

December 13, 2021

Dear Chairman Murray, Ranking Member Burr, and Members of the US Senate HELP Committee:

As former Commissioners of the Food and Drug Administration (FDA), we are writing to convey our strong support for confirmation of Dr. Rob Califf as Commissioner of Food and Drugs.

We appreciate the Committee's prompt consideration of Dr. Califf's nomination. It is hard to imagine a time when the need for a well-qualified and experienced Commissioner was greater. Thanks in part to timely, science-based, regulatory action by the FDA, the nation has an improving array of tools to fight the COVID-19 pandemic. Yet the emerging omicron variant, the continued evolution of the COVID crisis, and the need for continued advances to address these risks are all reminders of just how critical it is to have a confirmed Commissioner at the helm of the FDA right now. The agency has a dedicated and talented professional staff that has been working intensely on COVID-19 response efforts, and Acting Commissioner Dr. Janet Woodcock has provided invaluable, experienced leadership throughout our public health emergency. But the absence of a confirmed Commissioner complicates the agency's ability to undertake and sustain the leadership needed now to protect and promote the health of all Americans.

Confirming Dr. Califf is critical not only for moving beyond the COVID-19 emergency, but also to help meet FDA's many other major regulatory responsibilities where Senate confirmed leadership is essential for the nation's wellbeing. The FDA regulates up to one-quarter of the U.S. consumer economy, including potentially life-saving therapies, most of the nation's food supply, and tobacco and nicotine products. Confirming Dr. Califf as Commissioner will help ensure that the FDA is well positioned to adapt and respond to these critical public health issues as well.

At this extraordinary time, Dr. Califf has the experience to be effective from day one, having previously served as Commissioner with strong bipartisan support. His public service builds on a lifelong commitment to leadership in promoting public health and advancing clinical science. He has unique experience in leading clinical research as the founder of the renowned Duke Clinical Research Institute and as former Vice Chancellor of Duke University Health System, with over 1,300 academic publications. He has been a lead investigator of many important and impactful clinical trials, resulting in evidence that has helped transform the care of patients with heart attacks and cardiovascular disease as well as many other conditions. His leadership in the original network of the Patient-Centered Outcomes Research Institute (PCORI) advanced the role of collaborative research with direct involvement by patients. As part of his ongoing efforts to improve access to effective therapies to address the nation's opioid crisis, he helped organize the National Institute of Drug Abuse network that conducted key trials showing the effectiveness of medication-assisted therapy for opioid use disorder. As Head of Clinical Policy at Verily Life Sciences, Dr. Califf has helped develop the digital tools that can help us learn

more--and more quickly--about ways to improve the safety and effectiveness of treatments. This includes many efforts to increase the diversity of clinical trials, with more meaningful participation from Americans with different racial and ethnic backgrounds as well as rural Americans.

Many of us have had the privilege of working directly with Dr. Califf on key public health issues. We know that he is deeply committed to public service, to advancing science and clinical evidence, to effective and transparent communication, and to strengthening and modernizing the FDA so that it can address the unprecedented public health challenges and opportunities ahead. We urge you to act now.

Sincerely,

Andrew von Eschenbach, MD

Scott Gottlieb, MD

Stephen Hahn, MD

Margaret Hamburg, MD

Jane Henney, MD

Mark McClellan, MD PhD