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January 5, 2023

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

Re: Medical Devices; Voluntary Total Product Life Cycle Advisory Program Pilot [FDA-2022-N-2274]

Dear Dr. Califf,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Food and Drug Administration (FDA) Medical Devices; Voluntary Total Product Life Cycle Advisory Program Pilot Proposed Rule. Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,600 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.

The FDA Center for Devices and Radiological Health (CDRH) announced its voluntary Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot that will begin in fiscal year (FY) 2023 with the initial phase. The TAP Pilot is intended to facilitate improved strategic decision-making and better align expectations regarding evidence generation during device development, including through facilitating interactions between TAP participants and stakeholders, such as patients, providers, and payers. The FDA is requesting feedback and suggestions from industry and other stakeholders about the following question:

- *Are there specific patient, provider, or payer organizations whose members may be well-suited and willing to provide insights regarding evidence generation strategies to sponsors who wish to obtain such input?*

STS supports the development and use of data collection systems to ensure that patients, providers, and the FDA can make decisions based on the best available clinical evidence. Specifically, we encourage the use of physician-led clinical data registries to capture real-world data for evidence generation. The Society has a long history of rigorous real-world clinical data collection and quality improvement through the STS National Database and its four component registries (Adult Cardiac Surgery, General Thoracic, Congenital, and Intermacs/Pedimacs Databases). In addition, since 2011, STS has partnered with the American College of Cardiology (ACC) to develop and oversee the STS/ACC TVT Registry™. The Registry was jointly developed to track real world outcomes related to transcatheter aortic valve replacement therapy (TAVR) and serves as the main repository for all clinical data related to TAVR. 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 technology. This method of evidence generation creates value for manufacturers and the broader device ecosystem with significant benefits to 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, forcing stakeholders to generate varied data for different stakeholders to understand how new technologies work in patients. This can be accomplished by supporting the integration of clinical and administrative data which allows for important clinical analyses and feedback to stakeholders. Protocols should be designed to enhance the ability for partnerships among industry and professional societies with physician led clinical data registries to better align development and data collection efforts in order to meet the needs of regulators, payers, and patients.

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

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 a number of regulatory pathways.

Thank you for the opportunity to provide these comments. Please contact Molly Peltzman, Associate Director of Health Policy, at mpeltzman@sts.org or 202-787-1221 should you need additional information or clarification.

Sincerely,

John H. Calhoon, MD
President