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Dear Dr. Rodgers:

I am pleased to take this opportunity to respond to the Request for Information: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Strategic Plan Draft Document. In addition to this comment letter, I submitted a condensed version of these comments to the NIDDK comment web portal.

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF applauds the NIDDK's release of the draft Strategic Plan and the request for feedback. The Strategic Plan will shape the research for the coming years and will address the urgency of addressing chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States. Studies project that the 556,000 people in the U.S. currently on dialysis will increase to between 971,000 to 1,259,000 by 2030.<sup>i</sup> ESRD is devastating for the patient. Eighty percent of dialysis patients are too sick to work, and one in six dialysis patients can't afford their care. In addition to patient suffering and struggles, the costs to Medicare will increase. In 2018, Medicare spent \$49.2 billion on ESRD beneficiaries.<sup>ii</sup> The costs will increase as the number of people who experience kidney failure increases. Investments in research, prevention, early intervention, and cures will save lives and health care costs.

Additionally, the NIDDK's Strategic Plan should also reflect that the U.S. is now in a pandemic; nearly 38 million Americans have been confirmed to have COVID-19<sup>iii</sup>, and we do not know the long-term implications of the illness on the kidneys. Acute kidney injury early in the diagnosis of COVID-19 patients are indicators of a more likely severe illness.<sup>iv</sup> Subsequently, lower eGFR rates were found in COVID-19 patients discharged from the hospital, and kidney function deterioration over time is possible.<sup>v</sup>

Our comments on the draft Strategic Plan are below; we have organized them by page number.

## **Mission and Statutory Authority**

**Page 3, paragraph 3** should also project the urgency of addressing ESRD. We suggest adding this sentence about the prevalence of end-stage renal disease: “556,000 people in the United States rely on life- sustaining dialysis treatments, and another 210,000 have kidney transplants. Studies project that the number of people living with ESRD will increase to between 971,000 to 1,259,000 by 2030.”

## **Scientific Goal 1: Advance understanding of biological pathways and environmental contributors to health and disease**

### **Research Opportunity 1.2: Analyze the links between biology, behavior, and the environment, including social determinants of health, that contribute to disease heterogeneity and health disparities**

**Page 11, paragraph 2, Pursuing interdisciplinary research into how biological, behavioral, social, and environmental factors interact to affect human health:** People who are low-income experience food insecurity, face barriers to higher education, live in areas with higher pollution and/or live in areas with higher crime rates are more likely to have chronic diseases and illnesses. These non-medical conditions are called social determinants of health (SDOH) because they contribute to decreased health outcomes and greatly influence a person’s overall well-being. Social determinants of health include many more attributes than those listed in paragraph.

**We suggest that you include** the following sentence to **paragraph 3 on page 11:** “The social determinants of health (SDOH), which are the social, economic and environmental conditions that affect health and wellbeing and are significant contributors to health disparities. SDOH include income level, educational and job opportunities, access to housing and utility services, workplace safety, gender inequity, racial segregation, food insecurity, early childhood experiences, and exposure to violence and pollution.”

**Pages 11-12, paragraph on Advancing health equity research by understanding factors underlying health disparities:** We suggest adding the following to reflect the impact kidney failure and the COVID-19 pandemic on minority and ESRD populations: “Black Americans make up just 13% of the U.S. population, but they account for 35% of Americans with ESRD. Hispanic Americans are 1.6 times more likely than non-Hispanics to develop kidney failure and Native Americans are 1.2 times more likely than white Americans to develop kidney failure. Kidney disease and COVID-19 have adversely affected the same communities. Seventy-five percent of new kidney failure cases are due to diabetes and hypertension, and these are the same underlying chronic illnesses that have led to higher fatality rates from COVID-19 in communities of color. COVID-19 has

disproportionately impacted communities of color, which reinforces the knowledge that underlying health disparities must be addressed.”

### **Research Opportunity 1.3: Develop innovative technologies and resources to advance scientific progress and enhance health**

**Page 12, paragraph 2 on *Promoting technological development to advance the search for new drugs, diagnostics, and devices*:** We currently rely on eGFR testing to understand the kidney function but we do not have enough concrete biomarkers to predict who has a disposition for progressive kidney disease and will be ultimately have kidney failure. We suggest adding this sentence to the paragraph: “Moving from only functional tests, such as eGFR, which reflect the current state of the body and including biomarkers, which provide advance information of a predisposition to a certain disease state, will give patients and their health care providers an opportunity for early interventions.”

### **Scientific Goal 2: Advance pivotal clinical studies and trials for prevention, treatment, and cures in diverse populations**

#### **Research Opportunity 2.2: Increase the diversity of participants in clinical trials**

AKF applauds the NIDDK’s efforts to include diversity in clinical trials as a scientific goal. We serve low-income and communities of color; both populations have encountered issues joining clinical trials.

**Page 18, paragraph 6 on *Promoting participant engagement*:** The paragraph states that an obstacle of diversity in clinical trials include a “reluctance of some to volunteer for studies due a lack of trust.” Although that might be the case with individual volunteers, the phrase seems to put the responsibility of clinical trials on the patient. Many eligible low-income individuals are probably working two jobs, have no vacation or sick days, have limited transportation, and child care issues. Recruitment of patients for clinical trials should also focus on logistics of participants. Creating clinical trial outposts at Federally Qualified Health Centers (FQHCs), rural health centers, urgent care clinics, etc., would be more helpful. Patients with terminal or chronic illnesses will do what they can to be cured or have their health improved; that desire tends to overcome trust issues.

**We suggest adding the following sentence to the end of that paragraph at the top of page 19:** “Researchers should utilize community health centers when creating clinical trials, so patients can: 1) discuss the trials with their primary care physician; 2) do not have to travel a great distance; and 3) can go after-hours.”

### **Scientific Goal 3: Advance research to disseminate and implement evidence-based prevention strategies and treatments in clinical and community settings, to improve the health of all people, more rapidly and more effectively**

#### **Research Opportunity 3.1: Improve dissemination and implementation research, to accelerate the reach of prevention and treatment strategies proven successful in clinical trials**

Although the prevalence of early stages of our national health problem of CKD is comparable across different racial/ethnic and socioeconomic groups, the prevalence of kidney failure is greater for minorities than their non-Hispanic white peers.<sup>vi</sup> Prevention and early interventions work.

**Page 24, paragraph 4 on *Improving dissemination research strategies*:** Reaching people where they are, with use of organizations like departments of social services or housing administrations, is vital in reaching members of underserved communities. Additionally, utilizing community groups, including patient advocates and support groups, will also help with prevention and treatment strategies.

On **Page 30, paragraph 3**, we suggest adding the following groups to help with disseminating information: “patient advocates and support groups.”

### **Scientific Goal 4: Advance stakeholder engagement – including patients and other participants as true partners in research.**

#### **Research Opportunity 4.1: Comprehensively involve diverse stakeholders in each step of the research process, including patients, caregivers and family members, patient advocacy groups, and community-based organizations**

Patient engagement and participation in research goals and development of materials is vital for the researchers and the medical professionals so they can understand what patients need and want; it is also important for the patient to be able to understand written documents. When participating in expert panels, patients can feel intimidated.

AKF advises the NIDDK to create a patient training module after a person is accepted to serve as a patient advocate. The training can consist of learning the goals of the meeting, being taught the acronyms and vernacular language of the researchers and medical professionals, and understanding how they can best explain the wants and needs of the patient. We suggest adding the following paragraph to **page 31**: “*Training Patient Advocates to Serve on Expert Panels*: Representatives from patient groups or community organizations that do not have a science or medical background can be offered a training to receive background on the goals of the stakeholder meetings, explanation of acronyms and medical terms, and their role as a patient representative.”

### Research Opportunity 4.3: Develop new ways to address barriers to stakeholder engagement

AKF supports addressing barriers to stakeholder engagement. For many low-income people, the ability to participate on a committee is a luxury they cannot afford. In addition to addressing time, childcare, transportation, and financial issues, AKF believes that patient advocates should be paid. We suggest you add the following sentence **to page 32, paragraph 1**: “Patient advocates should be financially compensated for their time.”

Once again, thank you for the opportunity to comment on the draft NIDDK Strategic Plan. We look forward to continuing to work with you and your colleagues on kidney disease. Please do not hesitate to contact us if you need any additional information from us about our comments.

Sincerely,



LaVarne A. Burton  
President and CEO

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<sup>i</sup> Keith P. McCullough, Hal Morgenstern, Rajiv Saran, William H. Herman, & Bruce M. Robinson (2019). Projecting ESRD Incidence and Prevalence in the United States through 2030. *JASN*, 30 (1) 127-135. <https://jasn.asnjournals.org/content/30/1/127>

<sup>ii</sup> United States Renal Data System. 2019 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2019. <https://adr.usrds.org/2020/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd>

<sup>iii</sup> <https://coronavirus.jhu.edu/>

<sup>iv</sup> <https://www.news-medical.net/news/20210607/COVID-19-can-cause-long-term-consequences-for-the-kidneys.aspx>

<sup>v</sup> [Long-term effects of COVID-19 on kidney function – Authors' reply \(nih.gov\)](#)

<sup>vi</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3983362/>