Congress of the United States Washington, DC 20515

June 17, 2021

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Dear Secretary Becerra:

We are writing to applaud your leadership and commitment to eliminating racial and ethnic disparities in health care, including in our national response to the COVID-19 pandemic. However, we wish to call your attention to a critical and growing gap in Federal investments for the accelerated clinical development of new COVID-19 therapeutics, which are urgently needed to improve outcomes for hospitalized COVID-19 patients, who are disproportionately from heavily impacted, low-income communities and communities of color.

As you know, in spite of encouraging progress in the accessibility of safe and effective vaccines, the United States is still recording over 20,000 cases daily, and emerging SARS-CoV-2 variants threaten to alter the course of the pandemic, making it more difficult for the American public to return to work, safely reopen schools, and maintain economic growth. This is especially concerning for individuals from racial and ethnic minority groups, who the Centers for Disease Control and Prevention (CDC) reconfirmed as recently as April 12, 2021 "are disproportionately affected by COVID-19, including experiencing increased risk for infection, hospitalization, and death."

Since the beginning of the pandemic, Congress has invested billions of dollars in the Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) to develop critical COVID-19 countermeasures. These efforts have led to new public-private partnerships that have accelerated the development of vaccines, diagnostics, and therapeutics to help respond to the pandemic.

However, in spite of the critical work BARDA has done to date, we are concerned by recent actions taken to halt future investments in COVID-19 therapeutics. As of May 2021, BARDA has suspended future investments in COVID-19 therapeutics, despite available funding from the American Rescue Plan Act (PL 117-2) and a demonstrated gap in treatment options for hospitalized patients. Today, the number of treatments for these patients with Food and Drug Administration (FDA) approval or Emergency Use Authorization (EUA) can be counted on one hand.² This follows on the previous Administration's unexplained June 2020 decision to

¹ S Romano et. al (2021). "Trends in Racial and Ethnic Disparities in COVID-19 Hospitalization by Region – United States, March-December 2020." Morbidity and Mortality Weekly Report (April 2021). Centers for Disease Control and Prevention. Retrieved at https://www.cdc.gov/mmwr/volumes/70/wr/mm7015e2.htm

² K Wu, C Zimmer, J Corum (2021). "Coronavirus Drug and Treatment Tracker." *The New York Times*, May 18, 2021. Retrieved at https://www.nytimes.com/interactive/2020/science/coronavirus-drugs-treatments.html

suspend investments in "therapeutics targeting lung repair," which are critically important against COVID-19 and any future respiratory pandemic or emerging infectious disease.³

At the same time, under the National Institutes of Health (NIH), the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has evaluated hundreds of potential drugs and prioritized candidates for their master protocols, with an emphasis on repurposed drugs. ACTIV has recently expanded to nine active master protocols across mechanisms of action and stage of disease. However, NIH's larger Adaptive COVID-19 Treatment Trial (ACTT) studies have recently closed to new drug candidates, including those that are being investigated for the treatment of hospitalized COVID-19 patients.

There is an abundance of information on the disproportionate impact of COVID-19 on racial and ethnic minority groups⁴, including the increased disease severity these groups face from COVID-19. Accordingly, we believe it is imperative that the Biden Administration reverse these decisions in order to increase the therapeutic portfolio available to healthcare providers to improve treatment outcomes in hospitalized patients with COVID-19. These investments must be made rapidly to address urgent and unmet medical needs at this stage of the pandemic, recognizing the risks posed by emerging variants, as well as to prepare against future pandemic threats from other viral respiratory diseases such as SARS, MERS, and influenza.

Therapeutics will improve outcomes in hospitalized patients and inform future pandemic preparedness efforts, especially in our most vulnerable communities. Therefore, we encourage you to work across your Department to reverse decisions that impede investments in these urgently needed treatments and expand public-private partnerships targeting COVID-19 therapeutics.

Thank you for your attention to this matter. Should you or your staff have any questions, please do not hesitate to contact us.

Sincerely,

I hust

Bobby L. Rush

Member of Congress

³ K Thomas, "Coronavirus Attacks the Lungs. A Federal Agency Just Halted Funding for New Lung Treatments." *The New York Times*, June 19, 2020. Retrieved at https://www.nytimes.com/2020/06/19/health/coronavirus-lung-treatment-funding.html

⁴ CDC (2020). "COVID-19 Racial and Ethnic Disparities." CDC. Retrieved at https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/disparities-illness.html#ref7

Sanford D. Bishop, Jr. Member of Congress

Barbara Lee Member of Congress

Stephen F. Lynch Member of Congress

Nanette Diaz Barragán Member of Congress Eddie Bernice Johnson Member of Congress

Eddie Bern

John B. Larson Member of Congress

Alma S. Adams, Ph.D. Member of Congress

Lisa Blunt Rochester Member of Congress