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

RE: Ensuring Access to Adequate Information on Medical Products for All, With a Special Focus on Underrepresented Subpopulations, Including Racial Subgroups, 78 FR 41803

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the FDA's proposed communication plan to inform and educate health care providers and patients on the benefits and risks of medical products, and to address the important issue of how to ensure equitable access to medical information for all, with a particular emphasis on ensuring such access for traditionally underrepresented and underserved subpopulations. The AAMC is a not-for-profit organization representing all 141 U.S. allopathic medical schools, nearly 400 teaching hospitals and health systems, and 90 academic societies.

Health and health care disparities persist in the United States: certain populations including racial/ethnic minorities, the poor, rural populations, persons living with disabilities, and lesbian, gay, bisexual and transgender communities still suffer from disproportionate rates of morbidity and mortality. While many factors contribute to such inequities, issues of health care access and utilization play a role in creating and maintaining these disparities. Research has shown that disparities in health can be created or exacerbated when the diffusion of medical knowledge and innovation is not equitable. Easy, equitable access to current, useful information related to the risks, benefits and proper use of medical products is essential to address this mechanism.

The AAMC therefore applauds and supports the FDA's efforts to address the availability of educational information regarding medical products and to ensure the equitable diffusion of such information. The convening of an internal, agency-wide working group to strategize around traditional and electronic communication efforts, and to identify subpopulations of import is an essential first step in ensuring equitable access to medical information and safety alerts. Additionally, the specific opportunities identified by the working group, including targeted outreach to traditionally underserved subpopulations and increasing their representation in the FDA Patient Network, addressing the needs of Limited English Proficiency (LEP) populations, and leveraging the communication power of social media are all promising strategies.

In order to enhance these proposals, the AAMC offers the following recommendations.

1. While the FDA's utilization of electronic and social media to increase diffusion of medical information is both important and responsive to the changing communications

landscape, not all populations have access to such technology. While racial gaps in internet/smartphone access are closing, elderly Americans and those residing in rural communities (particularly in the southern United States), may not benefit from the infrastructure to avail themselves of electronic communications. We urge the working group to identify communication pathways that will be effective for these groups so as to avoid inadvertently creating inequities between age and geographic groups.

2. The FDA should not take as a given that electronic health communications are always effective means of influencing behavior and improving health. The issue is further complicated by the heterogeneity of the underrepresented subpopulations the FDA is hoping to reach. Different racial and ethnic groups and other populations vary in their experiences receiving health information electronically and in their responsiveness to information conveyed in this way.^{1,2} The FDA, through its Risk Communication Advisory Committee (RCAC) and in partnership with researchers and communities, should undertake qualitative investigations to better understand how specific populations best comprehend and react to health information and their preferred communication channels. Quantitative evaluation of communication efforts in specific communities should also be pursued in order to build an evidence-base for strategies that are effective in distinct populations.
3. FDA efforts to engage minority health professional organizations and advocacy groups to support effective communication and outreach to racial/ethnic subpopulations are important. Yet all providers and members of the allied health professions, regardless of their own race/ethnicity, must be both up-to-date on issues important to racial/ethnic subpopulations and competent at delivering the information in an effective and culturally sensitive way. The FDA should assure that all members of the health professions are aware of the resources available to them from the FDA and its Office of Minority Health that will allow them to better serve patients from all backgrounds.
4. As the FDA has identified, issues of health literacy and LEP status erect barriers when communicating the risks, benefits and proper use of medical products to patients. We support FDA's efforts, as it develops its Language Access Plan, to translate its literature into Spanish and into additional languages to better serve all patients. However, recent evidence suggests that general literacy – and not health literacy per se – is a primary barrier to the effective comprehension of health information. We encourage the FDA to explore issues of general literacy and to explore ways in which medical information and

¹ López, L., Green, A. R., Tan-McGrory, A., King, R., & Betancourt, J. R. (2011). Bridging the digital divide in health care: The role of health information technology in addressing racial and ethnic disparities. *Joint Commission Journal on Quality and Patient Safety*, 37(10), 437-445.

² Gibbons, M. C. (2011). Use of health information technology among racial and ethnic underserved communities. *Perspectives in Health Information Management/AHIMA*, American Health Information Management Association, 8(Winter).

alerts can be conveyed and displayed graphically or in a manner that does not assume overall literacy.

5. We encourage the FDA to work with hospitals, medical centers and electronic health record (EHR) developers to explore the possibility of enhancing or testing the use of automatic prompts via EHRs to alert providers, and therefore patients, to important safety and medical product information at the point of care. This or a similar strategy would assure the broadest possible dissemination of crucial information via practitioners well suited to interpret and deliver medical product alerts and updates.

The AAMC is grateful for the opportunity to comment, and we look forward to working with our member institutions to alert them to new patient safety and medical product communication efforts as the FDA implements them. Please contact Philip Alberti, Ph.D. at palberti@aamc.org or Heather Pierce, J.D., M.P.H. at hpierce@aamc.org in my office with any questions about these comments.

Sincerely,



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