

TESTIMONY OF ROBERT M. CALIFF, M.D.
BEFORE THE SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR AND
PENSIONS

INTRODUCTION

Chair Murray and Ranking Member Burr, I want to thank you and members of the Committee for inviting me here today to discuss my nomination to be Commissioner of the Food and Drug Administration (FDA). Five years ago, I was before you in the same position. Much has happened over those five years, including the devastating COVID-19 pandemic, but many fundamental issues I addressed at that time remain important areas for the FDA, our country and the world to advance towards an era of unprecedented health.

I am excited to be accompanied by family today. Sitting behind me are my wife of 48 years and high school sweetheart, Lydia; two of our three children, Sharon and Sam; and two of our six grandchildren, Brooke and Noah. I also want to take a moment to honor my parents, who were with me at the last hearing, and who passed away peacefully in their 90's. The support of my family has been essential to my career. The unique opportunity to help create a better world for my grandchildren is personally motivating.

I previously served with pride as FDA Commissioner, and I am honored that President Biden has nominated me to lead the FDA for a second time. I also want to thank Dr. Janet Woodcock, the rest of the FDA leadership team, and the entirety of the FDA workforce for their exemplary service over the years and especially during the COVID-19 pandemic.

To the many Committee members I have met with over the last several weeks: I thank you all for your willingness to share with me your perspectives on ways the FDA can better serve the American people. If confirmed, I will be a Commissioner who understands the importance of working closely with Congress, as well as other parts of the Executive Branch. I will also be a Commissioner who can hit the ground running because of my past experience as a civil servant and in leading the Agency.

BACKGROUND

My four-decade career has been dedicated to advancing the health of individuals and the public as a physician, researcher, and leader in both the public and private sector—as well as academia. But, like each of you, my understanding of our health system was shaped by both my personal and professional life experiences, which will guide my work at the FDA, if confirmed.

Personal

My family, like many American families, has experienced firsthand how important it is to find a critical balance between appropriate safeguards for patients and innovative treatments.

My daughter was born with a serious congenital heart defect requiring open heart surgery as an infant. My mom benefitted directly from the accelerated approval of new drugs for multiple myeloma that, without a doubt, added meaningful years to her life.

Professional

My professional experiences, too, have shaped my understanding of our health system over the years. When I began my career as a cardiologist, heart attack was the leading cause of death in the United States and our understanding of the cause of heart attack was limited. I, along with a global network of health professionals, worked to figure out why. Together we developed “clot busting” drugs to restore blood flow to the heart, improve the recovery of the heart muscle and help prevent future heart attacks. We also developed life-saving technologies, including balloon angioplasty, cardiovascular stents, and implantable defibrillators, that have helped millions of Americans; and we stopped the development of numerous drugs and devices for which the risks outweighed the benefits. Thanks to these technologies death rates from acute heart problems have been cut in half.

This experience also taught me about the painstaking work of developing a safe and effective medical product, then conducting the critical clinical trials and seeking FDA approval for that product. Like clinical decisions, FDA decisions are best made when the evidence is robust. My career has been focused on developing better systems for generating reliable evidence to support the everyday decisions that consumers, patients, clinicians and policy makers must make to achieve better health.

PRIORITIES

My priorities, if confirmed, would be: emergency preparedness and response; consumer and patient protection; and modernization and innovation.

When it comes to emergency preparedness and response, the FDA must continue to be a strong partner in battling COVID-19. And, it must have infrastructure in place that reflects lessons learned from this pandemic so it is ready for the next one.

Secondly, all FDA’s actions regarding the products the agency regulates must focus on protecting consumers and patients. Safety matters. Now is the time to develop a systematic approach to evidence generation that will improve patient safety and provide a much more efficient way to understand the benefits and risks of medical products when used in practice. The FDA must continue to build the science base needed to give people confidence that their food is safe and their medical products are safe and effective. And we must protect kids from tobacco products, as surveys indicate youth use remains at an alarming rate.

Our nation is also experiencing an epidemic of addiction and overdose, with over 100,000 overdose deaths recorded over a 12-month period for the first time ever. FDA must work with the public health, clinical and policy communities to turn the tide.

Third, FDA must stay current on the latest advances in science and technology in order to provide guidance to industry and stakeholders on everything from clinical trial development to best practices for protecting the safety of the U.S. food supply.

With each of these priorities, a common thread is my commitment to ensuring that the agency is more inclusive, diverse, equitable and accessible in the work it does for the American public.

As I work to implement these priorities, I would also continue my previous focus on investing in our workforce. Attracting and retaining the FDA's scientific workforce may be more important than any particular policy because it is the agency's day-to-day decision making that protects the public. The scientific and technical world is moving quickly—the FDA needs the talent to keep up and protect the public while supporting scientific innovation.

CONCLUSION

This is a once-in-a-generation time for public health, and the FDA must continue to play a vital role in protecting and promoting the health of all Americans by leveraging the acceleration in technology and biomedical knowledge. If confirmed, I would be honored to lead the agency again. Thank you for allowing me to testify before you today, and I am happy to take your questions.