

Congress of the United States
Washington, DC 20515

March 28, 2019

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

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

Dear Chairman DeLauro and Ranking Member Cole:

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) 2020 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 more than 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 health care system has fostered a sense of complacency with current therapies and technologies, and complex barriers deter innovators and investors from entering the kidney care space to develop therapies that improve the quality of life for patients and bring better value to the system. Americans affected by kidney diseases deserve better.

The status quo for treating and managing kidney diseases is far too costly to taxpayers to continue without intervention. The Government Accountability Office (GAO) reported in 2016 that 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.¹ Further, the prevalence of kidney diseases is growing and costs taxpayers and Medicare billions: \$114 billion in 2016 alone, or 23% of all Medicare spending.²

These findings highlight the need for KidneyX to address the barriers to innovation and investment. 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:

1. Providing funding to promising innovators to fill specific unmet patient product development needs—informed by patients—through a series of prize competitions.
2. De-risking the commercialization process by fostering coordination among the National Institutes of Health, the Food and Drug Administration, Centers for Diseases Control and Prevention, and

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

² United States Renal Data System. 2018USRDS 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, 2018.

the Centers for Medicare and Medicaid Services to provide a clear, predictable path towards commercialization.

3. Creating a sense of urgency within the private sector to develop new therapies for people with kidney diseases, repositioning the kidney space as an attractive and untapped market

The first prize competition, *Redesign Dialysis*, incentivizes the development of next-generation dialysis products, and KidneyX's portfolio will expand to incentivize innovation in other products such as diagnostics, devices, medications, and patient-centered tools to better manage kidney diseases.

KidneyX is a patient-driven solution supported by an invested community. KidneyX is a true public-private partnership: the private sector has already committed \$25 million to KidneyX and is committed to matching federal funding to achieve a total \$250 million in the first 5 years.

We respectfully request that the Labor-HHS Subcommittee begin a five-year commitment by appropriating \$25 million in FY 2020 for KidneyX, catalyzing private sector investment in kidney health. In addition, we also 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 more than 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 \$35 billion) in FY 2016 and that kidney disease accounted for 23% of Medicare spending (approximately \$114 billion) in FY 16. The Committee commends HHS for its efforts to improve the lives of these individuals through KidneyX.

Given the high cost of kidney disease in terms of health consequences and federal spending, the Committee recommends that a total of \$25,000,000 be added to the funds for the Office of the Secretary in FY 2020 for the Office of the Chief Technology Officer, and that those funds be made available to support KidneyX. These funds would represent the first of a five-year commitment to support KidneyX at \$25,000,000 each year. The Committee has included funding to support this recommendation. This funding will accelerate the development and adoption of novel therapies and 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,



Suzan K. DelBene
Member of Congress



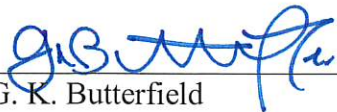
Larry Bucshon, M.D.
Member of Congress



Terri A. Sewell
Member of Congress



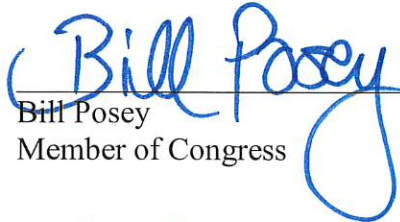
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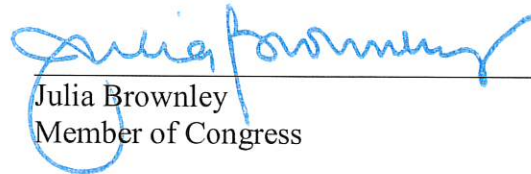
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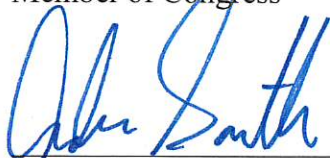
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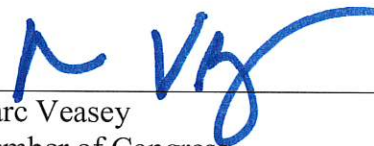
Adam Smith
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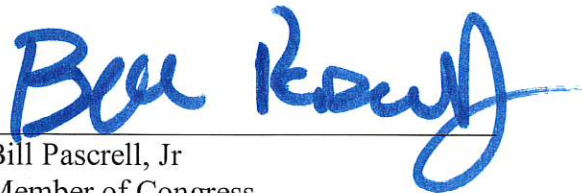
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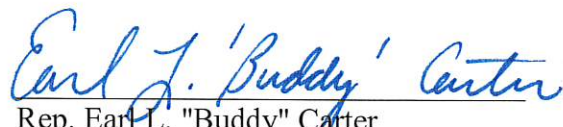
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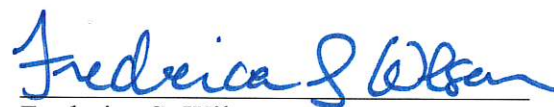
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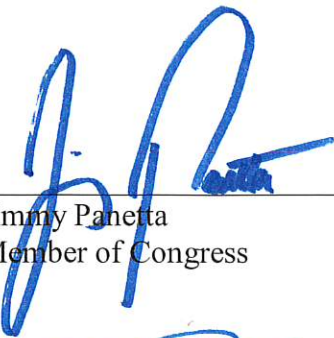
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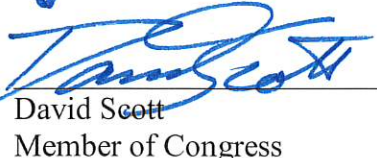
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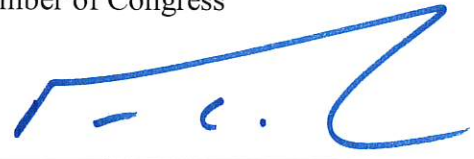
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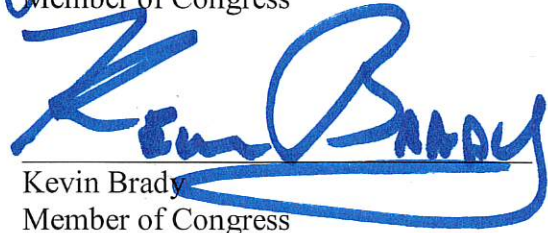
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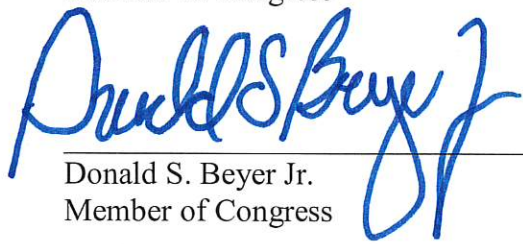
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Paul A. Gosar, D.D.S.

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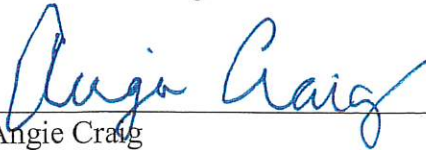
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