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February 25, 2020

Food and Drug Administration, HHS

**Re: Office of Minority Health and Health Equity Strategic Priorities; Establishment of a Public Docket; Request for Comments [Docket No. FDA-2019-N-4824]**

To Whom It May Concern,

The Association of American Medical Colleges (AAMC) appreciates the opportunity to offer comments on the Food and Drug Administration's (FDA) Office of Minority Health and Health Equity's (OMHHE) strategic planning process. The AAMC applauds FDA's effort to ensure that OMHHE's strategic plan addresses health inequities related to differential access to and utilization of FDA-approved drugs and devices. The AAMC is a not-for-profit association representing all 154 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. These institutions conduct over half of the research funded by the National Institutes of Health (NIH), and through these institutions and organizations the AAMC represents nearly 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

As OMHHE's efforts currently emphasize two programs of work, Outreach / Communication and Research / Collaboration, the AAMC has focused its comments on those two broad portfolios.

#### Addressing Health Inequities through Outreach and Communication

In previous comments to FDA, the AAMC has encouraged deep, bidirectional community- and patient-engagement to enhance recruitment efforts as well as to maximize the dissemination of important health information and study results - particularly results related to subgroup differences.<sup>1</sup>

The AAMC strongly believes that such patient and community partnerships are essential not only to effective communication with minority populations, but to regulatory science itself and that FDA and OMHHE should redouble efforts to ensure patients, families, and communities are engaged in all aspects of the research enterprise, including idea generation, study design, and the dissemination of research results back to the patient community.

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<sup>1</sup> AAMC Comment Letter, September 15, 2016, (available at <https://www.aamc.org/system/files/c/1/469650-aamclettertoFDA.pdf>)

**The AAMC therefore encourages OMHHE to collaborate to the fullest extent possible with the FDA’s Office of Patient Affairs (OPA)** as it continues to release guidance for scientists interested in partnering with patients and caregivers on FDA-related research as well as gathering patient input to enhance regulatory decision-making. While those efforts and resources are important, AAMC would like to reiterate its previous recommendation that **FDA work with patients and other key stakeholders to develop a framework for using patient experience data during the study design phase to help define the research objectives and questions**, which the Agency identifies as the first step in the eight-step process for “Conducting Studies about Patient Experience,” and what the AAMC believes to be one aspect of the research process where patient input and expertise are most critical.<sup>2</sup>

Too often patient engagement is viewed as a bookend strategy mostly important during recruitment and for final dissemination of results. **AAMC urges OMHHE and OPA to partner on efforts to deepen trusting relationships between FDA, researchers, patients, and caregivers in ways that shift the conversation from “Outreach” to “Partnership.”**

This relationship building will benefit recruitment and therefore increase studies’ representativeness and external validity. It will also ensure that the data collected are resonant beyond FDA and the research community by deploying patient-developed metrics assessing drugs and devices in ways most meaningful to the end users themselves, reinforcing trust and facilitating dissemination. Research supported by the Patient Centered Outcomes Research Institute (PCORI) will be instructive for FDA OMHHE as it seeks to more fully incorporate patient voice and perspectives into its science.

In terms of communication with minority populations in service of both recruitment and information dissemination, the AAMC would like to reemphasize four potentially effective strategies for building effective communication channels via patient and community partnerships:

- a. **Identify communication pathways that will be effective to reach patient populations** who may not benefit from the infrastructure and technologies that facilitate communication through electronic means and social media.
- b. **Work with minority health professional organizations and advocacy groups to support effective communication and outreach to racial/ethnic subpopulations.** Additionally, minority serving institutions and other professional networks (e.g. fraternities and sororities) are viable facilitators for raising awareness and increasing clinical trial participation/retention.
- c. While issues of low literacy or limited English proficiency may make engagement with certain populations more difficult, to exclude those patients from research and dissemination efforts risks cutting out critical perspectives. **The FDA should develop**

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<sup>2</sup> AAMC Comment Letter, September 11, 2018 (available at: <https://www.aamc.org/system/files?file=2019-07/AAMC-%20Comment-Letter-Patient-Focused-Drug-Development-Sept112018.pdf>)

**specific outreach to engage non-English speakers, individuals with low literacy, and those who speak English as a second language.**

- d. As FDA moves forward with these strategies for increasing patient and community participation, the **AAMC fully supports the evaluation and assessment of any new efforts to determine their effectiveness.** It is important to keep in mind the goals of patient engagement for FDA and to establish a definition for successful patient involvement. An ideal outcome should not only include medical products that meet the needs of a diverse patient population, but also the development of a broad community of patients who are active participants in medical product development. This will in turn facilitate dissemination efforts and outreach to populations that would benefit from information about those medical products.

By more fully engaging patients and community members in drug and device development – from idea generation through dissemination – FDA can contribute to the evidence base of solutions to health and health care inequities.

#### Addressing Health Inequities through Research and Collaboration

**In addition to partnerships with OPA, we encourage OMHHE to strengthen existing partnerships with Offices of Minority Health across the US Department of Health and Human Services (HHS), especially including agencies within HHS such as the Indian Health Service, to ensure alignment of research frameworks and health equity-related metrics and evaluation strategies.** This alignment will heighten HHS’ ability to address endemic inequities with one overarching strategy and with data that could be combined across the Agencies’ research efforts for additional statistical power and subgroup analyses.

Relatedly, **we urge FDA and HHS to incorporate their patient-engagement and health equity efforts into the Federal Interagency Health Equity Team (FIHET) so that health equity science and scholarship as well as strategies for comprehensive patient and community engagement can be developed and deployed across the federal government.** It is well understood that what influences a person’s and community’s health most exists largely outside of the health care system. Transportation, housing, education, criminal justice, the environment, etc. – the “social determinants of health” (SDOH) – are recognized as the main drivers of both wellbeing and of health inequities. These Agencies and others are all FIHET team members and would benefit from a singular, evidence-based health equity approach grounded in true patient and community engagement.

The importance of SDOH should also be reflected in OMHHE’s and FDA’s own science. Efforts to collect patient-level social risk data as well as community-level social determinant of health data are widespread with innovation occurring at all levels from local community health centers, to large academic health centers, to HHS itself as highlighted by the Centers for Medicare and Medicaid Services’ (CMS) and the Assistant Secretary for Planning and Evaluation’s (ASPE) efforts to incorporate social factor data into quality measurement and, potentially, hospital payments. **Therefore, we also suggest that FDA and OMHHE consider whether and if it is important to**

**incorporate social factor data that might impact clinical trial results.** While randomization should, of course, account for unmeasured social risk between trial arms, the ability to stratify by social factors would allow scientists and patients to better understand how such influences impact treatment outcomes.

**The incorporation of social factor data into FDA science would also benefit the priority research areas for the FDA’s Centers of Excellence in Regulatory Science and Innovation (CERSI).** Individual and neighborhood level social factors play significant roles in CERSI’s stated high-priority topic areas such as tobacco and opioid use and can play important facilitating or confounding roles in post-market evaluations of FDA-regulated products. To that end, **we also urge FDA to partner with local and state public health departments who have significant community engagement and data collection / analysis expertise,** particularly on issues related to community-level social determinants of health.

Finally, we acknowledge that many important strides have been made by the agency in developing new treatments for rare diseases and conditions that predominantly affect racial and ethnic minority groups, such as sickle cell anemia. However, **the AAMC encourages the FDA and OMHHE to broaden and diversify collaborations with local, regional, and national minority organizations, such as the NAACP.** Enlisting more concerted approaches to liaise with these groups could potentially increase clinical trial participation and address research gaps, particularly those related to complex, rare conditions. Additionally, OMHHE should leverage these relationships to augment awareness raising and advocacy for better disease management and help break down barriers to treatment, such as stigma, which exacerbate and perpetuate health care inequities among patients.

The AAMC appreciates the opportunity to provide comments to FDA and OMHHE on these important issues and would be happy to provide any further information which would be of use to FDA and HHS. Please contact me or my colleague Philip M. Alberti, Ph.D. Senior Director, Health Equity Research and Policy ([palberti@aamc.org](mailto:palberti@aamc.org)) with any questions about these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ross McKinney, Jr., M.D." with a stylized flourish at the end.

Ross McKinney, Jr., M.D.  
Chief Scientific Officer

cc: Philip M. Alberti, Ph.D.