KidneyX: Accelerating Innovation in the Prevention, Diagnosis and Treatment of Kidney Diseases

► Rachel Meyer

Director of Policy and Government Affairs American Society of Nephrology



School of Medicine & Health Sciences

Kidney X Mission: Accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases.



- How public-private partnerships can drive progress in otherwise neglected areas
- How a small organization can create transformative changes
- How realigning incentives can help patient needs come first





700,000 Americans have kidney failure

100,000 START DIALYSIS every year: >50% of them will **DIE WITHIN 5 YEARS**

1% Medicare population has kidney failure

7% Medicare budget dedicated to their care





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12 Hours

A typical in-center hemodialysis patient spends 12 hours a week attached to a machine

93% Patients

Among patients ages 18-54 years old at the start of dialysis, 93% were classified as disabled

<u>)</u> 100,000

Each year, more than 100,000 Americans begin hemodialysis as a result of kidney failure

¥ 40 Million

40 Million adult Americans are currently classified as having chronic kidney disease

¥ 13 Patients

Every day 13 patients die waiting for a kidney transplant

 48%

 Of Stage 4 CKD patients, 48%

 were unaware of their severe

 CKD

Jul 3.5 Times

African-Americans are 3.5x more likely to develop kidney failure ~

1.5 Times

Hispanics are 1.5x more likely to develop kidney failure













HHS

Research funder Market regulator Primary payer Public health steward

ASN

Nephrology expertise Global reach \$25 million committed Fundraising capacity





"...One of the key reasons for our failing policies is that kidney care in particular has some of the worst incentives in American healthcare."

- HHS Secretary Alex M. Azar II

Incentivizing New Products

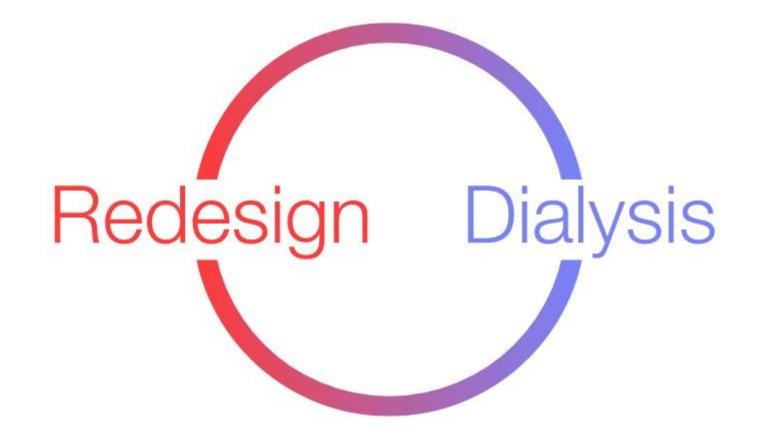
- 1. Offer funding opportunities Series of prize competitions
- 2. Improve coordination across HHS Clarify paths to commercialization (NIH, FDA, CMS)
- **3. De-risk commercialization** Attract outside investment capital
- **4. Create a sense of urgency** On behalf of people living with kidney diseases



KidneyX Principles

- Patient-Driven: Ensure all product development is patient-driven
- **Urgent:** Create a sense of urgency
- Achievable: Ground in scientifically-driven technology development
- Catalytic: Reduce regulatory and financial risks to catalyze investment
- Collaborative: Foster multidisciplinary approaches
- Additive: Addresses known barriers to innovation
- Sustainable: Invest in a diverse portfolio to balance risk







Redesign Dialysis: Solutions Sought

- Replacing kidney functions
- Improving patient quality of life
- Addressing engineering challenges
- Ancillary technologies
- Biomaterials development
- Biological and immunological modulation
- Biosensor development and safety monitoring

KIDNEY HEALTH INITIATIVE			
BRRT ROADMAP			



Phase One: Design Solutions

- Sought promising ideas on paper
- Awarded 15 teams \$75,000

"...we got 165 submissions, including a number of proposals that could help advance an artificial kidney...we're thrilled with this level of interest, and it shows what a prize competition can drive." – HHS Secretary Alex M. Azar II













Phase Two: Develop Solutions

- Seek prototype or component technology
- Up to 3 prizes of \$500,000
- Submissions accepted Q4 2019 Q1 2020





REDESIGN DIALYSIS: October 2018 - Q2 2020

Wearable or implantable dialyzers, bio-artificial kidneys, xenotransplant technology, etc.



MEDICATIONS

Drugs specifically designed to treat and slow progression of kidney diseases, as well as encompass the needs of kidney transplant patients



DEVICES

Devices that support the management and treatment of kidney diseases that are not dialyzers (such as vascular access technologies, etc.)



DIAGNOSTICS

Point-of-care or at home testing kits, real time kidney monitoring, etc.



PATIENT-CENTERED TOOLS

Tools designed to identify and track disease, applications to empower patients to manage kidney diseases (e.g., apps)



ASN and AAKP Advocacy for KidneyX







PUBLIC	PRIVATE		
\$25M FY20 congressional appropriation support	\$25M committed by ASN		
\$125M congressional funding over 5 years	\$100M in fundraising over 5 years		
PARTNERSHIP			
\$250M total driving kidney innovation over 5 years			



ASN and AAKP Advocacy for KidneyX

• 57 bipartisan House signatories

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 53.35 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:

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5 bipartisan Senate signatories

United States Senate

April 15, 2019

The Honorable Roy Blunt Chairman, Subcommittee on Labor, Health and Human Services, Education and Related Agencies United States Scratte Washington, D.C. 20510 The Honorable Patty Murray Ranking Member, Subcommittee on Laboe, Health and Human Services, Education and Related Agencies United States Senate Washington, D.C. 20510

Dear Chairman Blunt and Ranking Member Murray,

As you begin consideration of the Fiscal Year (FY) 2020 Labor, Health and Human Services, Education, and Related Agencies (LHHS) Appropriations bill, we respectfully request the subcommittee provide S25 million in matching funds for the Kidney Innovation Accelerator (KidneyX), a public-private partnership to accelerate innovation in the prevention, diagnosis, and treatment of Kidney diseases.

Kidney disease currently affects more than 40 million Americans, including approximately 700,000 Americans who have kidney failure for which there is no cure. The Medicare program annually spends more than 350 billion to manage kidney failure through the end stage renal disease benefit – accounting for more than 7 percent of all Medicare spending.¹ The prevalence of kidney diseases continues to grow at a cost to both patients and taxpayers: \$114 billion, or 23 percent of all Medicare spending, was dedicated to the care of kidney diseases in 2016.² Despite this significant burden, there has been a lack of innovation in the prevention, diagnosis, and treatment of kidney diseases for decades.

This underscores the need for programs like KidneyX to address the barriers to innovation and investment in new therapies for people with kidney diseases. KidneyX is a public-private partnership between the U.S. Department of Health and Human Services and the American Society of Nephrology, incentivizing innovators to fill unmet patient needs through a series of prize competitions. KidneyX also de-risks the commercialization process by fostering coordination among federal agencies, creating a sense of urgency on behalf of patients and families. The private sector has already committed \$250 million to KidneyX and is committed to matching federal funding to achieve a total of \$250 million to he first five years.

We respectfully request that the LHHS Subcommittee begin a five-year commitment by appropriating \$25 million in FY 2020 for KidneyX, catalyzing private sector investment in kidney health. Thank you for your consideration of our request.

Sincerely,

Ben Cardin Benjamin L. Cardin United States Senator

¹ United States Renal Data System, 2018 USHDS annual data report: Epidemiology of Kidney Decose in the United States. National Institutes of Health, Audional Institute of Objects and Objective and Ridney Diseases, Berhesda, ARD, 2018.





Appropriations Committee Releases Fiscal Year 2020 Labor-HHS-Education Funding Bill

April 29, 2019 | Press Release

 \$10 million for KidneyX, a new public-private partnership to accelerate the development and adoption of novel therapies and technologies to improve the diagnosis and treatment of kidney diseases.



"KidneyX has given me hope. As I watch my husband's quality of life decline, I want to do more and proceed in a positive direction. We both worked hard all our lives so we could enjoy travel, grandchildren, gardening, etc.

Instead, we devote about 32 hours/week to home hemodialysis. It is like having a full-time job again. We are just searching for newer and better ways to treat my husband's kidney failure before he succumbs to it. Please keep us informed about KidneyX."

-Wife of dialysis patient





KidneyX Contact Information

► KidneyX questions:

Connie Herndon, KidneyX Project Director <u>cherndon@asn-online.org</u> or Sandeep Patel, PhD, HHS <u>sandeep.patel@hhs.gov</u>

Advocacy-related questions:

Rachel Meyer, ASN Policy and Gov. Affairs rmeyer@asn-online.org

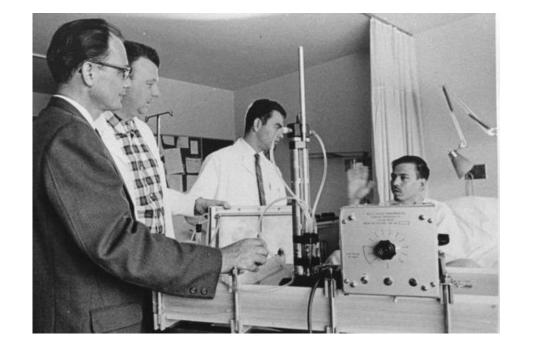
- Website: KidneyX.org
- ► Twitter: **@Kidney_X**



School of Medicine & Health Sciences

1960s Who gets dialysis?

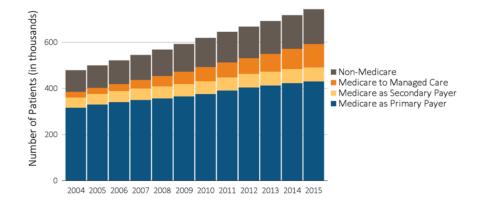
1972 Medicare ESRD Program



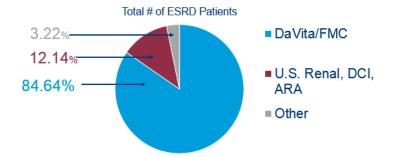




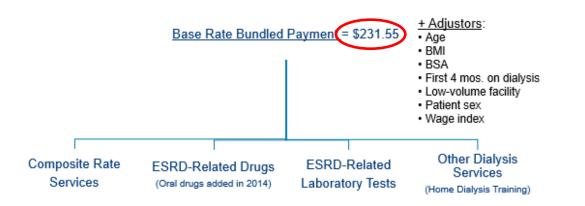
Single Payer (Virtually)



Consolidation



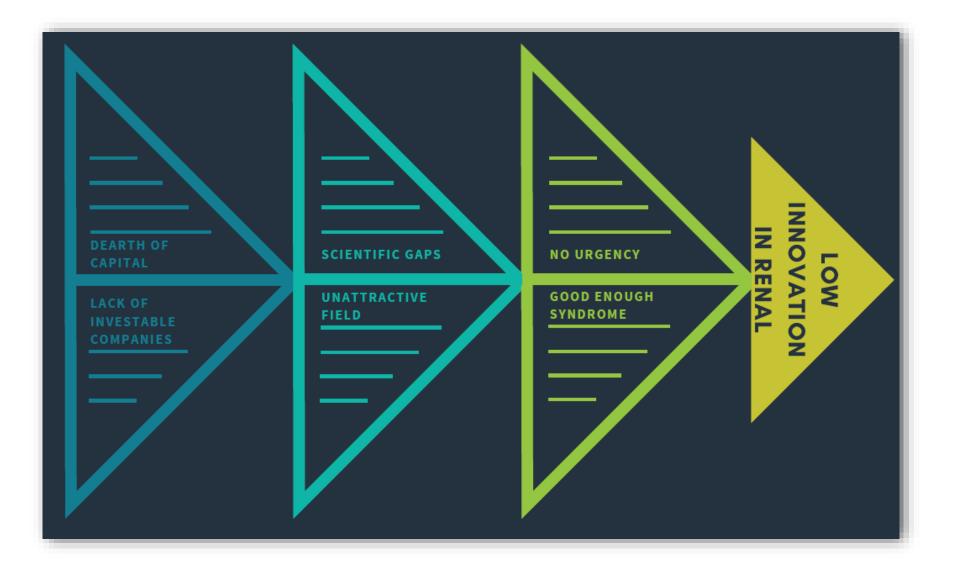
Fixed Bundled Payments



For-Profit Healthcare







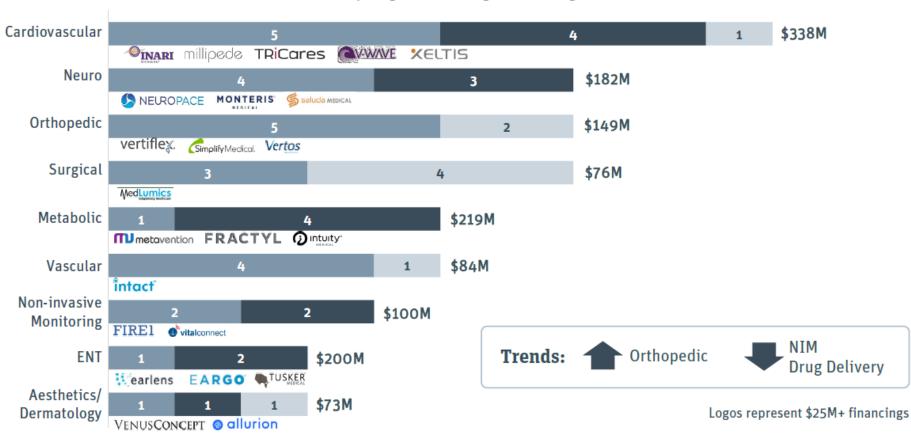


	Total Drug Approvals	Cancer	Kidney Diseases
2015	46	15	2 (patiromer for hyperkalemia and ferric pyrophosphate citrate for anemia)
2016	22	6	1 (calcifediol for SHPT)
2017	31	8	1 (etelcalcetide for SHPT)
Total 2015 - 2017	99	29	4 (all symptom management drugs)





DEALS | \$ MILLIONS



■ Early Stage ■ Late Stage ■ Undesignated

Silicon Valley Bank, Trends in Healthcare Investments and Exits Mid-Year 2018, Pitchbook

