

Friday, June 9, 2017

Leslie Kux
Associate Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-0455 for “Enhancing Patient Engagement Efforts Across the Food and Drug Administration”

Dear Mr. Kux:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comment on the March 9, 2017 request for public input regarding the potential establishment of an Office of Patient Affairs. ASN represents nearly 17,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care, including efforts to foster the development and delivery of innovative new products to patients with kidney diseases.

The society appreciates FDA’s ongoing efforts to engage patients and their families and commends the agency for making strides in this area. More than 40 million Americans have kidney diseases, which disproportionately affects underrepresented minorities. These patients suffer from multiple other serious chronic co-morbidities, including diabetes, hypertension, peripheral vascular disease, and heart failure, and commonly receive care from multiple specialists. Half of patients with advanced kidney diseases have 5 or more other co-morbid conditions. More than 680,000 patients have kidney failure and rely on either dialysis or transplantation to stay alive, costing Medicare \$32.8 billion on their care alone.

Clearly, this complex, vulnerable patient population has a unique set of medical issues and perspectives as patients—and are also in need of innovative therapies to improve their outcomes and quality of life. Recognizing this need, the Kidney Health Initiative (KHI) Patient and Family Partnership Council (PFPC) was established in 2015 to ensure that the patient’s voice and experience throughout the initiative was both meaningful and effective.

ASN and the FDA formed KHI as a public-private partnership in 2012 to “advance scientific understanding of the kidney health and patient safety implications of new and existing medical products and to foster development of therapies for diseases that affect the kidney.” The PFPC’s formation was a reflection of KHI’s belief—strongly shared by ASN—that the patient and family voice is a critical component in the work of the FDA.

Accordingly, ASN is supportive of creating an Office of Patient Affairs, and its proposed objectives to develop a nuanced understanding of the patient experience of disease and support patients and their advocates in understanding the regulatory processes and navigating the FDA.

By establishing this Office as a single entry point to the agency for the patient community, the FDA will be able to draw upon patients' rich knowledge and experiences and incorporate that information into its important work. ASN joins the KHI PFPC in encouraging the FDA to ensure that KHI and other patient-centric organizations are able to maintain and strengthen their existing relationships with the appropriate offices and centers.

Again, thank you for the opportunity to provide comment on this request for input. ASN would be pleased to discuss these comments with the FDA if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely,

A handwritten signature in cursive script, appearing to read "Eleanor D. Lederer".

Eleanor D. Lederer, MD, FASN
President