Congress of the United States

Washington, DC 20510

January 28, 2022

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

Dear Secretary Becerra:

We write with regard to the U.S. Food and Drug Administration's (FDA's) recent decision to suspend the emergency use authorizations (EUAs) of Eli Lilly's bamlanivimab and etesevimab (bam/ete) and Regeneron's REGEN-COV monoclonal antibody drugs (mAbs) used to treat COVID-19 patients. At a time when the federal government should be doing everything in its power to support states and healthcare providers fighting this pandemic, the Biden Administration has instead chosen to disrupt the response effort by unexpectedly cutting access to life-saving treatments that hundreds of thousands of Americans rely on. In Florida alone, the FDA's abrupt decision has resulted in more than 2,000 cancellations for patients seeking treatment at mAbs state sites and thousands more through private healthcare providers.

Florida is committed to protecting its residents and keeping its doors open by ensuring access to effective COVID-19 treatments. That is why the state led the nation in the delivery of mAbs with the creation of state administration sites. Those state sites, however, have shut down until further notice and families are scrambling to find alternative treatment options. Hospitals and healthcare providers across the state are still facing critical shortages of one such therapy, sotrovimab, forcing them to choose which patients receive available mAbs. States and providers still cannot order mAbs directly from drug manufacturers. To make matters worse, the Department of Health and Human Services (HHS) gave little notice and failed to coordinate with states and healthcare providers when a major change in policy was being considered. This heavy-handed approach has left Floridians in the dark and put thousands of lives at unnecessary risk. It demands accountability.

Given the major implications of HHS's recent actions to limit these life-saving therapies, we are requesting you immediately respond to the following questions:

1. What clinical data does the FDA cite as evidence in supporting their decision to suspend the use of bam/ete and REGEN-COV? Does this data support the FDA's conclusion that these treatments are without a doubt, completely ineffective in treating patients infected with Omicron?
2. In December 2021, the NIH COVID-19 Treatment Guidelines noted "[the Omicron variant] is predicted to have markedly reduced susceptibility to some anti-SARS-CoV-2 mAb products, including bamlanivimab plus etesevimab and casirivimab plus imdevimab. Sotrovimab appears to retain activity against [the Omicron] variant." What

subsequent communication to states occurred to allow Florida to prepare alternative treatments for thousands of individuals ahead of the January 2022 change in treatment guidelines?

3. Florida's mAbs state sites remain shuttered because they lack sufficient mAbs. What plan does HHS have in place to ensure Florida can reopen its state sites with adequate alternative treatment supply?
4. Though a small percentage of overall cases, some individuals are still testing positive for the Delta variant. The NIH guidance states, "…[because] real-time testing to identify rare, non-Omicron variants is not routinely available the Panel recommends against using bamlanivimab plus etesevimab or casirivimab plus imdevimab (AIII)." Given Florida's ample supply of bam/ete and REGEN-COV, how does HHS plan to expand real-time testing so those testing positive for the Delta variant — or any future variant for which bam/ete and REGEN-COV would be effective — can be treated with bam/ete and REGEN-COV therapies?
5. How does HHS plan to quickly and effectively roll out these treatments should the FDA determine they are effective again?
6. When will HHS grant Florida and healthcare providers the ability to order COVID-19 therapeutics directly from drug manufacturers?
7. FDA notes alternative therapies are expected to work against the Omicron variant, including antiviral pills Paxlovid and molnupiravir. Currently there are more limitations to treat patients with antiviral pills than there are for mAbs. How does FDA plan to expand access to Paxlovid, molnupiravir, and any future antiviral pills?
8. What is HHS's methodology in allocating all available therapeutics?
9. Why has HHS failed to increase the allocations of sotrovimab?
10. When should the American people expect new mAbs to be authorized?

It is imperative that our states and healthcare providers have every available, effective resource at their disposal to keep their citizens healthy. Americans deserve leaders that work diligently with states and healthcare providers to carry out transparent policies, providing them with plenty of time to respond. Ultimately, it is HHS's responsibility to work together with stakeholders to ensure states and healthcare providers have the tools they need to fight this pandemic, not to disrupt them with politically motivated decision-making.

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

Sincerely,

Marco Rubio
U.S. Senator

Maria Elvira-Salazar
Member of Congress

Michael Waltz
Member of Congress

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