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LaVarne A. Burton
President & CEO, ex-officio

September 14, 2018

Ross Bowling, Ph.D.
KidneyX
200 Independence Avenue SW
Room 624D
Washington, DC 20201

Re: KidneyX Project Comment (Request for Information #1)

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the Request for Information related to the Kidney Innovation Accelerator (KidneyX).

The American Kidney Fund is the nation's leading independent nonprofit organization working on behalf of the more than 30 million Americans with kidney disease. For the past half-century, AKF has existed to help people fight kidney disease and live healthier lives. We provide a complete spectrum of programs and services: top-rated education materials; free kidney disease screenings in numerous cities across the nation; clinical research funding; and need-based financial assistance enabling one in five U.S. dialysis patients to access lifesaving medical care, including dialysis and transplantation.

AKF strongly supports KidneyX and its goal to improve the quality of life for people living with kidney diseases by spurring innovation in prevention, diagnosis, and treatment. We commend the Department of Health and Human Services (HHS) for launching KidneyX and for its commitment towards the project's goals. AKF agrees that kidney health innovation has been stagnant for far too long. We are hopeful that KidneyX will help address the barriers to innovation in the kidney disease space, such as lack of capital, risks associated with early research and development, and low level of meaningful input from other medical, scientific, or technological fields.

As a patient organization, AKF is best suited to address the first question in the RFI:

What unmet needs – including those related to product development—should KidneyX prize competitions focus on? If you have ideas for more than one topic area/issue, how would you rank them in order of importance? If you are a person living with a kidney disease, what makes these topic areas for product development important?

AKF supports focusing on all the topic areas outlined in this RFI, but rather than rank them "in order of importance," we list the topic areas below in the order that they appear in the RFI and provide feedback on why they are important. Depending on a person's health status, disease progression, life circumstances, and treatment

preferences, there will be differences among people on how they perceive the importance of various kidney issues. Our feedback is informed by our work on behalf of people who are living with kidney disease, and hearing directly from them on the importance of these issues:

- ***Medications* – a variety of treatments for kidney diseases, including drugs and biologics**

Medications are critical to the health and well-being of kidney disease patients, including those with chronic kidney disease (CKD), on dialysis, patients with comorbid conditions and transplant recipients. However, for many patients, medication adherence can be a struggle, and for them it is imperative that innovators in the prescription drug and biologic space work towards reducing the medication burden for patients.

- ***Diagnostics* – point-of-care or at-home testing kits, better methods to measure kidney function**

Early detection of kidney disease can help prevent disease progression, and improvements in the methods to measure kidney function and diagnosing kidney disease would be a welcome innovation. Better diagnostic methods in the primary care setting and easy-to-use home testing kits that improve early detection would allow patients and their providers to implement a care plan at an earlier stage, leading to better outcomes.

- ***Patient-centered Tools* – electronic health record tools designed to identify and track diseases, applications to empower patients to manage kidney diseases, methods to improve communication within the patient community**

People living with kidney disease want to be empowered to manage their condition and live their best lives. AKF encourages the development of innovative patient-centered tools that enhance their ability to do so, but innovators, policymakers and government agencies also need to consider how to make these tools accessible to patients with low-incomes or limited access or experience with technology.

- ***Next Generation Dialysis* – wearable or implantable dialyzers, tissue engineering**

The development of wearable or implantable dialyzers and other alternative therapies for kidney failure hold the promise of giving end-stage renal disease (ESRD) patients an improved quality of life. As innovators develop the next generation of renal replacement therapy, it is imperative that new therapies address the factors that patients have identified as important priorities, such as reducing fatigue, cramping and dietary restrictions, and maintaining or restoring their ability to work and travel.

- ***Prevention* — methods to identify people at risk of kidney diseases and to slow the progression of those with early stage or chronic kidney disease**

Despite the prevalence of kidney disease, many people are not aware that they may be at risk or that they have kidney disease. Patients we work with have told us that they did not learn about

kidney disease until they ended up at a facility and on dialysis, which is obviously too late. Kidney disease prevention and education needs to happen earlier in the process, and in developing innovative prevention methods, innovators need to ensure that the methods are meaningful to people with different sociodemographic factors and different levels of health literacy.

Thank you for your consideration of AKF's comments, and we are happy to be available as a resource as KidneyX progresses.

Sincerely,



LaVarne A. Burton
President and CEO