



The Society of Thoracic Surgeons

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November 9, 2015

The Honorable Lamar Alexander, Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate 428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray, Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate 428 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Alexander and Senator Murray:

On behalf of The Society of Thoracic Surgeons (STS), I write in strong support of the nomination of Robert Califf, MD, as commissioner of the Food and Drug Administration (FDA). Based on his extensive leadership experience, in-depth knowledge of the FDA, and decades of clinical research, Dr. Califf is the best person to lead the FDA as commissioner.

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.

As FDA's current Deputy Commissioner for Medical Products and Tobacco, Dr. Califf delivers expert guidance on widespread initiatives, from improvements in clinical trials to using observational data from electronic medical records systems to expand patient access to new treatments. He has worked closely with the National Institutes of Health on precision medicine, an emerging method of individualized and effective care.

Before joining the FDA in January of this year, Dr. Califf collaborated with the agency on the Advisory Committee on Cardiovascular and Renal Drugs and its Science Board Working Group. He also served in leadership positions within the Institute of Medicine (IOM), including the IOM Clinical Research Roundtable, the IOM Committee on Medication Errors and the IOM Board on Health Sciences Policy. His exacting clinical research and over 1,200 peer-reviewed publications have made him one of the top ten most cited medical authors.

Notably, he was also the founding director of Duke's Clinical Research Institute (DCRI), the world's largest academic research organization. DCRI

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currently houses the STS National Database, one of the most robust and longest-running clinical data registries in existence. Because of this exceptional database, STS has more quality measures approved by the National Quality Forum than any other specialty society and remains on the cutting edge of efforts to improve health care quality and cut costs.

Dr. Califf's unique experience, both within and as an external advisor to the FDA, will enable him to deftly implement critical initiatives and further the agency's mission. As commissioner, his transformative leadership skills, impressive contributions to medical research, and demonstrated commitment to patient care would be amplified. STS strongly supports Dr. Califf for commissioner of the FDA.

Sincerely,

A handwritten signature in cursive script that reads "Mark S. Allen".

Mark S. Allen, MD
President