Why Dr. Robert Califf’s Nomination for Commissioner of the Food and Drug Administration Is Good for Heart Failure Patients

Christopher M. O’Connor, MD, FACC, Editor-in-Chief, JACC: Heart Failure

Although many appointments around Washington, DC, may be mundane, the nomination of Dr. Robert Califf to become the new Commissioner of the Food and Drug Administration (FDA) has received much enthusiasm amongst the community of patients, health care providers, policy makers, academic leaders, and industry in cardiology. It is not a surprise that Dr. Califf was nominated for the job; in fact, his name has been mentioned on previous occasions. During the Bush administration, he was asked to have an interview with the President. I had the opportunity to talk and counsel Rob about this interview and engage one of our friends who was a senator of North Carolina at that time. In typical fashion, Dr. Califf was thoughtful, careful, and accurate in all of his answers to the questions, but the decision was made to move forward with an alternative candidate. Eight years later, Dr. Califf’s name again emerged as a potential candidate, but ultimately Dr. Hamburg, who was former commissioner of New York City’s Department of Health and Mental Hygiene, would be appointed. Her subsequent term, one of the longest in the history of FDA, was quite notable. She pushed the agency to communicate better with drug and device companies, resulting in more approvals and increasing the energy around the development of biotech compounds. At the time, Congress was clearly interested in enhancing the abilities of the FDA to look at ways for getting medicines to patients more quickly.

Dr. Califf’s credentials are impeccable for being nominated as an FDA commissioner. He graduated at the top of his class at Duke University, and after completing his residency at University of California, San Francisco, he returned for his cardiovascular fellowship training and immediately joined the faculty and excelled. Although his interests initially were in the Duke Cardiovascular Databank, understanding large data from the likes of Eugene Stead, David Pryor, and Joseph Greenfield, he quickly realized that the randomized controlled clinical trial was a better method of developing evidence to change practice, and he engaged with his former colleagues from residency training, including Dr. Eric Topol, to form what was called the TAMI (Thrombolysis and Angioplasty in Myocardial Infarction) trials. This was a competing network of clinical trials with the National Heart, Lung, and Blood Institute-funded TIMI (Thrombolysis in Myocardial Infarction) trials chaired by Dr. Eugene Braunwald. Over the next decade, they conducted 10 clinical trials that provided enormous insight into the mechanisms and outcomes of patients experiencing acute ST-segment elevation myocardial infarction and undergoing treatment with thrombolytic therapy. His success in leading the data interpretation and coordination of these clinical trials led to the receipt of the GUSTO (Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries) trial program, which was the largest randomized clinical trial of myocardial infarction patients in the world, enrolling over 41,000 patients into the program across all continents (1). This allowed Dr. Califf to launch the academic research organization now known as the Duke Clinical Research Institute. Over the subsequent several decades, numerous
multicenter international mega trials provided the evidence base for patients with acute coronary syndromes, chronic ischemic heart disease, and heart failure. To date, the Duke Clinical Research Institute has conducted more “mega trials” than any other complete academic research organization in the world. While doing so, many drugs have been approved through the FDA, and many have not. The guidelines have been changed, and many patient lives have been improved.

This trajectory was not without challenges. The CAVEAT (Coronary Angioplasty Versus Excisional Atherectomy Trial), a randomized trial of atherectomy versus percutaneous coronary intervention funded by the atherectomy catheter company, showed an increased risk of myocardial infarction with the novel interventional device (2). There was enormous pressure on Dr. Califf and other investigators, and yet, it was both presented and published nationally to provide full transparency to the patients and the investigators who participated in the trial. Dr. Califf stood on principles that are even more stringent and important today. This was one of many examples of doing the right thing despite the economic opportunity and consequences.

It is best summarized that Dr. Califf is fair. He always advocated that if a clinical trial was done, it should be published. As an editor of the American Heart Journal, he facilitated publication of negative results because he believed it was fair for the patients who contracted with the investigative team that conducted the study to make results public. Dr. Califf was fair in the way that he gave credit to others. In both TAMI trials that he led, he mentored over several hundred academic cardiologists, residents, and fellows, many of whom stand in leadership positions across the country, a testimony to his philosophy of pursuing excellence and passing onto others what he learned. In the last 7 mega trials that Rob has been involved with, 4 have been negative, 2 positive, and 1 neutral; all have been published with full results, again, highlighting his unbiased approach to reporting results.

I joined Dr. Robert Califf’s presence in 1983 as a house officer who was interested in clinical cardiovascular research and became the first Robert Califf fellow in 1986. It was impressive to round with Dr. Califf in the coronary care unit and understand his advocacy for evidence-based medicine. He always asked where the evidence was and if we should be randomizing the patient into a clinical trial. I spent many nights and weekends in the intensive care unit consenting patients to be randomized for controlled clinical trials that have subsequently changed the practice of care.

I am grateful that I served as one of Dr. Califf’s first fellows during his very early career. I commented to Dr. Califf that because he saved lives through the great successes of acute intervention, the patients who were destined to die now are living with heart failure instead. This is what led me to pursue a career in this field. Dr. Califf shook his head and said, “All my trainees go into the field of acute coronary heart syndromes but I always thought you would be the black sheep.” Well, it is this black sheep that is grateful for the nomination of Dr. Califf as FDA commissioner, for I am convinced he will do more for our patients with heart failure to improve their quality and quantity of life.

ADDRESS FOR CORRESPONDENCE: Dr. Christopher M. O’Connor, Editor-in-Chief, JACC: Heart Failure, American College of Cardiology, Heart House, 2400 N Street NW, Washington, DC 20037. E-mail: jacchf@acc.org.

REFERENCES
