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# Advocacy Monthly



## Battle against Medicare Cuts Receives Strong Bipartisan Support

With the support of 135 national medical organizations—including STS—Representatives Ami Bera, MD (D-CA), and Larry Bucshon, MD (R-IN), and 244 colleagues sent a [letter to House leaders](#) urging them to stop impending Medicare reimbursement cuts. The bipartisan letter, which outlined how the cuts will impact patient access to care and impair the financial stability of the health care system, calls for Congress to stop the payment reductions from taking effect on January 1. Cardiothoracic surgeons face cuts of up to 9%.

During the STS Virtual Advocacy Conference in September, STS members met with Congressional representatives and their staff, asking them to sign the letter and work on long-term reforms that would bring stability to the Medicare program. The Society will continue the fight against these cuts. For more information on how to get involved, contact [advocacy@sts.org](mailto:advocacy@sts.org).



## New Legislation Could Connect Clinical Outcomes, Claims Data

As part of the Physician Clinical Registry Coalition, STS signed a [letter of support](#) to Representatives Bucshon and Kim Schrier, MD (D-WA), thanking them for introducing [H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act of 2021](#). This legislation would provide clinician-led clinical data registries—such as the STS National Database and STS/ACC TVT Registry—with access to federal health care claims data to help track patient outcomes, assess the safety and effectiveness of medical treatments, and provide necessary information to evaluate the long-term effectiveness of therapies. Currently, regulatory barriers prevent meaningful access to claims data. The legislation also codifies the authority of the Centers for Medicare & Medicaid Services (CMS) to grant new medical technology “coverage with evidence development” (CED) status while still collecting data on its use in real-world populations. This would allow CMS to cover new interventions more quickly and in a broader patient population. The Society is working to make sure that the bill receives enough support to pass during this Congress.

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## E-Cigarettes Get Formal FDA Approval—First Authorization of Its Kind

The US Food and Drug Administration (FDA) recently approved the marketing of three tobacco products, marking the first set of electronic nicotine delivery system (ENDS) products ever to be authorized by the agency through the Premarket Tobacco Product Application (PMTA). This approval includes an ENDS device and two accompanying tobacco-flavored e-liquid pods. According to the [FDA statement](#), the manufacturer’s data demonstrated that its products could benefit “addicted adult smokers who switch to these products ... by reducing their exposure to harmful chemicals.” While this action permits the tobacco products to be sold in the US, it does not mean they are safe or “FDA approved.” The agency may suspend or withdraw a marketing order issued under the PMTA pathway if the continued marketing of a product is determined to no longer be “appropriate for the protection of the public health.” The Society has a long-standing commitment to antitobacco efforts; more details are available at [sts.org/tobaccopaper](https://sts.org/tobaccopaper).

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## Tobacco Tax Provisions Would Protect Kids, Save Lives

The Society joined 50 medical organizations in signing a [Campaign for Tobacco-Free Kids letter](#) that strongly supports the tobacco tax provisions included in the [Build Back Better Act](#). The proposed legislation would double the current federal cigarette tax to \$2.01 per pack, close tobacco tax loopholes, and impose federal tax on e-cigarettes. Public health groups estimate that the increased federal cigarette tax would reduce the number of adult smokers by 1.1 million in the first year, prevent 507,000 young people from becoming smokers, and save more than 418,000 lives over time. “The evidence is clear that raising tobacco prices, including through higher taxes, is one of the most effective ways to reduce tobacco use, especially among youth,” the letter stated. Congressional leaders continue to negotiate the legislation but expect to finalize the details by October 31.

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## CMS Looks to Repeal MCIT Final Rule

In a [letter to CMS](#), STS shared comments about the agency’s decision to repeal the Medicare Coverage of Innovative Technology (MCIT) rule. The MCIT policy would have granted expedited Medicare coverage for up to 4 years for any FDA-designated breakthrough device that received or cleared market authorization. Although generally supportive of expedited coverage, the Society maintained that devices need careful monitoring in real-world populations, not just in clinical trials. The letter also warned that the MCIT policy, as originally proposed, could have the unintended consequence of stifling competition and innovation. CMS may consider reintroducing an expedited coverage pathway for breakthrough medical devices in the future. In the interim, STS is working to pass H.R. 5394 (see above), which will help ensure that CMS can continue using CED as a way to bring medical devices to patients quickly and safely.



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