AAMC

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April 16, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-2295, Request for Information "Specific Areas of Public Health Concern Related to Racial/Ethnic Demographic Subgroups for Additional Research by the Office of Minority Health"

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) request for information about specific areas of public health concern for racial/ethnic minority populations to enhance the development of its research agenda and inform funding decisions for the next fiscal year. The AAMC is a not-for-profit association representing all 141 accredited U.S. allopathic medical schools, nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers, and 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and post-doctoral trainees in the biomedical sciences.

The AAMC recognizes that health and health care disparities arise from conditions in which people are born, live, work and age. These disparities are often persistent in certain populations such as racial/ethnic subgroups, the elderly, veterans, individuals from lower socioeconomic status backgrounds, and LGBT and rural populations. While there is a vast amount of research aimed at identifying health inequities associated with these populations, the AAMC is committed to increasing the capacity of our member institutions to create the evidence-base for solutions to these health and healthcare gaps.

The AAMC commends the efforts of the FDA to expand the knowledge base about the health of racial/ethnic demographic subgroups in order to better inform healthcare decisions of providers and patients. Through targeted and well-designed regulatory science research and a comprehensive dissemination strategy, the Office of Minority Health (OMH) and the FDA are well positioned to help address the goal of achieving equitable healthcare for all. The AAMC offers recommendations in three broad categories: 1) identifying areas of public health concern for racial/ethnic minorities, 2) improving participation rates of racial and ethnic minorities in research, and 3) effectively disseminating important medical information to all populations.

1. Identifying areas of public health concern for racial/ethnic minorities

Actively seek input from racial/ethnic minority communities. The FDA should ensure that all relevant stakeholders from patient subpopulations have the opportunity to be engaged. The AAMC commends the FDA's commitment to increasing patient participation in regulatory discussions. The FDA could strengthen its commitment by utilizing resources that may reach voices of those rarely engaged. Working with minority health profession organizations and advocacy groups in conjunction with the existent FDA outreach strategy is key to soliciting input from racial/ethnic communities. As the FDA continues to implement new outreach strategies, the AAMC suggests the robust evaluation and assessment of any new communication efforts to determine their effectiveness.

Leverage public health departments' or non-profit hospitals' community health needs assessment (CHNA) data regarding prioritized health needs. Information about health outcome differences of racial/ethnic demographic subgroups should be evidence-based. The mission of the US Department of Health and Human Services Healthy People 2020 initiatives asks for multi-sector action "to strengthen policies and improve practices that are driven by the best available evidence and knowledge"[1]. Hospitals, health systems, and public health agencies work collaboratively to assess the critical health needs of the communities they serve. Additionally, the CHNA uses input from community residents to aid in identifying local health needs and to determine how some of those needs can be addressed. CHNA data could provide more insight into the areas of public health concern for racial/ethnic minorities as well as other priority populations. In addition to community input, using data sets such as federal public health surveillance systems which include state and county-level data can aid in creating a more complete picture of the health outcomes experienced by racial/ethnic subgroups.

Work with health systems and other federal agencies to standardize race/ethnicity and language (REL) data collection efforts. Standardizing patient race, ethnicity, and language data collection is critical to quality care. The Affordable Care Act (ACA) requires all federally funded health and health care programs to strengthen and standardize the collection and reporting of data on race, ethnicity, and primary language. The ACA also recommends monitoring the data collected to identify trends and track health disparities. Reliable REL data are essential to identify differences in population health outcomes and clinical care and to develop targeted interventions for specific populations.

2. Improving participation rates of racial and ethnic minorities in research

Inclusion of minorities in clinical trials and other research efforts is essential for drawing conclusions about the safety and efficacy of drugs and devices for all populations. The AAMC applauds the steps the FDA has made toward ensuring a broader inclusion of participants

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[1] Healthy People 2020 framework: the vision, mission and goals of Healthy People 2020. US Department of Health and Human Services, Office of Disease Prevention and Health Promotion, (available at http://www.healthypeople.gov/2020/Consortium/HP2020Framework.pdf).

in clinical trials. Those steps include developing measures of accountability for researchers, providing educational training for grant reviewers, and highlighting best practices in the design and analysis of clinical trials which include diverse populations. As noted in a November 20, 2013 comment letter in response to "Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products"[2] we urge the FDA to develop incentives for sponsors to align study samples with epidemiologic data for a particular disease and to coordinate policies regarding minority and sub-population recruitment across federal funding agencies.

Furthermore, we encourage the FDA to identify ways to solicit input directly from racial/ethnic minority community members concerning research participation motivations and barriers. By actively engaging these rarely heard from voices, the FDA can begin to develop effective strategies to target these sub-populations.

We also encourage the FDA to develop strategies for communicating clinical trial results to participants. Research has shown that many clinical trial participants would like to be informed on the results of their participation in the trial.[3] Sharing the results ensures improved transparency of clinical trials and may positively impact the recruitment of participants from diverse backgrounds.

3. Effectively disseminating important medical information to all populations.

The FDA should play a primary role in providing all populations with important and relevant medical information. In a September 5, 2013 comment letter in response to FDA's report on "Ensuring Access to Adequate Information on Medical Products for All, With a Special Focus on Underrepresented Subpopulations"[4] the AAMC offered recommendations on how to provide patients from unrepresented groups with equitable access to medical knowledge. These recommendations included:

- identifying effective communication channels to reach patient populations;
- working with minority health professional organizations to support effective communication and outreach to racial/ethnic subpopulations; and
- encouraging all health care professions regardless of their racial or socioeconomic background to deliver health information in ways that are both culturally relevant and sensitive.

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[2] AAMC Comment Letter, November 20, 2013,(available at https://www.aamc.org/download/362116/data/aamclettertofdaondemographicsubgroupdata.pdf)

[3] Frank, E. S., Price, K. N., Colten, M. E., Fax, R. G., Levine, M. A., Matyka, C., ... & Partridge, A. H. (2013). Abstract P4-18-01: Sharing clinical trial results with patient participants: A project of the Dana Farber/Harvard Cancer Center (DF/HCC) breast cancer research advocacy group. *Cancer Research*, *73*(24 Supplement), P4-18.

[4] AAMC Comment Letter, September 5, 2013,(available at https://www.aamc.org/download/353860/data/aamccommentsonfdasreportonensuringaccesstoadequateinformationon.pdf)

The development of the FDA Language Access Plan to translate its literature into Spanish and additional languages is a critical step to ensuring medical information is available for limited English proficiency patients. Evaluating methods to improve health communication which accommodate the varying literacy levels of patient populations is a need of great import. Research has shown that low general literacy is linked to poor health outcomes among racial and ethnic minorities.[5] **We encourage the FDA to develop specific strategies to communicate about new FDA actions (communications of risks, benefits, proper usage of medical products) with non-English speakers and those with low general literacy.**

We also urge the FDA to work with electronic health record (EHR) developers in increasing the usability of the automatic prompts to alert patients and providers of important safety and medical product information at the point of care.

Though there are focused efforts to understand the public health concerns of racial/ethnic minorities, there are other populations such as veterans, persons with disabilities, and LGBT and rural populations who are equally burdened by health disparities. We encourage the FDA to broaden its current efforts to include all populations who experience disproportionate morbidity and mortality.

The AAMC appreciates the opportunity to comment to the FDA on this issue and would be happy to provide any further information which would be of use to the FDA and HHS as they prepare the research agenda and funding portfolio for the next fiscal year. We would be pleased to work with the FDA and HHS to advance these initiatives. Please contact me or my colleagues Philip M. Alberti, Ph.D. (palberti@aamc.org) or Heather Pierce, J.D., M.P.H. (hpierce@aamc.org) with any questions about these comments.

Sincerely,

Ann Bonham

Ann C. Bonham, Ph.D.

Chief Scientific Officer

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[5] Berkman, N. D., Sheridan, S. L., Donahue, K. E., Halpern, D. J., Viera, A., Crotty, K., ... & Viswanathan, M. (2011). Health literacy interventions and outcomes: an updated systematic review.