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September 24, 2024

Dr. Robert McKinnon Califf
Commissioner Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA Guidance for Industry: Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies

Dear Commissioner Califf:

The American College of Chest Physicians (CHEST) is grateful for the opportunity to comment on the Food and Drug Administration (FDA) industry guidance on Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies. CHEST is professional medical society representing 22,000 pulmonologists, critical care, and sleep medicine clinicians that seeks advance the best health outcomes for patients with lung disease through education, advocacy, research, and philanthropy.

We applaud the FDA for taking action to improve representation in clinical trials to better mirror real-world populations and for giving appropriate focus to historically marginalized groups. At the same time, the implementation of new requirements on the research community should be approached with care and monitored over time for unintended consequences that may run counter to the overarching goals. We surface a few nuances for consideration here.

1. **Regarding research study design.**

We highlight that the requirement for a Diversity Action Plan should not influence the design of a clinical study or the ability to conduct robust statistical analysis that enables clear conclusions to be drawn.

In focusing on enrollment goals, we suggest adding emphasis on the intersectionality of racial identity and other social determinants of health. It should be acknowledged that race is a social construct, not a biologic variable. There is active study across the field looking at the removal of race as a variable in existing algorithms and assessment tools, and we caution against perpetuating language that further implies "races" have clearly bounded, distinct biologic traits, which is false. Compelling researchers to break down their findings by race might inadvertently cement the conflation of race and biology as a viable concept. This runs counter to the laudable goals of the Draft Guidance and the meaningful diversification of clinical trials.

2. **Regarding research study recruitment.**

We appreciate the emphasis on cultural training embedded in the document (Section C. 'Measures to Meet Enrollment Goals' in reference to the second bullet point, "Providing cultural competency and proficiency training for clinical investigators and research staff…" (Page 13, line 403]). However, we believe that it is more appropriate and impactful to train 'cultural humility' and not 'cultural competence'. Competence suggests a finite level of mastery, whereas humility denotes an enduring, continuous practice that more clearly mirrors what is necessary.

We also acknowledge that the compulsory inclusion of Diversity Action Plan goals and sample enrollment strategies (Section C. 'Measures to Meet Enrollment Goals [Page 3, line 385]) could result an increase in recruitment requests for individuals from historically underrepresented backgrounds who may qualify for multiple studies and recognize that the research community will need to be thoughtful in balancing the burden on these individuals.

3. **Regarding components not reflected in the Draft Guidance.**

We believe there was a missed opportunity in the document to address medical mistrust that exists in most historically excluded communities and individuals from marginalized backgrounds. Improving access to clinical studies, as noted on page 14 line 416, must include trust-building and retention strategies on behalf of the investigators towards the communities they are attempting to engage. Guidance must be provided to investigators and researchers to avoid transactional relationships that would further exploit already harmed communities and exacerbate the existing medical mistrust.

CHEST appreciates the opportunity to submit comments to the FDA regarding its Draft Guidance on Diversity Action Plans and its efforts to meaningfully expand the diversity of clinical trial participants. We welcome the opportunity to discuss our suggestions further.

Sincerely,

Jack D. Buckley, MD, MPH, FCCP
CHEST President

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