



NATIONAL KIDNEY
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December 3, 2021

The Honorable Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20857

Dear Acting Commissioner Woodcock,

We are writing on behalf of the 37 million individuals with chronic kidney disease, including the almost 230,000 kidney transplant recipients, to urge the U.S. Food and Drug Administration (FDA) to allow an Emergency Use Authorization for medications that mitigate the risk of kidney transplant patients and other immunosuppressed patients with kidney disease getting Covid-19. Transplant recipients and individuals requiring immunosuppressive therapy for treatment of their kidney disease are especially vulnerable to developing severe complications and even death because of their immunosuppression. Research has demonstrated that immunosuppressed patients, including organ transplant patients have an impaired immune response from the Covid-19 vaccination, and they remain susceptible to the detrimental effects of SARS-CoV-2. Therefore, patients with kidney disease undergoing immunosuppressive treatment, including transplant patients, patients with primary glomerular disease, renal vasculitis, lupus nephritis must have immediate access to pharmacological treatment for Covid-19 prevention, and we encourage the FDA to expedite these medications to market.

The National Kidney Foundation (NKF) is the largest, most comprehensive, and longstanding, patient-centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation, since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

NKF applauds everything FDA does to prioritize and optimize patient health. Taking the initiative to protect kidney transplant patients by implementing Emergency Use Authorization for safe and efficacious Covid-19 prevention medication could significantly improve their quality of life. As we care for the health of transplant recipients, we must also honor the selfless sacrifice that donors and families make to give the gift of life. If you have questions or would like to schedule a follow up conversation, please contact Morgan Reid, Director of Transplant Policy and Strategy via email at Morgan.Reid@kidney.org.

Thank you for your consideration of this request.

Sincerely,

Kevin Longino
CEO and Transplant Patient

Paul Palevsky, MD
President