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Fifth Circuit Determines FDA's E-Cigarette Review Standard Violated Notice-and-Comment Rulemaking: Creates a "De Facto" Ban Requiring a Remand for Continued Review

On August 19, 2026, a three-judge panel at the Fifth Circuit agreed with e-cigarette (e-cig) (including electronic nicotine delivery systems (ENDS)) litigants including NicQuid and others at the U.S. Food and Drug Administration (FDA) overstepped its authority when it repeatedly blocked approval of flavored e-cig products without a notice-and-comment period for its review standard, holding that the repeated denials constituted a rule that the agency must "rethink" or readopt properly.

The panel, consisting of U.S. Circuit Judges Patrick E. Higginbotham, Jerry E. Smith, and Andrew S. Oldham, vacated FDA's denials of various e-cig product applications, citing FDA's "comparative-efficacy standard" as a new substantive standard that required notice-and-comment rulemaking under the Administrative Procedure Act (APA). According to the judges, this new standard then required FDA to deny any Premarket Tobacco Product Application (PMTA) that lacked a study showing that the product's benefits to adult smokers outweighed risks for youth.

The judges stated, "We direct the FDA, on remand, either to rethink the rule, to re-adopt it consistently with the APA's information-forcing procedure that permits the many bound parties to have their say and contribute to rational and sound policy, or to undertake other appropriate proceedings consistent with this opinion."

The e-cig company litigants argued that FDA abused its authority when denying the approval of their flavored vapor products, including some that did not contain nicotine. According to the e-cig companies in their consolidated opening brief, FDA's

decision documents appeared to consist mainly of "boilerplate language." They added that over the years, FDA denied marketing orders for more than 1.2 million flavored e-cig products, mainly with flavors other than tobacco or menthol flavor, e.g., fruit, candy, or desserts.

During oral arguments in April, Eric Gotting of Keller & Heckman LLP, who represented the e-cig companies, said FDA did not take into account all available information, including its own youth survey data that he said showed minors were not using most of these products.

FDA argued that the agency applies a public health balancing standard to each application while relying on scientific literature. Supported by U.S. Department of Justice lawyer Kevin Soter, FDA said that the scientific literature shows that youth are attracted to e-cigs with non-tobacco flavors. For example, even though youth tobacco use has declined since its peak in 2019, FDA still saw e-cigarettes as the most widely used tobacco product among youth, with as many as 2.55 million youth users in 2022, adding that "[t]he evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of [e-cigarettes] among youth" and that "flavors not only facilitate initiation but also promote established regular [e-cigarette] use." FDA also stated that, as a result, the available evidence showed that "flavored [e-cigarettes], including menthol" present "a known and substantial risk of youth initiation and use." E-cig companies, therefore, need to demonstrate how their e-cig products can mitigate that risk or that their products benefit adult smokers enough to outweigh the potential harm to youths.

The panel asked Soter to explain how FDA could deny the non-tobacco-flavored e-cig products based on its comparative-efficacy standard, arguing the e-cig products lacked specific evidence, while at the same time not calling this standard a rule. Oldham said, "I can't think of another example in administrative law where that happens." The panel, however, did not take up the question whether FDA's application of its standard was "arbitrary and capricious."

The panel added, "Nevertheless, we credit petitioners' APA argument regarding the notice-and-comment requirement under this circuit's doctrine that a substantive rule binding an agency to one course of action and prospectively applying to an unbounded set of parties triggers APA requirements and due process concerns." FDA

used "informal adjudication to promulgate a substantive rule that binds the agency to its enforcement position," the panel it said.

"Although, as a policy matter, one might agree with the FDA's decision to severely police youth access to e-cigarettes, the procedural safeguards of the APA serve to promote informed, rational decisionmaking by administrative agencies," the panel noted. The panel noted that FDA has received over six million e-cig PMTAs (flavored and unflavored) but only approved 43 under its comparative-efficacy standard. The panel added: "In the few cases where the FDA has approved a flavored ENDS, the manufacturer provided comparative-efficacy evidence. This contrast, between the FDA granting applications that satisfy the comparative efficacy standard but denying many thousands that lack such a study, underscores the point that it uses comparative efficacy to determine the rights and obligations of parties." The court was skeptical whether the more than 1 million flavored e-cig products represented individualized products with materially indistinguishable facts and concluded more likely FDA conducted a "check-the-box exercise" to deny PMTAs for non-tobacco- or menthol-flavored e-cig products.

Takeaways

While the Fifth Circuit's decision does not eliminate FDA's authority to evaluate flavored e-cig products in view of a comparative-efficacy standard, it does require FDA to reconsider the standard or adopt it through a process consistent with APA's notice-and-comment process. In so doing, the Court elected not to determine whether FDA's application of the standard was arbitrary and capricious. The Court noted that the standard created a "de facto ban" of e-cig products that "sidestepped the notice-and-comment rulemaking requirement of the APA."

The next steps are up to FDA. We will continue to monitor and keep you updated with where this all lands.

This blog was drafted by Brian Malkin, co-lead of the Spencer Fane FDA Pharmaceutical and Biologics Market Team. For more information, visit spencerfane.com.

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