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September 8, 2020

Division of Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5360 Fishers Lane, Rm 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2020-N-1391 for “Office of Women’s Health Strategic Priorities; Establishment of a Public Docket; Request for Comments”**

The AAMC (Association of American Medical Colleges) is a not-for-profit association dedicated to transforming health care through medical education, patient care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America’s medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 115,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Additional information about the AAMC is available at [www.aamc.org](http://www.aamc.org).

We appreciate the opportunity to comment on the FDA’s request for comments to inform the strategic priorities for the Office of Women’s Health (OWH) and agree that the FDA can play a unique role in protecting and promoting women’s health through efforts to identify research priorities and opportunities for inter-agency and external collaboration. Additionally, the AAMC affirms the OWH’s reference to diversity throughout its strategic priorities, and we would like for the OWH to take note that intersectionality is a key tenet to ensuring the inclusion of women who hold multiple identities (e.g. racial, ethnic, sexual and gender minorities).

**I. Educational Outreach and Community Partnerships**

The AAMC appreciates the OWH’s intentions to communicate directly with diverse groups of women to promote access to relevant information about FDA-regulated products and encourage representation in clinical trials. Equally important is the recognition that patient and community partnerships are critical to these efforts and should be actively engaged in all key stages of the planning and development process to “ensure that important health concerns are carefully considered in establishing the OWH’s scientific, educational, and outreach priorities.” **As the Office takes steps to advance the health agenda for the FDA, the AAMC urges continued collaboration with key stakeholders to help build public trust, thereby strengthening the**

## **Agency’s relationship with researchers, patients, and caregivers in ways that shift the conversation from “outreach” to “partnership.”<sup>1</sup>**

In previous comments to the FDA, the AAMC has encouraged the development of robust bi-directional community and patient engagement to help educate the research community about FDA-related activities and optimize the dissemination of health information and clinical trial results. **We appreciate that the OWH has identified the need for dialogue about women’s health topics and opportunities for educational outreach as one of its strategic priorities, and recommend the Office work closely with the FDA’s Office of Patient Affairs (OPA) to further Agency efforts to develop guidance and educational resources on the use of patient experience data for medical product development and regulatory decision-making.<sup>2</sup>**

## **II. Clinical Trial Diversity and Participation of Women Across the Lifespan**

Efforts to increase participant diversity in research through the implementation of guidelines on the representation of women in clinical trials and incorporation of sex and gender considerations in clinical trial data analysis is a key component of the OWH’s mission and a priority the AAMC fully supports. The list below includes, but is not limited to, several potentially effective strategies for increasing clinical trial diversity:

- **Establish effective community partnerships**

Meaningful partnerships with sponsors and the patient community will not only help with the outreach and dissemination of important FDA-related information but help build trust which is beneficial for trial recruitment of diverse participants. We recommend that the OWH work closely with minority health professional organizations and advocacy groups to support effective communication with racial/ethnic subpopulations (e.g., minority serving institutions and professional networks such as fraternities and sororities are viable means for increasing awareness about participation/retention).

Industry support of patient organizations has increased,<sup>3</sup> and it is important to recognize the potential for financial and other conflicts of interest as a result. Community partners should not be solely professional advocates who have been selected, trained, or funded by drug, device or biotechnology companies. Instead, partnerships should be led by local organizations and community leaders who are better positioned to leverage existing positive relationships with minority populations, ensuring that recruitment is conducted in a culturally competent and sensitive manner that preserves public trust.

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<sup>1</sup> See AAMC Comment Letter, *Office of Minority Health and Health Equity Strategic Priorities* (February 25, 2020).

<sup>2</sup> See AAMC Comment Letter, *Enhancing Patient Engagement Efforts Across FDA* (June 12, 2017).

<sup>3</sup> McCoy, Carniol, Chockley, Urwin, Emanuel, & Schmidt, *Conflicts of Interest for Patient-Advocacy Organizations*. *New England Journal of Medicine*, 376:880-885 (2017).

- **Incorporate engagement and retention strategies for diverse populations in OWH guidelines**

Included in OWH’s mission is the implementation of guidelines concerning the representation of women in clinical trials. As the OWH develops methods for furthering its mission through its strategic priorities, the Office should ensure the guidelines include explicit strategies for the engagement and retention of populations that are underrepresented in research *and* populations whose communities suffer from health inequities. The research community will need clear guidance from the FDA on how to implement and evaluate any new policies or guidelines, and we recommend the FDA provide guidance to the OWH regarding how to incorporate relevant training or appropriate methods to facilitate successful implementation.

- **Develop educational opportunities and/or guidance related to the inclusion of women across the lifespan (e.g., pregnant women, reproductive-age and post-menopausal women)**

We agree that pregnant women, breast feeding women and other women with certain health conditions are frequently excluded from clinical trials and recommend the FDA’s efforts be coordinated with parallel efforts in the Department of Health and Human Services (HHS) and National Institutes of Health (NIH) as described further below.

In light of the ongoing public health emergency for the 2019 novel coronavirus, there is a critical need for the inclusion of these groups in current and ongoing COVID-19 research. In the FDA’s June 2020 guidance for industry, *Development and Licensure of Vaccines to Prevent COVID-19*, the Agency “encourages vaccine developers to consider early in their development programs data that might support inclusion of pregnant women and women of childbearing potential who are not actively avoiding pregnancy in prelicensure clinical trials.”<sup>4</sup> Given the current research needs, we urge the OWH to review and expand on key recommendations contained in the September 2018 report to Congress by the Department of Health and Human Services’ *Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)*, and work with PRGLAC to swiftly finalize the 2018 draft guidance, *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials*.<sup>5</sup>

Additionally, the disparate and rising rates of maternal mortality and morbidity among black, American Indian, and Alaskan Native women in the United States warrant concerted efforts to engage these populations as active participants in the formation of the OWH’s research and capacity building activities.

- **Increase efforts to recruit diverse investigators**

The OWH should develop initiatives and opportunities for the recruitment and training of women and minority investigators to increase trial participation and retention.

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<sup>4</sup> *Development and Licensure of Vaccines to Prevent COVID-19*, U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research (June 2020).

<sup>5</sup> *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials* (April 6, 2018).

- **Consider additional challenges that may limit trial participation and diversity**  
Additional barriers include but are not limited to the following: mistrust of research; impact of frequent site visits on participants; transportation expenses and other financial commitments (e.g., child care); and a lack of effective pathways to reach patient populations who may not benefit from mobile/web-based technologies, who have low literacy/limited English proficiency, persons with disabilities, and individuals from distinct contextual and geographic communities (rural populations).

### III. Coordination and Collaboration across Federal Agencies

We are pleased that the OWH intends to coordinate and collaborate with other Federal Agencies and external stakeholders to support its mission and strategic priorities. In addition to our recommendation for partnership with the FDA’s OPA, **we encourage the OWH to collaborate with the Office of Minority Health and Health Equity (OMHHE), and other agencies within the HHS, including the Indian Health Service, and Office for Human Research Protections’ Secretary’s Advisory Committee on Human Subject Protections.** To illustrate a benefit of such collaboration, OMHHE recently requested comment on its strategic priorities, addressing many of the same topics and issues included in the OWH’s strategic priorities (e.g., opportunities for community outreach, stakeholder collaboration, engaging minority populations in clinical research). Harmonizing efforts with OMHHE and other Federal Agencies conducting similar work would strengthen new and existing partnerships and ensure alignment with related activities across the federal government.

We recognize the partnership that the OWH has with the NIH Office of Research on Women’s Health to increase awareness related to the importance of women participating in clinical trials (“The Diverse Women in Clinical Trials Initiative”),<sup>6</sup> and **recommend that the Office harmonize with the NIH’s efforts to include women and minorities in clinical research.**<sup>7</sup> **The OWH should develop formal partnerships with other institutes such as the National Heart, Lung, and Blood Institute (NHLBI) and National Institute on Minority Health and Health Disparities (NIMHD),** especially given the ongoing efforts to address maternal health disparities among women of color in the United States. The OWH should continue to raise awareness around these issues through direct collaboration with the OPA, OMHHE, and other relevant agencies.

### IV. Mechanism for Evaluation

The OWH states in its mission that it will “identify and monitor the progress of crosscutting and multidisciplinary women’s health initiatives including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA’s mission.” **In support of**

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<sup>6</sup> <https://www.fda.gov/consumers/womens-health-topics/diverse-women-clinical-trials-campaign-partners> (last visited September 2, 2020).

<sup>7</sup> <https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm>. Also see, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html>

**these goals, we urge the OWH to include in its priorities a clear process with defined metrics for the evaluation and assessment of the Office's current and new activities.** As appropriate, the OWH should also solicit public feedback on specific priorities, keeping in mind that a successful outreach strategy requires participation from idea generation through dissemination and commitment to transparency by publicly sharing the results of the evaluation with interested stakeholders.

The AAMC is grateful for the opportunity to comment on the OWH's strategic priorities and would be happy to provide additional information as the Office moves forward with the development and implementation of its priorities. To the extent the AAMC can help advance these efforts or provide additional information, please contact me or my colleagues Daria Grayer, JD, MA ([dgrayer@aamc.org](mailto:dgrayer@aamc.org)) or Karey M. Sutton, Ph.D ([ksutton@aamc.org](mailto:ksutton@aamc.org)).

Sincerely,

A handwritten signature in blue ink that reads "Ross E. McKinney, Jr., MD". The signature is stylized and includes a small circular mark at the end.

Ross E. McKinney, Jr., MD  
Chief Scientific Officer