

November 17, 2022

Dr. Ashish Jha COVID Response Coordinator The White House Washington DC

Re: Request for a White House Summit on Next-gen COVID-19 Therapeutics and Alternative Treatments

Dear Dr. Jha:

We, the patient advocacy organization signers of this letter, and on behalf of many patients nationwide, are writing to encourage the White House OSTP to host a follow-on Summit to the July 28, 2022 White House Summit on the Future of COVID-19 Vaccines that would focus on ways to support patient access to next-gen therapeutics that are so vital for the estimated seven million Americans who are immunocompromised and those that have cancer, have an autoimmune disease and/or have had an organ transplant.

While we commend the Administration for its ongoing work to improve access to COVID-19 vaccines and to prepare for future pandemics, we also want to raise greater awareness to the fact that significant patient populations desperately need alternative COVID-19 prevention and treatment options than those currently available. We strongly believe that a new policy and regulatory framework should be considered to better address the unmet needs of these millions of patients and to ensure our country has an adequate supply of alternative next-gen therapeutics to overcome future COVID-19 variants as well as new infectious diseases that may arise.

Antibody treatments 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. These treatments need to be accessed by these patients and others. Without a diverse array of treatment and prevention options, including antibody treatments, our society's overall health is at risk, as so many are unable to get vaccinated.

Unfortunately, immunocompromised patients have struggled accessing antibody treatments during the pandemic in part due to hospitals not having enough in stock or providers restricting their use. And now, compounding the access problem, we note in this article in the Atlantic https://www.theatlantic.com/health/archive/2022/10/covid-variants-antibody-treatments-immunocompromised/671929/ that the only two monoclonal antibodies authorized for use are likely to be ineffective against the new variants that are beginning to circulate. Since monoclonal antibodies confer long-lasting immunity to the immunocompromised, we need more effective monoclonal antibodies to

counter these variants and the ones to come.

Here are some key policy recommendations:

1. A Public Health Arsenal with multiple tools (i.e., vaccines, test kits, antiviral treatments), including monoclonal antibodies, to better and more effectively prevent, treat and curb the spread of COVID-19 and its variants. Ensure a well-stocked supply of doses is available in the U.S. for immunocompromised patients.

2. Expedited Approval Pathways so new therapeutics are evaluated as efficiently as possible (e.g. consider dynamic adjustments to regulatory requirements as the risk/benefit profiles of platform technologies, like mRNA vaccines and RBD-targeted antibodies, evolves) with an end goal of having a continuous stream of safe, effective, and updated products ready to deploy when new variants arise.

3. Ongoing Support for Innovative Science to ensure research and development of new and innovative COVID-19 products continues in earnest and prepares us for future pandemics.

Thank you for your consideration of our request for a Summit on next-gen therapeutic options, and we are happy to provide patient advocate resources as needed to support the Summit event.

Very respectfully, Martha Nolan Senior Policy Advisor HealthyWomen

**Community Liver Alliance** National Consumers League Allergy & Asthma Network EveryLife Foundation for Rare Diseases The National Grange Alliance for Aging Research HealthHIV National Hispanic Council on Aging American Kidney Fund Healthy Men, Inc. National Kidney Foundation Arthritis Foundation Immune Deficiency Foundation National Psoriasis Foundation Autoimmune Association LUNGevity Foundation **Oncology Nursing Society** Vasculitis Foundation Caregiver Action Network National Caucus and Center on Black Aging

cc: Dr Matthew Hepburn, White House Senior Advisor, Office of Science & Technology Policy Dr. Stephen Cha, Counselor to HHS Secretary (FDA)