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# Supreme Court Allows Tobacco Retailers to Petition for Review of FDA Marketing Request Denial

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Today, in *FDA v. R.J. Reynolds Vapor Co.*, the Supreme Court held 7-2 that under the Family Smoking Prevention and Tobacco Control Act ("TCA"), any person "adversely affected by" the FDA's denial of a marketing request for a new tobacco or e-cigarette product—not just the applicant—may file a petition for review of the FDA's decision.

The TCA requires the petitioner to seek review in either the D.C. Circuit or the circuit where that person "resides or has its principal place of business." North Carolina-based R.J. Reynolds Vapor Co. had filed a petition for review of the FDA's order denying its marketing request for its Vuse products in the Fifth Circuit, citing as the basis for venue the fact that its petition was joined by a Texas retailer that sells Vuse products and a trade association for Mississippi stores that sell Vuse. The FDA sought to transfer the case to the D.C. Circuit on the ground that retailers lack standing under the TCA to file a challenge to an FDA denial of a marketing request by a manufacturer.

The Supreme Court affirmed the Fifth Circuit's denial of the FDA's motion to transfer the case to the D.C. Circuit. Writing for the majority, Justice Barrett focused on the text of the relevant provision of the TCA, which does not limit judicial review to "applicants" seeking to market their products, but rather refers to "any person adversely affected" by the FDA's decision. Justice Barrett explained that "adversely affected" is a term of art in administrative law used, most notably, in the Administrative Procedure Act ("APA"). The APA authorizes suit from anyone "adversely affected or aggrieved by agency action." The Supreme Court has previously interpreted this broadly to permit anyone to sue who even "arguably" falls within the "zone of interests" implicated by the statute in question. And the majority explained that there is a "presumption" that "adversely affected" bears that same meaning when used in statutes other than the APA.

The majority therefore agreed with the Fifth Circuit that the retailers were "adversely affected by the denial" within the meaning of the TCA, because the denial prevented them from selling the new product without risking imprisonment. In doing so, the majority rejected the FDA's argument that the fact that other provisions of the TCA limit certain relief to manufacturers themselves means that retailers are outside the "zone of interests" protected by the statute. Instead, the Court reasoned that if Congress had intended to similarly limit review of marketing denials, it would have specified that "applicants" may seek review, not "any person adversely affected." The Court declined to consider the FDA's argument that each petitioner in a joint petition for review under the TCA must independently establish venue, because the FDA had not raised that argument below.

Justice Jackson dissented, joined by Justice Sotomayor. In Justice Jackson's view, the majority opinion "essentially nullified" the "zone of interests" test by permitting retailers to petition for review of a TCA marketing request denial when retailers play no role in the application process itself. And, in doing so, Justice Jackson protested that the majority opinion permitted manufacturers like R.J. Reynolds to thwart the TCA's venue requirements by joining a petition with retailers located in a venue of their choosing, meaning an applicant can file a petition in any circuit court in the United States as long as it can find a local retailer to serve as its "proxy."

For now, the majority's decision gives the green light to a raft of petitions for review that e-cigarette manufacturers have recently filed in the Fifth Circuit following that court's decisions setting aside the FDA's rejections of several other companies' requests to market flavored vape liquids.

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