

June 21, 2022

The Honorable Charles E. Schumer
Majority Leader
United States Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
317 Russell Senate Office Building
Washington, DC 20510

Dear Majority Leader Schumer and Minority Leader McConnell,

The undersigned organizations, all committed to caring for the millions of Americans with impaired immune systems, seek your support to keep this vulnerable population a priority as you consider additional COVID-19 relief funding by prioritizing therapeutic purchasing and research for new therapeutics, such as prophylactic therapies and antiviral medications. Our immunocompromised/suppressed patients are at a higher risk for serious COVID-19 complications and mortality. As COVID-19 continues to evolve, presenting new variants and surges every few months, further federal investment is needed not only to secure an adequate supply of current therapeutics, but to also support the next generation of vaccines and treatments to protect those at highest risk.

Approximately 3% percent of the United States population is considered to be severely or moderately immunocompromised.¹ This includes an estimated seven million who are immunosuppressed for a variety of reasons including cancer treatments, bone marrow and organ transplants, autoimmune diseases, and other conditions. In addition to their higher risk for severe COVID-19, our immunocompromised/suppressed patients may be impacted by the longer-term complications of COVID-19. These patients may serve as a source of ongoing viral community transmission given suboptimal response to vaccines. Our patients may also serve as a reservoir for the emergence of new variants, given their inability to clear the virus quickly and efficiently. It is critical that our country's response to the pandemic maintains an active focus on our patients.

We appreciate the funding that has been provided to date to address the persistent challenges of COVID-19, which has supported the research, development, and distribution of interventions crucial for the health of all Americans—especially for our vulnerable patients. The existing COVID-19 interventions, such as prophylactic therapies (tixagevimab and cilgavimab (Evusheld)) and COVID treatments (nirmatrelvir and ritonavir (Paxlovid)) and other antiviral medications including antibodies) are critical for the care of immunocompromised/suppressed individuals, since vaccines often do not provide the same level of protection for these patients. We are thankful to have these options available for our patients and hopeful that additional research discoveries will continue to lead to other products that may be available for our patients as the virus continues to evolve. Evusheld is a preventive therapy that provides strong protection against infection for those who do not respond effectively to vaccines. Additionally, COVID treatments, such as Paxlovid and other antiviral medications, are especially critical for care of at-risk patients—including the vast majority of our patients. These therapies are already having a positive impact on our patients, and we encourage you to continue to ensure that the patients have access to these important therapies as well as new therapies that are developed as COVID-19 continues to evolve.

Many of our patients had suboptimal responses to the COVID-19 vaccine and had to make drastic life changes to protect themselves. Now that masking and social distancing are no longer required in most regions, social engagement has become even more risky for our patients. Prophylactic therapy with Evusheld provides protection, allowing the many who have been isolating now for more than two years to finally begin to see family and friends. With the protection afforded by prophylactic therapy, our patients have been able to resume lives that were drastically derailed by the pandemic. If infection does occur, treatment with the new antivirals reduces the risk of hospital admission and complications. The following examples show how valuable these therapies are to our patients.

- A 42-year-old woman received a lung transplant three years ago and will need to be on heavy immunosuppression for the rest of her life. She has received four doses of Pfizer vaccine but no immune response. Her children, ages 7, and 9, have attended school online during the two years of the pandemic to prevent household transmission of COVID-19. She has received Evusheld and has the continued option of receiving antivirals or monoclonal antibodies for treatment if she is infected. With this in mind, she has been able to send her children back to in-person schooling.
- A 69-year patient with chronic lymphocytic leukemia (CLL), the most common leukemia, was diagnosed just prior to the COVID-19 pandemic and then treated on a National Cancer Institute (NCI)-sponsored clinical trial. He has now been off therapy for a year. Despite vaccination, his antibodies were undetectable. He was working from home, not seeing friends, family or colleagues. With Evusheld, he now has some freedom to cautiously leave home, and furthermore, he is relieved to know that should he have a breakthrough infection, there are treatments that will reduce his risk of hospitalization and a bad outcome.
- A 50-year-old physical therapist who works with disabled children in a large medical care facility, has almost no immune globulin of her own due to her congenital immune defect. She also has lung damage due to prior infections. She had no vaccine response; however, after Evusheld she has been able to return to work so that the children do not have interrupted care.
- A 22-year-old with an aggressive B-cell lymphoma, had left college at the time of his diagnosis. He has had six months of chemotherapy and four doses of the Pfizer vaccine, but no response because of the treatment he recently received. He felt well and wanted to return to school, but had no detectable antibodies. With Evusheld and the reassurance that there are drugs to reduce risk should he have a breakthrough infection; he is back at college completing his degree and participating in the theatre program.
- A 57-year-old office executive who works with a large financial team has hyper IgM syndrome, which means that he cannot make any lasting, functional antibodies. However, with Evusheld he has been able to continue to work at the bank every day, and he also can travel as needed.
- A 65-year-old sole proprietor of a beauty shop is living with kidney failure and takes immunosuppressive medication to keep her from rejecting her five-year-old kidney transplant. She received three doses of Pfizer vaccine and one dose of Moderna vaccine, yet has not produced a measurable antibody response. She developed COVID-19 on the same day that she received her dose of Evusheld. With Evusheld, her symptoms were mild and she was able

to return to her daily activities quickly. If a repeat dose of Evusheld is not available to her after six months, this will put her at increased risk of reinfection.

With any new therapy there are always barriers to usage, and we saw this trend with these new COVID-19 interventions. For example, when Evusheld was first released there were supply chain issues, restrictions at institutions, and confusion amongst providers. Lotteries were established to identify patients to receive the very limited supply. Today, the supply is plentiful, but at many centers, the staffing and space required to make treatment available to patients are limited. As the therapeutic picture continues to evolve, our groups continue to partner with our federal agency colleagues to make sure our physicians and patients understand the benefits and use of all available therapies and that as many patients as possible that would benefit from these therapies receive them.

We are pleased that federal support to date has allowed such rapid and impactful innovation for COVID-19 interventions, including development of tests, vaccines, and the highly effective therapies that dramatically reduce the risks of severe illness and death, especially in our patients. Going forward, our country needs to be prepared to have all options available, especially for our vulnerable patients; jeopardizing access to existing and new therapies could put our patients and the general public in great danger—including increased risk of hospitalization and/or mortality; and significant impact on quality of life. Today, physicians who care for individuals with impaired immune systems, spend part of each patient visit discussing the risks of the pandemic and recommended strategies for survival. As the virus evolves, new and even more effective prophylactic and therapeutic strategies will be needed. Our patients are counting on us, Congress, and the pharmaceutical industry to continue to keep us prepared for future surges and variants.

We implore you to act swiftly to approve additional COVID-19 relief funds by making this vulnerable population a priority. Through continued federal support Congress can ensure equal access – especially important to the most vulnerable among us. Please consider all of the organizations listed below as a resource and keep us apprised on how we can work together to ensure that our patients are optimally protected.

American Academy of Allergy, Asthma & Immunology
American College of Allergy, Asthma & Immunology
American College of Chest Physicians
American College of Rheumatology
American Society of Hematology
American Society of Nephrology
American Society for Transplantation and Cellular Therapy
American Society of Transplantation
Center for International Blood and Marrow Transplant Research
National Marrow Donor Program/Be The Match

CC: Members of the United States Senate

¹ <https://www.yalemedicine.org/news/what-does-immunocompromised-mean>