

January 09, 2020

Stephen Hahn, MD Commissioner US Food and Drug Administration Office of the Commissioner 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Dr. Hahn:

On behalf of the American Society of Nephrology (ASN) and the Kidney Health Initiative (KHI), congratulations on your confirmation as Commissioner of the US Food and Drug Administration (FDA). Your vast experience in both medicine and clinical research will support FDA's efforts in assuring health and safety throughout the United States while accelerating medical innovation.

ASN looks forward to working with you to strengthen the relationship between FDA and the kidney community, especially the more than 37 million Americans with kidney diseases. KHI, ASN's public-private partnership with FDA, was founded in September 2012 with the goal of catalyzing innovation and the development of safe and effective patient-centered therapies for people living with kidney diseases.

Since its establishment in 2012, KHI has grown into an organization with over 100 member organizations. Through the help of FDA and member organizations KHI has completed, initiated, or approved 22 projects. The leadership of KHI and ASN appreciate the active support from FDA, which has been instrumental in KHI's success and recognition throughout the kidney community. Without the support and involvement of FDA staff and leadership this initiative would not be as successful or widely recognized. In particular, we would like to commend the efforts of Kristen Miller, PharmD, who is the FDA Liaison to KHI; Carolyn Y. Neuland, PhD, of the Center for Devices and Radiological Health; James P. Smith, MD, MS, of the Center for Drug Evaluation and Research, Aliza M. Thompson, MD, MS, of the Center for Drug Evaluation and Research and Celia Witten, MD, PhD, of the Center for Biologics Evaluation and Research, who are members of the KHI Board of Directors.

On behalf of the more than 100 member organizations of KHI, ASN's 20,000 members, the 37 million Americans living with kidney diseases, and the entire kidney community, we look forward to updating you on KHI's progress as projects are completed and priorities are initiated. Additionally, we encourage you to contact us if KHI or ASN can ever be of service to the FDA or you.

Again, thank you. To discuss this letter, KHI, or ASN, please contact us at <u>aagarwal@uabmc.edu</u> or and <u>ray.harris@vumc.edu</u>.

Sincerely,

Anupam Agarwal MD, FASN ASN President Raymond C. Harris, MD, FASN ASN Co-Chair of KHI

cc: Tod Ibrahim Kristen Miller, PharmD Carolyn Y. Neuland, PhD James P. Smith, MD, MS Aliza M. Thompson, MD, MS Melissa West Celia Witten, MD, PhD