvement of the ARC Act in advance of its reintroduction in the 118<sup>th</sup> Congress.

Expanding access to screening and increasing public awareness of PAD and other relevant conditions will be impactful for millions of at-risk patients, while also aligning with existing policy goals to provide better mechanisms for the management of various chronic diseases. The SVS looks forward to continued collaboration to achieve these goals. If you would like more information, please contact Megan Marcinko, SVS Director of Advocacy, at [mmarcinko@vascularsociety.org](mailto:mmarcinko@vascularsociety.org).

Sincerely,



Matthew J. Sideman, MD  
Chair, SVS Advocacy Council