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September 14, 2018

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

Re: KidneyX Prize Comment (Request for Information #2)

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

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 this first KidneyX prize competition that seeks to develop alternative therapies for kidney failure that improve and extend patient quality of life. As a patient organization, AKF is best suited to provide feedback on the first two questions in the RFI:

1. *Do you think that the scope [described below] is appropriate for this proposed prize competition? Are there additional areas for consideration in improving renal replacement therapy?*

The RFI lists the following areas in which the first prize competition seeks solutions:

Replicating Kidney Functions:

- Blood Filtration (filtering blood to remove waste and excess fluid)
- Electrolyte Homeostasis (maintaining appropriate levels of key minerals in the blood)
- Fluid Regulation (regulating the amount of and/or removing excess fluid)
- Toxin Removal and Secretion (limiting or preventing toxins in the bloodstream)
- Filtrate Drainage and Connectivity (removing excess filtrate after processing; connectivity issues for filtration, processing, and exterior drainage)

Improving Patient Quality of Life:

- Minimizing impact/intrusion of therapy on family/care partner(s) and social life
- Improving ability to work, travel, and engage in recreational activities

- Minimizing burden on the family and care partner(s) and improving quality of life
- Increasing mobility and physical activity
- Reducing disease and treatment complications
- Providing more choices for treatment
- Liberalizing diet and fluid regulation
- Reducing medication burden

Improved renal replacement therapy access (vascular or peritoneal access needed for treatment)

Addressing engineering challenges (e.g., preventing clotting, bleeding, and infection in vascular circuit and associated devices)

Ancillary technologies

Safety monitoring functions

AKF believes the scope is appropriate for this prize competition. In particular, the areas under “Improving Patient Quality of Life” are issues that patients have consistently identified as having an important impact on their ability to lead as normal a life as possible. However, there are two areas that should also be considered in improving renal replacement therapy: helping patients deal with the mental and behavioral health needs that can occur along with kidney disease and improving pain management.

People with chronic kidney disease (CKD) and end-stage renal disease (ESRD) face higher rates of depression as a group, and depression can lead to poorer health outcomes, increased hospitalizations, lower quality of life and more. Solutions to the other patient quality of life factors, such as reducing disease and treatment complications, improving ability to work and increasing mobility and physical activity, could help alleviate some of the stressors that exacerbate depression. But as innovators and solvers develop improvements to renal replacement therapy, mental and behavioral health needs and a patient’s emotional well-being should not be overlooked.

Improving pain management should also not be overlooked, and we encourage innovators to consider the physical pain that accompany current treatments for kidney disease and develop ways to improve upon that as they develop alternative renal replacement therapies.

2. Particularly for individuals who have experience receiving or providing dialysis, what issues or shortcomings have you observed regarding dialysis treatment? Are there particular elements of the treatment process that might be improved?

Many of the current shortcomings in dialysis treatment are well-known and need to be improved, including the time commitment, fatigue, medication burden and difficult dietary and fluid restrictions. In speaking with patients, an element of the treatment process that is particularly burdensome is the feeling of isolation that comes with dialysis. As HHS undertakes this first KidneyX prize competition, we encourage participants to consider solutions and treatment options beyond in-center dialysis that are accessible to a greater number of patients that will help improve patients’ social lives, their physical mobility and activity, their ability to maintain or go back to work, ability to travel and do things that many healthy people may take for granted.

Thank you for your consideration of AKF's comments.

Sincerely,



LaVarne A. Burton
President and CEO