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High Court E-Cig Ruling Opens Door For FDA Challenges

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On June 20, in U.S. Food and Drug Administration v. R.J. Reynolds Vapor Co., the U.S. Supreme Court **concluded** that marketing denial orders issued by the FDA regarding new tobacco products can be challenged not only by the applicants — typically, the manufacturer or importer of the products — but also by retailers of such products.[1]

As a result, we are likely to see more challenges to marketing denial orders brought before the U.S. Court of Appeals for the Fifth Circuit, where litigants have generally had greater success relative to other appellate courts.

This decision also opens the door for other types of interested parties to challenge marketing denial orders, possibly offering more venues for appeals.

The Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, or TCA, requires that new tobacco products, including electronic cigarettes, receive FDA marketing authorization before they can be marketed or sold.[2]

If the FDA denies such authorization, the TCA allows for "any person adversely affected" to seek judicial review of the marketing denial order under the Administrative Procedure Act in either the U.S. Court of Appeals for the District of Columbia Circuit or the circuit court where the person resides or has their principal place of business.[3]

In this case, the FDA issued marketing denial orders to RJR Vapor for flavored e-cigarette products under the Vuse Vibe, Vuse Solo and Vuse Alto brands, including several menthol-flavored products.[4] These products had been on the market when the FDA instituted a new requirement that manufacturers or importers of e-cigarettes and other previously unregulated tobacco products apply for authorization from the agency to continue marketing those products.

RJR Vapor applied for authorization with the FDA within the time frame required by the agency's guidance. Three years later, the FDA denied the applications, finding that RJR Vapor had failed to demonstrate that marketing of the products would be "appropriate for the protection of public health," as required by the TCA.[5]

RJR Vapor, joined by retailers located within the Fifth Circuit, filed joint petitions for review challenging the marketing denial orders in the Fifth Circuit.[6] The court noted that RJR Vapor is incorporated and has its principal

place of business in North Carolina. Had the company filed alone, its options would have been limited to the D.C. Circuit and the U.S. Court of Appeals for the Fourth Circuit.

The FDA argued that the retailers were not adversely affected by the denial and thus had no right to appeal. The FDA requested the Fifth Circuit to dismiss the petitions for lack of venue or to transfer them to the D.C. Circuit or Fourth Circuit. The Fifth Circuit denied the FDA's motions, however, concluding that "venue was proper over the joint petition to review the FDA's denial order."[7]

The key question on appeal at the Supreme Court was who qualifies as a person adversely affected by a marketing denial order, giving them the right to appeal. Is it only the manufacturer that submitted the application for marketing authorization? Or does it also include a retailer of products subject to the application at issue?

RJR Vapor and the retailers' position was that any person adversely affected may include retailers that face financial harm as a result of a marketing denial order.

The companies observed that a different TCA judicial review provision in the context of withdrawal of marketing authorization allows only applicants to sue, but here, Congress chose the phrase "any person adversely affected" — which must extend to at least one person beyond the applicant itself. Because the TCA's marketing authorization provisions refer to sales, they argued that the retailers are next in line.

The FDA argued that RJR Vapor was forum shopping since it only sought review in the Fifth Circuit because its principal argument — that the FDA acted arbitrarily and capriciously by changing the evidentiary standards for flavored electronic cigarettes after manufacturers submitted their applications — was previously rejected by other courts.

The FDA also argued that retailers are not actually within the "zone of interests" protected by the statutory provision at issue, which should extend only to the applicant whose marketing application is denied. The agency asserted that, without marketing authorization, the sale of the products is unlawful (even though the FDA allowed the continued sale of the products pursuant to an enforcement discretion policy), so the retailers' legal rights are not changed by virtue of the marketing denial order and are instead bystanders.[8]

Ultimately, the Supreme Court sided with RJR Vapor and the retailers, stating that a person does not have to be actually within the zone of interests protected by the statute to be adversely affected. Instead, consistent with prior Administrative Procedure Act cases, the court concluded that a petitioner "with an interest 'arguably sought to be protected by the statute'" was sufficient.

According to the court, retailers fit the bill because, "[i]f the FDA denies an application, the retailers, like the manufacturer, lose the opportunity to profit from the sale of the new tobacco product — or, if they sell the product anyway, risk imprisonment and other sanctions."

As a result, the Supreme Court held that the Fifth Circuit "correctly concluded that at least one proper petitioner had venue" because two of the retailers that joined in the petition had their principal places of business within the Fifth Circuit.

In a dissenting opinion, Justice Ketanji Brown Jackson, joined by Justice Sonia Sotomayor, argued that Congress intended the judicial review provision of the TCA to protect manufacturers, not retailers. The dissent emphasized that the TCA's premarketing authorization scheme "involves an exchange between tobacco manufacturers and the FDA that occurs when said manufacturers wish to market a new tobacco product," and retailers "have no rights and play no role" in this FDA authorization process.

So, what happens next?

In the short term, many marketing denial order cases that were stayed pending a decision in this case are likely to resume. Indeed, on July 19, the Fifth Circuit consolidated six such cases that had all been stayed and granted the joint motion to lift the stay, signaling that a wave of follow-on decisions is likely as courts apply the Supreme Court's reasoning to these pending challenges.[9]

In the longer term, these and other follow-on cases will still need to answer several outstanding issues.

First, the court left open the question of whether "each petitioner in a joint petition for review must independently establish venue," as the FDA asserted. The court explained that no court, including the Fifth Circuit, had analyzed the question before, and the court rarely addresses arguments for the first time, particularly because of the possible implications such a decision could have on other venue statutes.

Therefore, it remains to be seen whether manufacturers may ultimately join with retailers to review a marketing denial order in the Fifth Circuit, even if the retailers, and potentially other interested persons, could separately bring a challenge there. The Fifth Circuit has not indicated whether it will hear additional briefing on this issue regarding whether each petitioner must independently establish venue; however, this issue will likely be addressed in the future.

Second, the court's interpretation of the TCA's cause of action could extend beyond retailers. The court held that any person "arguably sought to be protected by the statute" may have standing to challenge a marketing denial order.

Although the court's analysis focused on the direct financial interests of retailers, its reasoning could apply to other parties that demonstrate a "significant, direct impact" from a marketing denial order. For example, individual adult smokers or nicotine users might argue that a marketing denial order denies them the opportunity to purchase and consume a less harmful nicotine product. It remains to be seen whether courts would allow such a challenge or seek to distinguish the harm to consumers as "marginally related to" the TCA.

Third, there might yet be some retailers that would not qualify as adversely affected, even if they wish to sell products subject to a marketing denial order. In this case, the court found that "[i]f the FDA denies an application, the retailers, like the manufacturer, lose the opportunity to profit from the sale of the new tobacco product."

Importantly, however, the retailers here had already sold Vuse products in the U.S., including several of the products at issue, for years.[10] Would a court still find that a retailer is adversely affected by a marketing denial order where the retailer has never sold the premarket tobacco product application applicant's products but desires to do so?

On the one hand, the retailer would still lose the opportunity to profit from the sale of the new product, which the court suggested was sufficient. On the other hand, one could argue that a retailer's interest in selling a future product is too speculative and attenuated. Future cases may resolve this question.

In sum, the Supreme Court's decision on June 20 significantly broadens the scope for challenging FDA marketing denial orders by allowing retailers and other interested parties, alongside manufacturers, to seek judicial review. This expansion is likely to lead to an increase in marketing denial order challenges, particularly in the Fifth Circuit, while also expanding the venues where these appeals may be brought.

Stakeholders should monitor how the Fifth Circuit and other jurisdictions apply this ruling and how they consider the question regarding the need for each petitioner to independently establish venue in marketing denial order appeals.

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[1] FDA v. R. J. Reynolds Vapor Co. , 145 S. Ct. 1984 (2025).

[2] See 21 U.S.C. §§ 331(a), 387b(6)(A), 387j(a)(2)(A).

[3] 21 U.S.C. § 387l(a)(1).

[4] See FDA News Release, FDA Denies Marketing of Two Vuse Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard (Jan. 24, 2023); FDA News Release, FDA Denies Marketing of Two Vuse Solo Menthol E-Cigarette Products (Mar. 17, 2023); FDA News Release, FDA Denies Marketing of Six Flavored Vuse Alto E-Cigarette Products Following Determination They Do Not Meet Public Health Standard (Oct. 12, 2023).

[5] R. J. Reynolds Vapor Co., 145 S. Ct. at 1990 (quoting 21 U.S.C. § 387j(c)(2)(A)).

[6] See R.J. Reynolds Vapor Co. v. FDA, Nos. 23-60037, 23-60128, 23-60545 (5th Cir.).

[7] R. J. Reynolds Vapor Co., 145 S. Ct. at 1990.

[8] See FDA Guidance Document, Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Apr. 29, 2020).

[9] See Breeze Smoke, L.L.C. v. FDA, No. 24-60304 (5th Cir. June 14, 2024); Vertigo Vapor, L.L.C. v. FDA, No. 24-60332 (5th Cir. June 28, 2024); Lead by Sales, L.L.C. v. FDA, No. 24-60424 (5th Cir. Aug. 24, 2024); Vapermate L.L.C. v. FDA, No. 24-60628 (5th Cir. Dec. 10, 2024); Elite Brothers v. FDA, No. 25-60098 (5th Cir. Mar. 6, 2025); American Vapor v. FDA, No. 25-60369 (5th Cir. Jul. 11, 2025).

[10] Brief for Respondents, FDA v. R.J. Reynolds Vapor Co., No. 23-1187 (5th Cir. Dec. 18, 2024).

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