JOE MANCHIN III
WEST VIRGINIA

SUITE 306
HART BUILDING
WASHINGTON, DC 20510
(202) 224–3954

United States Senate
WASHINGTON, DC 20510–4804

COMMITTEES
APPROPRIATIONS
ARMED SERVICES
ENERGY AND NATURAL RESOURCES
VETERANS' AFFAIRS

January 13, 2022

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

Dear Secretary Becerra,

West Virginia is working overtime to contain the current Delta outbreak and anticipated Omicron surge, but we need the help and support of our federal partners. The continued shortages and recent changes made to the Department of Health and Human Services' (HHS) COVID-19 therapeutics program and the distribution have only made that job more difficult. The monoclonal antibodies HHS has on hand can and will save lives in West Virginia, and I am urging you to do everything in your power to get these essential treatments to places like West Virginia that need them most.

The HHS COVID-19 Therapeutics program currently offers four different monoclonal antibodies (mABs) and two oral antiviral pills authorized to states. Each therapy has been authorized for emergency use by the Food and Drug Administration (FDA) and has different clinical applications for COVID-19, including pre-exposure prophylaxis, treatment of mild-to moderate symptoms and treatment for those with severe cases of COVID-19. While I appreciate HHS putting in additional orders of the Paxlovid and Molnupirivir oral antibodies, these treatments come with complex drug interactions that are particularly difficult in West Virginia. For example, Paxlovid includes a contraindication for heart disease drugs such as statins. West Virginia has a higher rate of heart disease than the country on average, meaning that our patients that are most at risk from complications from COVID-19 may also be taking a statin, making use of the Paxlovid difficult. This makes other COVID-19 therapeutics more important for West Virginia, considering our patient population.

While we appreciate the Food and Drug Administration's (FDA) recent guidance allowing the Remdesivir IV antiviral to be administered in an outpatient setting, reimbursement for this treatment remains unclear. The West Virginia COVID Response Team has indicated this as a major barrier to administering Remdesivir. Due to our limitations on utilizing treatments such as Paxlovid, Remdesivir is incredibly important in our response to this COVID surge. Hospitals and providers are working on purchasing the therapy on the commercial market, however it is coming at a huge cost to the providers and patients. Recently, the Administration released billing codes for providers, however we need to ensure that these codes are incorporated into State Medicaid programs, as well as utilized by all insurance providers.

West Virginia continues to see lower rates of Omicron than the rest of the country, with a majority of counties reporting only 26% of cases due to Omicron. The REGEN-COV and BAM/ETE monoclonal antibodies still present a clinically appropriate response to the Delta variant. I appreciate that HHS has not stopped allocating these therapies, however despite therapies not going to states with a majority of Omicron cases, West Virginia has not seen an increase in their distribution. West Virginia likely has a short window, roughly 2-3 weeks as indicated by the West Virginia COVID Response Team, to address the current Delta outbreak. As a result, the state has a need to immediately increase their supply of these two therapies, especially as other states are reducing their usages of these mAbs.

On Monday, January 10th, the Administration indicated that they are ordering 600,000 more doses of the Sotrovimab mAB, which has shown clinical effectiveness against Omicron. I understand manufacturing of mABs is difficult, and has led to this continued shortage of the therapies, however these doses are not likely to arrive until February or March. This will be coming later than when West Virginia anticipates to see a peak of the Omicron surge, and certainly after most of the country. The federal government has certain authorities, such as the Defense Production Act (DPA), to improve manufacturing of critical materials such as mABs. We are at crisis levels in our response to this outbreak, and now is the time to be doing everything possible to increase production of these life saving therapies.

The population of West Virginia is particularly vulnerable to COVID-19, as we have high rates of chronic illnesses, such as heart disease and diabetes, as well as one of the oldest populations in the country. To anticipate how hard this new surge will hit our state, the West Virginia COVID Response Team is requesting the ability to provide a fourth booster dose to our most vulnerable residents. Findings out of Israel show a fourth dose to be safe just fourth months from the first booster. It also shows that one week after the fourth dose, there is a five-fold increase in antibody levels. West Virginia stands ready to test this, and hopefully prevent hospitalizations and deaths as this next surge hits our state.

As West Virginia works to respond to the current Delta surge and anticipates a growing Omicron surge, COVID-19 therapeutics are crucial to saving lives. To appropriately respond to this crisis, I ask you to respond to my following concerns:

1. When reviewing allocations of therapeutics, are you taking into account the health of a state's population and how it interacts with therapeutics such as the Paxlovid oral antiviral?
2. Are you providing guidance and direction for how hospitals and health providers should be reimbursed for administering Remdesivir IV Antiviral? Have you followed up with State Medicaid programs on incorporating the new billing codes? Have you provided direction to insurance providers for coverage?
3. Are you reallocating the limited supply of the REGEN-COV and BAM/ETE mABs from states with majority Omicron to states that still have predominate Delta variants? How quickly are these reallocations happening?
4. Are you or utilizing or planning on utilizing the DPA or similar authorities to increase supply of therapeutics, in particular the Sotrovimab mAB?
5. Are you reviewing West Virginia's request to test utilizing a 4th booster shot for the most vulnerable patients? How quickly can the State anticipate a response?

Thank you for addressing my concerns. I appreciate a timely response to my questions and look forward to working with you on these issues.

Sincerely,

Joe Manchin III
United States Senator

Cc:
Dawn O'Connell, Assistant Secretary for Preparedness and Response
Jeff Zients, White House COVID-19 Response Coordinator