NATIONAL KIDNEY FOUNDATION®

April 12, 2022

The Honorable Frank Pallone
Chairman, Energy & Commerce Committee
US House of Representatives
2107 Rayburn HOB
Washington, DC 20515

The Honorable Cathy McMorris Rogers
Ranking Member, Energy & Commerce Committee
US House of Representatives
1035 Longworth HOB
Washington, DC 20515

RE: H.R. 7667, The "Food and Drug Amendments of 2022" Act

Dear Chairman Pallone and Ranking Member McMorris Rogers:

The National Kidney Foundation supports the provisions of H.R. 7667, the "Food and Drug Amendments of 2022" Act. As the oldest and largest patient-centric organization representing and supporting kidney patients, kidney donors, their families and kidney health providers, NKF is supports provisions in this bill that will bring new drugs, devices, and cellular products to kidney patients, a population that has largely not benefited from the kinds of innovation that mark other therapeutic areas.

Since 1992, the Prescription Drug User Fee Amendments (PDUFA) program has helped improve the efficiency of the drug development process, bolster the U.S. Food and Drug Administration (FDA)'s public health mission, and advance regulatory science. For the estimated 37 million adults in the US living with chronic kidney disease (CKD), novel treatments for CKD and kidney failure, improved dialysis technology, and the promise of xenotransplantation are priorities.

The bill and the FDA commitments outlined in the PDUFA VII Goals Letter incorporate policies that are of significant interest to NKF including solutions to challenges in rare disease development, increased hiring in the Centers for Drugs and Biologics, patient-focused drug development, leveraging real-world evidence (RWE) in product development, and strengthening Accelerated Approval. Most importantly, we are pleased that FDA and Sponsors will work together on clinical trial diversity action plans. Patients of color are disproportionately impacted by kidney disease, and yet clinical trials routinely fail to adequately include them, leading to a lack of trust and a lack of understanding about the impact of treatments and therapies on diverse communities.

NKF is heartened to see this bipartisan legislation addressing the important role FDA plays in improving the health of our nation, and of kidney patients in particular. As we face the looming threat of over one million patients entering kidney failure by 2030, we must prioritize innovation that is available to all people who need it. Thank you for your focus on this important issue, and please reach out to Lauren Drew (lauren.drew@kidney.org) with any questions on our position or our kidney health priorities.

Sincerely,

Kevin Longino
CEO and Transplant Recipient

Paul Palevsky, MD
President