Tobacco Retailers Obtain Increased Flexibility in Choosing a Venue to Challenge FDA Decisions

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FDA v. R.J. Reynolds Vapor Co., 145 S. Ct. 1984 (June 20, 2025)

In *FDA v. R.J. Reynolds Vapor Co.*, the U.S. Supreme Court held that retailers adversely affected by the Food and Drug Administration's (FDA) denial of a tobacco product marketing application may seek judicial review under the Family Smoking Prevention and Tobacco Control Act (TCA). This decision expands the scope of who may challenge agency decisions and offers disappointed applicants flexibility in choosing a venue for judicial review.

The TCA requires manufacturers to apply for and receive approval from the FDA before marketing any new tobacco products—including e-cigarettes. R.J. Reynolds Vapor Co. (RJR Vapor) accordingly applied to the FDA for authorization to market its flavored Vuse Alto e-cigarette products. The FDA denied the application, finding that RJR Vapor had provided insufficient evidence that its products were "appropriate for the protection of public health." RJR Vapor, joined by a retailer and a trade association of retailers, filed a joint petition for review of the FDA's denial order in the Fifth Circuit. The FDA moved to dismiss or transfer the case, arguing that only the manufacturer—the applicant—was "adversely affected" under the TCA and thus eligible to seek judicial review.

Under the TCA, "any person adversely affected" by the FDA's denial of premarket authorization may petition for judicial review in either the D.C. Circuit or "the circuit in which such person resides or has their principal place of business." The FDA moved to dismiss the petition or to transfer it to the D.C. Circuit because RJR Vapor is incorporated and has its principal place of business in North Carolina, which is in the Fourth Circuit, not the Fifth. The Fifth Circuit denied the FDA's motion, holding that venue was proper in the Fifth

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Circuit because the petitioners included a retailer from Texas and a trade association from Mississippi.

In a 7-2 decision, the Supreme Court affirmed the Fifth Circuit's denial. Writing for the majority, Justice Barrett emphasized that the phrase "any person adversely affected" in the TCA should be interpreted broadly, consistent with its usage in other federal statutes. Under that broad interpretation, "The TCA's cause of action thus extends to any petitioner with an interest arguably sought to be protected by the statute." The Supreme Court concluded that the retailers who lost the opportunity to profit from the sale of RJR Vapor's products (or risk legal penalties if they sold the unauthorized products anyway) are within the "zone of interests" protected by the statute and may therefore challenge denial orders.

The Supreme Court declined to address whether each petitioner in a joint petition must independently establish venue, as the FDA had not raised that argument in the lower courts. Moreover, the issue itself had never been considered by any lower court. The Supreme Court emphasized that "[p]rudence . . . dictates awaiting a case in which the issue was fully litigated below, so that we will have the benefit of developed arguments on both sides and lower court opinions squarely addressing the question."

In dissent, Justice Jackson, joined by Justice Sotomayor, argued that the statutory scheme of the TCA centers on manufacturers and excludes retailers from the premarket authorization process, suggesting that Congress did not intend to grant retailers a right to judicial review.

Key Takeaways

- The TCA's judicial review provision applies to any person "adversely affected," including retailers impacted by FDA denial orders.
- The Supreme Court's interpretation of the TCA reinforces a broad zone-of-interests standard for petitioners seeking review of agency action.

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- The decision offers parties disappointed by administrative decisions flexibility in where they seek judicial review.

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