



November 10, 2021

Karina W. Davidson, PhD, M.A.Sc.
Chairperson
U.S. Preventive Services Task Force
North Shore University Hospital
350 Community Drive
Manhasset, NY 11030

Michael J. Barry, MD
Vice-Chair
U.S. Preventive Services Task Force
Internal Medicine Associates Team 2
15 Parkman Street
Boston, MA 02144

Dear Drs. Davidson and Barry,

I am writing on behalf of Kidney Care Partners (KCP) to encourage the U.S. Preventive Services Task Force (USPSTF) to reconsider making a recommendation for Chronic Kidney Disease (CKD) screening. When USPSTF last reviewed the literature of CKD screening nearly 10 years ago, the Task Force found that there was insufficient evidence to support routine screening and declined to make a recommendation. However, given the low rates of CKD diagnosis compared to the estimated prevalence of the disease, KCP is concerned that the lack of a recommendation has led to a significant delay in diagnosis. Such a delay not only makes it more difficult to manage the disease, but also reduces the potential success in delaying the onset of more serious stages of CKD, including kidney failure. Therefore, we encourage USPSTF to take a proactive approach to addressing CKD.

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, and manufacturers organized to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD).

CKD affects an estimated 37 million Americans; yet only 10 percent of those affected are aware they have the disease. Without treatment, the prognosis of CKD advancing to kidney failure and death is grave. According to the U.S. Renal Data System 2020 Annual Report, the probability of dying within one year of diagnosis is roughly 1 in 4 in patients with stage 5 CKD and a little less than 1 in 5 in patients with stage 4 CKD. These numbers have not significantly changed during the last 10 years.

Communities of color disproportionately experience the burdens associated with the lack of early diagnosis. CKD disproportionately affects Black and Hispanic individuals. According to the U.S. Renal Data System 2019 Annual Report, the adjusted prevalence of ESRD (kidney failure) was 3.4 times higher in Blacks than Whites in 2018. The prevalence of CKD in individuals 66 years or older in the NHANES data from 2015-18 identified 43.3 percent of Black Americans as having CKD, while the percentage for Whites with the disease was 37.9 percent. The systemic barriers to accessing basic health care likely play a substantial role people of color developing kidney disease and progressing to kidney

Dr. Karina W. Davidson
Dr. Michael J. Barry
November 10, 2021
Page 2 of 3

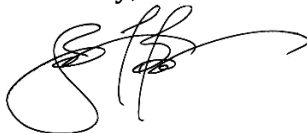
failure. The leading causes of CKD and ERSD are hypertension, diabetes, and obesity. Black and Hispanic individuals are diagnosed with these diseases more than other Americans.¹ We know from several years of research that people of color have greater difficulties accessing preventive care and chronic disease management services. It is very likely that the challenges these individuals faced when trying to access basic health care services resulted in chronic diseases, such as diabetes, obesity, and heart disease, not being fully managed, which led to the development of kidney disease.

One of the first step in addressing this health care inequality is diagnosing CKD in individuals as early as possible so that they can begin the process of managing their disease. Since 2012, the clinical community generally and the kidney care community in particular has learned more about how to effectively screen individuals for CKD. There have also been significant strides in treating early stages of CKD. Yet, without screening, these effective interventions are unlikely to be tried or prescribed because CKD has no distinguishing symptoms. A clinical test is needed to diagnose the disease.

KCP remains committed to working with the federal government to find ways to address the challenges that individuals living with kidney disease face. Getting an accurate and timely diagnosis is one of those challenges. To that end, KCP strongly supports H.R. 4065/S. 1971, "The Chronic Kidney Disease Improvement in Research and Treatment Act of 2021" introduced in the House by Representatives Terry Sewell (D-AL) and Vern Buchanan (R-FL) and in the Senate by Senators Ben Cardin (D-MD) and Roy Blunt (R-MO). Section 101 of this legislation seeks to add CKD screening to the annual wellness benefit to allow Medicare beneficiaries at risk for kidney disease and kidney failure to learn if they in fact have the disease and seek treatment to slow the progression toward kidney failure or better prepare for transplant or dialysis. Having a clear recommendation from USPSTF would help in these efforts.

Thank you for considering this request. Please do not hesitate to contact our counsel in Washington, Kathy Lester, if you have any questions or would like to discuss our recommendations with KCP members. She can be reached at 202-534-1773 or klester@lesterhealthlaw.com.

Sincerely,



John Butler
Chairman

¹ Richard V. Reeves & Faith Smith. "Up Front: Black and Hispanic Americans at Higher Risk of Hypertension, Diabetes, and Obesity: Time to Fix Our Broken Food System." *Brookings*. <https://www.brookings.edu/blog/up-front/2020/08/07/black-and-hispanic-americans-at-higher-risk-of-hypertension-diabetes-obesity-time-to-fix-our-broken-food-system/> Aug. 7, 2020). accessed June 28, 2021.

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Amgen
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
BBraun
Cara Therapeutics
Centers for Dialysis Care
Cormedix
DaVita
DialyzeDirect
Dialysis Patient Citizens
Dialysis Vascular Access Coalition
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Nephrology Nursing Certification Commission
Otsuka
Renal Physicians Association
Renal Healthcare Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma