United States Senate
WASHINGTON, DC 20510-0908

September 30, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

As our nation continues its work to fully reopen and recover from the coronavirus (COVID-19), the best way forward to defeating this virus is making sure Americans have adequate prevention and treatment options against this terrible disease.

The Trump administration made incredible steps to develop, pre-purchase and distribute the COVID-19 vaccine through Operation Warp Speed. They also purchased substantial doses of monoclonal antibodies to reduce hospitalizations.

With the current surge of the COVID-19 delta variant, hospitalizations are up despite an increase in vaccination rates. Given this fact, we find the Department of Health & Human Services' (HHS) recent decision to change the availability of monoclonal antibodies for states and hospitals incredibly disturbing. This change in policy could reduce the availability of these lifesaving medications to Floridians as well as individuals and families in other states. Under this new policy, Florida's allocation has been set at about 31,000 doses of monoclonal antibodies, despite the fact that Florida needs about 36,000 doses each week.[1] This stark difference in doses available as compared to doses used, and rationing of supply, will jeopardize the health and safety of Floridians, increase hospitalizations, and could lead to higher mortality rates.

To ensure our state and public health officials have every resource they need to keep families healthy, we request your immediate response to the following questions:

1. Did HHS do any modeling of what the COVID-19 surge could be when the delta variant was labeled a variant of concern, including potential hospitalizations and the need for medications? How accurate was the model to what we are experiencing?
2. Has HHS done any modeling of the other COVID-19 variants of concern?
3. Has HHS done any modeling of possible COVID-19 surges later this year?
4. The monoclonal antibody treatment Sotrovimab received an Emergency Use Authorization (EUA) in May 2021.[2] At the time of its EUA, Sotrovimab was

[1] https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/Update-13Sept21.aspx
[2] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-monoclonal-antibody-treatment-covid-19

shown to be 85% effective at preventing hospitalization, making it potentially more effective than the monoclonal antibodies that received an EUA in 2020.[3, 4] Why did HHS not purchase a supply of Sotrovimab?

5. What has the Biden administration done to expand manufacturing capacity for all EUA authorized monoclonal antibody therapies, especially to ensure domestic manufacturing for all authorized therapies?
6. Why did HHS not develop a robust plan to promote and expand the supply of monoclonal antibody therapy?
7. Under the new allotment system that HHS is imposing, what guidance is HHS providing to states for how to allocate available monoclonal antibodies to providers?
8. Do immunocompromised individuals have equal access to monoclonal antibody treatment for post-exposure prophylaxis, or are they a lower priority to another group?
9. If a provider follows state or HHS guidance on prioritizing patients due to the shortage of monoclonal antibody treatments, and that patient suffers hospitalization or another serious outcome, is there any liability protection for the provider?
10. When does HHS believe that monoclonal antibody supply will be sufficient to meet demand?
11. Why has HHS not developed public-private partnerships for translational research at the National Institutes of Health for new meaningful therapies?

The only way through this global pandemic is to ensure prevention and treatment options are available for every American. We are vaccinated, and we encourage every American to talk to their doctor and consider getting the vaccine. However, we know that for the vaccinated and unvaccinated alike, proper treatment with monoclonal antibodies can mean the difference between beating COVID-19 or succumbing to this terrible virus. Restricting the supply of lifesaving treatment is unethical and inexcusable.

We appreciate your immediate attention to this urgent matter and look forward to your prompt response.

Sincerely,

Rick Scott
United States Senator

Marco Rubio
United States Senator

[3] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-monoclonal-antibody-treatment-covid-19
[4] https://www.wsj.com/articles/regeneron-covid-19-antibody-drug-reduced-risk-of-hospitalization-death-by-70-in-late-stage-trial-11616479200