Testimony of

Thomas E. MacGillivray, MD

President

The Society of Thoracic Surgeons

Before the

Committee on Energy and Commerce

Subcommittee on Health

U.S. House of Representatives

Innovation Saves Lives:

Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology

July 18, 2023

Chair Guthrie, Ranking Member Eshoo, and members of the Committee, thank you for the opportunity to testify today about the important topic of coverage pathways for innovative therapies, including medical devices.

I am Dr. Tom MacGillivray, a cardiothoracic surgeon, and President of The Society of Thoracic Surgeons (STS). Founded in 1964, STS is a not-for-profit organization representing more than 7,900 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

In my professional life, I serve as the Physician Executive Director and Chairman of the Department of Cardiac Surgery at MedStar Health's Heart and Vascular Institute in Washington D.C and Maryland. I specialize in the surgical treatment of adults with congenital heart disease, acquired heart disease, thoracic aortic disease, and end-stage cardiopulmonary failure.

STS National Database

Established in 1989 to provide cardiothoracic surgeons with tools for quality improvement and patient safety, the STS National Database has become the gold standard for clinical registries. Our Database provides a true clinical benchmark and contains data on more than 9.4 million cardiothoracic surgeries performed by more than 4,300 surgeons. It allows hospitals and cardiothoracic surgeons to identify best practices and potential gaps, and evaluate their performance against national and regional competitors. Since the Database is updated continuously, participants can monitor their progress and make decisions on a day-to-day basis.

The STS Database and quality program includes 4 component registries and the STS/ACC TVT Registry™. The TVT Registry has been instrumental in bringing innovative lifesaving therapies to patients all around the country. Created by a collaboration between STS and the American College of Cardiology (ACC), the

TVT Registry monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures. Employing state-of-the-art heart valve technology, transcatheter heart valve procedures often provide innovative treatment options for patients who would otherwise not be eligible for conventional heart valve replacement or repair surgery. The TVT Registry has been approved by the Centers for Medicare and Medicaid Services (CMS) to meet the registry requirements outlined in the national coverage determination (NCD) for transcatheter aortic valve replacement (TAVR) and transcatheter edge-to-edge repair (TEER).

The TAVR procedure is an exceptional example of how tying an NCD to coverage with evidence development (CED) requirements can both validate the effectiveness of emerging and innovative therapies, but also expand access to additional populations based on ongoing real-world data. When TAVR was first approved under the NCD with CED in 2012, only the most at-risk individuals were eligible to receive the procedure. These populations were too health-compromised to undergo open heart surgery for surgical aortic valve replacement (SAVR). Over time, intermediate and low risk populations have gained access to this once novel therapy based on the data collected in the TVT Registry, which was made possible by the CED requirement that persist today.

Coverage with Evidence Development

As illustrated by the TVT Registry, CED helps ensure that Medicare beneficiaries have timely access to innovative technologies while simultaneously promoting the collection of real-world evidence to fill gaps in clinical knowledge. CED offers numerous advantages that benefit both Medicare beneficiaries and innovators in the field of medical technology. It provides beneficiaries with earlier access to innovative technologies that may not be covered under traditional Medicare policies in a timely fashion. This ensures that patients have access to cutting-edge treatments that could significantly improve their health outcomes.

As previously noted, CED often utilizes clinical data registries, which have proven to be instrumental in collecting evidence and answering important questions about the safety and efficacy of innovative medical devices for Medicare beneficiaries. Clinical data registries like the STS National Database and STS/ACC TVT Registry fill gaps in evidence left by clinical trials that are unable to reflect the diversity of patient populations. Significant population segments are often under-represented in clinical trials including those with significant comorbidities and variations in age, race, geographic location, and gender. This is especially important for emerging medical devices because clinical trials for these technologies tend to be small, often only a few hundred enrolled patients. Limited clinical trials cannot adequately reflect the findings of real-world evidence captured by clinical data registries during CED.

Key Considerations for Reforms

Recently the Administration issued the Transitional Coverage of Emerging Technologies (TCET) notice with comment that would create an alternative, expedited pathway to coverage and payment for emerging devices and diagnostics. It is imperative that any reforms strike a balance between providing access to innovative technologies and ensuring the collection of robust evidence to inform coverage decisions. The STS believes that it is essential that any reforms to coverage for emerging therapies:

- Prioritize the collection of real-world data, particularly for new, innovative medical devices. Data collection creates opportunities to fill post-market evidence gaps and better define patient benefits and risks.
- Permit early discussions and coordination between the agency and relevant stakeholders to allow sufficient time for appropriate application, design, and implementation of any CED requirements.
- Provide flexibility for data collection mechanisms to adjust based on new developments in the evidence.

- Registries need timely, cost effective, and continuous access to Medicare claims data to perform longitudinal studies.

Enhanced Access to Medicare Claims Data

Clinician-led clinical data registries, such as the STS National Database, are sources of real-world evidence that are uniquely positioned to drive quality improvement and meaningful health care research, but they face significant regulatory barriers that stifle their potential.

A "clinician-led clinical data registry" is a clinical data repository that is led by clinicians and is designed to collect detailed, standardized data on medical procedures, services, or therapies for particular diseases or conditions and provide feedback to participants. Clinician-led clinical data registries must also meet certain quality and privacy standards. Clinician-led clinical data registries play a significant role in gathering quality and clinical outcomes data to better inform value-based care.

It is essential that clinician-led clinical data registries, such as the STS National Database, have timely, broad, and continuous access to Medicare claims data to enhance our understanding of the long-term impacts of innovative therapies. For example, if given access to Medicare claims data combined with data in the STS/ACC TVT Registry and STS Adult Cardiac Surgery Database, we would be better able to study the outcomes of both TAVR and SAVR to determine which procedure is most beneficial for low-risk patients. Access to this type of data was permitted in Section 105(b) of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), but CMS has refused to provide clinician-led clinical data registries with a meaningful way to gain continuous access. CMS has referred STS and other similarly positioned organizations to the Research Data Assistance Center ("ResDAC") process, but after numerous attempts it is clear this avenue is insufficient. It is limited to narrowly defined research questions and is slow, costly, and cumbersome.

CMS' failure to properly implement Section 105(b) hinders clinician-led clinical data registries' ability to perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes. Tying Medicare claims data to clinical outcome information enables clinician-led clinical data registries to better track patient outcomes over time, expand their ability to assess the safety and effectiveness of medical treatments, and provide patients with the information necessary to assess the cost-effectiveness of alternative therapies.

STS urges Congress to advance reforms such as the H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act of 2021, from Reps. Larry Bucshon, MD, and Kim Schrier, MD, which would require that enhanced access be provided to clinician-led registries such as the STS National Database.

Reduce Burden on Registry Vendors

Clinician-led registries play a critical role in improving quality and access to care. These registries must be provided with flexibility so they can be leveraged to a greater degree and have a greater impact on patient care. However, the burdensome and restrictive requirements by of CMS on registry vendors prohibits their ability to function at their full capacity.

For example, although STS has run a successful registry for CED data collection and quality improvement, STS stopped participating in the Merit-based Incentive Payment System (MIPS) program as a Qualified Clinical Data Registry (QCDR) in 2022 due to a pattern of increasingly burdensome and irreconcilable requirements placed on QCDRs, such as:

- Mandating QCDR reporting of Promoting Interoperability measures and Improvement Activities
- Requiring specific data validation requirements that are unnecessarily duplicative of internal quality data standards, which should be recognized and accepted by CMS.
- Requiring provider level audits that are time consuming, cost prohibitive, and do not enhance overall data quality or validity.

CMS must reduce the burden and expense placed on clinician-led registries so that they are able to capture relevant, actionable data for better performance measurement, improvement, and transition to value-based health care delivery.

To close out, I will say that STS's experience with the STS/ACC TVT Registry has shown that CED helps protect the patient while offering innovative health care solutions. The findings from small pre-market clinical trials do not always generalize to the real-world setting. Without ongoing evidence collection in the real-world setting and access to longitudinal claims data, the efficacy and appropriateness of emerging innovative technologies is uncertain, impairing physicians' ability to make the best decisions for our patients.