



The Society of Thoracic Surgeons

STS Headquarters

633 N Saint Clair St, Floor 23
Chicago, IL 60611-3658
(312) 202-5800
sts@sts.org

STS Washington Office

20 F St NW, Ste 310 C
Washington, DC 20001-6702
(202) 787-1230
advocacy@sts.org

www.sts.org

October 25, 2016

Benjamin Eloff, PhD
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Building 66, Room 2254
Silver Spring, MD 20993

Via Electronic Submission: <http://www.regulations.gov>

**Re: Use of Real-World Evidence to Support Regulatory
Decisionmaking for Medical Devices; Draft Guidance for Industry
and Food and Drug Administration Staff; Availability [Docket No.
FDA–2016–D–2153]**

On behalf of The Society of Thoracic Surgeons (STS), I write to thank you for the opportunity to provide comments on the Use of Real-World Evidence to Support Regulatory Decision-making for Medical Devices: Draft Guidance for Industry and Staff. Founded in 1964, STS is an international not-for-profit organization representing more than 7,300 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

The Society agrees that real world evidence (RWE) can help to inform our understanding of the benefits and risks of medical devices at every stage during the device lifecycle and allow patients to access new treatment options in a more timely fashion. We are pleased that the Food and Drug Administration (FDA) is carefully considering how to implement policies that will support a learning healthcare system that can improve patient access to safe and effective medical devices and help monitor the safety and efficacy of those devices as they are utilized in the broader population. We look forward to working with the agency to implement new policies on the utilization of RWE, specifically RWE from clinical data registries.

We appreciate FDA's recognition of the utility of clinical registry data throughout the product lifecycle. The STS National Database was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. There are three components to the STS National Database, each focusing on a different area of cardiothoracic surgery—Adult Cardiac, General Thoracic, and Congenital Heart Surgery, with the availability of Anesthesiology participation within the Adult Cardiac and Congenital Heart Surgery Database components. The STS/ACC TVT Registry™,

established by STS and the American College of Cardiology (ACC), monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures – emerging treatments for valve disease patients. As FDA is aware, the STS/ACC TVT Registry™ is in many respects a model for leveraging RWE. Data from the STS/ACC TVT Registry™ are used by the medical device industry and the FDA for ongoing surveillance, post approval studies, and continued access protocols. We look forward to working with FDA to clearly define how clinical data registries can be further leveraged, as well as identify impediments to the utilization of RWE from clinical data registries.

One example of an impediment is the current ambiguity in the interpretation of the Common Rule for human subjects research. Currently, many clinical data registries collect identifiable patient information or protected health information (PHI) primarily for purposes of quality improvement. In doing so, organizations that oversee clinical data registries typically enter into HIPAA-compliant business associate agreements with their participating hospitals or medical practice groups. They also typically obtain waivers from an institutional review board (IRB) of the HIPAA authorization and Common Rule informed consent requirements to allow for the collection and use of PHI for research purposes. The organizations obtain these waivers even though, according to Office for Human Research Protections guidance, the Common Rule generally should not apply to the majority of registries because they do not receive federal funding or conduct federally-regulated research. However, many hospitals and other data sources will not submit data to a registry that engages in some research analysis without such IRB waivers. Many hospitals take the position that they must obtain separate waivers from their local IRBs or, even worse, that they must obtain HIPAA authorizations and Common Rule informed consent from patients before submitting their data to a clinical data registry that conducts research analysis of the data, even if such analysis uses de-identified data or a limited dataset as defined by HIPAA. The Society recommends that the FDA explicitly provide guidance instructing IRBs on the use of real world data with a preference for regulatory reform allowing waivers of informed consent consistent with the requirements of the Common Rule.

In general, clinical data registries are not designed to host investigational devices exemption (IDE) trials. Instead, they are designed to observe performance of a therapy or care plan or other similar type of activity and incidentally capture related data, such as information pertaining to off-label uses. In light of this, clinical data registries typically do not meet the rigorous requirements for IDE trials. As such, when real world data are captured without the intent to use such data for label expansion, full IDEs should not be required to use registry data to expand label indications. Instead, we urge FDA to create a new mechanism allowing for the use of registry data when making a determination regarding label expansion, but taking into account the structure, governance and operations of clinical data registries. For more information, please refer to earlier correspondence between the ACC, STS and the FDA on this subject.

Thank you for the opportunity to share these comments. If you have any additional questions, please contact STS Director of Government Relations Courtney Yohe by phone at 202-787-1222 or by e-mail at cyohe@sts.org.

October 25, 2016
Benjamin Eloff, PhD
3

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Bavaria", with a stylized flourish at the end.

Joseph E. Bavaria, MD
President