Under Trump, FDA Seeks to Abandon Expert Reviews of New Drugs

The agency would like to get away from assembling panels of experts to examine and vote on individual therapies.

September 18, 2025 By Arthur Allen and KFF Health News

Food and Drug Administration (FDA) leaders under President Donald Trump are moving to abandon a decades-old policy of asking outside experts to review drug applications, a move critics say would shield the agency's decisions from public scrutiny.

The agency "would like to get away" from assembling panels of experts to examine and vote on individual drugs, because "I don't think they're needed," said George Tidmarsh, head of the FDA's Center for Drug Evaluation and Research. He relayed the message Tuesday at a meeting of health care product makers and Wednesday to an FDA advocacy group.

In addition to being redundant, Tidmarsh said, advisory meetings on specific drugs were "a tremendous amount of work for the company and for the FDA. We want to use that work and our time to focus on the big questions."

The FDA's advisory committees were created in their current form by a 1972 law aimed at expanding and regulating the government's use of experts in technical decisions. They're periodically summoned for advice, including to review evidence and vote on whether the FDA should approve drugs, vaccines, and medical devices, often when FDA officials face a difficult decision.

FDA actions have traditionally aligned with committee votes. A departure can provoke controversy and public debate, as was the case with the split 2021 decision on whether to approve the Biogen drug Aduhelm to treat Alzheimer's disease.

The FDA approved the drug despite a "no" vote from its advisory committee, whose members felt the medicine did little to treat the disease. The conflict over Aduhelm laid bare the FDA's struggle to reconcile pressure from industry and desperate patients with its rigorous evaluation of drug risks and benefits.

Tidmarsh said the committees would still be consulted on general issues like how to regulate different classes of drugs. But meetings on specific drugs, in which experts plow through piles of

studies and hours of testimony from FDA and company officials, were mainly useful, he said, because they allowed the public to see how the FDA worked.

This month the FDA began publishing the “complete response letters” it sends to companies when it declines to approve their products. Releasing the letters, which previously required filing requests under the federal Freedom of Information Act, promotes a level of transparency akin to the advisory meetings’, Tidmarsh said.

Advisory committee meetings on individual drugs “are redundant when you have the complete review letters,” he told KFF Health News in a brief interview after appearing at the health care products conference.

Former FDA officials and academics who study the agency disagree. The meetings help FDA scientists make decisions and increase public understanding of drug regulation, and abandoning them doesn’t make sense, they said.

Tidmarsh’s reasoning is “hard to follow,” former FDA Commissioner Robert Califf told KFF Health News. “It’s extremely useful for people inside FDA to find out what other experts think before they make their final decisions. And it’s important to do that in a way that enables the public to understand the points of view.”

“Experts might ask questions of the company or FDA that neither of them thought of on their own,” said Holly Fernandez Lynch, an associate professor of bioethics and law at the University of Pennsylvania. “The public has few other opportunities to comment about FDA decisions.”

Spokespeople for FDA and the Health and Human Services Department did not respond to repeated requests for elaboration on Tidmarsh’s comments.

Califf at times disagreed with advisory committees as commissioner of the agency and once floated the idea that it might be better if they deliberated but did not vote on products. Still, while “maybe someone can come up with a better one, I always thought it was an amazing system,” he said.

The FDA is not obliged to ask the outside experts to review drugs and usually hasn’t. It calls on them mainly for important new types of medications or when a decision is especially tricky because of high demand for a product that may have limited value, Aduhelm being a classic example.

The advisory committees are “an important resource” for the FDA, said Sarah Ryan, a spokesperson for the Pharmaceutical Research and Manufacturers of America. “They can play an important part of the rigorous human drug review process we have in the U.S.”

The committees are often asked to help settle disagreements within the FDA about how to move forward on a regulatory decision, said Reshma Ramachandran, a health services researcher and clinician at the Yale School of Medicine.

She and other researchers and former FDA officials praised FDA Commissioner Marty Makary's decision to publish the complete response letters.

But the letters don't obviate the need for committee meetings, said Peter Lurie, a former associate FDA commissioner who heads the Center for Science in the Public Interest.

"A disclosed complete response letter tells the public that a company's application was rejected and why," Lurie said. "An advisory committee meeting says to outside experts and the public, 'Here's what we're thinking of doing and we'd love your input before we decide.' Plainly, those are not equivalent."

The changes Tidmarsh described are already playing out on the ground. The FDA has held only seven advisory committee meetings since Trump reentered the White House, compared with 22 over the same time frame last year. Officials say they will now release complete response letters as they are sent, and published a batch of 89 earlier in September.

Makary has to some extent replaced the advisory committees, whose members have traditionally been vetted for expertise and biases and which are required to deliberate in public, with panels of handpicked scientists who support his views on subjects such as hormone replacement therapy and antidepressants.

Diana Zuckerman, an FDA watchdog, attended the July hormone replacement therapy panel that considered the FDA's black-box warning listing dangers of the treatment. Makary had wanted the warning removed and packed the panel with like-minded experts.

The event was hastily called with no opportunity for the public to review discussion materials or comment on them, she said.

"All that was transparent was that they didn't want to hear from anyone who disagreed with them," said Zuckerman, who leads the National Center for Health Research.

Before becoming commissioner, Makary pushed for more advisory committee meetings. In early 2022, he blasted the FDA's decision to approve COVID boosters for children ages 12 to 15 without consulting its Vaccine and Related Biological Products Advisory Committee. Makary posted on the social platform X at the time, "It is a slap in the face to science for @US_FDA to circumvent the standard convening of the expert advisory board."

But Tidmarsh seems to disagree.

Instead of asking an advisory committee to vote in favor of or against a Duchenne muscular dystrophy drug, for example, he said the FDA would be better served by a committee studying the best way to evaluate such drugs, such as which outcomes, or end points, to measure. "Is this end point correct for Duchenne muscular dystrophy? That's an important question that cuts across many different companies," he told KFF Health News.

FDA official Vinay Prasad canceled a planned July advisory committee meeting to discuss a Duchenne drug made by the biotech company Capricor Therapeutics. The FDA later published its rejection, or "complete response letter," to Capricor, which then published its own letter of response to the FDA. Prasad was later pushed out and rehired with fewer powers.

An advisory committee meeting could have worked through the drug's risks and benefits in a calmer, public, less politicized atmosphere, Ramachandran said.

The FDA usually agrees with the votes of its several dozen advisory committees. A 2023 study found that the FDA agreed with 97% of "yes" votes and 67% of "no" votes.

That's why Tidmarsh's comments "come as a complete surprise," said Genevieve Kanter, an associate professor of public policy at the University of Southern California, who wrote commentary accompanying the study. The FDA has postponed a lot of meetings this year, but "everyone thought it was temporary, with the transition and all the firings."

"Another theory is that this decision is strategic," she said, "in terms of consolidating power in the agencies so that you are no longer accountable to outside experts or the public."

This story was published by KFF Health News on September 12, 2025. It is republished with permission.
