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May 21, 2021

Mariell Jessup, MD Chief Science and Medical Officer American Heart Association 7272 Greenville Avenue Dallas, TX 75231

Hani Jneid MD, FACC, FAHA, FSCAI Chair AHA/ACC Task Force on Clinical Data Standards 2400 N Street, NW Washington, DC 20037

Dear Drs. Jessup and Jneid:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to thank you for the opportunity to provide comments on the 2021 American Heart Association (AHA)/American College of Cardiology (ACC) Key Terms and Definitions for Race and Ethnicity Categorization in Cardiovascular Clinical Research. This past year has brought into stark relief the inequities that have been occurring in our society and specifically the urgency with which they need to be addressed in health care and clinical research to ensure that patients are provided individualized care, free from structural barriers and system failures, particularly for historically marginalized populations.

The AMA has been examining racism, and racial and ethnic biases in our organization as well as in the medical community. In November 2020, the AMA House of Delegates adopted three pivotal policies that are a foundation for the AMA's work to eliminate health inequities and their root causes. Our policies assert that race is a social construct, explicitly distinct from genetic diversity or biology, and we are committed to ending racial essentialism in medicine (defined as the belief in a genetic or biological essence that defines all members of a racial category). The modern scientific consensus is that race is a social construct based on prevailing societal perceptions of physical characteristics, and that there are no underlying biological traits that unite people of the same racial category. Decades of rigorous genetics research have confirmed that genetic and biological variation exists within and among populations across the planet, and groups of individuals can be differentiated by patterns of similarity and difference, but these patterns do not align with socially defined racial groups (e.g., white, Black) or continentally defined geographic ancestral clusters (e.g., Africans, Asians, Europeans).

It is for these reasons that we are concerned with the AHA and ACC draft document on race and ethnicity categorizations in its current form. The AMA believes that this document has the ability to significantly elevate conversations about race and ethnicity in clinical trials and clinical research, but more stakeholder dialogue needs to be conducted to establish the proper foundation before AHA/ACC should move ahead with this proposal as currently drafted.

Our internal review team, which includes staff from AMA's Center for Health Equity, Improving Health Outcomes, Professional Satisfaction and Practice Sustainability, and Advocacy found that overall, the draft does not adequately address the social construction of racial and ethnic categories. The draft document states "Race refers to grouping by common characteristics shared by a group passed down through genes, with individuals sharing physical features." Although the document does go on to acknowledge that race is a social construct, it never reconciles that assertion with its earlier claim of genetic differences, noting that "a biological definition of race has classically been used" (page 6). The document continues, "Racial and ethnic groups have differing disease patterns, and categories can

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estimate subgroupings to which individuals are assigned based on ancestry, skin color, and country of origin" (page 6). The document never addresses the root cause of racial differences in health outcomes, that is structural inequities based in systemic racism.

We respectfully suggest that the introduction, upon which the rest of the document stands, be grounded in the most up-to-date evidence and perspectives in order to ensure that the proposed standard is one that can be widely accepted and used. The point of departure of this important effort should be that race is a socially constructed way of grouping people, based on skin color and other apparent physical differences, which has no genetic or scientific basis. If not, we are concerned that the standard proposed will be based on misguided racial essentialism and will not accomplish the intent of the writing committee, the sponsoring organizations, the larger health care and clinical research community and, most importantly, not serve our patients.

Please do not hesitate to contact, Dr. Christopher Holliday, Director of Population Health, at christopher.holliday@ama-assn.org to discuss these recommendations further. The AMA looks forward to continuing to work with you on this important document.

Sincerely,

James L. Madara, MD

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¹ Jones, CP, Levels of Racism: A Theoretic Framework and a Gardener's Tale, Am J Public Health. 2000;90: 1212–1215. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446334/pdf/10936998.pdf