Congress of the United States Washington, DC 20515

November 16, 2021

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

Dear Secretary Becerra,

The Department of Health and Human Services (HHS) received a letter on September 13, 2021 inquiring about the September 3, 2021 HHS announcement that changed the COVID-19 monoclonal antibody (mAb) ordering process "to help promote optimal and equitable use of the available supply of monoclonal antibodies." This September letter specifically inquired into whether or not there was a "current or expected shortage of any monoclonal antibody treatments in the U.S." However, this letter has yet to be responded to.

Additionally, on September 17, 2021, your Department hosted a Friday afternoon bicameral and bipartisan telephonic briefing for Members of Congress regarding HHS transitioning "from a process by which administration sites could directly order product from the distributor to a state/territory-coordinated distribution system." On this call, we repeatedly asked if there was a current or expected shortage, what our manufacturing capacity was for mAb treatments, and how that compared to demand. These questions went unanswered on that call and have not been addressed since that time.

Despite HHS saying it is "dedicated to transparency throughout this effort" multiple attempts from Congress to better understand HHS's role in regulating the mAb supply chain and distribution have gone unanswered. Now, we have heard of instances of individuals being refused mAb treatments, with a recent case regarding a man in Texas being refused treatment based on the color of his skin. Current Emergency Use Authorization guidelines list criteria for high-risk individuals including "for example, race or ethnicity" in considering who receives treatment.

If there is no supply issue, as your Department's silence would indicate, then why is HHS rationing the treatment? Additionally, under no circumstance should an individual be turned away from receiving medical care due to the color of his or her skin. Refusing to care for an individual based on the color of his or her skin raises very serious questions about potential violation of the 14th Amendment to the U.S. Constitution and the Civil Rights Act of 1964. Any guidelines, regulations, directives, or policies of any

 $[\]frac{1}{\underline{\text{https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/mAb-ordering-update-3Sept2021.aspx}$

 $^{^2 \, \}underline{\text{https://roy.house.gov/sites/roy.house.gov/files/Roy\%20Letter\%20to\%20Becerra\%20-\%20Antibody\%20Treatment\%209.13.21.pdf}$

kind causing any doctor to deny access to care based on skin color should be immediately prohibited by your Department.

In addition to a response to the September 13, 2021 letter, please respond to the below questions by November 29, 2021.

- 1. Is there, or has there ever been a shortage of any monoclonal antibody treatments in the U.S.?
 - a. If so, which treatments?
- 2. Is there an expected shortage of any monoclonal antibody treatment in the U.S?
 - a. If so, which treatments?
- 3. What is the U.S.'s manufacturing capacity for monoclonal antibody treatments?
- 4. Do HHS regulations or programs, at any level of the Department, offer physicians guidelines for determining who receives monoclonal antibody treatments that is based on the patient's skin color?
 - a. If so, how?
 - b. Does HHS require licensed medical professionals to follow such guidelines or risk losing their licenses?
- 5. Will your agency commit to removing any directives, policies, guidelines, or regulations that could be interpreted in any way by any medical professional to cause denial of medical treatment based on race?

Thank you for your attention to this important matter.

Sincerely,

Chip Roy

Member of Congress

Randy K. Weber

Member of Congress

Kandy K. Wale

Lance Gooden

Member of Congress

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Thomas Massie

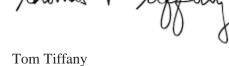
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