Congress of the United States
Washington, DC 20510

September 23, 2021

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

Dear Secretary Becerra,

We write to express concerns with the U.S. Department of Health and Human Services' (HHS) September 13th, 2021 announcement to abruptly transition monoclonal antibody (mAb) distribution from a direct ordering process to a federally controlled distribution process.

Overnight, our healthcare providers were made aware that they may run out of mAbs, at a time of heightened demand, as states will need to sift through layers of bureaucracy and contracting in order to safely and accurately distribute the lifesaving treatment. Many states do not have the infrastructure in place to take on this unnecessary challenge amidst a spike in COVID-19 cases and will likely need to spend scarce state resources to contract solutions. This type of change is ill advised and will lead to significant delays that will limit patient access to mAb treatment in many states.

As you are aware, the Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) to several mAb therapies as treatment for COVID-19. This therapy is known to reduce the amount of the SARS-CoV-2 virus that may reside within a patient's system and is most effective if a patient has had symptoms for ten days or less. Time is of the essence for administering this therapy most effectively. A study from the New England Journal of Medicine shows that a treatment course of mAbs can reduce COVID-19 hospitalization rates up to seventy percent[1].

We have heard from physicians, providers, and hospitals in our respective states that the use of mAbs has saved countless lives. Prior to this announcement, the private distribution network worked well – getting providers and their patients the therapies they needed in a timely fashion. Now, we have heard from providers in our state who cannot get orders for mAbs as states scramble to set up a new distribution methodology.

This change in distribution threatens to reduce or delay access to this life saving therapy for the patients who need it most. Additionally, a slight delay in administration of this therapy could be fatal. As you know, providers and health systems are already required to report mAb distribution data to HHS. The federal government should not hinder the efforts of providers seeking to

[1] https://www.nejm.org/doi/full/10.1056/NEJMoa2102685

procure and administer this product. Disallowing direct supply of mAb while a new distribution system is being developed will cause further delays.

In regards to our concern, we have a number of questions for the agency:

1. What allocation formula and criteria are being used to ensure fairness among the states for the distribution of mAb?
2. How do you plan to manage the mAb inventory?
3. How are you communicating to stakeholders who need mAb supply right now?
4. Do you plan to federally allocate future COVID-19 therapeutics in this way?
5. How many treatments were administered in underserved communities as a result of $150 million allocated to expand mAbs access to underserved communities[2]?
6. While HHS is anticipating a mAb shortage, why are there mAbs available under EUA that the government has stated it will not purchase?

We are very concerned with this sudden change, which further emphasizes the urgent need for investment from this Administration in COVID-19 therapeutics. As we have seen from breakthrough cases, we know that vaccinated people can contract COVID-19. New variants of the COVID-19 virus are expected to occur, as is seen across different viruses. In order for the United States to remain resilient against COVID-19 in the face of novel variants and uncertainty regarding length of immunity from vaccination, we must deploy every available means to combat the disease and prevent hospitalizations and deaths. The development of new COVID-19 therapeutics, as well as a predictable supply of currently available treatments such as mAb, are key as the country continues to respond to the public health emergency.

Thanks to Operation Warp Speed, safe and effective vaccines against COVID-19 are readily available and we continue to encourage Americans to consult with their physician and get vaccinated. However, therapeutics remain a crucial weapon in our fight against this virus, and this order threatens our constituents' access to some of the most effective available options. Accordingly, we strongly urge you to reconsider the order.

We appreciate your prompt attention to this matter.

Sincerely,

Scott DesJarlais, M.D.
Member of Congress

Earl L. "Buddy" Carter, R.Ph.
Member of Congress

[2] https://www.hhs.gov/about/news/2021/03/17/biden-administration-to-invest-150-million-to-expand-access-to-covid-19-treatments-in-underserved-communities.html

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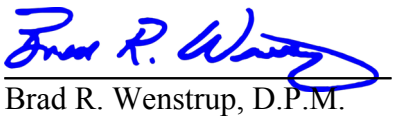

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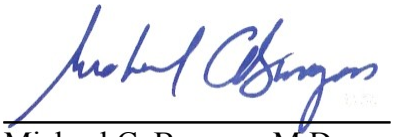

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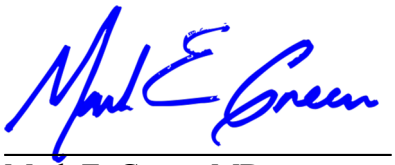

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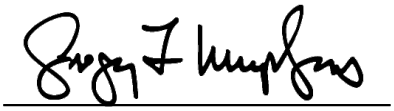

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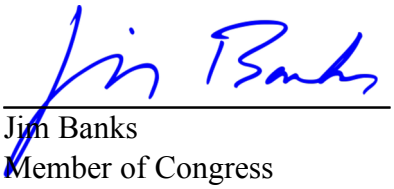

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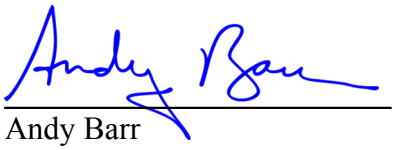

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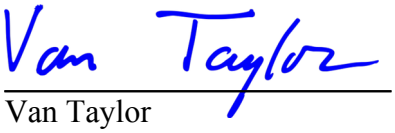

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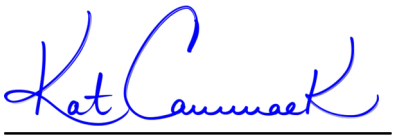

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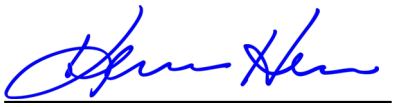

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