Congress of the United States Bouse of Representatives

Washington, DC 20515

December 30th, 2021

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

Dear Secretary Xavier Becerra,

We write regarding the U.S. Department of Health and Human Services' (HHS) new policy halting the federal supply of monoclonal antibody therapies to regions with a greater than 80% prevalence of the omicron variant of COVID-19. Medical providers throughout New York State have contacted our office to express their concerns that this move takes away an important tool they use to help patients with persistent covid pneumonia and multiple comorbidities. With a severe shortage of these treatments in the private market and with other therapies subject to strict limits, this change threatens to leave a large portion of vulnerable patients without treatment options. As a result, we request an immediate explanation on why HHS decided to halt distribution of monoclonal antibody therapies instead of simply adjusting guidance for clinicians. We also request information on HHS's plan to address the needs of patients who cannot take the other federally approved COVID-19 therapeutics.

While we are aware that some monoclonal antibody therapies are not effective against omicron, the threshold of 80% prevalence still means there are up to 20% of patients who could benefit from this treatment – this number could conceivably be even higher given changes that have been made to datasets. We know that over the past year, these therapies have proven incredibly successful, reducing rates of hospitalization by 70% in these vulnerable patients. This includes many older individuals and those with diabetes, hypertension, persistent covid pneumonia, and autoimmune diseases in both the vaccinated and unvaccinated population.

Additionally, many of the individuals who seek monoclonal antibody therapies have conditions or are on medications that would prevent them from taking other forms of treatment, leaving monoclonal antibodies therapies as their best and maybe even only therapeutic option. In addition, we have heard from medical professionals that even though an increasing number of cases in our region are now omicron, delta cases still represent a large percentage of severe cases requiring further treatments. For these cases, the monoclonal antibodies that you are now withholding remain the best therapeutic treatment. These medical professionals have further expressed a desire for better testing capabilities to tell omicron cases from delta, so they can tailor therapeutic treatments appropriately. This is the kind of innovation we must deliver.

With hospital capacity limited in much of our region, many in our medical community have requested additional options for treating their patients, not fewer. They repeatedly state that any tools to prevent patients from being hospitalized and placed on a ventilator significantly

increases the likelihood of a full recovery. This means access to multiple therapeutic options is a win-win for both patients and providers. We therefore urge you to reconsider your decision to take these therapeutic tools out of the hands of clinicians and consider instead simply revising guidance while continuing to ensure a supply is made available to New York and other states.

Thank you again for considering our concerns. We look forward to hearing back regarding what actions you are taking to restart distribution of this vitally important tool to combat COVID and deliver life-saving relief to the most vulnerable populations.

Sincerely,

Claudia Tenney Member of Congress

Chris Jacobs Member of Congress

Nicole Malliotakis Member of Congress Lee Zeldin

Member of Congress

Elise Stefanik

Member of Congress