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January 26, 2022

Jeff Zients
White House Coronavirus Response Coordinator
1600 Pennsylvania Avenue NW
Washington, DC 20500

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

The Honorable Janet Woodcock
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, Maryland 20993

Dear Mr. Zients, Secretary Becerra, and Acting Commissioner Woodcock:

Thank you for your tireless work to ensure the health and well-being of all Americans, particularly in the face of the ongoing COVID-19 public health emergency. I write today with deep concerns about shortages of COVID-19 therapeutics and prophylactics. Although the omicron variant produces milder symptoms in most people than previous strains, Connecticut hospitals – and other hospitals around the country – continue to experience a surge in patients needing medical care, leading to an urgent need for additional treatments and prophylactics.

There are several monoclonal antibody treatments authorized by the U.S. Food and Drug Administration (FDA) for use in the United States, but only one has shown effectiveness against the omicron variant.[i] Further, a combination of monoclonal antibodies, Evusheld, has been authorized for the pre-exposure prevention of COVID-19 in immunocompromised individuals who may not benefit from the protection of a vaccine.[ii] Additional treatments have also been authorized, such as oral antivirals like Pfizer's Paxlovid and Merck's Molnupiravir.[iii] These therapeutic treatments are distributed to hospitals across the country through a federal allocation system through which state public health departments distribute supplies to local hospitals. Despite the authorization of these therapeutics and prophylactics, recent articles from the

Stamford Advocate and *CNN*[iv] highlighted an alarming reality that I have heard about as I tour the state: therapeutics and prophylactics against COVID-19 – especially those that treat the omicron variant – are in short supply.[v]

Unfortunately, this nationwide shortage has forced health care providers to prioritize high risk patients— leaving out individuals who may benefit greatly from these treatments.[vi] Some hospitals, like the Hartford HealthCare facility mentioned in the *Stamford Advocate* article, are waiting for production of these treatments to increase so that they do not have to continue operating with limited supply and compromising their patients' care.

Providers have reported that while these treatments, especially Pfizer's Paxlovid, are "game-changers," they are currently having little effect due to their scarce supply.[vii] While I applaud President Biden for doubling his order of this treatment from 10 million to 20 million doses and accelerating the time frame for delivery up to June, continued action is urgently needed.[viii] Further, I have heard from immunocompromised constituents concerned about shortages of Evusheld and the impact it could have on those who need it to prevent infection.

Another hurdle doctors are grappling with is identifying which variant is causing the infection. The vast majority of COVID-19 cases are not genetically sequenced—viral sequencing takes time and requires a specimen to be sent out to a third party lab. This means that doctors rely on regional projection data to track the dominate strain then reserve the medication that works against omicron for patients that may be the most sick or at a higher risk of developing complications.[ix]

We must do better to ensure the COVID-19 patients who contract this virus are able to receive the best treatment possible, speeding recovery and reducing the demand on hospital beds. We further must ensure that immunocompromised individuals who do not achieve sufficient immune response from vaccines have access to pre-exposure prevention methods.

As we continue to navigate our way through this crisis, I am writing to ask for further information on the following questions:

- What steps are being taken to speed up production of treatments, specifically for the omicron variant, and prophylactics?
- What procedures are in place to expedite distribution of such treatments and prophylactics so as to ensure medical facilities have sufficient supplies of new therapeutic and prophylactic treatments?
- Are additional orders of COVID-19 therapeutics or prophylactics being considered at this time? If so, how many additional doses of each therapeutic or prophylactic are being ordered and what is there timeline for delivery to states?
- Are additional therapeutics or prophylactics currently being reviewed by FDA and is FDA able to analyze how effective they might be in combating future COVID-19 variants?
- Does FDA have information on how long each of the currently authorized therapeutics and prophylactics can last and are plans being made to stockpile these therapeutics and

prophylactics so large supplies can become available immediately during potential future surges?

I greatly appreciate the challenges facing the regulatory agencies as we continue to grapple with this pandemic and look forward to your response.

Sincerely,

RICHARD BLUMENTHAL
United States Senate

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[i] "COVID-19 Monoclonal Antibody Therapy: What You Need to Know," *University of Utah Health Communications*, January 6 2022, https://healthcare.utah.edu/healthfeed/postings/2021/10/monoclonal-antibodies.php.

[ii] Cohen,Elizabeth et. al, "There's a new drug to prevent COVID-19, but there won't be nearly enough for Americans who are eligible," *CNN Health*, December 24, 2021, https://www.cnn.com/2021/12/24/health/prevent-covid-19-evusheld/index.html.

[iii] "COVID-19 Treatments and Therapeutics," *U.S. Department of Health & Human Services*, https://www.hhs.gov/coronavirus/covid-19-treatments-therapeutics/index.html.

[iv] Cohen,Elizabeth et. al, "There's a new drug to prevent COVID-19, but there won't be nearly enough for Americans who are eligible," *CNN Health*, December 24, 2021, https://www.cnn.com/2021/12/24/health/prevent-covid-19-evusheld/index.html.

[v] Fenster, Jordan Nathaniel, "Most Effective Treatment against Omicron in Short Supply in CT, Experts Say," *Stamford Advocate*, January 11 2022, https://www.stamfordadvocate.com/news/article/Most-effective-treatment-against-omicron-in-short-16766324.php?src=sthpdesecp.

[vi] Ibid.

[vii] Shepherd, Katie, "Doctors Bemoan Limited Supply of Game-Changing Antiviral Pills amid Winter Surge," *The Washington Post*, January 4 2022, https://www.washingtonpost.com/health/2022/01/04/antiviral-pills-supply-omicron/.

[viii] Cook, Sara and Watson, Kathryn, "U.S. Doubling and Accelerating Order of Pfizer Antiviral Pills," *CBS News*, January 4 2022, https://www.cbsnews.com/news/biden-pfizer-covid-pill-antiviral-double-shipment/.

[ix] Fenster, Jordan Nathaniel, "Most Effective Treatment against Omicron in Short Supply in CT, Experts Say," *Stamford Advocate*, January 11 2022, https://www.stamfordadvocate.com/news/article/Most-effective-treatment-against-omicron-in-short-16766324.php?src=sthpdesecp.