NATIONAL HEALTH COUNCIL

June 13, 2022

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

The National Health Council (NHC) appreciates the opportunity to provide input to the Draft Food and Drug Administration (FDA) guidance on "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials."

Created by and for patient organizations more than 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 145 national health- related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The NHC is fully committed to mobilizing our members to advance health equity from the patient perspective and has historically engaged in health equity advocacy through much of the work that we do with our members, including in issues related to medical research such as patient engagement and clinical trial design. The COVID-19 pandemic and the national dialogue on equity that emerged in 2020 strengthened our resolve to focus on a more coordinated, mission-focused approach to our health equity work. We undertook an 18-month long effort to identify where equity gaps exist in the health ecosystem. Through engagement with leaders in the health and other sectors, we found consensus on defining the problem and areas of prioritization, reflected in the recommendations of our report, Access, Affordability and Quality: A Patient-Focused Blueprint for Real Health Equity. The four core areas of focus are:

- Equitable Access to Affordable and Comprehensive Health Insurance Coverage;
- Access to Care;
- Social Determinants of Health; and
- Medical Innovation.

Increasing the participation of people from marginalized populations in clinical trials is a primary focus of the medical innovation policy recommendations. **We commend the FDA for providing this needed guidance and helping to ensure that the diversity of participants is considered in every clinical trial.**

We offer the following recommendations for additions or modifications to the draft guidance. Most are designed to ensure greater patient engagement while addressing the issue of diversity in trials.

Patient and Community Engagement Aspects of the Diversity Plan

The NHC encourages the FDA to add a category to the plan components on patient and community engagement. Specifically, sponsors should be asked to include information about how they plan to partner with patient and community-based organizations in their outreach and enrollment efforts. This is in addition to expectations that the patient community has for sponsors to engage the patients throughout the research continuum as part of FDA's Patient Focused Drug Development (PFDD) program. This section should include consultation with affected communities and action based on their input.

In addition, the first section of the plan that describes available data on disease prevalence in underrepresented populations should include information about what data is not available and potential solutions to getting such data. For instance, a trial sponsor may partner with a disease-specific advocacy group to help build a disparity report to inform efforts. Too often, a lack of data on disease disparities is used to explain underrepresentation. We need to begin to address this in a systemic way.

Timing

We appreciate that the FDA offers flexibility on timing of plan submission while still requiring it be submitted before enrollment of the pivotal trial. We appreciate this flexibility, as different trials and different disease populations will have different needs. However, we urge the FDA to stress "as soon as practicable" to allow for identification of safety signals and disparities earlier in development.

Additionally, early communication between the FDA and sponsors is critical. Once plans are submitted, we encourage the FDA to provide clarity from the Agency about whether or not plans suit the needs of reviewers or if changes will be needed to ensure sponsors are collecting the right information and have a plan to address disparities. This will be especially true soon after the implementation of this guidance before strong precedents are set.

Research Team Demographics

The makeup of the research team itself can influence the diversity of participation in clinical trials. If participants see that members of their community are leading efforts, they will have more trust in the process. We recommend that the plans also include information on the demographic makeup of the research team.

Continued Focus on Marginalized Populations

While we recognize that this specific guidance is targeted at increasing participation among racial and ethnic demographics, we urge the FDA to continue to focus on effort to engage other marginalized populations. Future efforts should continue to focus on racial and ethnic demographics but also on people with disabilities, pregnant and lactating women, members of the LGBTQ+ community, and more. We encourage the FDA to issue future guidelines that help sponsors engage all marginalized populations.

Using Diversity Plans to Develop Best Practices

The NHC recommends that the FDA monitor and collect best practices as this guidance is implemented.

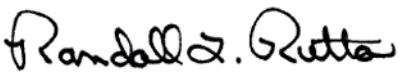
First, we recommend that the FDA regularly publish information about the usefulness and impact of diversity plans. At a minimum, the FDA should share aggregate information about whether trials met enrollment goals and reasons why goals were not met. This information will allow the FDA, advocates, and sponsors to learn from the diversity planning process to improve clinical trials and/or improve this guidance or lead to additional policy changes.

Second, the NHC recognizes that the global nature of many trials both assists and complicates efforts to diversify participation in clinical trials. In order to explore these issues, we recommend that the FDA convene meetings to explore clinical trial diversity in the context of global trials.

Conclusion

Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs if you or your staff would like to discuss these issues in greater detail. He is reachable via e-mail at egascho@nhcouncil.org.

Sincerely,



Randall L. Rutta
Chief Executive Officer