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

Rachel Meyer
Director of Policy and Government Affairs
American Society of Nephrology
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

$35 BILLION Annual Medicare Spend
<table>
<thead>
<tr>
<th>12 Hours</th>
<th>93% Patients</th>
<th>100,000</th>
<th>40 Million</th>
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<tr>
<td>A typical in-center hemodialysis patient spends 12 hours a week attached to a machine.</td>
<td>Among patients ages 18-54 years old at the start of dialysis, 93% were classified as disabled.</td>
<td>Each year, more than 100,000 Americans begin hemodialysis as a result of kidney failure.</td>
<td>40 Million adult Americans are currently classified as having chronic kidney disease.</td>
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<table>
<thead>
<tr>
<th>13 Patients</th>
<th>48%</th>
<th>3.5 Times</th>
<th>1.5 Times</th>
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<tbody>
<tr>
<td>Every day 13 patients die waiting for a kidney transplant.</td>
<td>Of Stage 4 CKD patients, 48% were unaware of their severe CKD.</td>
<td>African-Americans are 3.5x more likely to develop kidney failure.</td>
<td>Hispanics are 1.5x more likely to develop kidney failure.</td>
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<tr>
<td>HHS</td>
<td>ASN</td>
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<td></td>
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<tr>
<td>Research funder</td>
<td>Nephrology expertise</td>
<td></td>
<td></td>
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<tr>
<td>Market regulator</td>
<td>Global reach</td>
<td></td>
<td></td>
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<tr>
<td>Primary payer</td>
<td>$25 million committed</td>
<td></td>
<td></td>
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<tr>
<td>Public health steward</td>
<td>Fundraising capacity</td>
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“…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
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

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<th>PUBLIC</th>
<th>PRIVATE</th>
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<tr>
<td><strong>$25M</strong></td>
<td><strong>$25M</strong></td>
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<tr>
<td>FY20 congressional appropriation support</td>
<td>committed by ASN</td>
</tr>
<tr>
<td><strong>$125M</strong></td>
<td><strong>$100M</strong></td>
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<tr>
<td>congressional funding over 5 years</td>
<td>in fundraising over 5 years</td>
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**PARTNERSHIP**

**$250M total**

driving kidney innovation over 5 years
Congress of the United States
Washington, D.C. 20515

March 25, 2010

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 Chairwoman DeLauro and Ranking Member Cole:

We write to request that $25 million in standing 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) 2022 Labor, Health and Human Services, Education and Related Agencies Appropriations Bill.

More than 40 million people in the United States are living with kidney disease, 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 area compared to other areas of medicine. Our health care system has fostered a sense of complacency with current therapies and technologies, and complex human data interpreters and investors have limited the ability to exploit research that can improve the quality of life for patients and bring better value to the system. Americans affected by kidney diseases deserve better.

The need for new 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.8 Further, the prevalence of kidney diseases is growing and more expensive and Medicare’s “Peer-” spends $1.74 billion in 2010 alone, at 27 percent of all Medicare spending.

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

KidneyX’s introduction of the commercialization of new therapies while providing a catalyst for the investments by the private market in these specific ways that are not currently addressed by market forces or federal efforts.

United States Senate
Washington, D.C.

Dear Chairwoman Murkowski and Ranking Member Hirono:

Given the consideration of the Fiscal Year (FY) 2021 Labor, Health and Human Services, Education, and Related Agencies (HHS, Labor, and Education Appropriations) Bill, we request that $25 million in standing funds be included for KidneyX, a public-private partnership to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases.

KidneyX currently affects more than 10 million Americans, approximately 700,000 of whom require renal replacement therapy. The Medicare program annually spends more than $30 billion to manage kidney failure through Medicare’s End Stage Renal Disease (ESRD) program. States’ efforts to manage the prevalence of kidney diseases continue as an area to seek further research and support. In FY 2018, 23 states reported making progress in addressing the rate of kidney failure. However, despite the significant burden, the lack of innovation in the prevention, diagnosis, and treatment of kidney diseases is a significant barrier.

This legislation is the need for KidneyX to address the barriers to innovation and investments. KidneyX’s introduction of the commercialization of new therapies while providing a catalyst for the investments by the private market in these specific ways that are not currently addressed by market forces or federal efforts.

Thank you for your consideration of our request.

Sincerely,

The Honorable Richard Shelby
The Honorable John Hoeven
Chairman, Senate Committee on Labor, Health, and Human Services, Education, and Related Agencies
United States Senate
Washington, D.C.

The Honorable Patty Murray
Ranking Member, Senate Committee on Labor, Health, and Human Services, Education, and Related Agencies
United States Senate
Washington, D.C.

57 bipartisan House signatories

5 bipartisan Senate signatories
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 cherndon@asn-online.org or Sandeep Patel, PhD, HHS sandeep.patel@hhs.gov

- Advocacy-related questions:
  Rachel Meyer, ASN Policy and Gov. Affairs rmeyer@asn-online.org

- Website: KidneyX.org

- Twitter: @Kidney_X
1960s
Who gets dialysis?

1972
Medicare ESRD Program
Single Payer (Virtually)

Consolidation

Fixed Bundled Payments

For-Profit Healthcare

Base Rate Bundled Payment = $231.55

+ Adjustors:
- Age
- BMI
- BSA
- First 4 mos. on dialysis
- Low-volume facility
- Patient sex
- Wage index

Composite Rate
Services
ESRD-Related Drugs
(Civet drugs added in 2014)
ESRD-Related
Laboratory Tests
Other Dialysis
Services
(Home Dialysis Training)

Total # of ESRD Patients
- DaVita/FMC: 3.22%
- U.S. Renal, DCI, ARA: 12.14%
- Other: 84.64%

Market summary > DaVita Inc
NYSE: DVA - Jan 23, 4:37 PM EST
79.04 USD + 0.09 (0.11%)
LOW INNOVATION IN RENAL

DEARTH OF CAPITAL

LACK OF INVESTABLE COMPANIES

SCIENTIFIC GAPS

UNATTRACTIVE FIELD

NO URGENCY

GOOD ENOUGH SYNDROME
<table>
<thead>
<tr>
<th>Year</th>
<th>Total Drug Approvals</th>
<th>Cancer</th>
<th>Kidney Diseases</th>
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<tbody>
<tr>
<td>2015</td>
<td>46</td>
<td>15</td>
<td>2 (patiromer for hyperkalemia and ferric pyrophosphate citrate for anemia)</td>
</tr>
<tr>
<td>2016</td>
<td>22</td>
<td>6</td>
<td>1 (calcifediol for SHPT)</td>
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<tr>
<td>2017</td>
<td>31</td>
<td>8</td>
<td>1 (etelcalcetide for SHPT)</td>
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<tr>
<td><strong>Total 2015 - 2017</strong></td>
<td><strong>99</strong></td>
<td><strong>29</strong></td>
<td><strong>4 (all symptom management drugs)</strong></td>
</tr>
</tbody>
</table>
Silicon Valley Bank, Trends in Healthcare Investments and Exits Mid-Year 2018, Pitchbook