



January 26, 2023

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

Dear Secretary Becerra,

Considering the FDA's recent announcements that the two monoclonal antibodies used for COVID-19 prevention and treatment (Evusheld and Bebtelovimab respectively) are no longer authorized for emergency use, we write to express our concern for immunocompromised (IC) and immunosuppressed (IS) patients. The organizations listed below urge the Department of Health and Human Services, and its operating divisions, to take the strongest possible mitigating measures against COVID-19 and other communicable diseases, and not abandon those with impaired immune systems.

CLL Society is dedicated to addressing the unmet needs of the chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL) community through patient education, advocacy, support, and research. Our patients live with a chronic, rare cancer of the immune system. As such, we actively engage policymakers on behalf of the estimated seven million immunocompromised or immunosuppressed (IC/IS) Americans who continue to be (i) likely incubators of COVID-19 variants and (ii) at high risk for poor outcomes should they become infected with COVID-19.

IC/IS patients' antibody responses to COVID-19 vaccines have repeatedly proven to be less predictable and robust when compared to the general population.¹ They have a much greater risk of developing severe disease² from a COVID-19 infection, resulting in higher rates of hospitalization, ICU admissions, and death;³ higher rates of breakthrough infections after being fully vaccinated;⁴ higher rates of their infection spreading to household contacts; and have well-documented difficulty clearing the virus from their bodies-leading to novel variant mutations that lead to significant implications for society at large.

Although recent statements from the Administration appear to suggest COVID-19 is simply a long-term problem with attendant deaths to be expected, we urge HHS to immediately undertake the following actions to protect the estimated seven million IC/IS Americans with the following actions:

- Regularly update vaccines and make them available a no cost sharing to at-risk patients;
- Include IC/IS patients in clinical trials for new COVID-19 vaccines, preventatives, and treatments (they were previously excluded from many vaccine trials);

¹ CDC, COVID-19 Vaccines for Moderately to Severely Immunocompromised People available at www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

² CDC, Immunocompromised available at www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-who-are-immunocompromised.html

³ CDC MMWR July 8, 2022, available at www.cdc.gov/mmwr/volumes/71/wr/mm7127a3.htm

⁴ Supra at note #1



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- Encourage rapid development and deployment of new and/or modified COVID-19 monoclonal antibodies (CmAbs) and other therapeutics for Pre-Exposure Prophylaxis (PrEP), Post Exposure Prophylaxis (PEP), and treatment for the IC/IS community to keep up with the continually emerging variants of concern;
- Provide ongoing, consistent funding for research on PEP and PrEP for COVID-19;
- Continually reassess the role of high-titer COVID-19 Convalescent Plasma, especially when administered early to IC/IS patients who have tested positive for COVID-19, and keep in mind differential benefit-risk considerations of the IC/IS community;
- Monitor and eliminate barriers to accessing COVID-19 care and treatment;
- Simplify access to newly developed CmAbs intended to prevent (e.g., Evusheld) and treat (e.g., Bectelovimab) for IC/IS patients;
- Develop IC/IS-specific immunization recommendations for preventative CmAbs based on the Advisory Committee on Immunization Practices (ACIP) recommendations. This will help ensure appropriate preventive coverage under the requirements of the ACA and CARES Act;
- Provide ongoing information to IC/IS patients and educational programs for healthcare providers regarding the utility of tests, vaccines, and prophylactics concerning emerging variants of concern;
- Proactively increase the number of outpatient healthcare centers offering Remdesivir as a COVID-19 treatment for IC/IS patients, and decrease barriers to access as it is now the only remaining non-oral treatment option available in the absence of Bectelovimab and Evusheld for those who cannot take Paxlovid;
- Ensure insurance coverage for all treatments without prior authorization delays that are particularly onerous for at-risk individuals;
- Continue real-time monitoring and reporting of COVID-19 case numbers so that IC/IS patients and their loved ones can appropriately gauge their level of risk;
- Study the long-term effects of COVID-19, specifically including IC/IS patients in these data gathering efforts. Long COVID, stroke, and heart disease are only some of the reported sequelae from COVID-19, and the impact on those who are IC/IS is very concerning;

We appreciate your ongoing work to protect public health in the face of this novel coronavirus. We stand ready to work alongside you to help inform, develop, and implement the policies outlined above which will protect all Americans, including those who are immunocompromised and immunosuppressed.

Respectfully,

CLL Society
Alpha-1 Foundation
American Academy of Allergy, Asthma & Immunology
Family Voices Affiliate of New Jersey
Haystack Project
Immune Deficiency Foundation
Lupus and Allied Diseases Association, Inc.
Solve ME
SPAN Patient Advocacy