April 27, 2015

Leslie Kux, Esq.
Associate Commissioner for Policy
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Comments on "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System" – Docket No. FDA – 2012-N-0359-0005

Dear Ms. Kux:

On behalf of The Society of Thoracic Surgeons (STS), I appreciate the opportunity to provide comments on the National Medical Device Post-market Surveillance System (MDS) Planning Board report titled, "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System." Founded in 1964, STS is an international not-for-profit organization representing more than 7,000 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.

STS recognizes the potential benefits of an MDS to the health care system as a whole and we believe there is great potential for stakeholders to work together in establishing an MDS to function in tandem with, and build upon, existing methodological tools. In 1989, the Society developed the STS National Database as an initiative for quality improvement and patient safety. The STS National Database has three components – Adult Cardiac, General Thoracic, and Congenital Heart Surgery. We believe that our experience with the STS National Database, along with the STS/ACC TVT Registry ™ (TVT Registry), will be invaluable to the development of a robust MDS that will enhance and improve the safety and quality of health care in the United States. The report lays out an ambitious vision for the future of MDS, and the Society is pleased to offer targeted comments.

We appreciate that the report recognizes the TVT Registry as an example of the type of public/private partnership that the Planning Board is seeking to emulate in the MDS. Our work, in collaboration with the American College of Cardiology, the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the medical device industry, provides an example of how multi-stakeholder collaboration and leadership can appropriately govern an initiative like the MDS. Although this multi-stakeholder partnership has been (and continues to be) extremely fruitful, the

Planning Board should be aware that translating this experiment to a macro MDS infrastructure will require considerable work, resources, and buy-in from all parties.

STS applauds the overall emphasis of patient well-being at the core of the MDS. We also agree that the foundation for an MDS will be largely contingent upon the establishment, promotion, and integration of a unique device identifier (UDI) system into electronic health information. The MDS should rely on further development of national and international registries, modernization of adverse event reporting, and the development of new methods for evidence generation. That being said, STS has some concerns regarding the data gaps and other infrastructure challenges that could impede development of a system for post-market surveillance of medical devices.

Electronic health records (EHRs) have not yet achieved interoperability among the various systems, and there is very little exchange currently between EHRs and clinical registries. The planning board states, "Registries hold the potential for becoming key data hubs linking EHRs with other data sources on devices and patients and may be important elements of MDS." STS agrees that clinical registries will be an essential component of the MDS. However, one of the major challenges going forward will be establishing a broader understanding of the difference between a clinical registry and an EHR. A true clinical data registry, like the STS National Database, has highly structured, standardized data definitions and strict control over the accuracy and integrity of the data. On the other hand, EHR data are primarily unstructured and lack specific data definitions or controls over who enters the data. The data sets are very different, and while it is possible to link some data elements between EHRs and clinical registries, for many other data elements it is currently impossible to establish proper links. Interoperability standards have to be established between the various EHR systems in the market, as well as between EHRs and registries (e.g., demographic data), in order to support the MDS objective of interoperability across data sources. Linking between the data sets will require testing to demonstrate that data collected in EHRs can be validated against the gold standard of clinical registries.

It is clear that creating interoperability between EHRs and registries remains an important, but lofty goal. If EHRs are to be a valued source of measuring medical device effectiveness, then the entities developing and introducing EHR technology must be persuaded to integrate and adopt new and pioneering solutions. The Planning Board should leverage its influence with policy makers to a) facilitate incentives for EHR interoperability and b) encourage EHR vendors to work with legitimate clinical data registries on the development of the electronic infrastructure that is necessary to support a functional MDS.

In addition to interoperability, the adoption of UDIs as part of EHRs, claims, and registries – albeit costly – could dramatically improve post-market surveillance of medical devices. As the Planning Board is aware, there are several benefits of incorporating UDIs in EHRs, including facilitating timelier product recalls, prompt identification of malfunctioning devices, and more precise adverse event reporting. Additionally, the inclusion of UDIs in EHRs will allow providers to make more informed decisions on patient care, especially when patients see multiple physicians. STS strongly supports inclusion of UDIs in medical claims and EHRs. The Planning Board should be aware that without incorporating UDIs in medical claims and EHRs, the ability to implement the goals of the MDS would be very limited. We continue to encourage CMS, EHR vendors, and all relevant parties to commit to this important, albeit costly, endeavor.

The inclusion of UDIs in claims could provide payers with analyses on devices that will help them compare outcomes across device models and enhance communication between health plans and beneficiaries during a recall. Further, the FDA Sentinel Initiative could use claims data for longitudinal analyses of device safety. The FDA has utilized Sentinel to successfully evaluate drug and biologic safety, and the Sentinel primary investigators underscore that using this system to assess device safety is not feasible without adding UDIs to claims. We also stress the importance of Sentinel in providing the FDA with data that are unavailable through other post-market surveillance tools. Despite the absence of unanimity among Planning Board members on the inclusion of UDIs in claims, we recognize the considerable advantages of their inclusion for MDS.

By linking clinical data registries with UDIs and claims information, greater specificity on device surveillance could enhance long-term outcomes data. Registries have the potential to collect detailed data on patient outcomes and facilitate innovation. Incorporating UDIs into registries could yield new insights into comparative effectiveness research and personalized medicine. However, this too comes at a considerable cost to the registries themselves.

While we support the Planning Board's desire to have UDIs in all data sources in order to simplify the process for device surveillance, we think that the financial and administrative burden of incorporating UDIs is understated given the considerable cost for technology and staff resources. In order to overcome significant hurdles to UDI adoption in claim forms and EHRs, mature registries will need to re-engineer their data elements and infrastructure according to national IT standards. These changes will require significant investment of resources.

Further, STS is concerned about the system's anticipated funding mechanisms. The MDS is not currently funded, and the Planning Board estimates that the cost to implement and maintain the MDS over the first five years could be $200-250 million in federal and private sector support. Congress would have to mandate funding for the project through the FDA, and with reauthorization of the Medical Device User Fees Act still two years away, it will be difficult to find the funding necessary to get the MDS off the ground. Unfortunately, the lofty goals of the MDS will not be met without considerable attention to this important detail.

Thank you for considering our comments regarding the planning and implementation of a robust MDS. We look forward to working with MDS leadership to help ensure that effective, safe, and timely medical device surveillance can become more readily available for impacted stakeholders. Should you have any questions or like to discuss our comments further, please contact Courtney Yohe, STS Director of Government Relations, at (202) 787-1222 or by email at cyohe@sts.org.

Respectfully,

Mark S. Allen, MD
President