

Congress of the United States
Washington, DC 20515

March 19, 2018

The Honorable Tom Cole
Chairman
House Committee on Appropriations
Subcommittee on Labor, HHS,
Education and Related Agencies
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member
House Committee on Appropriations
Subcommittee on Labor, HHS,
Education and Related Agencies
Washington, DC 20515

Dear Chairman Cole and Ranking Member DeLauro,

We write to request that \$25 million in matching funds be included for KidneyX, a public-private partnership to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases, in the Fiscal Year (FY) 2019 Labor, Health and Human Services, Education and Related Agencies Appropriations bill.

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, Medicare 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 products for people with kidney diseases. Founded in 2018, KidneyX was designed to reduce the specific barriers that hinder innovation in the prevention, diagnosis, and treatment of kidney diseases, and catalyze private sector involvement.

KidneyX stimulates the commercialization of new therapies while providing a catalyst for investment by the private market in three specific ways that are not currently addressed by market forces or federal efforts:

- De-risks the commercialization process by fostering coordination among the National Institutes of Health, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services to provide a clear, predictable path towards commercialization
- Provides non-dilutive funding to seed, incent, and accelerate breakthroughs to promising innovators, selected through a competitive process
- Offers participating innovators access to investors and business experts and repositions the kidney space as an attractive and untapped market

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

While the first round of seed funding focuses on the development and commercialization of an artificial kidney, the portfolio will expand to include diagnostics, other devices, medications, and patient-centered tools to more effectively and efficiently manage kidney diseases. KidneyX is sustainable: revenue generated from breakthrough commercialized developments will be cycled back to support KidneyX, funding future therapies without the need for additional public investment beyond the first five years. Similar public-private accelerators, like the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), have shown great success in catalyzing private sector investment to transform another stagnant field.

KidneyX is a patient-centered solution driven by an invested community. KidneyX is a true public-private partnership: the private sector is committed to providing matching funds to achieve the total \$250 million required for the first five years. **To date, \$25 million has been committed to KidneyX from the private sector.** KidneyX will issue its first round of seed funding using private contributions in 2018. Now it is our turn to step up to the plate.

We respectfully request that the Labor-HHS Subcommittee begin a five-year commitment by appropriating \$25 million in FY 2019 for KidneyX, catalyzing private sector investment in kidney health. In addition, we ask that you include the following language in the report accompanying your Committee's appropriations bill:

The Committee is aware that more than 40 million U.S. citizens are living with kidney diseases, and for nearly 700,000 of those individuals, the diseases progress to kidney failure, requiring access to dialysis or kidney transplantation to live. The Committee notes that kidney failure alone accounted for more than 7% of Medicare spending (approximately \$34 billion) in FY 2015.

Given the high cost of kidney disease in terms of health consequences and federal spending, the Committee recommends that of the total allotted to HHS in FY 2019, that \$25,000,000 be made available to KidneyX—the first of a like five-year commitment of \$125 million to support KidneyX. The Committee has included funding to support this recommendation. This funding will accelerate the development and adoption of novel technologies that improve the diagnosis and treatment of patients with kidney diseases, through a variety of fund awards, technical assistance, and other support resources and services.

Thank you for your consideration of this important request.

Sincerely,




Brian Babin, D.D.S.
Member of Congress




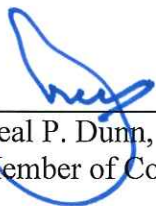
Tom Marino
Member of Congress




Suzan DelBene
Member of Congress



John Lewis
Member of Congress


Terri A. Sewell
Member of Congress

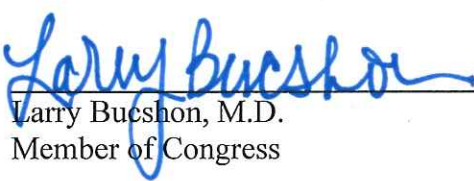

Neal P. Dunn, M.D.
Member of Congress


Danny K. Davis
Member of Congress



Peter A. DeFazio
Member of Congress


Paul A. Gosar, D.D.S.
Member of Congress


G. K. Butterfield
Member of Congress



Larry Bucshon, M.D.
Member of Congress


Cedric Richmond
Member of Congress


Adriano Espaillat
Member of Congress


Lisa Blunt Rochester
Member of Congress


Daniel W. Lipinski
Member of Congress


Earl Blumenauer
Member of Congress