



May 4, 2026

The Honorable Andy Harris
Chairman
Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies
House Committee on Appropriations
2362-A Rayburn House Office Building
Washington, DC 20515

Via Electronic Communication

Re: FDA's request to remove consumer representatives from advisory committees

Dear Chairman Harris:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to express concerns regarding the U.S. Food and Drug Administration's (FDA) request for statutory changes that would eliminate the current requirement to include consumer representatives on advisory committees and scientific advisory panels. We are concerned that this proposal would significantly weaken the patient and consumer voice in FDA decision-making.

As outlined in the FDA congressional justification for the fiscal year (FY) 2027 budget, this proposal would grant the Agency flexibility to appoint representatives of consumer and industry interests "only where appropriate," rather than as a standing requirement. While we support FDA's efforts to strengthen conflict-of-interest disclosures and ensure that advisory deliberations are grounded in rigorous, gold-standard science, we are concerned that eliminating the statutory requirement for consumer representation risks undermining the patient and consumer perspective that plays a critical role in FDA decision-making.

Consumer representatives offer valuable insights that are meaningfully different from scientific, technical, or industry expertise. While scientific experts assess data quality, methodology, and statistical validity, consumers provide expertise based on the lived experiences of patients and caregivers, ensuring that advisory committee deliberations fully consider how benefits and risks are experienced in practice and the real-world implications of decisions. As FDA itself has emphasized, "patients are at the heart of what the FDA does and are vital to our work protecting the public health," and patient experience can help inform FDA's understanding of a medical condition throughout the regulatory lifecycle.¹

By translating this principle into practice, consumer representatives help ensure that advisory committee discussions reflect the lived experience of patients and caregivers, including how diseases affect daily life, how treatment benefits and risks are experienced, and which outcomes matter most to patients. Recognizing the importance of consumer representation is not

¹ U.S. Food & Drug Admin., *Learn About FDA Patient Engagement*, <https://www.fda.gov/patients/learn-about-fda-patient-engagement#:~:text=Patients%20are%20at%20the%20heart,stages%20of%20approving%20new%20products>.

unique to FDA. In 2025, the Centers for Medicare and Medicaid Services (CMS) required all Pharmacy and Therapeutics Committees to include a consumer representative.² CMS recognized that a consumer representative can provide “. . . additional insight into the patient perspective regarding the practical use of therapies and effects on quality-of-life outcomes. . .”³ Thus, there is a growing understanding and recognition that consumer and patient participation brings critical attention to issues such as quality of life, treatment burden, and access challenges that may otherwise be overlooked. Accordingly, the consumer voice serves as an essential safeguard, reinforcing patient-centered, transparent, and balanced decision-making that reflects those most directly affected.

We therefore urge the Committee to deny the FDA’s request for increased flexibility that would limit consumer participation to only when the FDA deemed it appropriate. We encourage the Committee and the FDA to pursue alternatives that improve advisory committee efficiency, transparency, and conflict-of-interest management without losing the essential consumer perspective.

Thank you for your attention to this matter. We welcome the opportunity to discuss this issue further or provide additional information to the Committee. Please feel free to contact us at obackhaus@aimedalliance.org should you have any questions or wish to continue the discussion.

Sincerely,

Olivia Backhaus
Staff Attorney

² CMS, *2025 Notice of Benefit and Payment Parameters*, <https://www.federalregister.gov/documents/2024/04/15/2024-07274/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2025>.

³ *Id.*