



February 6, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Prioritization of innovative research and increased investment in therapeutics for immunocompromised kidney patients

Dear Commissioner Califf:

On behalf of the 37 million Americans with chronic kidney disease (CKD), including the almost 800,000 with kidney failure who are at significant risk for COVID-19 infection, the National Kidney Foundation writes today to strongly encourage the U.S. Food and Drug Administration and other biotechnology stakeholders to increase investments in innovative research and expedited access to therapeutics to protect kidney patients against COVID-19. While we support FDA's decision to revoke Evusheld's authorization for emergency use in light of its lack of efficacy on newer Omicron subvariants, it is more important than ever that kidney patients have access to vaccines and therapies that meet rigorous safety and efficacy against burgeoning subvariants.

The vulnerability of all kidney patients remains heightened as the COVID-19 pandemic continues and places these patients at a higher risk for infection and mortality at alarming rates, particularly in-center and home dialysis patients, transplant recipients, and immunosuppressed chronic kidney disease (CKD) patients (e.g., patients with glomerular disease, auto-immune disorders, etc.). **For the first time in 50 years since the enactment of the Medicare End Stage Renal Disease (ESRD) benefit, the greatest decline in the total number of patients on dialysis within a single year occurred in 2021 due to COVID-19 related deaths.**¹ Despite the implementation of national infection prevention and management guidelines, hospitalization incidence and death rates prior to hospitalization were exacerbated post COVID-19 diagnoses for both CKD and ESRD populations.² **Lastly, we would like to emphasize important considerations regarding low seroconversion and increased risk of vaccine-immunosuppressive drug interactions for select members of this patient population.**³

As the FDA continues to research the next generation of prophylactic and therapeutic monoclonals as we enter an endemic phase, we recommend the inclusion of high-risk patients, specifically kidney patients including those on dialysis or after transplantation, into clinical trials as it is important to

¹⁻² <https://usrds-adr.niddk.nih.gov/2022/supplements-covid-19-disparities/13-covid-19-supplement>

³ Babel N, Hugo C, Westhoff TH. Vaccination in patients with kidney failure: lessons from COVID-19. Nat Rev Nephrol 2022; 18:708–723. <https://doi.org/10.1038/s41581-022-00617-5>


ensure that innovative therapies are safe and effective for this population. Further, to protect immunocompromised patients from future COVID-19 variants, we urge the development of accelerated paths for approval and authorization of new monoclonals currently in the clinical trial phase. The utilization of this approach can assure safety while also making a timely and exponential impact on millions of lives.

Thank you for the opportunity to provide these comments to the U.S. Food and Drug Administration. We welcome the possibility to partner with you as a thought leader on future initiatives regarding this matter. Please contact Ivory Harding, Quality and Regulatory Affairs Director, at ivory.harding@kidney.org with any questions or concerns.

Sincerely,



Kevin Longino
CEO and transplant patient



Sylvia Rosas, MD
President