CHIP ROY
21ST DISTRICT, TEXAS

1005 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4236

Congress of the United States
House of Representatives
Washington, DC 20515-4606

December 29, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Becerra,

I write to you today to inquire about the Department of Health and Human Services' (HHS) recent update to COVID-19 monoclonal antibody (mAb) distributions. The latest COVID-19 variant, Omicron, has reportedly become the dominant strain of COVID-19 in the United States.[1] However, the CDC has also recently revised projections that Omicron comprised 77% of cases the week ending December 18 to just 22%.[2] Despite this correction and the confusion surrounding the prevalence of Omicron cases, your Department is once again making major changes to mAb distributions.

Due to the projected prevalence of the Omicron strain, your Department, "Beginning next week (the week of Jan 3), and in alignment with HHS guidelines, [does] not plan to allocate bam/ete or REGEN-GOV to jurisdictions in regions with greater than 80% prevalence of the Omicron variant." This change causes further concern for treatment access for patients with different variants such as Delta. In fact, per Centers for Disease Control (CDC) data, the week ending December 25, the Delta variant accounted for over 41% of cases in the U.S.[3]

Further, only one currently authorized mAb treatment, Sotrovimab, appears to be working for patients with the Omicron strain, this is as mAb treatment sites are running dry of this treatment. In Texas, including in Austin, El Paso, Fort Worth, San Antonio and the Houston area, sites have completely run out of Sotrovimab and have no choice but to wait without recourse because your Department has taken full control of the supply chain. In fact, according to the Sotrovimab website, "GSK has entered into a contract with the U.S. government to purchase Sotrovimab. Sotrovimab is not available for commercial purchase at this time."[4]

As you know, I have previously sent multiple inquiry letters to your Department due to foreseeable consequences of supply and access issues for mAb treatments due to your Department's changes. On

[1] https://www.usnews.com/news/health-news/articles/2021-12-28/cdc-omicron-overtook-delta-as-dominant-variant
[2] https://www.reuters.com/world/us/omicron-estimated-be-586-coronavirus-variants-us-cdc-2021-12-28/
[3] https://covid.cdc.gov/covid-data-tracker/#variant-proportions
[4] https://www.sotrovimab.com/

September 13, 2021 I sent your Department a letter inquiring about changes made to the acquisition and distribution of mAb treatments – a change that moved the entire mAb supply chain into the control of HHS.[5] I also sent a letter on November 16, 2021 with colleagues inquiring about troubling reports of individuals being turned away from treatment due to racial biases.[6] These inquiries have gone unanswered.

My recurring inquiries as discussed in multiple letters and reiterated over a bicameral congressional briefing led by your Department on September 17, 2021 have been focused on a few main questions: 1) Is there, or has there ever been a shortage of any monoclonal antibody treatments in the U.S.? If so, which treatments? 2) Is there an expected shortage of any monoclonal antibody treatment in the U.S; and If so, which treatments? 3) What is the U.S.'s manufacturing capacity for monoclonal antibody treatments?

The above questions should not be hard for your Department to answer, and perhaps now more than ever it is imperative your Department begins to be transparent with Congress and the American people about what to expect from the mAb supply chain and distributions. The decisions your Department made surrounding mAb treatment supply chain changes caused immediate disruptions to mAb treatment access, and disruptions have only gotten worse as COVID-19 has continued to circulate through our communities. The fallout of these decisions could prove fatal. This, while your Department has not even at a minimum been transparent about the manufacturing capabilities and supply levels of various mAb treatments whilst denying commercial purchase to block separate recourse to a life-or-death situation.

It is essential your Department releases restrictions to purchasing mAb treatments for all variants and immediately answers the questions asked in this letter as well as the questions previously asked in my September 13, 2021 and November 16, 2021 letters.

Thank you for your attention to this important matter, and I look forward to receiving immediate answers.

Sincerely,

Chip Roy
Member of Congress

[5] https://roy.house.gov/sites/roy.house.gov/files/Roy%20Letter%20to%20Becerra%20-%20Antibody%20Treatment%209.13.21.pdf
[6] https://roy.house.gov/sites/roy.house.gov/files/Final%20Roy%20HHS%20mAb%20treatment%20ltr%2011.16.21.pdf