

Wednesday, October 17, 2018

The Honorable Alex Azar, JD
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

We write today to commend you and your colleagues in the U.S. Department of Health and Human Services (HHS) for your efforts to establish KidneyX. We strongly support the formation of this public-private partnership to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases.

As you know, more than 40 million people in the United States are living with kidney diseases, and nearly 700,000 have kidney failure, for which there is no cure. Despite the significant burden of kidney diseases, there has been a dearth of innovation in this space compared to other areas of medicine. Our healthcare system has fostered a sense of complacency with current therapies and technologies, and the bundled payment system for dialysis is a deterrent for innovators and investors to enter the kidney care space.

Treating and managing kidney diseases and kidney failure is costly to the federal government. As the Government Accountability Office (GAO) highlighted in 2016, the Medicare program spent \$33.9 billion to manage kidney failure through Medicare's End Stage Renal Disease (ESRD) program—more than 7 percent of all Medicare spending in 2015.¹

The GAO's findings highlight the need for KidneyX, a public-private partnership to seed, incent, and accelerate breakthroughs to promising new therapies for people with kidney diseases. We believe that KidneyX is well-positioned to reduce the specific barriers that hinder innovation in the prevention, diagnosis, and treatment of kidney diseases, and propel private sector involvement. Specifically, we support the focus on commercializing new therapies and providing a catalyst for investment by the private market in three specific ways that are not currently addressed by market forces or federal efforts by:

- De-risking the commercialization process by fostering coordination among the National Institutes of Health, the Food and Drug Administration, Centers for Disease Control and Prevention, Health Resources and Service Administration, and the Centers for Medicare and Medicaid Services to provide a clear, predictable path towards commercialization.
- Providing non-dilutive funding to seed, incent, and accelerate breakthroughs to promising innovators, selected through a competitive process.
- Offering participating innovators access to investors and business experts so that the kidney space is repositioned as an attractive and untapped market.

Similar public-private accelerators—such as the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)—have shown great success in catalyzing private sector investment to transform another stagnant field. We look forward to monitoring KidneyX's progress, particularly its focus on building a diverse portfolio that includes next-generation

¹ National Institutes of Health: Kidney Disease Research Funding and Priority Setting, GAO-17-121 (Dec. 2016)

dialysis, diagnostics, other devices, medications, and patient-centered tools to more effectively and efficiently manage kidney diseases.

KidneyX's patient-centered focus on engaging a community of researchers, innovators, investors, and other stakeholders, while seeding promising companies will enable and accelerate the commercialization of therapies to benefit people with and at risk for kidney diseases. We applaud HHS's efforts to launch KidneyX and for sending a clear message to investors and innovators that the kidney space is ready for and desires new therapies in the fight against kidney diseases.

Sincerely,

Akebia
Alliance for Home Dialysis
Alport Syndrome Foundation
American Association of Kidney Patients
American Kidney Fund
American Nephrologists of Indian Origin
American Nephrology Nurses Association
American Society of Diagnostic and Interventional Nephrology
American Society of Nephrology
American Society of Pediatric Nephrology
American Society of Transplant Surgeons
Atlantic Dialysis Management Services
Atypical HUS Foundation
Baxter
Centers for Dialysis Care
Children's Organ Transplant Association
DaVita, Inc.
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Home Dialyzors United
IGA Nephropathy Foundation of America
Kidney Care Council
Kidney Care Partners
Lowe Syndrome Foundation
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
NxStage
Polycystic Kidney Disease Foundation
Renal Pathology Society
Renal Physicians Association
Renal Support Network
Rogosin Institute
Satellite Healthcare, Inc.
U.S. Renal Care

CC: Eric D. Hargan, JD
Edwin J. Simcox, JD