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February 20, 2024

Robert M. Califf, MD
Commissioner
Food and Drug Administration (FDA)
Department of Health and Human Services
5630 Fishers Lane
Rockville, MD 20852

Re: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices [FDA–2023–D–4395]

Dear Commissioner Califf,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the FDA Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,700 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.

FDA issued draft guidance to clarify how real-world data (RWD) will be evaluated to determine whether they are of sufficient quality for generating real-world evidence (RWE) that can be used in FDA regulatory decision-making for medical devices. This draft guidance expands on the 2017 recommended guidance issued by FDA. In the updated guidance, FDA lists registries as appropriate data sources for RWD collection and as a mechanism for collecting data to support marketing authorization. FDA recognizes that aggregation of RWD in a registry may prove useful as a post-market control suitable for providing ongoing device safety surveillance and additional evidence for effectiveness.

STS appreciates the guidance provided by FDA that specifically address the effectiveness of clinical data registries for RWD collection and analyses to help ensure that patients, providers, and regulators can make informed decisions based on the best available clinical evidence**. Leveraging the RWE from clinical data registries is a powerful tool for informed decision making.**

FDA's use of RWE to guide regulatory decision making has provided important new evidence for health care decisions and facilitated clearer understanding of the risks and benefits of therapies for patients, providers, and payers. STS, in partnership with the American College of Cardiology (ACC) has learned firsthand how the use of clinical data registries can capture RWD to inform CMS coverage for FDA approved devices. During the past decade, the STS/ACC TVT Registry™ and Coordinated Registry Network supported 23 regulatory decisions and ensured evidence-based evaluation of Transcatheter Valve Therapy (TVT) technology. This method of RWE generation creates value for manufacturers and the broader device ecosystem with significant benefits to the public health.

STS believes that data collection and the pursuit of quality improvement encourages collaboration among different stakeholders including professional societies, government agencies, industry, and patient groups. Different government agencies often have dissimilar evidentiary needs, requiring the generation of varied data for different stakeholders in order to understand how new technologies work in patients. This can be accomplished by supporting the integration of clinical and administrative data which allows for clinical analyses and feedback to stakeholders. This includes quality improvement in value-based care. STS appreciates FDA's work in designing and enhancing guidance that encourages partnerships among industry and professional societies to better align development and data collection efforts in order to meet the needs of regulators, payers, and patients.

STS' experience with the STS/ACC TVT Registry™ and STS National Database demonstrate that this model is an effective platform to support collaboration and meet the needs of varied stakeholders. The STS/ACC TVT Registry™ relies on the integration of clinical and administrative data (i.e., clinical data can be linked to CMS MEDPAR information) to obtain longitudinal outcomes data. The Registry tracks relevant outcomes, which allows stakeholders to use the information to enhance evidence-based shared decision-making with patients and caregivers.

As recognized by the FDA Total Product Life Cycle Advisory Program (TAP), it is important to engage relevant stakeholders early and to start the data collection for the regulatory and coverage process to ensure sufficient time to identify and capture the appropriate data elements. During the TAVR effort, STS and ACC initiated conversations with CMS, FDA, and other relevant stakeholders early to ensure upfront agreement on the components and structure of the STS/ACC TVT Registry™. Lessons learned from STS/ACC's experience developing the STS/ACC TVT Registry™ suggest that RWE to inform policy decisions can be successful if federal agencies facilitate early discussions among relevant stakeholders to ensure appropriate application, design, and implementation of data collection.

STS applauds FDA's recognition that data collection should evolve to respond to the changing evidentiary and technology landscape, which may introduce new or different indications, outcomes, and subpopulations. Data collection should be used to identify anomalies, target the causes of adverse events, or identify the reason for changes in outcomes. Registries provide a pragmatic way to develop answers to questions and registry data collection crosses agency boundaries providing a tangible asset to address several regulatory pathways.

Thank you for the opportunity to provide these comments. Please contact Molly Peltzman, Associate Director, Health Policy at mpeltzman@sts.org, or Derek Brandt, Vice President of Government Relations at dbrandt@sts.org should you need additional information or clarification.

Sincerely,

Jennifer Romano, MD
President