

The Society of Thoracic Surgeons

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Robert M. Califf, MD Commissioner of Food and Drugs Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Califf:

On behalf of The Society of Thoracic Surgeons (STS), I would like to congratulate you on your recent Senate confirmation as commissioner of the Food and Drug Administration (FDA).

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 how crucial your expertise will continue to be as the FDA plays an expanding role in the changing healthcare arena. We especially appreciate your prioritization of developing a national postmarket medical device surveillance system, and the inclusion of unique device identification (UDI) in Medicare claims to further this goal. As you may know, in 2011, STS and the American College of Cardiology (ACC) launched a first-of-its-kind clinical registry to monitor the safety and efficacy of transcatheter valve therapy (TVT). STS believes the STS/ACC TVT Registry plays an important role in tracking long- and short-term outcomes; helps the FDA approve life-saving devices earlier; and provides an exceptional opportunity to work closely with regulatory agencies and industry in the pursuit of high-quality patient care.

We hope you will consider the Society and its members as resources and allies during your tenure. Again, congratulations. We look forward to working with you to ensure the health and safety of all Americans. Please contact Courtney Yohe, Director of STS Government Relations (202-787-1222 or cyohe@sts.org) if you have questions about STS, the STS National Database, or if we can be of any help in the future.

Sincerely,

Joseph E. Bavaria, MD

President