The day an FDA advisory committee met to weigh the merits of an experimental treatment for amyotrophic lateral sclerosis was one of the worst of Mitze Klingenberg’s life.

Her son Matt had benefited, she said, from an ALS treatment under review for approval by the Food and Drug Administration. However, the expert panel voted against the therapy on that day, Sept. 27, 2023. Panelists dismissed his experience, and that of other patients, as anecdotal, saying it could stir up false hope, Klingenberg said Thursday during an impassioned speech at an [FDA town hall meeting](#). The meeting,
which several patient advocates attended, was meant to dissect existing advisory committee protocols — and come up with ways to “optimize” the agency’s use of the committees.

“This was personally devastating, as my son did have hope, as this treatment worked for him,” she said. “And to be basically ignored and unacknowledged during that time rates the ad comm as the second-most difficult day in our ALS journey — topped only by his initial diagnosis.”

Klingenberg’s experience underscores one of the main tensions apparent at ad comm meetings, which have been convened by the FDA for more than five decades to help gauge the efficacy of particularly complex drugs and devices seeking approval. At Thursday’s meeting, FDA Commissioner Robert Califf invited comments from the public on how to make the advisory panels “stronger than ever.”

Final approval decisions rest solidly on regulators’ shoulders, but they do take the expert panels and public testimonies into account. There’s been disagreement, though, over whether it’s helpful or harmful to have the advisers vote at the end of committee meetings.

A 2023 study in *JAMA Health Forum* found that between 2010 and 2021, the agency’s choices aligned with advisory committees 97% of the time when the experts voted in favor of the treatment. But when advisers voted down a treatment, regulators agreed only 67% of the time.

This asymmetry is one indicator that the advisory panel system is an important but imperfect process — so regulators are now considering changes to the advisory committee design.

Some believe that voting is an integral part of the advisory committee process, because it offers an overall view of a drug or device after long and detailed discussions.

“Importantly, without a vote, it would be easier for the FDA or the sponsor of a marketing application to spin the discussion as they wish, and to disregard the committee’s advice,” said Robert Steinbrook, director of consumer advocacy group Public Citizen’s health research arm. “Moreover, a vote, particularly in instances when the FDA does not follow a committee’s recommendations, increases the chances the agency will clearly and publicly state why it reached a different decision.”
The composition of these panels is under review: There’s concern that patient voices, and their lived experiences, don’t have enough representation on the expert panels. Advocates said the FDA lacks understanding about the intricacies of rare diseases in particular, and pressed the FDA during the meeting, billed as a “listening session,” to include more nuanced perspectives from guest committee members.

“The continuing disconnect and maybe even cognitive dissonance between what the FDA does and what it says it can do has our community whipsawed,” Kara Berasi, CEO of the Haystack Project, a nonprofit advocating for ultra-rare diseases.

This stirs up worry over conflicts of interest: On one hand, it’s difficult to find panel members who are subject matter experts and don’t have some sort of industry ties. By focusing too heavily on conflicts of interest, important voices are excluded, advocates say. At the same time, there’s been long-standing criticism that many panelists have connections to industry — and this skews the advisory committee votes.

A 2018 analysis in Science found that of the 107 physicians who voted on advisory committees, 40 received more than $10,000 over the course of nearly four years in funding from the makers of drugs — or their competitors — that the panels voted to approve. And the analysis found that 26 physicians earned more than $100,000 from interested drugmakers, and six more than $1 million. These payments were disclosed in scientific journals, but not by the FDA.

“COI rules shouldn’t be relaxed in order to have more experts serving,” said Itisha Jefferson, a medical student at Loyola University.

There’s concern that these panelists — designated during their service on the panels as special government employees, or SGEs — don’t offer diverse perspectives in terms of race, gender, geographic location, sexual orientation, or cultural background. And there’s a lot of redundancy in the review process which the FDA is hoping to eliminate.

“A measure of our success will be if SGEs spend less time on paperwork and more time digesting the complicated science, public health, and medical issues,” Califf said. The FDA compensates the SGEs for each meeting day of the panel on which they serve, and they receive travel and per diem reimbursements.

The FDA is inviting written and electronic comments on optimizing advisory committees to be submitted by Aug. 13. Officials didn’t say when or how they might propose any changes to the advisory panel design.