



August 9, 2024

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Optimizing the Food and Drug Administration’s Use of and Processes for Advisory Committees; Public Meeting [Docket No. FDA–2024–N–1809]

Dear Commissioner Califf:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 130,000 family physicians and medical students across the country, I write to thank you for your leadership on issues impacting family physicians and their patients and to offer our response to your request for comments regarding how to optimize the Food and Drug Administration’s (FDA) use of and processes for advisory committees, as requested by the notice posted in the April 30, 2024, [Federal Register](#). The AAFP appreciates the opportunity to offer recommendations on clarifying and enhancing the role of advisory committees in the FDA’s workflows and decision-making processes.

Topic 1: Composition of Advisory Committees

The AAFP strongly believes the FDA should specifically seek to have more primary care and family medicine physicians who practice in clinical settings included on its advisory committees. Doctors on the front lines of care are uniquely suited to provide scientific and medical advice on the safety, effectiveness, and appropriate use of products that the FDA regulates, as well as offer insights on how those products are received by patients. Additionally, the AAFP supports the inclusion of primary care specialists on appropriate advisory committees, such as obstetrics-trained family physicians and obstetrician-gynecologists serving on pregnancy-related committees. Evidence continues to affirm that longitudinal, relationship-based care delivered by primary care physicians and their teams leads to better control of chronic conditions, fewer emergency department visits and hospital stays, and improved health outcomes.ⁱⁱⁱ The perspective of a practicing primary care physician is critically important to these advisory committees being able to provide the full breadth of clinical advice and real-world experience the FDA needs to best serve the public.

[Family physicians](#) are personal doctors for people of all ages and health conditions, often serving as the first line of defense for preventive care, chronic care management, and acute illness. Through enduring patient-physician relationships, family physicians help patients set health goals; prevent, understand, and manage illness; and navigate an increasingly complex health care landscape. Family doctors and their staff adapt the care they provide to the unique needs of their individual patients and communities, and the [scope of family medicine](#) encompass all ages, all genders, each organ system, and every disease entity. As such, family physicians are ideal partners for public health, perfectly positioning them to support the FDA’s mission of protecting and promoting public

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health through advisory committee participation. We encourage the FDA to prioritize inclusion of actively practicing physicians on their advisory committees, as physicians in research environments may not have the same breadth and depth of clinical experience and patient interaction.


Family physicians provide the majority of care for America's [underserved rural and urban populations](#), and primary care is the only health care component where an increased supply is associated with better population health and more equitable outcomes.ⁱⁱⁱ Seventeen percent of our members live and work in rural areas – the highest percentage of any medical specialty – and as a result, family physicians are an essential source of emergency services, maternity care, hospital outpatient services, and primary care in rural areas. As multipurpose specialists, the variety of health care services provided and the diversity of clinical cases experienced make family doctors uniquely suited to serve on the FDA's advisory committees. Focusing discussions on patient care, posing clinically relevant questions, and providing perspectives on the translation and dissemination of information to patients are a few of the reasons family medicine physicians should be included on more FDA advisory committees.

Topic 3: Public Perception and Understanding of Advisory Committees

The AAFP supports the FDA's efforts to expand public awareness of its advisory committees and agrees that the work of these advisory committees would be strengthened by greater public participation. We recommend the FDA develop good governance practices and timelines that would apply to all advisory committees, such as providing notice of all meetings at least one month prior to its scheduled date, publicly posting meeting materials at least one week prior to the meeting, and publishing a meeting's minutes within one week of occurrence. Once those reforms have been finalized, the AAFP recommends the FDA undertake a public education campaign – including traditional press, FDA website updates, and an increased social media presence – to expand the public's awareness of FDA advisory committees and how they can be involved in the process. We also believe that inclusion of a diverse panel of researchers and practicing physicians will aid in the perception and credibility of these committees with the public.

Thank you for the opportunity to respond to this request for public comment regarding the optimization of the FDA's processes for advisory committees. The AAFP appreciates being able to offer recommendations on strengthening the role of advisory committees in the FDA's decision-making procedures through increased participation by practicing primary care physicians, which the AAFP believes could improve patient outcomes long-term. We look forward to continuing to work with you to ensure the implementation of reforms that best support family physicians and the patients they serve. If you have any questions, please contact Mandi Neff, Regulatory and Policy Strategist at mneff2@aafp.org.

Sincerely,



MD, MPH, MBA

Tochi Iroku-Malize, MD, MPH, MBA, FAAFP
American Academy of Family Physicians, Board Chair

ⁱ Cabana MD, Jee SH. Does continuity of care improve patient outcomes? *J Fam Pract.* 2004 Dec;53(12):974-80. PMID: 15581440

ⁱⁱ Shrank WH, Rogstad TL, Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. *JAMA.* 2019;322(15):1501–1509. doi:10.1001/jama.2019.13978

ⁱⁱⁱ Rodgers DV, Wendling AL, Saba GW, Mahoney MR, Speights JSB. Preparing Family Physicians to Care for Underserved Populations: A Historical Perspective. *Fam Med* 2017;49(4):304-310