

1 November XX, 2018

2
3 Alex Azar, JD
4 Secretary
5 U.S. Department of Health and Human Services
6 200 Independence Avenue, SW
7 Washington, DC 20201
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9 Dear Secretary Azar:

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11 We write to commend you and your colleagues in the U.S. Department of Health and Human
12 Services (HHS) for your support in establishing KidneyX. The formation of this public-private
13 partnership to accelerate innovation in the prevention, diagnosis, and treatment of kidney
14 diseases is transformational and we strongly encourage the Department to continue to make it a
15 priority.

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17 As you know, more than 40 million people in the United States are living with kidney diseases,
18 and nearly 700,000 have kidney failure, for which there is no cure. Despite the significant
19 burden of kidney diseases, there has been a dearth of innovation in this space compared to
20 other areas of medicine. Our healthcare system has fostered a sense of complacency with
21 current therapies and technologies, and multifactorial barriers deter innovators and investors
22 from entering the kidney care space. Americans affected by kidney diseases deserve better.

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24 Treating and managing kidney diseases is also costly to the federal government. The
25 Government Accountability Office (GAO) reported in 2017 that the Medicare program spent
26 \$33.9 billion to manage kidney failure through Medicare's End Stage Renal Disease (ESRD)
27 program—more than 7 percent of all Medicare spending in 2015.¹

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29 The GAO's findings highlight the need for KidneyX to address the barriers to innovation and
30 investment, fostering the development of new kidney therapies and technologies by:

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32 1. Providing funding to promising innovators to fill specific unmet patient product
33 development needs—informed by patients—through a series of prize competitions.
34 2. De-risking the commercialization process by fostering coordination among the National
35 Institutes of Health, the Food and Drug Administration, Centers for Diseases Control and
36 Prevention, Health Resources and Service Administration, and the Centers for Medicare
37 and Medicaid Services to provide a clear, predictable path towards commercialization.
38 3. Creating a sense of urgency to develop new therapies for people with kidney diseases.
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40 We applaud HHS's efforts to launch KidneyX and to send a clear message to investors and
41 innovators that new therapies in the fight against kidney diseases are urgently needed. In
42 particular, we commend HHS for dedicating funds to support the first KidneyX prize competition,
43 focusing on next-generation dialysis. We look forward to monitoring KidneyX's progress on this
44 prize, as well as its focus on building a diverse prize competition portfolio that includes
45 diagnostics, other devices, medications, and patient-centered tools to more effectively and
46 efficiently manage kidney diseases. Thank you again for your vision and leadership on this
47 critical and innovative program.

48
49 Sincerely,

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