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.,
*Respondents.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit**

## BRIEF IN OPPOSITION

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## QUESTIONS PRESENTED

Respondents manufacture and sell Vuse e-cigarettes, which have been on the market for the better part of eight years. The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776, requires e-cigarettes to obtain marketing authorization from FDA.

If FDA denies authorization, the Tobacco Control Act allows "any person adversely affected" by the denial order to "file a petition for judicial review" in the D.C. Circuit or "the circuit in which such person resides or has their principal place of business." 21 U.S.C. § 387*l*(a)(1). Here, FDA denied authorization for menthol-flavored Vuse Alto, and four entities, including the manufacturer and retailers of the product, filed a petition for review in the U.S. Court of Appeals for the Fifth Circuit. That court determined that venue is proper under the Act because the retailers are "adversely affected" by the denial order—FDA's order means they cannot legally sell the product—and located in the Fifth Circuit. The questions presented are:

1. Whether a retailer that may not sell a tobacco product due to an FDA denial order qualifies as "any person adversely affected" under the Tobacco Control Act such that it may file a petition for judicial review of the denial order in the circuit where it resides or has its principal place of business.

2. Where multiple petitioners join a single petition for review of an FDA denial of a marketing application for a tobacco product, whether all petitioners may participate in the case if one petitioner has established venue.

## RULE 29.6 STATEMENT

R.J. Reynolds Vapor Company and RJR Vapor Company, L.L.C. are direct, wholly owned subsidiaries of RAI Innovations Company; RAI Innovations Company is a direct, wholly owned subsidiary of Reynolds American Inc.; and Reynolds American Inc. is an indirect, wholly owned subsidiary of British American Tobacco, p.l.c., a publicly traded company.

Mississippi Petroleum Marketers and Convenience Stores Association is a nonprofit, statewide trade association of petroleum marketers and convenience store operators. It has no parent company and no publicly traded corporation owns stock in the Association.

Avail Vapor Texas, L.L.C. is a limited liability company formed in Texas. Its parent company is Avail Vapor L.L.C., a Virginia limited liability company.

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## STATEMENT

1. In the mid-2000s, e-cigarettes emerged as an alternative to traditional cigarettes without the health risks of inhaling the smoke from burned tobacco. E-cigarettes heat a nicotine-containing liquid into an inhalable aerosol. Per the Director of FDA's Center for Tobacco Products ("CTP"), "tobacco products exist on a continuum of risk."[1] Relative to cigarettes, e-cigarettes are far down on that continuum. E-cigarettes are potentially 95% less harmful than cigarettes.[2] FDA's Commissioner said, "If you could take every adult smoker … and fully switch them to e-cigarettes, that would have a substantial public health impact."[3]

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (the "TCA" or the "Act"), Pub. L. No. 111-31, Div. A, 123 Stat. 1776. The Act requires manufacturers of certain "new" tobacco products (those not marketed by 2007) to obtain FDA marketing authorization via a premarket tobacco product application. 21 U.S.C. § 387j. The standard for authorization is whether marketing the product is "appropriate for the protection of the public health." *Id.* § 387j(c)(2). The Act initially covered only certain tobacco products (e.g., cigarettes and roll-your-own tobacco), but it

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[1] Brian A. King & Benjamin A. Toll, *Commentary on Wackowski* et al., 118 Addiction 1892 (2023).

[2] Royal College of Physicians, *Nicotine Without Smoke: Tobacco Harm Reduction* (2016), https://tinyurl.com/d7y4hna7.

[3] CSPAN, *FDA Commissioner on E-cigarettes and Public Health Concerns*, at 10:25 (Sept. 25, 2018), https://tinyurl.com/mujce8hr.

also gave FDA the authority to "deem[ ]" other tobacco products subject to the Act's requirements. *See* 21 U.S.C. § 387a(b).

In 2016, FDA deemed e-cigarettes subject to the premarket-authorization requirements of the TCA. *Wages & White Lion Invests. v. FDA*, 90 F.4th 357, 363 (5th Cir. 2024) (en banc). As a result, manufacturers had to obtain marketing authorization from FDA, even for e-cigarettes that had already been on the market for years. *Id.* FDA, however, determined that removing on-market e-cigarettes would harm the public health; as a result, it established an enforcement-discretion policy to allow certain such e-cigarettes (including menthol Vuse Alto) to remain on the market pending the filing and resolution of marketing applications.[4]

2. Respondent R.J. Reynolds Vapor Co. ("RJRV") manufactures and markets tobacco- and menthol-flavored Vuse e-cigarettes. *See* C.A. Stay Mot. 3, *R.J. Reynolds Vapor Co. v. FDA*, No. 23-60545 (5th Cir. Oct. 20, 2023) ("*Alto*"). Vuse is the Nation's market-leading e-cigarette brand among adults, and Vuse Alto is the most popular Vuse product. *Id.* at 1.

Respondent Avail Vapor Texas, L.L.C. ("Avail"), and members of Respondent trade association Mississippi Petroleum Marketers and Convenience

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[4] *See* 81 Fed. Reg. 28,974, 28,977 (May 10, 2016); *see also id.* at 29,001 ("as a practical effect of the Agency's compliance policy … FDA expects that many manufacturers … will continue to market their products"); FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market Without Premarket Authorization* 27 (Apr. 2020).

Stores Association ("Mississippi Association"), are retailers that sell menthol-flavored Vuse Alto. Avail principally sells Vuse products and, "if Avail were not allowed to sell Vuse products, … Avail would cease its business operations." *See* C.A. Amended Order 4, *Alto* (5th Cir. Feb. 2, 2024).

3. As noted above, e-cigarettes need to obtain FDA authorization. In compliance with that requirement, RJRV spent millions of dollars and thousands of employee hours on its Vuse applications, and timely submitted each of them. *Alto* C.A. Stay Mot. 7 (Oct. 20, 2023).

In a series of orders, FDA denied marketing authorization for four styles of menthol Vuse e-cigarettes, including Vuse Alto. The same Respondents petitioned for review of each of those denial orders. *See* C.A. Pet. for Rev., No. 23-60037 (5th Cir. Jan. 24, 2023) ("*Vibe*"); C.A. Pet. for Rev., No. 23-60128 (5th Cir. Mar. 17, 2023) ("*Solo*"); *Alto* C.A. Pet. for Rev. (Oct. 12, 2023). The Fifth Circuit consolidated these actions and stayed FDA's denial orders as to RJRV's currently marketed products. *Vibe* C.A. Consolidation Order (Mar. 22, 2023); *Alto* C.A. Consolidation Order (Oct. 19, 2023); *Vibe* 65 F.4th 182 (5th Cir. 2023); *Solo* C.A. Stay Order (Mar. 29, 2023); *Alto* C.A. Stay Order (Feb. 2, 2024). The Fifth Circuit concluded that Respondents are likely to succeed on their claims that FDA acted arbitrarily in issuing the denial orders and "instituted a *de facto* ban on non-tobacco-flavored e-cigarettes without going through notice-and-comment." *Vibe*, 65 F.4th at 194.

In doing so, the Fifth Circuit rejected FDA's venue objections. First, in staying the denial order as to menthol Vuse Vibe, the Fifth Circuit held "[v]enue is proper because [Mississippi Association] has its 'principal place of business' here." *Vibe*, 65 F.4th at 188 & n.5. The Fifth Circuit also summarily rejected FDA's motion to transfer the *Vibe* and *Solo* cases to the D.C. Circuit. *Vibe* C.A. Order (June 27, 2023). And the court of appeals denied FDA's motion to dismiss or transfer the *Alto* petition to the Fourth or D.C. Circuit, holding, "All the Petitioners are 'persons adversely affected' under the Act, and two of the Petitioners, Avail Vapor Texas and [Mississippi Association], have their principal places of business here in the Fifth Circuit." *Alto* C.A. Amended Order 3 (Feb. 2, 2024). Judge Higginson dissented. The Fifth Circuit then denied FDA's petition for rehearing en banc of the *Vibe* stay order, in which FDA again raised its venue objection. *Vibe* C.A. Order (Feb. 6, 2024).

Having failed to persuade the Fifth Circuit, FDA now turns to this Court, seeking interlocutory review of two splitless issues.

## REASONS FOR DENYING THE PETITION

The TCA's judicial-review provision allows "any person adversely affected" by FDA's marketing denial order to "file a petition for judicial review" in the D.C. Circuit or "the circuit in which such person resides or has their principal place of business." 21 U.S.C. § 387*l*(a)(1). Basic rules of statutory interpretation, as well as this Court's "zone of interests" test for statutory standing, show that the Fifth Circuit correctly concluded that manufacturers

and retailers—both of whom are regulated and protected by a number of provisions in the TCA—qualify as "any person[s] adversely affected." *Id.* Simply put, when an FDA order prohibits a retailer from selling a product, the retailer is "adversely affected" by the order. And when such a retailer petitions in its home circuit, any other adversely affected person may join that petition.

Additionally, as FDA admits, there is no circuit conflict over the meaning of this venue provision. And other vehicle problems abound. FDA is not only asking this Court to take the highly unusual step of being the first appellate court to review an interlocutory procedural order (because this case was first filed in the court of appeals), but FDA is also asking this Court to become a court of first review on the second question presented (because FDA never raised it below). And FDA makes the request without even trying to make the extraordinary showing that is required to seek certiorari before judgment. In any event, interlocutory review of these questions, even if resolved in FDA's favor, would not resolve this case or even afford FDA the relief it seeks.

This Court should therefore deny FDA's petition.

## I. THE FIFTH CIRCUIT'S DECISION IS CORRECT.

The TCA provides that "any person adversely affected" by a denial order may "file a petition for judicial review" in the D.C. Circuit or "the circuit in which such person resides or has their principal place of business." 21 U.S.C. § 387*l*(a)(1). A retailer that cannot sell a product because of an FDA denial order is obviously "adversely affected" by that order. The Fifth Circuit thus correctly held that

manufacturers and retailers—like Respondents here—are "'persons adversely affected' under the Act," and that they therefore have a statutory right to seek judicial review of a denial order. *Alto* C.A. Amended Order 3 (Feb. 2, 2024). And because Avail and Mississippi Association "have their principal places of business … in the Fifth Circuit"—facts that FDA does not dispute—venue is proper in the Fifth Circuit. *Id.*[5] The plain text of the TCA's judicial-review provision and well-established "statutory standing" doctrine compel such a conclusion.

FDA's alternative argument—that where multiple adversely affected parties petition for review together, each must individually satisfy the statute's venue requirements—fares no better. In addition to being wrong, FDA forfeited this argument by failing to raise it below. Nothing in the statute requires retailers and manufacturers to file separate petitions in different courts to challenge the same FDA denial order.

1. The TCA expressly and unambiguously allows retailers like Respondent Avail and members of Respondent Mississippi Association to challenge FDA marketing denial orders. The Act says, "any person adversely affected by" a denial order "may file a petition for judicial review of such … denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business." 21 U.S.C. § 387*l*(a)(1). FDA claims that the retailer

[5] Mississippi Association and Avail also reside in the Fifth Circuit because they are incorporated or formed there. *Alto* C.A. Opp'n to Mot. to Dismiss or Transfer 6 (Oct. 30, 2023).

Respondents (who are indisputably located in the Fifth Circuit) cannot provide the basis for venue because they are not "adversely affected" by FDA's denial order and therefore lack a statutory right to challenge that order. The Fifth Circuit correctly rejected that argument.

Retailers (including Respondent Avail and members of Respondent Mississippi Association) who sell the product subject to a denial order are plainly "adversely affected" by an order that will cause them to lose substantial revenue and, in the case of Respondent Avail, shutter its operations if it is not allowed to sell Vuse products. They therefore fall squarely within the provision's scope.

FDA does not dispute that retailers are injured by FDA's denial order in an Article III sense.[6] Instead, FDA contends that retailers—even those suffering cognizable injury—are *never* "adversely affected" by a denial order, and only the applicant (*i.e.*, manufacturer) is. In other words, the fact that FDA's denial order for menthol Vuse Alto directly harms the retailer Respondents does not, in FDA's view, qualify as an "adverse[ ] [e]ffect." FDA's position flouts both the TCA's text and this Court's permissive criteria for assessing whether a party invoking a judicial-review provision has statutory standing.

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[6] Below, FDA at one point seemed to suggest that the agency's objection had something to do with jurisdiction. However, FDA's petition for certiorari makes clear that its objection is to venue, not jurisdiction. *See Alto* C.A. Opp'n to Mot. to Transfer 4 (Oct. 30, 2023) (noting FDA "abandon[ed] reliance on 28 U.S.C. § 1631").

a. Start with the statute's plain text: "any person adversely affected." 21 U.S.C. § 387*l*(a)(1). As this Court has explained, "the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind.'" *United States v. Gonzales*, 520 U.S. 1, 5 (1997). So Congress made clear that *all* persons (so long as they are adversely affected by an order) are entitled to file suit. Accordingly, Respondents (who are indisputably "persons" under the Act) clearly fall within the category of "*any* person." The key phrase then is "adversely affected." "Adverse" means "in opposition to one's interests." *Webster's Third New Int'l Dictionary* 31 (1981). And "affected" means "to produce an effect … upon" or "to have a detrimental influence on." *Id.* at 35. Thus, the full phrase means a person who experiences an effect or detrimental influence that is in opposition to their interests. Here, it is clear as can be that the denial order will have a "an effect upon" and "a detrimental influence on" the retailer Respondents' interests, since they cannot sell the product at issue and if they do, will be subject to severe penalties, *see infra* p. 12. Therefore, under the plain text, retailer Respondents are "any person adversely affected" by FDA's order.

b. FDA tries to escape the statute's plain text by emphasizing that "'adversely affected' is a term of art in administrative law," Pet. 11, but the Agency fares no better under this Court's statutory standing jurisprudence. The zone-of-interests test that this Court has applied to determine when a party is sufficiently aggrieved to challenge agency action "is not meant to be especially demanding." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v.*

*Patchak*, 567 U.S. 209, 225 (2012). A party has statutory standing if it asserts an interest that is "arguably" protected or regulated by the statute. *E.g.*, *id.* at 225–26. The zone-of-interests test "forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Id.* All that is required is "some indicia—however slight—that the litigant before the court was [(i)] intended to be protected … or [(ii)] regulated by the statute"—either suffices. *Calumet Indus., Inc. v. Brock*, 807 F.2d 225, 228 (D.C. Cir. 1986). This is assessed using "traditional tools of statutory interpretation." *Bank of Am. Corp. v. City of Miami*, 581 U.S. 189, 197 (2017). And "the benefit of any doubt goes to the plaintiff." *Match-E-Be-Nash-She-Wish*, 567 U.S. at 225. "[F]inancial injury … satisf[ies] the 'cause-of-action' (or 'prudential standing') requirement." *Bank of Am.*, 581 U.S. at 197.

This Court's decision in *Bank of America*—which involved a statute with virtually identical language about who can sue—controls this case. There, the City of Miami sued several banks under the Fair Housing Act ("FHA"), alleging that the banks engaged in discriminatory lending in the residential housing market that caused the City economic harm. In concluding that the City came within the FHA's zone of interests, the Supreme Court stressed the textual breadth of the FHA's judicial-review provision: "The FHA permits any 'aggrieved person' to bring a housing-discrimination lawsuit." *Id.* (quoting 42 U.S.C. § 3613(a)). Because the City

claimed that the banks' lending practices caused the City's lost tax revenue, the Court concluded the City was at least "arguably … within the FHA's zone of interests"—even though the City did not suffer discrimination. *Id.* at 200–01.[7]

Given this precedent, it is no wonder the Fifth Circuit rejected FDA's argument under the TCA. The statutory language here—"any person adversely affected"—is, if anything, broader than the FHA's "aggrieved person" language. And the connection between the retailers' injuries and the interests protected by the TCA is far more direct than the connection between the City's lost tax revenue in *Bank of America* and the FHA. This case thus follows *a fortiori* from *Bank of America. See also Truck Ins. Exch. v. Kaiser Gypsum Co.*, 144 S. Ct. 1414, 1423 (2024) (holding "an insurer such as Truck with financial responsibility for a bankruptcy claim is a 'party in interest' because it may be directly and adversely affected by the reorganization plan").[8]

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[7] Notably, the government filed an amicus brief in support of the position this Court adopted. *See* Brief for U.S. as Amicus Curiae Supporting Respondent, *Bank of America*, 581 U.S. 189, 2016 WL 5903233.

[8] The retailers' interests would establish standing even under Justice Thomas's dissenting opinion in *Bank of America.* Justice Thomas concluded that the City's asserted injuries (lost revenues and increased costs) did not implicate the interests protected by the FHA. 581 U.S. at 207–09. (Thomas, J., concurring in part, dissenting in part). Here, there is no question that the retailers' injuries (inability to sell a tobacco product) directly implicate the interests protected by the TCA. *See infra* p. 12.

c. This straightforward interpretation of § 387*l*(a)(1), moreover, is confirmed by the structure of the TCA and statutory context. FDA seems to assert that, in allowing "*any person* adversely affected" to sue, 21 U.S.C. § 387*l*(a)(1) (emphasis added), Congress actually meant that "*only* a manufacturer of a product subject to a marketing denial order" or "*only* an applicant whose premarket application is denied" could sue. But Congress knows how to limit judicial-review provisions in that way, and, indeed, did so elsewhere in the TCA itself. *Compare id.* ("any person adversely affected" may challenge marketing denial orders for tobacco products), *with id.* § 387j(d)(2) ("[t]he holder of an application" may challenge the withdrawal of marketing authorization for tobacco products). For § 387*l*(a)(1), in contrast, it uses the capacious phrase "any person adversely affected." And "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Alto* C.A. Amended Order 4–5 (Feb. 2, 2024) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)); *see also id.* at 5 ("Congress did not limit access to the courts for those challenging a denial order in the same way it did for those challenging a withdrawal order. If the FDA disagrees with Congress's policy choice in so drafting the [TCA], its concerns are better directed to Congress than to this court.").

Congress also included rulemaking in the TCA's judicial-review provision. 21 U.S.C. § 387*l*(a)(1) ("any person adversely affected *by such regulation*"

(emphasis added)). Under FDA's interpretation, "any person adversely affected" would thus mean two different things in the *same* provision: for rulemaking, "any person adversely affected" means "any person adversely affected," but for a denial order, "any person adversely affect" means "only the adversely affected manufacturer." Basic interpretive rules reject such a reading. In a given statute, there is a presumption of consistent usage: the same term usually has the same meaning across different applications. *See Clark v. Martinez*, 543 U.S. 371, 378 (2005) ("To give these same words [in a statutory phrase] a different meaning for each category would be to invent a statute rather than interpret one.").

The evidence that Congress meant what it said does not stop with the TCA. The U.S. Code is replete with provisions that, unlike § 387*l*(a)(1) here, expressly limit the class of potential petitioners to parties who either played some specific role in the administrative proceedings or satisfy other specified criteria. *See, e.g.*, 21 U.S.C. § 1047 ("the affected *applicant*") (emphasis added); 12 U.S.C. § 4634 ("Any *party to a proceeding*") (emphasis added); 29 U.S.C. § 3247 ("any *party to a proceeding*") (emphasis added); 42 U.S.C. § 5311 ("Any *recipient* which receives notice") (emphasis added); *id.* § 6869 ("If any *applicant* is dissatisfied") (emphasis added); 7 U.S.C. § 228b-3 ("the *live poultry dealer*") (emphasis added); 8 U.S.C. § 1189 ("the *designated organization*") (emphasis added); 10 U.S.C. § 1508 ("A *person who is the primary next of kin*") (emphasis added); 31 U.S.C. § 6717 ("A *unit of general local government* which receives notice") (emphasis added); 41 U.S.C. § 1327 ("a *party*" to the order) (emphasis added); *id.* § 7107

("a contractor"); 42 U.S.C. § 263b ("the *owner or operator*") (emphasis added).

A retailer thus easily falls within the statute's zone of interests. *Bank of Am.*, 581 U.S. at 197 ("claims of financial injury … satisfy … 'prudential standing'").

d. Looking at the statute more broadly reinforces that retailers are within the zone of interests of both the TCA as a whole and its premarket review provisions in particular. Assessing this question, courts generally ask whether the relevant statute regulates or protects the party. *Calumet Indus.*, 807 F.2d at 228 (citing *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). If the statute does, then the party is within the zone and has statutory standing. Here, it is clear that the TCA both regulates and protects retailers.

First, the TCA directly regulates retailers by:

- prohibiting retailers from selling products that FDA does not authorize, 21 U.S.C. §§ 331, 387b(6);
- authorizing seizures, fines, injunctions, and criminal penalties against retailers who sell unauthorized products, *id.* § 334(a), (g); § 333(a), (f)(9)(A); § 332(a);
- prohibiting retailers from selling products with unauthorized "modified risk" claims, *id.* § 387k(a);
- requiring retailers to limit the location and amount of any distribution of free samples of tobacco products, *id.* § 387a-1(d);

- requiring retailers to adhere to certain labeling requirements for any cigarette advertisements, 15 U.S.C. § 1333; and
- requiring retailers to adhere to certain labeling requirements for any smokeless tobacco product advertisements, *id.* § 4402.

Among these numerous provisions, it is notable that a denial order under the TCA dictates what products a retailer may sell. And FDA's enforcement efforts show that the statute means what it says. In announcing its denial orders for menthol Vuse Vibe and Ciro, for example, FDA said that it "intends to ensure compliance by distributors and *retailers*."[9] Similarly, in announcing its denial order for menthol Vuse Alto, FDA stated, "If the product is already on the market, it must be removed from the market or risk FDA enforcement."[10] Moreover, in 2020, FDA warned retailers it would enforce the TCA against them.[11] FDA has made good on that threat, issuing warning letters and civil penalties to retailers who sold products that received marketing denial

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[9] *E.g.*, FDA, *FDA Denies Marketing of Two Vuse Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard* (Jan. 24, 2023), https://tinyurl.com/4ck9644b (emphasis added).

[10] *E.g.*, FDA, *FDA Denies Marketing of Six Flavored Vuse Alto E-Cigarette Products* (Oct. 12, 2023), https://tinyurl.com/5n8nb7c7.

[11] *E.g.*, FDA, *FDA Warns Manufacturers and Retailers* (Apr. 27, 2020), https://tinyurl.com/uttfu7p7 ("If the recipients of these warning letters do not cease the manufacture, distribution and/or sale of these unauthorized tobacco products, they risk additional FDA action such as an injunction, seizure and/or civil money penalty actions.").

orders.[12] Just this March, FDA announced that it had issued warning letters to 61 retailers for selling unauthorized tobacco products.[13] FDA also has sought and obtained injunctions against retailers. *E.g.*, Consent Decree of Permanent Injunction, *United States v. Lucky Convenience & Tobacco, LLC*, No. 6:22-cv-1237 (D. Kan. Jan. 26, 2023). The TCA thus obviously *regulates* tobacco retailers.

Second, the TCA also directly *protects* retailers by:

- preserving retailers' ability to sell tobacco products by forbidding FDA from banning all cigarettes and certain other product categories, 21 U.S.C. § 387f;
- providing retailers with an opportunity for a hearing prior to a no-tobacco-sale order, *id.* § 333(f)(8);
- providing retailers with several procedural protections regarding certain alleged violations of the Act, *id.* § 333 note; and
- exempting retailers from certain recordkeeping requirements, *id.* § 387t(b)(5).

Significantly for assessing whether retailers fall within the TCA's zone of interests, the Act expressly declares Congress's purpose "to continue to permit the sale of tobacco products to adults," including

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[12] FDA, *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products*, https://tinyurl.com/mrxxt3ja (last visited July 2, 2024).

[13] FDA, *FDA Warns 61 Brick and Mortar Retailers for the Sale of Unauthorized E-Cigarettes Popular Among Youth* (Mar. 26, 2024), https://tinyurl.com/mpx2bjky.

through retailers who comply with the TCA. 21 U.S.C. § 387 note. FDA cannot seriously maintain that retailers like Respondents Avail, Mississippi Association, and RJR Vapor Co. L.L.C. fall outside the Act's zone of interests when those entities are a constant and integral subject of the Act's provisions.

e. For its part, FDA argues that "aspects of the statutory structure demonstrate that the denial of a manufacturer's application does not adversely affect a seller." Pet. 11. But FDA only points to two (inapposite) provisions. The first provision is 21 U.S.C. § 387j(d)(2), where Congress provided that only "the holder of an application" may challenge the withdrawal of marketing authorization. As noted above, that provision cuts *against* FDA because "Congress did not limit access to the courts for challenging a denial order in the same way it did for those challenging a withdrawal order." *Alto* C.A. Amended Order 5 (Feb. 2, 2024). This provision thus demonstrates that Congress knew how to limit judicial review when it wanted to, and yet for the denial of a premarket tobacco product application, authorized a challenge by "*any person adversely affected*" by it. *See supra* pp. 9–11. The second provision to which FDA points is § 387f(c), where Congress limited non-manufacturers' access to certain information under the Freedom of Information Act. That provision, however, says nothing about—and certainly does not contradict—the provision allowing judicial review by "any person adversely affected." Nor does FDA address the numerous provisions that show beyond doubt that the TCA regulates and protects retailers. *See supra* pp. 12–14.

FDA's other counterarguments fare no better. FDA argues that the Fifth Circuit's decision "nullifies the Act's venue restrictions." Pet. 15. According to FDA, that is because a manufacturer can always find a retailer in a preferred circuit and sue there, rather than in the manufacturer's home circuit or the D.C. Circuit. Even if so, the remedy would lie with Congress; FDA's argument does not authorize courts to ignore the statute's plain text. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018) ("Policy arguments are properly addressed to Congress, not this Court.").

FDA's argument is, in any event, wrong because the fact that a manufacturer and some retailers may join in a single petition does not render the Act's venue restrictions a nullity. Venue must still be established. One petitioner must be located in the relevant circuit unless it is the D.C. Circuit. *See* Order Granting Mot. to Transfer, *Shenzhen Yibo v. FDA*, No. 24-60191 (5th Cir. May 20, 2024) (granting FDA's motion to transfer Shenzhen Yibo's petition to the D.C. Circuit because there was no local retailer).[14] In addition, a manufacturer whose products are only sold in one area of the country cannot file wherever the manufacturer wants because retailers outside that one area would not be able to allege injuries in fact. For example, a Vermont manufacturer that sells its own products (as many vape shops do) and is incorporated and operates only in Vermont cannot file a petition in the

[14] There undoubtedly will be cases where there will not be a retailer who sells or wants to sell the denied product—or at least who is not motivated to pursue litigation.

Fifth Circuit. The venue provision thus operates to limit available forums in that sort of case. But the TCA does not entirely shut out of court adversely affected retailers that wish to petition in their home circuit. Indeed, under FDA's theory, a retailer could *never* challenge a denial order—a position that plainly conflicts with the statutory text.

2. FDA poses an alternative argument, but it, too, misses the mark. FDA argues that *each* petitioner must independently establish venue, so that even if Avail and the Mississippi Association have statutory standing and can establish venue, RJRV (which concededly has statutory standing) may not participate in the case but, instead, must file a separate case in a different court challenging the same denial order. Pet. 12–14. This argument is both forfeited and wrong.

a. As an initial matter, FDA never advanced this argument below. While FDA did object to venue repeatedly in the Fifth Circuit, FDA's argument was that retailers could not sue at all under the TCA, and that without them venue was not proper. FDA did not, however, argue that each petitioner needed to independently establish venue. That argument appeared nowhere in FDA's Motion to Transfer. It appeared nowhere in FDA's Opposition to Respondents' Motion to Stay. And it appeared nowhere in FDA's Petition for Rehearing En Banc of the *Vibe* stay order (or in any other filing). Because this argument "was never presented to any lower court," it is "forfeited." *OBB Personenverkehr AG v. Sachs*, 577 U.S. 27, 37 (2015); *see also Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005) ("[W]e are a court of review, not of first view.").

b. In any event, FDA is wrong. Nothing in the statutory language requires each petitioner to individually establish venue. To the contrary, Congress enacted the TCA's venue provision against a long-standing backdrop of similarly worded venue provisions governing suits against the government, which federal courts have uniformly interpreted to mean that venue needs to be proper for only one petitioner or plaintiff.

The Hobbs Act governs review in the courts of appeals of certain actions by a number of federal agencies. In language that clearly served as a model for the TCA's judicial-review provision, the Hobbs Act provides that venue shall be "in the judicial circuit in which the petitioner resides or has its principal office" (or in the D.C. Circuit). 28 U.S.C. § 2343. Courts have uniformly interpreted this language to mean that, as long as one petitioner resides or has its principal place of business within the circuit, venue is proper for all petitioners. *See, e.g.*, *Global Van Lines, Inc. v. ICC*, 691 F.2d 773, 774 n.1 (5th Cir. 1982); *Atchison, T. & S. F. Ry. Co. v. United States*, 549 F.2d 1186, 1187 n.1 (8th Cir. 1977); *Radio Relay Corp. v. FCC*, 409 F.2d 322, 324 (2d Cir. 1969); *Anglo Canadian Shipping Co. v. United States*, 238 F.2d 18, 20 (9th Cir. 1956); *see also* 16 Charles Alan Wright et al., *Federal Practice and Procedure* § 3941 n.6 (4th ed. 2023) ("When more than one petitioner seeks review of the same order, the venue opportunities may expand considerably.").

Similarly, the general venue statute authorizes suits against the federal government "in any judicial district in which … the plaintiff resides." 28 U.S.C. § 1391(e)(1)(C). For over five decades, federal courts

have uniformly interpreted that provision to mean that venue can be established by *any* plaintiff. *Sidney Coal Co. v. Soc. Sec. Admin.*, 427 F.3d 336, 344–45 (6th Cir. 2005) ("Each court faced with the same issue has interpreted 'the plaintiff' to mean 'any plaintiff,' finding that Congress intended to broaden the number of districts in which suits could be brought against government entities.") (citing cases). The government agrees. *See* U.S. Dep't of Justice, Civil Resource Manual 41 Venue ("Only one of the plaintiffs need reside in the district for venue to be proper under 28 U.S.C. § 1391(e)(3)."), https://tinyurl.com/58msjksk.[15]

The TCA was enacted in 2009 against this legislative backdrop. "When administrative and judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its administrative and judicial interpretations as well." *Bragdon v. Abbott*, 524 U.S. 624, 645 (1998); *see also* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 322 (2012). Thus, Congress did not intend for each petitioner to have to establish venue individually under the TCA. Instead, if venue is proper for any one of the petitioners, then the TCA's venue requirement is satisfied.

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[15] DOJ's Manual appears to have a typo—the correct reference is "28 U.S.C. § 1393(e)(4)," not (e)(3). Nonetheless, the statute was amended in 2011 (after the manual was published), at which point § 1391(e)(4) became § 1391(e)(1)(C). The relevant language remains the same. Federal Courts Jurisdiction and Venue Clarification Act of 2011, Pub. L. No. 112-63, 125 Stat. 758 (eff. Dec. 7, 2011).

This longstanding and uniform interpretation, moreover, makes sense. Otherwise, different petitioners would have to file separate lawsuits in different courts challenging the same agency action. Indeed, in some situations, there could be a petition in every regional circuit and the D.C. Circuit. While those petitions would be assigned to one circuit eventually, *see* 28 U.S.C. § 2112(a), there is no reason to *force* litigants and the court system to engage in this meaningless kabuki dance. When parties coordinate and file a single petition, it saves everyone time and resources (including FDA, which will only have to respond to one petition). *See Exxon Corp. v. FTC*, 588 F.2d 895, 898–99 (3d Cir. 1978) ("[R]equiring every plaintiff in an action against the federal government or an agent thereof to independently meet section 1391(e)'s standards would result in an unnecessary multiplicity of litigation. The language of the statute itself mandates no such narrow construction. There is no requirement that all plaintiffs reside in the forum district."), *overruled on other grounds*, *Reifer v. Westport Ins. Corp.*, 751 F.3d 129 (3d Cir. 2014); *see also Sidney Coal*, 427 F.3d at 345 (collecting cases); *Quarles v. Gen'l Inv. & Dev. Co.*, 260 F. Supp. 2d 1, 12 (D.D.C. 2003) (citing *Exxon* and finding that section 1391 contains "a far less restrictive requirement" than other venue statutes given the problems inherent in suing government entities); *Ry. Labor Execs.' Ass'n v. Interstate Commerce Comm'n*, 958 F.2d 252, 256 (9th Cir. 1991) (citing *Exxon* with approval as to avoiding "multiplicity of similar suits in different courts").

Likewise, the longstanding interpretation makes sense when one considers the statutorily enumerated scope of relief when a denial order is challenged. The statute expressly contemplates that an improper denial order will be "set[ ] aside." 21 U.S.C. § 387*l*(c). So even if the manufacturer and retailer were to file separate petitions to have a denial order set aside, the end result (if either prevails) would be the same. As such, there is no sensible reason to force the manufacturer and retailer to sue in different forums.

Conversely, FDA's interpretation does not make sense because it would not even solve the problem that FDA purports to identify. A retailer, for example, could challenge a denial order for a product that it sells in its home circuit within ten days of the denial order. Then, after those ten days but before expiration of the thirty-day statute of limitations, a manufacturer could challenge the same denial order in its home circuit. The result: both petitions would be consolidated in the court in which *the retailer* filed, *see* 28 U.S.C. § 2112, thus (i) landing the case where FDA (erroneously) claims it does not belong, and (ii) multiplying the work of the appellate courts.

Because nothing in the Act requires each petitioner challenging a denial order to independently establish venue, the Fifth Circuit's decision was correct. *See Alto* C.A. Amended Order (Feb. 2, 2024).

c. Attempting to support its (forfeited) venue-as-to-each-petitioner argument, FDA relies on two, century-old cases interpreting irrelevant statutes. *See Smith v. Lyon*, 133 U.S. 315 (1890); *Camp v. Gress*, 250 U.S. 308 (1919). Neither case helps FDA.

In both cases, the statute provided, "[W]here the jurisdiction is founded only on the fact that the action is between citizens of different states, suit shall be brought only in the district of the residence of either the plaintiff or the defendant." *Smith*, 133 U.S. at 317; *Camp*, 250 U.S. at 310. In *Smith*, two plaintiffs, one from Arkansas and one from Missouri, sued a Texan. The Court held that venue under the diversity-jurisdiction provision was lacking because the two plaintiffs were not from the same state. *See id.* (holding that the statute "makes no provision in terms for the case of two defendants or two plaintiffs who are citizens of different states"). In so holding, the *Smith* Court looked to Chief Justice Marshall's opinion in *Strawbridge v. Curtiss*, which established the complete diversity rule—for diversity jurisdiction, no plaintiff can be from the same state as any defendant. 3 Cranch 267 (1806). Whatever the wisdom of that rule and Chief Justice Marshall's interpretation of the venue provision,[16] the Court consistently applied it when interpreting that venue statute governing diversity jurisdiction; because Congress (in 1890) had not legislatively changed the relevant language interpreted by *Strawbridge*, the *Smith* Court reasoned that Congress accepted the Court's interpretation. Forty years later, *Camp* followed *Smith* and applied the same rule for defendants in diversity cases—they all had to be from the same state. *Camp*, 250 U.S. at 310.

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[16] *Strawbridge* was doubted by even the Great Chief Justice himself. *See Louisville C. & C.R Co. v. Letson*, 43 U.S. 497, 555–56 (1844) (Wayne, J.) ("[b]y no one was the correctness of [*Strawbridge* and its progeny] more questioned than by the late chief justice who gave them").

*Smith* and *Camp* are plainly irrelevant here.

First, *Smith* and *Camp* dealt with a restrictive provision that is no longer on the books. *See Smith*, 133 U.S. at 319 (noting that "the purpose of the legislature [was] to restrict rather than to enlarge the jurisdiction of the circuit courts"). Indeed, "much has changed since the Court's ruling in *Smith*." *Sidney Coal Co. v. Massanari*, 221 F. Supp. 2d 755, 764 (E.D. Ky. 2002).

"[W]hen *Smith* was decided, … the venue statute in effect today did not exist." *Zumft v. Doney Slate Co.*, 698 F. Supp. 444, 446 (E.D.N.Y. 1988). "In 1966, to cure the problem created where the residences of co-plaintiffs or co-defendants made the proper laying of venue impossible, a venue statute providing for commencement of an action in the district where the claim arose was passed." *Id.* (citing *Brunette Machine Works, Ltd. v. Kockum Industries, Inc.*, 406 U.S. 706, 710 n.8 (1972)). Under that new statute, "dismissal is not necessarily required where venue cannot be premised on the parties' citizenship." *Id.* In other words, diversity cases can now be heard where the claim arose—thus negating the need to look at parties' residences altogether in some cases. Moreover, "the statute at issue in *Smith* was superceded in 1966 by Congress's enactment of 28 U.S.C. § 1406, which provided district courts some flexibility when making a venue determination." *Sidney Coal*, 427 F.3d at 345 n.12. Specifically, § 1406 "gives district courts discretion to either dismiss an improperly venued case or 'if it be in the interest of justice' to transfer such case to any district or division in which the case could have been commenced." *Zumft*, 698 F. Supp. at 446. In other

words, even when it comes to diversity cases now, *Smith* has limited application given these intervening legislative changes.[17]

Second, and more importantly, *Smith* and *Camp* dealt with venue in *diversity* cases—not cases against the *federal government*. When it came to suits against federal officials, there is a long and unbroken history establishing that today only one plaintiff needs to establish venue. Before 1962, "the law on the proper place of suit for actions against federal officers and agencies was quite unsatisfactory." Wright & Miller, *supra*, § 3815. Essentially, most plaintiffs had to sue in the District of Columbia. *Id.* To cure this "evil" as some put it, *Natural Resources Defense Council, Inc. v. TVA*, 459 F.2d 255, 257 (2d Cir. 1972), Congress added 28 U.S.C. § 1391(e), which was intended "to broaden the venue of civil actions which could previously have been brought only in the District of Columbia." *Schlanger v. Seamans*, 401 U.S. 487, 489 (1971); *Sidney Coal*, 427 F.3d at 344–45 & n.12; *see* Wright & Miller, *supra*, § 3815. In particular, the new statute allowed the plaintiff to sue where "the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1)(C). As court after court concluded, "interpreting the phrase 'the plaintiff' to mean 'all plaintiffs' or 'each plaintiff'

[17] Even before *Smith*, this Court recognized that "[i]t is not denied that under the constitutional provision as to the judicial power, Congress might, if they had thought proper, have given to the Circuit Courts jurisdiction of all cases between citizens of one or more states on one side, and citizens of one or more other states on the other side." *Louisville, C. & C.R. Co.*, 43 U.S. at 500–01.

would substantially limit the statute's breadth and undermine congressional intent." *Sidney Coal*, 427 F.3d at 344 (collecting cases). "Each court faced with the same issue has interpreted 'the plaintiff' to mean 'any plaintiff,' finding that Congress intended to broaden the number of districts in which suits could be brought against government entities." *Id.* at 344–45. "Thus, *Smith* has no bearing on this Court's interpretation of" venue provisions governing actions against the federal government. *Id.* at 345 n.12.

Third, the statutory language at issue in *Smith* and *Camp* is different from the TCA's venue provision. The provision in *Smith* and *Camp* said, "suit shall be brought *only* in the district of the residence of *either* the plaintiff or the defendant." *Smith*, 133 U.S. at 317 (emphasis added). But there is no similarly restrictive language in the TCA's venue provision. It allows "*any* adversely affected person" to sue in the circuit "in which such person resides or has their principal place of business." 21 U.S.C. § 387*l*(a)(1). Thus, *Smith* and *Camp* have no application here.

FDA also looks for support in secondary sources to argue that "[the Supreme] Court long ago held that venue must be proper as to each party." Pet. 13 (quoting 14D Charles Alan Wright et al., *Federal Practice and Procedure* § 3807 (4th ed. 2023)). But if the Agency read on, it would find that Wright & Miller addresses *this* situation—civil actions against federal agencies—and explains, as detailed above, that "[i]n cases involving multiple plaintiffs, venue is proper where *any one of them resides*." Wright & Miller, *supra*, at § 3815 (emphasis added). In short, FDA is without support for its position.

* * *

This Court has long observed that it is the "'plaintiff's venue privilege,'" *not* the defendant's—and certainly not the federal government's, with its national omnipresence. *Atl. Marine Constr. Co. v. U.S. Dist. Ct. W. Dist. Tex.*, 571 U.S. 49, 63 (2013) (quoting *Van Dusen v. Barrack*, 376 U.S. 612, 635 (1964)). Nothing about the TCA's venue provision displaces that settled privilege. It neither prohibits retailers from seeking relief in their home circuits to vindicate their own interests independent of a manufacturer nor prohibits a manufacturer from joining retailers in their properly filed petitions.

Respondent Avail was formed and has its principal place of business in Texas, and Respondent Mississippi Association is incorporated and has its principal place of business in Mississippi. FDA does not dispute those facts. Thus, the Fifth Circuit was correct to hold that venue is proper in that circuit. *See* 21 U.S.C. § 387*l*(a)(1).

## II. THERE IS NO CIRCUIT SPLIT AND THE ALLEGED "EFFECTS" ARE INCREASINGLY RARE.

The Fifth Circuit's decision is not only correct, but there is also no circuit conflict over either of the issues presented by this case. Pet. 17. Moreover, the "effects" that FDA laments are overblown because the Agency can only identify three petitions out of dozens in the almost year and a half since the *Vibe* decision that it contends "belong elsewhere." Pet. 16–17; *see generally* FDA, *Tobacco Products Marketing Orders*, Marketing Denial Orders (MDO),

https://tinyurl.com/3jnp9f52 (last updated Jun. 6, 2024).

1. FDA admits that "the Fifth Circuit's decision does not create a circuit conflict about the meaning of the TCA's venue provision." *Id.* The Fifth Circuit is the first and only circuit court to have analyzed whether a retailer has statutory standing to invoke the TCA's judicial-review provision and, as explained above, its analysis falls squarely within this Court's established precedent. *See supra* pp. 7–9. Indeed, as explained, it accords with the uniform decisions of the federal courts in related contexts. *See supra* pp. 16–20.

Nevertheless, FDA attempts to manufacture a "conflict" as to its (forfeited) alternative argument that each petitioner must establish venue independently. Pet. 14. In so doing, FDA invokes a single case, *Amerada Petroleum Corp. v. Federal Power Commission*, 338 F.2d 808 (10th Cir. 1964), which was decided forty-five years before the TCA was even enacted. FDA claims that *Amerada Petroleum* held that "out-of-circuit companies could not join a local company to seek review in that circuit." Pet. 14. That is wrong. In *Amerada Petroleum*, the Court was faced with "*separate* applications [to the federal agency] of natural-gas companies," only one of which was located in the Tenth Circuit. *Id.* at 810 (emphasis added). Because the statute clearly contemplated a separate "order relating to [each] particular natural-gas company," each company needed to bring its own suit over each order, and thus independently satisfy venue. *See id.* Here, by contrast, all Respondents are "adversely affected" by FDA's *single* order on *one* application. 21

U.S.C. § 387*l*(a)(1); *see supra* pp. 9–14. And so the general rule that only one plaintiff needs to have venue applies. *See supra* pp. 16–20.

2. The purported "effects" of the Fifth Circuit's decision are also no reason for this Court to step in. Pet. 16.

For all of FDA's hand-wringing about "[o]ther out-of-circuit manufacturers … using the same tactic to obtain judicial review of FDA orders in the Fifth Circuit," one would expect many more petitions like this one. *Id.* It has been almost a year and a half since the Fifth Circuit held that "venue is proper in this circuit," *Vibe*, 65 F.4th at 188, and FDA can only identify three petitions out of dozens filed since then that it claims "belong elsewhere." Pet. 17; *see generally* FDA, *Tobacco Products Marketing Orders*, Marketing Denial Orders (MDO), https://tinyurl.com/3jnp9f52 (last updated Jun. 6, 2024).[18]

Moreover, while FDA has issued hundreds of thousands of denial orders, *see Vibe*, 65 F.4th at 192 ("[FDA] has denied over 355,000 such applications."), FDA had made "determinations on more than 99%

[18] FDA identifies three petitions for judicial review it claims "belong elsewhere." Pet. 16–17. There now appear to be three more petitions for judicial review in the Fifth Circuit with a retailer establishing venue. *See NicQuid LLC v. FDA*, No. 24-60272 (5th Cir. Jun. 3, 2024); *Breeze Smoke, LLC v. FDA*, No. 24-60304 (5th Cir. Jun. 12, 2024); *Vertigo Vapor v. FDA*, No. 24-60332 (5th Cir. Jun. 28, 2024). At best then, FDA can point to only *six* petitions for judicial review (other than the Vuse petitions) out of hundreds of thousands of denial orders.

of" applications filed by the time *Vibe* was decided.[19] And, under the statute, petitions must be filed thirty days after a denial order. *See* 21 U.S.C. § 387l(a). Thus, there will not—indeed, cannot—be an onslaught of petitions filed in the Fifth Circuit. While it is true that new tobacco products must seek authorization, FDA's onerous requirements for marketing authorization have made it such that few manufacturers can even attempt to comply. Put another way, fewer applications will mean fewer petitions for judicial review.

Equally misplaced are FDA's claims about the Fifth Circuit's decision "contribut[ing] to a 'youth vaping epidemic.'" Pet. 18 (quoting *Avail Vapor, LLC v. FDA*, 55 F.4th 409, 426 (4th Cir. 2022), *cert. denied*, 144 S. Ct. 277 (2023)). As an initial matter, the Fifth Circuit's decision simply relates to which court may decide the case; it does not dictate the correct substantive result in any case, let alone contribute to an epidemic. Moreover, youth use has dropped by more than 25% since 2022.[20] And Vuse, while the leading e-cigarette among adults, is not popular among youth, ranking behind brands like Elf Bar (three times more popular among youth than Vuse) and Esco Bars, and continues to decline.[21]

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[19] FDA, *FDA Makes Determinations On More Than 99% of the 26 Million Tobacco Products For Which Applications Were Submitted* (Mar. 15, 2023), https://tinyurl.com/yxcf2dfm.

[20] FDA, *National Survey Shows Drop in E-Cigarette Use Among High School Students* (Nov. 2, 2023), https://tinyurl.com/3nn4tvar.

[21] *See* Jan Birdsey, et al., *Tobacco Product Use Among U.S. Middle and High School Students—National Youth Tobacco Survey, 2023*, 72 MMWR 1173 (Nov. 2023).

Indeed, only 1.5% of middle and high school students reported using any Vuse product last year.[22] FDA cannot credibly claim that the Fifth Circuit's decision is contributing to any supposed youth vaping epidemic.

### III. THIS PETITION IS A POOR VEHICLE.

Even if the question presented were otherwise worthy of this Court's attention, this petition would be an exceedingly poor vehicle for answering it. First, the specific interlocutory posture of this case is highly irregular, requiring this Court to become the first appellate court to review a procedural order (because the case was originally filed in the court of appeals) and the first court to review the second (forfeited) question. Second, even if FDA were to prevail on the venue issue in this Court, the case would not be over.

1. The interlocutory posture of this case makes the petition highly irregular. The general rule is that a district court's order denying a motion to dismiss or transfer on venue grounds is *not* immediately appealable. *See, e.g.*, *Lauro Lines s.r.l. v. Chasser*, 490 U.S. 495, 498 (1989) (venue); *Van Cauwenberghe v. Biard*, 486 U.S. 517, 519 (1988) (*forum non conveniens*). And while a different statute governs certiorari before judgment in cases pending at the court of appeals, 28 U.S.C. § 1254(1), the government cites no on-point case in which this Court has ever granted review of an interlocutory venue decision in this procedural posture.

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[22] Birdsey, et al., *supra*.

Instead, the government points to four other cases that it says support review of the interlocutory decision below. But each of these cases is distinguishable.

*TC Heartland*, *Walden*, and *Atlantic Marine* all involved cases where the court of appeals had entered a final order or judgment for purposes of the appeal before it. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. 258, 263 (2017) (mandamus); *Walden v. Fiore*, 571 U.S. 277, 291 (2014) (judgment); *Atlantic Marine*, 571 U.S. at 54 (mandamus). This case is a far cry from those, as the Fifth Circuit's decision below merely entered an interlocutory order denying a motion to dismiss or transfer in a case filed in the court of appeals in the first instance.

The closest the government comes is *Mercantile National Bank v. Langdeau*. But that case analyzed a prior version of 28 U.S.C. § 1257, which lays out a separate standard for certiorari review of final judgments from *state courts*. The Court held in that particular case that § 1257 was satisfied because a state supreme court had issued a final order on venue, the only federal issue in the case—and petitioner had made a "substantial claim" that a "federal statute" "prohibit[ed] further proceedings against the defendants in the state court in which the suit is now pending." 371 U.S. 555, 558 (1963). In other words, the venue decision meant that the only federal question had been addressed and it was thus sufficiently final for purposes of federal review. Here, however, this case remains pending in the Fifth Circuit and has not proceeded to final judgment. Pet. 19 (conceding that "no final judgment on the merits

has been entered"). Unlike in *Mercantile*, there are a litany of other federal issues that will be pressed and passed upon before final judgment, meaning that this cannot be characterized as a final federal judgment. *Cf. Lauro Lines*, 490 U.S. at 501 (concluding that plaintiff's interlocutory appeal to enforce a forum-selection clause "does not fall within … the collateral order doctrine").

As to the second question, FDA's petition is even more irregular. As noted above, FDA has forfeited this issue; the Agency never presented its argument before the Fifth Circuit. *See supra* p. 16; *Sachs*, 577 U.S. at 37. Because the Fifth Circuit did not have the chance to pass upon the question, this Court would effectively be stepping in as the court of first review. FDA cites no case where this Court has granted review under such circumstances.

2. The Fifth Circuit's decision does not finally resolve this case. As even FDA concedes, the Fifth Circuit has not decided the merits or rendered final judgment. According to Rule 11, then, review is presumptively inappropriate. *See* Sup. Ct. R. 11. Yet the government does not explain why the interlocutory order addressing venue "is of such imperative public importance as to require immediate determination in this Court." *Id.* (citing 28 U.S.C. § 2101(e)). That is particularly notable because FDA has already resolved 99% of applications filed by September 9, 2020, and the time to challenge such denials has long since run. *See supra* at p. 26. The universe of cases in which this issue can now arise is therefore tiny, and if it is as important as FDA claims, can be resolved after final judgment.

In addition, even if this Court concluded that retailers lack statutory standing, FDA would not be entitled to the result it seeks—transfer or dismissal. Venue is not lost even if the party whose presence was necessary for venue is dismissed from the case. *See, e.g.*, *Exxon*, 588 F.2d at 899; *Horihan v. Hartford Ins. Co.*, 979 F. Supp. 1073, 1076 (E.D. Tex. 1997). The exception is where a party's claims are frivolous or joinder is fraudulent. *See* Wright & Miller, *supra*, at § 3815 n.40 (collecting cases). FDA does not contend either here. *Cf. B, Inc. v. Miller Brewing Co.*, 663 F.2d 545, 549 (5th Cir. 1981); *Honey Holdings I, Ltd. v. Alfred L. Wolff, Inc.*, 81 F. Supp. 3d 543, 558 n.16 (S.D. Tex. 2015). Nor could it, especially since the Fifth Circuit has upheld retailers' rights to assert the claims at issue.

Further, if FDA were to prevail on its alternative argument (that each party must establish venue), the case would still continue.[23] At best for FDA, RJRV and RJR Vapor Co. would be dismissed from the case. But that would not affect the retailers' case. And if the retailers are successful, the denial order will be vacated, regardless of whether the manufacturers are parties.

In short, even if FDA were to prevail in this Court, the case would neither be dismissed nor transferred.

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[23] This Court has granted review in *FDA v. Wages & White Lion*, No. 23-1038, which raises many of the same merits issues as Respondents' case. But granting *Wages* does not change anything about FDA's petition for certiorari in this case, which should plainly be denied for the reasons state above.

## CONCLUSION

The petition for a writ of certiorari should be denied.

July 3, 2024

Respectfully submitted,

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