



National
Kidney
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July 2, 2019

Acting Commissioner Norman E. Sharpless, M.D.
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2019-N-1619: List of Patient Preference-Sensitive Priorities; Establishment of a Public Docket; Request for Comments

Dear Acting Commissioner Sharpless,

The National Kidney Foundation applauds the Agency for recognizing end-stage renal disease (ESRD) as a preference sensitive area. Ensuring that ESRD patients can select a treatment option that is aligned with their lifestyle values, preferences, and goals is a priority for the patients whose voices the National Kidney Foundation (NKF) represents.

As the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the United States, NKF commends the Center for Devices and Radiological Health (CDRH) for its ongoing commitment to incorporating patient preference information (PPI) into the evaluation of medical devices. We strongly affirm the value of the patient perspective in defining important clinical study outcomes and meaningful changes within them, as well as in clarifying the most significant benefits and risks of a medical device and how patients understand these tradeoffs.

An estimated 37 million American adults have chronic kidney disease (CKD) and many more are at risk. In some cases, CKD progresses to ESRD, also known as kidney failure. Although kidney transplant is a superior option for many ESRD patients, the critical shortage in organs available for transplant results in most patients turning to dialysis to replace kidney function. Innovation in the devices used to manage ESRD or replace kidney function, including hemodialysis and peritoneal dialysis systems, vascular access devices, and future artificial wearable/implantable renal replacement therapies, are urgently needed. NKF, alongside the kidney community, is working to expand ESRD treatment options, in order to ease burden on patients and their caregivers and improve patient outcomes and quality of life.

Patient engagement from product concept design throughout the product lifecycle is a key element of improving ESRD devices. NKF encourages CDRH to continue to advance its efforts to incorporate ESRD PPI into medical device development by collaborating with stakeholders who are working to remove barriers to greater ESRD patient engagement and developing tools to enable this engagement.

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Patient feedback gathered during a 2015 Kidney Health Initiative (KHI) workshop on stimulating patient engagement in medical device development in kidney disease identified that while patients are interested in contributing to research projects that reflect their preferences and priorities, there is a “knowledge gap” that limits their ability to do so. During the workshop, patients articulated the need for a network where they can learn about opportunities to participate in the device development process, in addition to other types of research projects and clinical trials.¹ Next year, NKF will launch the NKF Patient Network, a centralized access point where patients across the full spectrum of CKD, including dialysis and transplant, will be able to provide data on their health history, outcomes, and preferences that supplement clinical and laboratory data from electronic health records.² The NKF Patient Network will leverage this unique combination of data to provide personalized education to patients while also meeting the need for a portal where patients can learn about clinical trials, provide their input to shape patient-centered trial designs, and contribute to post-trial surveillance. The NKF Patient Network will be a unique data repository, collecting a large, diverse dataset of patient outcomes, perceptions, and priorities that may improve how patients experience research and treatment and thus, their clinical outcomes. NKF would be pleased to partner with CDRH to discuss how the NKF Patient Network can serve as a source of PPI from ESRD patients.

NKF recommends that CDRH continue to extend the reach of the Patient Preference Initiative by sustaining existing collaborations and building new ones with organizations and consortia that are collecting and operationalizing data from kidney patients on their perspectives and priorities. The more we can work together to amplify the message that there is broad stakeholder consensus that patients must be at the center of innovation in kidney disease, the more likely we are to see devices coming to market that meaningfully improve the lives of patients. Sharing knowledge about the singular value of the patient perspective, as well as how to gather patient feedback and incorporate it in research, benefits the entire kidney community.

We finally advise CDRH to continue to emphasize that patient reported outcomes (PROs) are an invaluable element of patient centric medical product development. A complete understanding of the impact of treatment on a patient’s symptoms, functioning, and quality of life is especially important in ESRD, for which there are multiple current treatment options. During a sensitive time when their health status is rapidly changing, patients and their caregivers must make tradeoffs between these multiple options in order to select a treatment that meets their preferences and goals for their care. High-quality information from PRO measures provides essential data that enable patients and their providers to fully

¹ Hurst, F. P., MD, Chianchiano, D., JD, MPA, Upchurch, L., MBA, MHA, Fisher, B. R., PhD, Flythe, J. E., MD, MPH, Lee, C. C., . . . Neuland, C. Y., PhD. (2017). Stimulating Patient Engagement in Medical Device Development in Kidney Disease: A Report of a Kidney Health Initiative Workshop. *American Journal of Kidney Diseases*, 40(4), 561-569. doi:[https://www.ajkd.org/article/S0272-6386\(17\)30608-X/fulltext](https://www.ajkd.org/article/S0272-6386(17)30608-X/fulltext)

² <https://www.kidney.org/news/nkf-to-develop-first-ever-patient-registry-chronic-kidney-disease>

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understand the impact of treatment on their everyday experiences and ultimately make a treatment decision that best meets their needs.

We point CDRH to important work being conducted by the Standardised Outcomes in Nephrology (SONG) initiative, an international effort to develop a set of core outcome domains across kidney diseases. Core outcome domains that reflect treatment effects that are shared priorities of all relevant stakeholders, most importantly patients, have been developed for hemodialysis, peritoneal dialysis, and transplantation. The availability of a widely accepted, standardized set of outcomes that should be measured and reported in all trials ensures that medical device development is rooted in outcomes that are meaningful to patients.

NKF thanks FDA for its commitment to the patient voice. We look forward to continued partnership with the Agency on patient centric efforts to improve kidney care. We would welcome the opportunity to discuss how NKF can work with FDA to incorporate kidney patient perspectives into medical product development. Please contact Tonya Saffer, Vice President, Health Policy, at tonya.saffer@kidney.org or 202.244.7900 extension 717.

Sincerely,

Kevin Longino

Kevin Longino
CEO and Transplant Patient

Holly Mattix-Kramer

Holly Mattix-Kramer, MD, MPH
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