TED CRUZ
TEXAS

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JOINT ECONOMIC COMMITTEE

United States Senate

January 27, 2022

The Honorable Janet Woodcock
Acting Commissioner of Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20993

Acting Commissioner Woodcock:

I write to you today deeply concerned about the U.S. Food and Drug Administration's (FDA) recent decision to limit the use of certain monoclonal antibodies to treat COVID-19.

Since the start of the COVID-19 pandemic in March 2020, the medical community has been working non-stop to combat this disease. There have been many discoveries regarding the prevention and treatment of COVID-19. One of these discoveries includes the use of monoclonal antibodies for individuals who have tested positive for COVID-19. The Department of Health and Human Services' Combat COVID-19 webpage refers to monoclonal antibodies as a "promising COVID-19 treatment."[1]

As we continue to see different variants of COVID-19 emerge around the world, most recently the Omicron variant, we need to keep every available option to fight COVID-19 at our disposal to ensure Americans can choose the best options and tools for themselves.

It is puzzling to me as to why the FDA has revised the authorizations for two of the monoclonal antibody treatments including bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab).

The January 24th announcement made by the FDA regarding limiting the use of certain monoclonal antibodies to treat COVID-19 raises a number of questions. I request your full and complete responses to the questions below no later than February 8, 2022. Please provide a response below each question instead of a narrative response.

1. Identify who specifically decided to limit the use of these monoclonal antibodies to treat COVID-19.

[1]https://combatcovid.hhs.gov/possible-treatment-options-covid-19/monoclonal-antibodies-high-risk-covid-19-positive-patients

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2. What was the reason for limiting the use of these monoclonal antibodies' treatments on January 24th, 2022 allegedly due to Omicron, when the first confirmed U.S. case of Omicron was on December 1, 2021?
3. Is there a possibility of new COVID-19 variants emerging? If so, why would the FDA limit access to these treatments now when they could be highly effective against other, future-emerging variants?
4. In your January 24, 2022, announcement regarding limiting the use of certain monoclonal antibodies to treat COVID-19, you justified that choice "Because data show these treatments are highly unlikely to be active against the omicron variant." Please identify and release all data you are referring to in this statement.
5. In most cases, doctors are unable to sequence patients prior to treatment for COVID-19. Do these monoclonal antibodies treatments cause harm or are they merely ineffective? And if they are merely ineffective against Omicron, why would the FDA limit their use when doctors are unsure which variant is afflicting a particular patient?
6. The Biden Administration has demonstrated a preference for certain preventative measures and treatments over others. Specifically, the Administration has controlled the supply of these treatments and limited states' ability to access monoclonal antibodies treatments, preferring instead to push vaccines. Did the Biden Administration's preferences play into your decision-making process? Please be specific.
7. Did any person in the White House or in the office of the Secretary of Health and Human Services contact you regarding their strategy in connection with these monoclonal antibodies treatments and/or their availability? If so, please identify each individual by name and provide copies of all related communications.

Sincerely,

Ted Cruz
United States Senator