

May 8, 2020

The Honorable Richard Shelby
Chair, Senate Committee on Appropriations
304 Russell Senate Office Building
Washington, DC 20510

The Honorable Patrick Leahy
Ranking Member, Senate Committee on
Appropriations
437 Russell Senate Office Building
Washington, DC 20510-4502

The Honorable Roy Blunt
Chair, Subcommittee on Labor, Health
and Human Services, Education
and Related Agencies
347 Russell Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, Subcommittee on
Labor, Health and Human Services,
Education and Related Agencies
154 Russell Senate Office Building
Washington, DC 20510

Dear Senator Shelby, Senator Leahy, Senator Blunt, and Senator Murray:

On behalf of the 37 million Americans living with kidney diseases, including the more than 750,000 with kidney failure, thank you for your efforts to advance kidney health. Our organizations are deeply appreciative of the continued investments Congress has made into basic kidney science research at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and other key institutes, as well as the investment in innovation through KidneyX. As you continue responding to the COVID-19 pandemic, we ask that you provide \$100,000,000 in emergency supplemental funding for NIDDK and \$200,000,000 for KidneyX to meet the unique challenges facing people with kidney diseases for the current and future crises.

People with kidney diseases are among the most vulnerable to infectious diseases and there is mounting evidence that COVID-19 poses a unique risk: hospitalized COVID-19 patients with kidney diseases are two and half times more likely to die from the virus¹. The risks posed by COVID-19 are especially salient among people with kidney failure receiving in-center dialysis or living with a kidney transplant². Sadly, the first COVID-19 death in the US was a kidney patient.³ In addition, while it is commonly understood that COVID-19 causes damage to the lungs, increasing evidence suggests that the SARS-CoV-2 virus causes kidney injury. Anecdotal evidence from New York and China suggest that as many as 14-30% of intensive care unit patients with COVID-19 lose kidney function and require emergency kidney replacement therapy.⁴

To date, NIDDK has identified several opportunities for research of the impact of COVID-19 on the kidney and on people with kidney diseases⁵. However, as currently structured, such research is funded out of previously obligated Fiscal Year 2020 appropriations, limiting the scope of research NIDDK will be able to support. The scientific challenges facing the kidney

¹ Achenbach, J. Medical databases show 1 in 10 hospitalized middle-aged coronavirus patients in U.S. do not survive. Washington Post. April 11, 2020.

² Abelson, R. Dialysis Patients Face Close-Up Risk From Coronavirus. New York Times. April 11, 2020.

³ Rubin R. Finding Ways to Reduce Coronavirus Exposure During Dialysis. JAMA. Published online April 16, 2020. doi:10.1001/jama.2020.6158

⁴ Bernstein, L., Johnson, C. Y., Kaplan, S., & McGinley, L. Coronavirus destroys lungs but doctors are finding its damage in kidneys, hearts and elsewhere. Washington Post. April 15, 2020.

⁵ NIDDK. Notice of Special Interest (NOSI): Availability of Urgent Competitive Revision Supplements on Coronavirus Disease 2019 (COVID-19) within the Mission of NIDDK. April 9, 2020.

community -- such as the link between COVID-19 and kidney injury, the unique susceptibility of people with kidney diseases to COVID-19, and the response of people with kidney diseases to vaccines and medications developed to address COVID-19 -- are critical for providing optimal care during the current pandemic and improving the response to future pandemics, and require immediate and dedicated funding. We request that Congress provide \$100,000,000 in emergency supplemental funds to NIDDK, identical to what was provided in the CARES Act to the National Heart Lung and Blood Institute to study questions of similar urgency.

The current US kidney health infrastructure relies heavily on in-center hemodialysis to treat kidney failure, a care modality that requires mass congregation of vulnerable populations and large numbers of medical personnel. People receiving in-center hemodialysis are unable to follow federal guidelines recommending social distancing, the therapy requires sitting in close proximity to other immune-compromised patients for 12-16 hours every week. While numerous efforts undertaken by Congress and the Administration, especially the Executive Order on Advancing American Kidney Health, have started to transform the status quo of care, the COVID-19 pandemic has demonstrated that more must be done to accelerate the development of novel therapies that could mitigate the challenges facing people with kidney failure. New technology, such as the artificial kidney, could enable more patients to safely receive the care they need at home while maintaining a higher quality of life.⁶ An artificial kidney would mitigate challenges posed by the current pandemic – such as the current shortage of critical hemodialysis supplies in New York⁷ -- and making our kidney health system more resilient to future pandemics, natural disasters, and other crises.

The first prize competitions held by KidneyX have fulfilled their objective to accelerate innovation by focusing on redesigning dialysis and identifying patients' innovations in their own care⁸. This, in turn, has stimulated the private markets' attention to promising technologies for people with kidney failure. Based on KidneyX's Redesign Dialysis Phase 1 and 2 prize competitions, new approaches and innovators have surfaced. Wearable or implantable artificial kidney technology are progressing to stages that with appropriate support could be ready for regulatory consideration within 3 years. While total to-market costs for the artificial kidney will likely exceed \$400,000,000 per prototype, prize purses of \$50,000,000 will be sufficient to draw the attention of private investors. We request that Congress provide \$200,000,000 to KidneyX in emergency supplemental funding to catalyze the development of the artificial kidney.

Again, thank you for your continued support of people with kidney diseases, and your efforts to ensure the health of all Americans during the COVID-19 pandemic. We stand ready to assist any efforts to ensure the health of vulnerable Americans living with kidney diseases through investment in research and innovation. Should you have any questions about the requests raised in this letter, please contact Rachel Meyer at rmeyer@asn-online.org or (202) 640-4659.

Sincerely,

Akebia
Alliance for Home Dialysis

⁶ Huff, C. How artificial kidneys and miniaturized dialysis could save millions of lives

After decades of slow progress, researchers are exploring better treatments for kidney failure — which kills more people than HIV or tuberculosis. *Nature*. March 11, 2020.

⁷ Abelson, R., Fink, S., Kulish, N., Thomas, K. An Overlooked, Possibly Fatal Coronavirus Crisis: A Dire Need for Kidney Dialysis. *New York Times*. April 18, 2020

⁸ Prize Competitions. KidneyX. <https://www.kidneyx.org/PrizeCompetitions>. Accessed April 22, 2020.

American Kidney Fund
American Nephrology Nurses Association
American Society of Diagnostic and Interventional Nephrology
American Society of Transplantation
American Society of Nephrology
Atlantic Dialysis Management Services
Baxter
Children's Organ Transplant Association
Dialysis Clinic, Inc.
Home Dialyzors United
IGA Nephropathy Foundation of America
Greenfield Health Systems
Lowe Syndrome Association
National Kidney Foundation
National Renal Administrators Association
NephCure Kidney International
Nephrology Nurses Certification Commission
Northwest Kidney Centers
Polycystic Kidney Disease Foundation
Rare Disease Kidney Foundation
Renal Physicians Association
Renal Support Network
The Rogosin Institute
Satellite Healthcare
The Oxalosis and Hyperoxaluria Foundation
Vasculitis Foundation