American Kidney Fund®
FIGHTING ON ALL FRONTS

September 26, 2024

The Honorable Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane Rockville, MD 20852

RE: Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies [Docket No. FDA-2021-D-0789]

Dear Commissioner Califf,

The American Kidney Fund appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) draft guidance for industry on "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies."

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 1 in 7 American adults living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF commends the FDA for issuing this draft guidance, which is intended to assist sponsors conducting certain clinical studies involving drugs, biological products, and devices to meet requirements for the submission of Diversity Action Plans (DAP) under section 505(z) and section 520(g)(9) of the Federal Food, Drug, and Cosmetic Act 19 (FD&C Act) as added by section 3601 of the Food and Drug Omnibus Reform Act of 2022 (FDORA). Increasing clinical trial diversity is a critical step towards advancing health equity and ensuring treatments work for all people with serious chronic conditions such as kidney disease. The FDA rightly recognizes the importance of representativeness in clinical research, noting in the draft guidance: "consistent implementation of actions to improve representativeness in clinical studies can support more equitable and timely access to medical discoveries and innovations, improve the generalizability of results across the intended patient populations, improve our understanding of the disease and/or medical product under study, and inform the safe and effective use of the medical product for all patients."

11921 Rockville Pike | Suite 300 | Rockville, MD 20852
301.881.3052 voice | 301.881.0898 fax | 800.638.8299 toll-free | 866.300.2900 Español
Member: CFC 11404 | **KidneyFund**.org

A key pillar of AKF's health equity efforts is advocating for policies to increase clinical trial diversity. We also educate the public on the facts of the clinical trial process, the importance of clinical trial diversity, and how to search for clinical trials that may be of interest to them or their family. While people from communities of color have a disproportionate disease burden for leading chronic conditions such as kidney disease, they are underrepresented in clinical trials, overall. For example, Black people make up more than 3 in 10 people with kidney failure but only about 1 in 10 clinical trial participants. People of Hispanic ethnicity are nearly 1.3 times more likely to have kidney failure compared to non-Hispanics, but only about 1 in 10 clinical trial participants are Hispanic, while nearly 7 in 10 participants are non-Hispanic.

AKF supports the recommendations in the draft guidance regarding the form and content of the diversity action plans that sponsors must submit, including the recommendations on enrollment goals, rationale for enrollment goals, and measures to meet enrollment goals. We strongly support and appreciate the recommended clinical study enrollment and retention strategies, which expands on the recommended strategies in the April 2022 draft guidance and includes recommendations we made in our comment letter on that guidance. Specifically, we appreciate that the draft guidance encourages sponsors to consult with patients and health care providers as part of the process of developing a diversity action plan, including for considering enrollment and retention strategies.

We also strongly support the inclusion of the following in the draft guidance as examples of enrollment and retention strategies: sustained community engagement, including with community organizations; providing cultural competency and proficiency training for clinical investigators and research staff; improving study participant awareness and knowledge of the clinical study and providing language assistance for persons with limited English proficiency; reducing participant burden, including reimbursement for costs incurred and allowing flexible hours for study visits; improving access to the clinical study by selecting clinical study site locations that would facilitate enrollment of a representative study population; and employing clinical study decentralization when appropriate. Strategies such as these will help improve the communication, awareness, and trust that is essential in enrolling and retaining a clinical study population that is representative of the intended use population.

An additional enrollment and retention strategy that the guidance should address is health literacy. There may be different levels of health literacy among a population, including populations that have been underrepresented in clinical studies. The guidance should encourage sponsors to develop and implement strategies to assess the health literacy of their target populations, and ensure communication and materials are accessible and easy to understand so potential participants can make an informed choice on clinical trial participation.

Another recommendation we have for the draft guidance is for FDA to provide more guidance on recommended strategies to ensure clinical trials for rare diseases are representative of the populations affected by them. Rare diseases, including rare kidney diseases, often have small and geographically dispersed patient populations, which can make achieving diversity in

clinical trials especially difficult. It would be helpful for the FDA's guidance to include possible strategies for sponsors to implement to address these challenges in rare diseases. For example, the guidance could provide alternative methods for estimating the prevalence of rare diseases, since traditional methods of calculating prevalence may not be applicable given the small size of rare disease populations. Also, the guidance should include strategies to enroll and retain diverse participants from a small and dispersed population, which could include collaborating with rare disease organizations, leveraging patient registries, and developing innovative trial designs (e.g., clinical study decentralization) that may be more appropriate for a rare disease population.

Thank you for the opportunity to comment on this draft guidance.

Sincerely,

LaVarne A. Burton
President and CEO