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RADM Richardae Araojo, PharmD, MS
Associate Commissioner for Minority Health
Office of Minority Health and Health Equity
Food and Drug Administration
Department of Health and Human Services

120 South Riverside Plaza
Suite 2190
Chicago, Illinois 60606-6995
800.877.1600

1120 Connecticut Avenue NW
Suite 460
Washington, D.C. 20036

Re: FDA-2019-N-4824, Office of Minority Health and Health Equity Strategic Priorities; Establishment of a Public Docket; Request for Comments

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to provide comments to the FDA Office of Minority Health and Health Equity on the office’s strategic priorities. Representing more than 107,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionist researchers, the Academy is the largest association of food and nutrition professionals in the United States and is committed to improving the nation’s health through food and nutrition across the lifecycle.

The Academy supports the mission of the Office of Minority Health and Health Equity to promote and protect the health of diverse populations through research and communication of science that addresses health disparities. Included in the Academy’s strategic plan are goals to “increase equitable access to nutrition and lifestyle services” and “increase the diversity and cultural competence of the workforce to reflect the communities they serve.” Below are recommendations to FDA on generating generalizable clinical evidence, conducting outreach to minority populations promote access to information on medical products, and collaboration opportunities.

Efforts that generate clinical evidence to improve generalizability of clinical trial findings and bridge the knowledge gap about the medical products' performance in racial and ethnic minority populations.

There is a great need to support and prioritize research that includes persons from traditionally underrepresented groups, especially in clinical trials related to illnesses or diseases that have high prevalence or mortality rates among underrepresented groups. Generalizability or effectiveness of interventions may vary across groups, especially if the characteristics of treatment-seeking individuals vary. This is particularly salient to weight and blood lipid management, where prevalence may be high in some racial and ethnic minority populations but characteristics such as initial weight, response to medications, etc. may differ.^{1,2} Moreover, priority for clinical trials or other research that include significant numbers of persons from underrepresented groups need to include a patient-centered

¹ Naito, R., Miyauchi, K., & Daida, H. 2017. Racial Differences in the Cholesterol-Lowering Effect of Statin. *J Atheroscler Thromb* 24(1): 19-25.

² Franko, D., Thompson-Brenner, H., Thompson, D., et al. 2012 Racial/ethnic differences in adults in randomized clinical trials of binge eating disorder. *J Consult Clin Psychol* 80(2): 186-95.

focus.^{3,4,5} The Academy encourages FDA to prioritize support for this type of research through its research and collaboration program. FDA should also prioritize communication to health care providers about the shortcomings of the current body of clinical evidence to help them make more informed, patient-centered care decisions where relevant evidence may be limited.

Direct outreach to racial and ethnic minority, underrepresented, and underserved populations to promote access to relevant information on medical products to improve safety and efficacy.

Culturally appropriate materials: Although significant improvements have been made in health outcomes, race and ethnic disparities remain a persistent challenge. To overcome these challenges, it is critical that information is provided in a manner that is easily understood and is culturally sensitive. Both written and oral communication targeting minority populations should be developed using language that is easily comprehended, user friendly, and takes into consideration language differences among different communities.

Racial/ethnic groups are heterogeneous: Racial/ethnic groups, as typically categorized in the United States, are not monolithic and represent a diversity of cultures, nationalities, and languages. The development of health and safety information on FDA-regulated medical foods, medical products, medications, etc. should take this heterogeneity into account. The Academy encourages FDA to include these intersectional considerations when developing its own health and safety communications to minority populations.

Identification of opportunities of collaboration to generate efforts to address research gaps that predominantly affect racial and ethnic minority populations.

Targeted research focusing on specific racial and ethnic groups is essential for researchers and practitioners to have a better understanding of minority populations and to address the specific diseases that are predominate among these individual groups. Collaborations that could help address these disparities include strategic partnerships with organizations that have an interest in minority health outcomes such as:

- **The Academy of Nutrition and Dietetics:** The Academy is home to several member interest groups that represent nutrition professionals from a variety of racial and ethnic minority background. The **National Organization of Blacks in Dietetics and Nutrition (NOBIDAN)** is the largest member interest of group of the Academy, representing over 600 nutrition and dietetics practitioners who are African American or of African-decent.⁶ The **Latinos and Hispanics in Dietetics and Nutrition (LAHIDAN)** is the oldest member interest group of the Academy, devoted to the improvement of food, nutrition and health care for Latinos and Hispanics in the United States and its territories.⁷ The **Asian Americans and Pacific Islanders (AAPI) member interest group** promotes culturally-relevant evidence-based nutrition and dietetics practice for people of Asian or Pacific Islander origin.⁸ The **Indians in Nutrition and Dietetics (IND) member**

³ Noah, B. 2003. The participation of underrepresented minorities in clinical research. *Am J Law Med* 29(2-3): 221-45.

⁴ Fisher, J. & Kalbaugh, C. 2011. Challenging Assumptions About Minority Participation in US Clinical Research. *Am J Public Health* 101(12): 2217-22.

⁵ Frank, L., Basch, E., Selby, J., & the Patient-Centered Outcomes Research Institute. 2014. The PCORI perspective on patient-centered outcomes research. *JAMA* 312(15): 1513-4.

⁶ <https://www.nobidan.org/home>

⁷ <https://www.eatrightlahidan.org/home>

⁸ <https://www.aapimig.org/home>

interest group brings together practitioners of [South Asian] Indian origin or those interested in learning more about this culture.

- **National Minority Quality Forum:** NMQF is a research and educational organization that aims to ensure that high-risk racial and ethnic populations and communities receive optimal health care. The organization integrates data and expertise in support of initiatives to eliminate health disparities.
- **National Medical Association:** NMA is the oldest national organization representing African American physicians and their patients in the U.S., this professional and scientific organization represents the interests of more than 30,000 African American physicians and the patients they serve.

Conclusion

The Academy appreciates the opportunity to inform the strategic plan of the FDA Office of Minority Health and Health Equity. Please contact either Jeanne Blankenship by telephone at 312-899-1730 or by email at jblankenship@eatright.org or Hannah Martin by telephone at 202-775-8277 x6006 or by email at hmartin@eatright.org with any questions or requests for additional information.

Sincerely,



Jeanne Blankenship, MS, RDN
Vice President
Policy Initiatives and Advocacy
Academy of Nutrition and Dietetics



Hannah Martin, MPH, RDN
Director
Legislative & Government Affairs
Academy of Nutrition and Dietetics