



July 20, 2022

The Honorable Robert M. Califf, M.D., MACC  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Califf,

As organizations representing consumers, patients and providers, we are writing to raise our serious concerns that millions of vulnerable Americans who have limited options for protection against COVID-19 are going to remain isolated and frustrated that they could be left on the sidelines while society continues to disregard safety protocols.

We commend the FDA on the actions it has taken to expedite the development of safe vaccines and treatments that diminish the spread of the virus and save lives. Despite the progress we have made with this pandemic, we must remain nimble and on guard. It is clear that we are entering a new, endemic phase of our battle with COVID-19; navigating ever-evolving variants and the reality of a pandemic-fatigued public will require continued focus as well as collaboration and ingenuity.

For many of our constituents, and especially for all the estimated seven million immunocompromised individuals in the U.S., the stakes may be even higher than they were two years ago. We know that

current vaccines and treatments don't work for everyone, and some are unable to take any of the options currently offered, and the risk to those who remain vulnerable to severe disease, including COVID-19, is compounded today by the removal of mask requirements, a push to return to "normal," and ever-diminishing social distancing and caution by individuals.

Our organizations frequently field questions from the communities we represent asking when it will be their turn to feel safe in this environment. Organ transplant patients and those who rely on medications that suppress their immune systems do not feel protected. People living with conditions that compromise the strength of their immune systems, such as HIV, cancer and many autoimmune diseases, feel exposed. And many older Americans who manage their chronic conditions through multiple medications are now severely limited in their options for treatment given the fear of drug interactions.

COVID-19 has been particularly devastating to Black and Latinx populations. While the disease is expected to reduce overall life expectancy in 2020 by just over a year, estimated reductions for Black and Latinx populations are three to four times more than that for whites.

All of the organizations signing below urge the FDA to continue its extraordinary commitment to ensuring that we have a variety of COVID-19 treatment and prevention options in place to address new variants as they arise and that broaden protections for everyone, but particularly for the most vulnerable among us. Antibody treatments in particular show incredible promise for both prevention and treatment of COVID-19 for patients living with weakened immune systems. They also hold lower risk of drug interaction for individuals living with chronic diseases who rely on multiple medications.

The U.S., normally the world leader in biomedical research, was caught unprepared for such an unprecedented pandemic event. Now, after two years of COVID-19 infections and extraordinary mortality, the U.S. has a far greater understanding of this virus and its unpredictability and, subsequently, the reasons we need to act now. As the administration has warned of another wave of COVID-19 infections during the fall, it would be unconscionable to remain ill-prepared to protect every single member of our population. Without a diverse array of treatment and prevention options, including antibody treatments, our society's health and the health of our economy will be held hostage by the unpredictable nature of future variants.

We would welcome the opportunity to meet with you in order for you to hear from these vulnerable patients firsthand. We want to discuss ways in which we can be supportive of the FDA's efforts to ensure that a wide array of safe and effective treatments are available so every American is able to protect and effectively treat themselves against this deadly virus.

Respectfully,

Healthy Women

Allergy & Asthma Network

Alliance for Aging Research

American Kidney Fund

Arthritis Foundation

Autoimmune Association

Caregiver Action Network

Community Liver Alliance

EveryLife Foundation for Rare Diseases

HealthHIV

Healthy Men, Inc.

Immune Deficiency Foundation

LUNgevity Foundation

National Caucus and Center on Black Aging

National Consumers League

The National Grange

National Hispanic Council on Aging

National Kidney Foundation

National Psoriasis Foundation

Oncology Nursing Society

Vasculitis Foundation