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June 12, 2017

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

Re: Docket No. FDA-2017-N-0455, "Enhancing Patient Engagement Efforts Across FDA; Establishment of a Public Docket; Request for Comments"

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the FDA's efforts to advance public health through improving and expanding its patient engagement initiatives by establishing an Office of Patient Affairs. The AAMC is a not-for-profit association representing all 145 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences.

The AAMC acknowledges the importance of engaging patients, caregivers, and their advocates in the regulatory process and development of new drugs, biologics, and devices. We recognize that the FDA has previously taken steps to include patient perspectives in the Agency's decision-making process through the establishment of the first Patient Engagement Advisory Committee and are pleased that the FDA's interest in establishing an Office of Patient Affairs was directly informed by public feedback in accordance with the stakeholder engagement responsibilities outlined in the Food and Drug Administration Safety and Innovation Act of 2012 (Pub. L. 112-144). **We support the FDA's efforts to establish an Office of Patient Affairs and agree that a central entry point for the patient community could improve transparency around patient engagement activities and demonstrate the Agency's commitment to increasing patient participation in the Agency decision-making process.**

We encourage continued efforts to expand and increase patient engagement across the Agency as well as the types of patients that are engaged. In order to enhance the FDA's future engagement activities, the AAMC offers the following recommendations.

1. The FDA identifies two objectives for its patient engagement activities that the Office of Patient Affairs would coordinate across medical product centers and offices that engage with patients and their advocates. The first is to "[d]evelop a nuanced understanding of the patient experience of disease by: [g]athering patient perspective on what is clinically meaningful, assessing attitudes towards benefit-risk and tolerance of uncertainty, and enhancing the science of eliciting and integrating patient input." **We support this objective and urge the FDA to engage a broad community of patients to include diverse patient viewpoints that are not typically considered in**

the medical decision-making and regulatory process. This should include patients and advocates from groups historically underrepresented in medical research such as minorities, women, the LGBT community, and limited English proficiency populations. To achieve this, the FDA through its Office of Patient Affairs should establish partnerships with a wide variety of minority advocacy groups, community organizations, and community leaders to increase the number of contributors from these communities and develop a better understanding about the most appropriate and effective communication pathways. The AAMC encourages the FDA to collaborate and connect with the Patient-Centered Outcomes Research Institute (PCORI) to effectively and appropriately engage patients and other stakeholders in research.

In light of our recommendation that the FDA engage a diverse patient and advocate population, we strongly urge that the Agency take measures to ensure that patient advocates and patient representatives engaged in these activities are not solely professional advocates selected, trained, or funded by drug, device, and biotechnology companies. Industry support of patient advocacy organizations has increased,[1] and it is important to recognize the potential for financial and other conflicts of interest as a result. Those providing input to the FDA's Office of Patient Affairs should represent the true, unbiased feelings and needs of patients and their families, and the FDA should avoid the appearance that industry needs are being communicated through a channel designed to obtain information from a very different type of stakeholder.

In AAMC's response to the FDA's July 2013 report outlining the Agency's communication plan to better inform and educate healthcare providers and their patients from underrepresented populations on the benefits and risks of medical products, the Association wrote: "[w]hile many factors contribute to [health and healthcare disparities], 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."[2] We encourage the FDA to include efforts to reach patient sub-populations and underrepresented patients as one of the primary activities the Office of Patient Affairs will undertake. This will ensure those perspectives are included in the Agency's medical decision-making and regulatory process.

2. The AAMC supports the FDA's second objective to educate patients and advocates about the regulatory process by communicating information about Agency positions and activities, connecting patients and advocates with resources, and resolving challenges and needs. **We encourage the FDA to work with key stakeholders to develop strategies on how the Agency will engage and convey this information to patients and their advocates and note that using the Federal Register as a primary or sole communication vehicle is not an adequate or appropriate way to reach patients.** It is important that patients and advocates understand how to submit comments on draft guidance, policy changes or proposed regulations pertaining to specific FDA activities. Educating patients about

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[1]McCoy, Carniol, Chockley, Urwin, Emanuel, & Schmidt (2017). Conflicts of Interest for Patient-Advocacy Organizations. *New England Journal of Medicine*, 376:880-885.
[2]AAMC Comment Letter, September 5, 2013 (available at: https://www.aamc.org/download/353860/data/aamccommentsonfdasreportonensuringaccesstoadequateinformationon.pdf).

the regulatory process helps increase competency about the Agency's decision-making process, builds public trust, and encourages promotion of, and participation in, FDA's patient engagement initiatives. Efforts should also be made to understand how patients and specific populations within the patient community (e.g., minority groups, limited English proficiency populations, LGBT) would effectively comprehend this information.

3. In order to achieve the objectives proposed, **creating a central Office of Patient Affairs could allow for better recruitment of diverse patients and advocates to serve on disease-specific committees as well as the regular recruitment and review of patients to serve as Special Government Employees (SGEs) on FDA's advisory committees.** Related, FDA should ensure that the patients recruited as SGEs are properly educated about their roles and responsibilities as advisory committee members, an objective that could fall under the purview of the Office of Patient Engagement. FDA must also ensure there are ample opportunities to educate all SGEs about the role and perspectives of patients in the advisory process. Such bi-directional education is essential for authentic partnerships and should be a priority for the Office of Patient Affairs. Efforts should also be made to establish a pipeline or database of patients recruited as SGEs in addition to the establishment of formal communication mechanisms that are used to recruit patient SGEs whether through publication in the Federal Register or other appropriate channels.

4. The AAMC commends the FDA in its intention to host and maintain "robust data management systems that would incorporate and formalize knowledge shared […] by patient stakeholders and FDA's relationships with patient communities […]." We also appreciate that the Agency plans to conduct regular evaluation of the office of Patient Affairs and FDA's overall patient engagement efforts. The information collected from the FDA's data management systems could also serve as a mechanism to ensure the Agency is using the most current evidence to evaluate whether specific goals and activities are being met. The FDA should ensure patients are included in the process for developing its data management systems. The FDA should also work with patients, their families, and communities to evaluate the research results and effectively communicate those results back to the broader patient community. This evaluation, which should be a regular activity of the Office of Patient Affairs, would demonstrate an important precedent of accountability and commitment to ensuring FDA's patient engagement objectives are clearly articulated and responsive to the needs of patient communities. **We encourage the FDA solicit input from key stakeholders and experts on how patient-reported data will be generated, standardized, and integrated into the regulatory process so that it is reliable and appropriately reflects the viewpoints of the patient community.**

5. Finally, the FDA has identified that an evaluation of the Office of Patient Affairs and FDA's overall patient engagement efforts will take place on *biennial* basis. Instead, **we urge the FDA to conduct *annual* evaluations of the office's activities and as appropriate, solicit public feedback on specific priorities such as the implementation of the Patient Focused Drug Development provisions (Sec. 3001-3004) as required by the 21st Century Cures Act.**

The AAMC appreciates the opportunity to comment on this important issue and applauds the FDA in its efforts to enhance its patient engagement efforts. To the extent we can continue to help the FDA identify ways to further advance the activities of the Office of Patient Affairs or the patient engagement activities for the Agency's other centers and offices, please contact me or my colleague Heather Pierce, JD, MPH, at hpierce@aamc or (202) 478-9926.

Sincerely,

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