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 20001-6704
(202) 787-1230
advocacy@sts.org

www.sts.org

July 18, 2013

Sylvia Mathews Burwell
Director
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

**RE: Release of the Unique Device Identifier Final Rule**

Dear Ms. Burwell:

On behalf of The Society of Thoracic Surgeons (STS), the largest organization representing cardiothoracic surgeons in the United States and the world, I write to urge you to finalize U.S. Food and Drug Administration (FDA) regulations establishing a device identification system. This unique device identifier (UDI) system will serve as the cornerstone to improving medical device safety and quality. Section 614 of the Food and Drug Administration Safety and Innovation Act mandated that the administration finalize the UDI regulations by June 19, 2013. Further delay will impair the FDA's ability to conduct important safety surveillance of medical devices to improve patient safety and the quality of care.

Founded in 1964, STS is an international, not-for-profit organization representing more than 6,600 surgeons, researchers, and allied health care professionals in 85 countries who are dedicated to providing patient-centered high quality care to patients with chest and cardiovascular diseases, including heart, lung, esophagus, transplantation, and critical care. 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 continues to play an important role in the quickly-evolving medical device policy landscape. STS joined with the American College of Cardiology (ACC) to help to facilitate the near parallel approval and coverage with evidence development of a Transcatheter Aortic Valve Replacement (TAVR) device. STS and ACC's ongoing experience with longitudinal studies based on robust and broadly-utilized clinical registries was instrumental in this groundbreaking collaboration.

In a November 7, 2012 letter, STS endorsed the laudable goals of the UDI program: including providing rapid and continuous access to key information related to the device, simplifying the integration of device use information into data systems, providing more rapid identification of medical devices with adverse events, providing more rapid development of solutions to reported problems, providing more rapid, more efficient resolution of device recalls, better-focused and more effective FDA safety communication, and providing an easily-accessible source of definitive device identification information.

The UDI program will provide a new and exciting opportunity to collect data on the different types of medical devices used in cardiothoracic surgery practice. For example, collecting patient demographic information along with UDIs, researchers will be able to identify if certain patient characteristics make it more likely that that an individual patient will have a successful outcome with a specific device. STS believes that this approach to medical research will foster innovation in targeted healthcare rather than stifle the development of new products.

Considering the importance of this new device identification system to improve patient care and the missed June 19, 2013 statutory deadline, we strongly urge you to promptly complete review of the UDI final rule. This will clear the way for the FDA to begin implementing this new device identification system and achieving its significant benefits to physicians, manufacturers and—most importantly—patients.

Sincerely,

Douglas E. Wood, MD
President