March 9, 2021

The President of the United States
The White House
Washington DC

Dear Mr. President:

The U.S. Food and Drug Administration is playing a critical role in our nation's response to the Covid pandemic. The FDA is advancing new medical countermeasures to and is protecting consumers with enforcement actions against unproven products that made misleading Covid-related claims. Right now, the agency is implementing new guidance that lays out a clear and efficient framework for how we will modernize vaccines, drugs, and diagnostics to keep up with dangerous new SARS-CoV-2 variants. The coming days and weeks will require further timely and effective actions, for example to support the development of antiviral treatments and advance the availability of reliable, easy-to-use tests. At the same time, the FDA must continue to advance its work across its uniquely broad and diverse portfolio. For example, the agency is implementing new regulations for tobacco products to reduce death and disease from cigarettes, implementing new food safety provisions, making more biosimilar drugs available at a lower cost, and taking enforcement actions against manufacturers for misleading claims.

Last fall, we warned about threats to the agency's independence and support to carry out these essential science-based regulatory activities in the Covid context, and about threats to the public perception of the agency's independence from outside pressures. Since then, despite attacks on the agency and its science-based methods, we have been heartened by the ongoing, strong leadership of the Agency's Centers and its career staff, who continue to stand up for and implement independent, science-based regulatory approaches. We are also pleased to see your Administration's strong expressions of support for relying on science and the professional expertise and judgment of the expert career staff at the nation's public health agencies, including FDA. The agency remains an aggressive advocate for public health across its entire portfolio while it continues to advance the nation's response to Covid.

In this context, we are also grateful for Dr. Janet Woodcock's willingness to take on the role of Acting Commissioner, and her commitment to FDA's scientific mission and its career staff. Experienced leadership of the agency reinforces your commitment to scientific rigor and science led decision making. Across Democratic and Republican administrations, we have worked closely with Dr. Woodcock across a range of critical issues. Dr. Woodcock is a highly effective advocate for advancing the FDA's mission – a role she has continued from her first day as Acting Commissioner.

To continue to advance the agency's mission, and promote its independent role, we urge you to prioritize securing its leadership team, including through seeking the formal nomination and confirmation of an FDA Commissioner. The agency's experienced staff and its science-based regulatory processes will play a critical role in helping the nation confront the evolving pandemic.

Sincerely,

Robert Califf, MD
Google-Verily, Duke University, and Stanford University
FDA Commissioner, 2015-2017

Scott Gottlieb, MD
American Enterprise Institute
FDA Commissioner, 2017-2019

Margaret Hamburg, MD
Nuclear Threat Initiative
FDA Commissioner, 2009-2015

Jane Henney, MD
University of Kansas Medical Center
FDA Commissioner, 1999-2001

Mark McClellan, MD PhD
Duke University
FDA Commissioner, 2002-2004

Andrew C. von Eschenbach, MD
Samaritan Health Initiatives
FDA Commissioner, 2006-2009