No. 23-1187

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONERS

v.

R.J. REYNOLDS VAPOR CO., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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If the Food and Drug Administration (FDA) denies an application for authorization to market a new tobacco product, an adversely affected person may seek judicial review in the circuit where it is based. See 21 U.S.C. 387*l*(a)(1)(B). But in the decision below, the Fifth Circuit held that a manufacturer may seek review in a circuit where it is not based, so long as it is joined by an in-circuit seller of its products. That decision lacks merit and effectively nullifies the statute's limits on venue. It warrants this Court's review because it undercuts the authority of other courts of appeals and, in conjunction with the Fifth Circuit's other decisions, has serious consequences for public health. And contrary to respondents' contention, this case is an appropriate vehicle for resolving the question presented. This Court should grant the petition for a writ of certiorari.

A. The Decision Below Is Wrong

1. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776, allows an "adversely affected" person to obtain judicial review of an FDA order denying an application for marketing authorization. 21 U.S.C. 387*l*(a)(1)(B). FDA's denial of a manufacturer's application does not "adversely affect" a retail seller of that manufacturer's products.

Respondents do not deny that the phrase "adversely affected" is a term of art; that it requires a person to show that its interests fall within the zone of interests protected by the statute; or that the zone's scope depends on the statute's structure. See Pet. 9. The Tobacco Control Act's structure shows that a retailer may not challenge the denial of a manufacturer's application. Respondents do not dispute that the Act requires FDA to maintain the confidentiality of manufacturers' applications, or that only the manufacturer is entitled to notice of FDA's denial order. See Pet. 10. Respondents fail to explain why Congress would have granted retailers the right to challenge denial orders, but not the right to receive notice of those orders. Nor do they explain how a retailer could meaningfully challenge a denial without access to the underlying application.

This case illustrates the point. Respondents claim that FDA unfairly surprised R.J. Reynolds Vapor Co. (Reynolds) by changing the evidentiary standard under which it evaluated Reynolds' applications. See *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182, 189 (5th Cir. 2023). Yet they fail to explain how Reynolds' retailers —who, under the statute, are privy to neither Reynolds' application nor FDA's order—could raise such a claim.

Respondents emphasize (Br. in Opp. 12-15) that the Act regulates retailers, including by prohibiting them from selling unauthorized tobacco products. But the Act gives retailers no role in FDA's authorization of a tobacco product in the first place. And respondents concede (Br. in Opp. 11) that the Act precludes retailers from seeking judicial review of an order in which FDA withdraws marketing authorization that it previously granted. Withdrawals of a manufacturer's authorization, which require retailers to stop previously lawful sales, affect retailers' interests more directly than denials. See Pet. App. 7a (Higginson, J., dissenting). Respondents fail to explain why Congress would have allowed retailers to challenge denials, yet prohibited them from challenging withdrawals.

This case, at bottom, involves an agency order issued in response to a particular person's application. Only that person is properly regarded as adversely affected by an order denying its application. Any interests of other parties, such as retailers, are entirely derivative of, and adequately protected by, the applicants' interests. By contrast, if FDA issues a rule that directly regulates retailers, then an "adversely affected" retailer may seek review. See 21 U.S.C. 387*l*(a)(1)(A).

Essentially ignoring the Tobacco Control Act's basic structure, respondents principally rely (Br. in Opp. 8-9) on dictionary definitions of the words "adversely" and "affected" and on this Court's decisions in *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians* v. *Patchak*, 567 U.S. 209 (2012), and *Bank of America Corp.* v. *City of Miami*, 581 U.S. 189 (2017). None of those sources has any bearing on this case. The phrase "adversely affected" is a legal term of art, see *Director,*

Office of Workers' Compensation Programs v. *Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 126 (1995), and a court must interpret such a term of art in accordance with its "ordinary *legal* meaning," which "often differs" from the "common meaning" reflected in non-legal dictionaries, Antonin Scalia & Bryan A. Garner, *Reading Law* § 6, at 73 (2012) (emphasis added). *Patchak* involved prudential standing under the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.*, see 567 U.S. at 224-225, and this Court has explained that "what comes within the zone of interests of a statute for purposes of * * * the APA may not do so for other purposes," *Bennett* v. *Spear*, 520 U.S. 154, 163 (1997). *Bank of America* involved a suit under the Fair Housing Act (FHA), 42 U.S.C. 3601 *et seq.*, which contains a special definition of "aggrieved person" that is even broader than that term's customary legal meaning. See 42 U.S.C. 3602(i); *Bank of America*, 581 U.S. at 197-199.

2. The Fifth Circuit compounded its error by holding that an out-of-circuit manufacturer may seek judicial review in the circuit so long as it is joined by an in-circuit retailer. The Tobacco Control Act provides that "any person adversely affected" may file a petition for review in "the circuit in which *such person* resides or has their principal place of business." 21 U.S.C. 387*l*(a)(1) (emphasis added). As the words "such person" indicate, a person may file a petition in a circuit only if *that person* resides or has its principal place of business there. Respondents in effect rewrite the statute to allow a person to file a petition in "the circuit in which such person *or a retail seller of such person's products* resides or has its principal place of business."

Respondents attempt (Br. in Opp. 24) to dismiss, as "plainly irrelevant," this Court's decisions establishing the default rule that, in multi-party cases, "each plaintiff must be competent to sue" and "each defendant must be liable to be sued" in the chosen venue. *Smith* v. *Lyon*, 133 U.S. 315, 319 (1890); see *Camp* v. *Gress*, 250 U.S. 308, 311-316 (1919). Respondents instead emphasize (Br. in Opp. 19-20, 25-26) instances in which lower courts and treatise authors have read two other venue statutes, 28 U.S.C. 1391(e)(1)(C) and 28 U.S.C. 2343, to allow multiple plaintiffs or petitioners to sue the federal government so long as venue is proper as to one of them. But the decisions applying Section 1391(e)(1)(C) relied on that statute's legislative history—specifically, "the hearing transcripts of the House Committee on the Judiciary," which purportedly showed that Congress enacted that provision with the "specific purpose of easing plaintiffs' burdens when suing government entities." *Sidney Coal Co.* v. *SSA*, 427 F.3d 336, 344 (6th Cir. 2005), cert. denied, 547 U.S. 1020 (2006). And the decisions that respondents cite concerning Section 2343 provided no legal analysis at all in concluding that venue need be proper only as to a single petitioner. See, *e.g.*, *Global Van Lines, Inc.* v. *ICC*, 691 F.2d 773, 774 n.1 (5th Cir. 1982). Those decisions carry little weight in the interpretation of the Tobacco Control Act.

Finally, respondents complain (Br. in Opp. 21) that, under the government's interpretation, "petitioners would have to file separate lawsuits in different courts challenging the same agency action." But the Act allows parties to seek judicial review in the D.C. Circuit regardless of whether they reside or have their principal places of business there. See 21 U.S.C. 387*l*(a)(1). If

parties from different circuits wish to file a single petition for review in a single circuit, they could always avail themselves of that option. In addition, separate petitions filed in different circuits could be consolidated in a single circuit. See 28 U.S.C. 2112.

3. As Judge Higginson's dissent explained, the Fifth Circuit's decision effectively nullifies the statute's limits on venue. See Pet. App. 6a-7a. Respondents argue (Br. in Opp. 17-18 & n.14) that a manufacturer can benefit from the decision below only if its products are sold outside its home circuit—and that the venue provision can still do some work in cases where a manufacturer's products are sold in only one circuit or where no retailer wants to sell them anywhere. In other words, respondents suggest that Congress affirmatively enabled forum shopping by large manufacturers whose products are sold nationwide, though not by small manufacturers whose products are sold only "in one area." *Id.* at 17. But if Congress meant to allow a manufacturer to sue wherever its products are sold, it would have said so. Congress instead authorized a person to seek judicial review only where it "resides" or has its "principal place of business." 21 U.S.C. 387*l*(a)(1). The decision below negates that congressional choice.

B. The Question Presented Warrants This Court's Review, And This Case Is A Suitable Vehicle For Resolving It

1. Respondents do not dispute that the Fifth Circuit has resolved the venue issue in a published opinion and now regards that issue as settled. See Pet. 15-16. Indeed, respondents have already filed amicus briefs in the Fifth Circuit contending that the court has "rejected FDA's venue arguments" in a "published opin-

ion" and in "unpublished orders"; that the "published holding on venue" "is binding"; and that the "prior rulings control." Reynolds et al. Amicus Br. at 2, 4, *Shenzhen Youme Information Tech. Co.* v. *FDA*, No. 24-60060 (5th Cir. June 14, 2024) (Resp. *Shenzhen Youme* Amicus Br.); see Reynolds et al. Amicus Br. at 2, 4, *Shenzhen IVPS Tech. Co.* v. *FDA*, No. 24-60032 (5th Cir. May 24, 2024).

Although respondents recently told the Fifth Circuit that it has "repeatedly resolved this issue against FDA," Resp. *Shenzhen Youme* Amicus Br. at 2, they now claim that the venue issue arises only "rare[ly]," Br. in Opp. 27 (capitalization omitted). That is incorrect. In the petition for a writ of certiorari (at 16-17), we cited six petitions for review—including three from Reynolds alone—filed in the Fifth Circuit using the maneuver approved in the decision below. That total has since grown to nine. In June 2024, NicQuid (an Ohio manufacturer), Breeze Smoke (a Michigan manufacturer), and Vertigo Vapor (a Washington manufacturer) all filed petitions for review in the Fifth Circuit joined by their Texas distributors. See Pet. for Review at 1-2, *NicQuid, LLC* v. *FDA*, No. 24-60272 (5th Cir. June 3, 2024); Pet. for Review at 1-2, *Breeze Smoke, LLC* v. *FDA*, No. 24-60304 (5th Cir. June 14, 2024); Pet. for Review at 1-2, *Vertigo Vapor LLC* v. *FDA*, No. 24-60332 (5th Cir. June 28, 2024). That trend is likely to continue unless this Court intervenes.

Respondents seek to minimize the importance of that trend by observing (Br. in Opp. 29) that FDA has denied marketing authorization for "hundreds of thousands" of new tobacco products. But that figure is misleading: A single manufacturer sometimes seeks authorization to

market thousands of products. See, *e.g.*, FDA, News Release, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health* 1 (Aug. 26, 2021) (describing decisions about "55,000 flavored [e-cigarette] products from three applicants"). And the entities that have taken advantage of the Fifth Circuit's decision include some of the Nation's largest manufacturers. For instance, Reynolds claims (Br. in Opp. 30) that its products are "not popular among youth," but the study it cites for that proposition estimates that 420,000 middle- and high-school students used Reynolds' Vuse e-cigarette products in 2023, making Vuse the third most popular e-cigarette brand among youth. See Jan Birdsey et al., Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Tobacco Product Use Among U.S. Middle and High School Students—National Youth Tobacco Survey, 2023*, 72 Morbidity and Mortality Weekly Report 1180 (Nov. 3, 2023).

Respondents insist (Br. in Opp. 28-29) that this Court should nonetheless deny review because the Fifth Circuit's decision does not create a circuit conflict. As an initial matter, the decision conflicts with *Amerada Petroleum Corp.* v. *Federal Power Commission*, 338 F.2d 808 (10th Cir. 1964), which held that a materially identical venue provision did not permit out-of-circuit companies to seek review alongside an in-circuit company. Respondents seek to distinguish *Amerada Petroleum* as a case involving "'separate applications,'" rather than a "single order on one application," Br. in Opp. 28 (brackets, citation, and emphases omitted), but the agency had consolidated the separate applications and

issued a single order resolving them. See 338 F.2d at 809-810. And respondents' theory—that "[n]othing in the statutory language requires each petitioner to individually establish venue," Br. in Opp. 19—does not distinguish between an order denying separate applications and one denying a single application.

Even putting aside *Amerada Petroleum*, this Court should grant review. Out-of-circuit manufacturers, including Reynolds, have repeatedly evaded adverse precedent in the D.C. Circuit and their home circuits by enlisting retailers to join petitions for review in the Fifth Circuit. The Fifth Circuit, for its part, has repeatedly approved that tactic. Regardless of whether the Fifth Circuit's decisions create a circuit conflict, they undermine the venue provision and the authority of other circuits in a manner that warrants this Court's intervention.

Finally, as respondents' and other manufacturers' decisions to file petitions for review in the Fifth Circuit demonstrate, manufacturers regard that circuit as a uniquely favorable forum in which to litigate against FDA. Now that the Fifth Circuit has approved a tactic that enables any out-of-circuit entity to file a petition for review there, it is unlikely that any manufacturer will feel the need to try the same tactic in other circuits, that the venue issue will percolate in those circuits, or that a circuit conflict will ever develop. In such circumstances, the absence of a circuit conflict should not dissuade the Court from granting review.

2. Contrary to respondents' suggestion (Br. in Opp. 31-34), this case is a suitable vehicle for resolving the question presented. To start, respondents simply err in saying (*id.* at 5, 33) that FDA is asking this Court to

grant certiorari before judgment—*i.e.*, to review a *district court's* decision before the court of appeals has acted. Rather, FDA is asking the Court to review a *court of appeals'* interlocutory decision—specifically, the Fifth Circuit's order denying the motion to dismiss in *Alto*. See Pet. 6. Respondents claim (Br. in Opp. 31) that this Court has never previously granted certiorari "in this procedural posture," but the Court did just that in *National Association of Manufacturers* v. *Department of Defense*, 583 U.S. 109 (2018), and has on many other occasions reviewed venue questions in an interlocutory posture. See Pet. 19-21.

Respondents also err in arguing (Br. in Opp. 5, 18, 33) that FDA has forfeited its secondary contention that venue must be proper as to each party. "Once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below." *Yee* v. *City of Escondido*, 503 U.S. 519, 534 (1992). Respondents do not dispute that FDA preserved its venue claim in the Fifth Circuit.

In any event, this Court may consider an issue that was "pressed *or* passed upon below." *United States* v. *Williams*, 504 U.S. 36, 41 (1992) (emphasis added; citation omitted). Contrary to respondents' suggestion (Br. in Opp. 33), the Fifth Circuit plainly passed upon the question whether venue must be proper as to each party; it held in *Alto* that venue was proper because "two of the [four] Petitioners * * * have their principal places of business in the Fifth Circuit." Pet. App. 3a. By the time FDA moved to dismiss in *Alto*, moreover, the Fifth Circuit had already held, in its published opinion in *Vibe*, that "venue is proper in this circuit" so long

as "*a* petitioner" is based there. *R.J. Reynolds*, 65 F.4th at 188 (emphasis added). It would have been futile for FDA to argue in *Alto* that venue must be proper as to each party.

Respondents further contend (Br. in Opp. 18) that FDA did not adequately argue in *Vibe* that venue must be proper as to each party. But because FDA is asking this Court to review the Fifth Circuit's order in *Alto*, not its order in *Vibe*, any purported forfeiture in *Vibe* is beside the point. And although FDA did not specifically argue that venue must be proper as to each party when it first raised venue in its emergency stay briefing in *Vibe*, the Fifth Circuit reached out, resolved that unbriefed issue, and held in a published opinion that "venue is proper in this circuit" so long as "*a* petitioner" is based there. *Reynolds*, 65 F.4th at 188 (emphasis added). Thus, in *Vibe*, as here, the question whether venue must be proper as to each party was "passed upon below." *Williams*, 504 U.S. at 41.

Finally, respondents err in contending (Br. in Opp. 34) that Reynolds may continue litigating in the Fifth Circuit even if the retailers are dismissed from the case. The cases cited by respondents state only that "venue is determined at the outset of the litigation" and that a case that was "properly venued" "is not affected by a subsequent change in parties." *Exxon Corp.* v. *FTC*, 588 F.2d 895, 898-899 (3d Cir. 1978). But this case was not "properly venued" "at the outset of the litigation," *ibid.*; rather, for the reasons discussed above, venue has been improper from the beginning. At any rate, because the Fifth Circuit did not rely on that alternative rationale, this Court would not need to address it if it grants the petition for a writ of certiorari.

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The petition for a writ of certiorari should be granted.

Respectfully submitted.

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