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 Writ Of Certiorari
To The United States Court Of Appeals
For The Fifth Circuit

BRIEF FOR RESPONDENTS

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QUESTIONS PRESENTED

Respondents manufacture and sell Vuse e-cigarettes, which have been on the market for more than eight years. The Family Smoking Prevention and Tobacco Control Act 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 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 certain Vuse Alto e-cigarettes, and four entities, including the applicant and retailers of the product, jointly 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—FDA's denial 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 qualifies as "any person adversely affected" under the Tobacco Control Act, such that it may file a petition for judicial review of the denial 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, 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.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

CONSTITUTION, STATUTES, AND RULES

REGULATORY MATERIALS

OTHER AUTHORITIES

ORDER BELOW

The court of appeals' order (Pet. App. 1a–8a) is unreported.

JURISDICTION

This Court lacks jurisdiction, as Part I explains.

STATUTORY PROVISIONS INVOLVED

The pertinent statutory provisions are reprinted in Petitioners' Brief Appendix (1a–15a).

INTRODUCTION

E-cigarettes are critical to public health because they offer cigarette smokers a potentially less risky product. Nonetheless, e-cigarettes need FDA authorization. When FDA denies authorization, the Tobacco Control Act allows "any person adversely affected" to 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).

FDA denied marketing authorization for menthol Vuse e-cigarettes. As a result, the products could not be sold. Indeed, FDA threatened retailers with enforcement action, which can include criminal penalties, if they did not immediately remove the products from their shelves.

Four entities—Avail Vapor Texas, L.L.C. ("Avail Texas"), Mississippi Petroleum Marketers and Convenience Stores Association ("Mississippi Retailers"), R.J. Reynolds Vapor Co. ("RJRV"), and RJR Vapor Company, L.L.C. ("RJR Vapor Co.")—jointly petitioned for review of each denial. The Fifth Circuit stayed FDA's orders as to currently marketed products.

Avail Texas and members of Mississippi Retailers sell menthol Vuse e-cigarettes and were among the retailers threatened with FDA enforcement after FDA denied marketing authorization. These entities would lose significant revenue if not allowed to sell Vuse e-cigarettes, with Avail Texas likely forced to "cease its business operations." They petitioned for review in the Fifth Circuit because both Avail Texas and Mississippi Retailers were formed and have their principal places of business in the circuit.

Despite the undisputed financial harm facing these petitioners—and despite FDA's enforcement threats—FDA contends that retailers are not "adversely affected" under the TCA. The Fifth Circuit rejected that argument, denying FDA's repeated requests to dismiss or transfer the petitions. Undeterred—though without a final judgment—FDA petitioned for certiorari, adding an argument never raised below.

The Court should dismiss the certiorari petition or affirm the order below.

To start, this Court lacks jurisdiction. FDA invokes the certiorari statute, but that statute does not allow this Court to review interlocutory orders in a case that originated in a court of appeals. Granting certiorari before judgment entails stepping into the Fifth Circuit's shoes and reviewing the "case," 28 U.S.C. § 1254(1)—but in this posture, that means reviewing FDA's denial, which would be *original* jurisdiction that the Constitution does not confer on this Court for this type of case.

If the Court reaches the merits, it should affirm the order below. FDA's first argument is that "any person

adversely affected" encompasses only applicants and thus excludes retailers. Basic rules of statutory interpretation and this Court's zone-of-interests test, however, show that retailers easily qualify as "any person[s] adversely affected." Indeed, the TCA specifically distinguishes between applicants and "any person adversely affected"—yet FDA's interpretation would drain that distinction of meaning. And once the phrase "any person adversely affected" is interpreted to extend to at least one person beyond the applicant itself, it obviously covers retailers, who, next to the applicant, are the "person[s]" *most* "adversely affected."

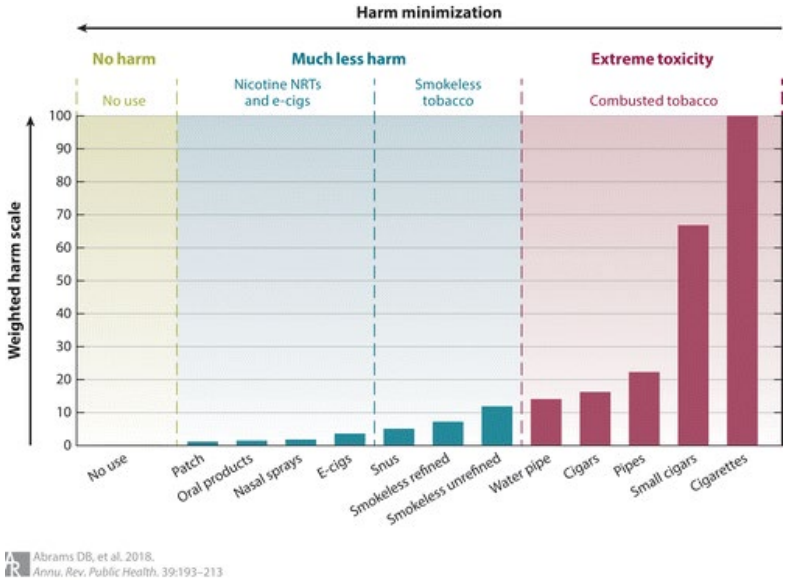
FDA next claims that each party challenging a denial must independently satisfy venue. Because FDA did not present this argument below, this Court should not reach it. In any event, FDA's position would upend decades of precedent, which has uniformly interpreted near-identical statutes (including the Hobbs Act and the general venue statute) as requiring only one party to establish venue in cases against the government. Congress adopted the TCA's review provision against that backdrop. And it is well-established that when "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 … judicial interpretations as well." *Bragdon v. Abbott*, 524 U.S. 624, 645 (1998).

STATEMENT

A. E-Cigarettes

E-cigarettes are critical to tobacco-harm reduction.

The Director of FDA's Center for Tobacco Products has said that "tobacco products exist on a continuum of risk."[1] Relative to cigarettes, e-cigarettes are far down on that continuum[2]:



As then-FDA Commissioner Gottlieb explained, "If you could take every adult smoker … and fully switch them to e-cigarettes, that would have a substantial public health impact."[3]

B. FDA's Quagmire

In 2009, Congress enacted the Tobacco Control Act both to regulate the tobacco industry and to

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

[2] David Abrams, *et al.*, *Harm Minimization and Tobacco Control*, 39 Annual Rev. of Pub. H. 193, 194 (2018).

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

"encourage the development of innovative products" that could reduce the "harm associated with continued tobacco use." 21 U.S.C. § 387r(b)(1). The Act requires new tobacco products to obtain premarket authorization before they can be sold. *Id.* § 387j. If the applicant meets the statutory criteria, then FDA "shall … issue an order" allowing the product "into interstate commerce." *Id.* § 387j(c)(1)(A)(i). Initially, however, the Act covered only certain tobacco products (principally combustible cigarettes). *See id.* § 387a(b).

In 2016, FDA exercised its authority to "deem" other tobacco products, including e-cigarettes, subject to the Act's requirements. *Id.*; *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1134 (5th Cir. 2021) (stay op.). But by that time, "manufacturers were widely marketing"—and retailers were widely selling—e-cigarettes. *Wages*, 16 F.4th at 1134. FDA's action thus created a dilemma. Its action in theory required the removal of e-cigarettes from the market. But FDA also recognized that such removal would harm the public health, since e-cigarettes "potentially help some adult users who are attempting to transition away from combusted products." 81 Fed. Reg. 28,973, 28,977 (May 10, 2016).

To solve this conundrum, FDA established an enforcement-discretion policy to allow certain e-cigarettes (including menthol-flavored cartridge e-cigarettes) to remain on the market as long as they were subject to a timely filed application that had not yet been denied. *Id.* at 29,001. FDA eventually set the application deadline for September 9, 2020.

C. Vuse Alto

RJRV manufactures and markets tobacco- and menthol-flavored Vuse-brand e-cigarettes. There are four lines of Vuse-branded e-cigarettes: Alto, Solo, Ciro, and Vibe. *See* C.A. Stay Mot. A20, No. 23-60545 (5th Cir. Oct. 20, 2023) ("*Alto*"). Vuse is the market-leading e-cigarette brand among adults, and Alto is the most popular Vuse product. *Id.* at A4 ("Mras Declaration").

Avail Texas and some members of Mississippi Retailers are retailers that sell menthol-flavored Vuse Alto. Avail Texas principally sells Vuse products and, "if Avail were not allowed to sell Vuse products, … Avail would cease its business operations." *See Alto* C.A. Amended Order 4 (Feb. 2, 2024). Mississippi Retailers has members "who own and/or operate" convenience stores in Mississippi, and some members sell and derive revenue from sales of menthol-flavored Vuse Alto. *See Alto* C.A. Stay Mot. A15–16 (Oct. 20, 2023) ("Chamblee Declaration").

RJRV manufactures Vuse Alto and is incorporated and headquartered in North Carolina. *See R.J. Reynolds Vapor Co., Bus. Corp. Ann. Rep., 2022*, at 1 (Jan. 30, 2023).[4]

It is "undisputed" that Avail Texas was formed and has its principal place of business in Texas. Pet.App.5a. It is likewise undisputed that Mississippi Retailers is incorporated and has its principal place of business in Mississippi. *Id.*; *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 188 n.5 (5th Cir. 2023) ("*Vibe*").

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[4] RJR Vapor Co. is an online retailer that sold, and may again sell, Vuse Alto. Mras Declaration A3.

RJRV submitted timely applications for its Vuse products. *Alto* C.A. Stay Mot. A21 (Oct. 20, 2023) ("Junker Declaration"). In a series of orders, FDA denied marketing authorization for all menthol Vuse e-cigarettes, including the Alto products at issue here.[5]

In announcing its denials, FDA made clear the impact on retailers. Announcing its denial of menthol Vibe, FDA said it "intends to ensure compliance by distributors and *retailers*."[6] Similarly, FDA said of Alto, "If the product is already on the market, it must be removed from the market or risk FDA enforcement."[7]

D. Procedural History

The TCA's judicial-review provision provides that "any person adversely affected" by FDA's denial 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). Thus, Avail Texas, Mississippi Retailers, RJRV, and RJR Vapor Co. jointly petitioned for review of each of the denials in the Fifth Circuit, where Avail Texas and Mississippi Retailers were formed and have their principal places of business. *See* C.A. Pet.

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[5] FDA also denied authorization for mixed-berry Vuse Alto. That product is not currently on the market, consistent with FDA's prior guidance. Mras Declaration A3.

[6] *E.g.*, FDA, *FDA Denies Marketing of Two Vuse Menthol E-cigarettes Products* (Jan. 24, 2023) ("*FDA Denies Vibe*"), https://tinyurl.com/4ck9644b (emphasis added).

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

for Rev., No. 23-60037 (5th Cir. Jan. 24, 2023) ("V*ibe*"); 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 those actions and stayed FDA's orders as to currently marketed Vuse products. *Vibe* C.A. Consolidation Order (Mar. 22, 2023); *Alto* C.A. Consolidation Order (Oct. 19, 2023); *Vibe*, 65 F.4th 182; *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 the merits because FDA's denials were arbitrary and FDA "instituted a *de facto* ban on non-tobacco-flavored e-cigarettes without going through notice-and-comment." *Vibe*, 65 F.4th at 194.

The Fifth Circuit also rejected each objection that FDA raised to venue and statutory standing. FDA first raised venue and standing objections when it opposed the stay motion in *Vibe*. *See Vibe* C.A. Opp'n to Stay Mot. 10 (Feb. 15, 2023). FDA claimed that Avail Texas and Mississippi Retailers "have not sufficiently alleged standing," and expressed "concerns about jurisdiction and venue." *Id.* The Fifth Circuit rejected FDA's concerns, holding that "venue is proper because [Mississippi Retailers] has its 'principal place of business' here," and that "Article III's case-or-controversy requirement is satisfied" because RJRV "has standing." *Vibe*, 65 F.4th at 188 & n.5. FDA then moved to transfer the *Vibe* and *Solo* cases to the D.C. Circuit on the ground that retailers were not "adversely affected" by the denials and therefore could not provide the basis for venue. *See Vibe* C.A. Mot. to Transfer 8 (June 15, 2023). The Fifth Circuit summarily denied that motion. *Vibe* C.A. Order (June 27, 2023).

FDA then moved to dismiss or transfer the *Alto* petition, once more arguing that "[t]he TCA does not give retailers a right … to obtain judicial review." *Alto* C.A. Mot. to Dismiss or Transfer 3, 8–10 (Oct. 18, 2023). Over Judge Higginson's dissent, the court denied FDA's motion. Although the court was bound by the *Vibe* decision, the court also held, "All the Petitioners are 'persons adversely affected' under the Act, and two of the Petitioners, Avail Vapor Texas and [Mississippi Retailers], have their principal places of business here in the Fifth Circuit." Pet.App.3a. Finally, the Fifth Circuit denied FDA's petition for rehearing en banc of the *Vibe* stay order, where FDA again raised its venue objection. *Vibe* C.A. Order (Feb. 6, 2024). Notably, FDA argued throughout that the retailers lacked statutory standing; that, as a result, they could not provide the basis for venue; and that, without the retailers, RJRV could not alone establish venue. But nowhere in its four challenges did FDA argue that *each petitioner* must *independently* satisfy venue.

This Court granted interlocutory review of the Fifth Circuit order denying FDA's motion to dismiss or transfer the *Alto* petition.

SUMMARY OF ARGUMENT

I. This Court lacks jurisdiction. The certiorari statute does not allow this Court to review interlocutory orders in a case that originated in a court of appeals (rather than a district court). Granting certiorari before judgment entails stepping into the Fifth Circuit's shoes and reviewing the "case" before it. 28 U.S.C. § 1254(1). Here, that would mean reviewing FDA's denial, which would be an exercise of

original jurisdiction—jurisdiction that the Constitution does not confer on this Court for this type of case.

II. Retailers can file a petition for judicial review. The TCA 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). This Court's zone-of-interests test and basic rules of statutory interpretation show that the Fifth Circuit correctly concluded that retailers qualify as "any person[s] adversely affected." *Id.* The TCA's review provision incorporates the APA's review provision verbatim, explicitly references the APA, and governs challenges to agency action, meaning the APA's lenient approach—whereby a person factually harmed by agency action falls within the statutory zone of interests when their interests are "arguably" related to the statute—applies. *Bank of Am. v. City of Miami*, 581 U.S. 189, 200–01 (2015). The TCA review provision governs what products may be *sold*, and the retailers are market participants undisputedly harmed by FDA's denial, which bars them from selling the product. And by allowing "any person adversely affected" to sue—in contrast to a different TCA judicial-review provision allowing only applicants to sue—the judicial-review provision here is meant to extend to *at least* one person beyond the applicant itself, and the retailers are next in line. Thus, the statutory text, this Court's precedent, and common sense all compel the conclusion that retailers are

"adversely affected" and "may file a petition for judicial review of [the] denial." 21 U.S.C. § 387*l*.

III. By not raising it below, FDA forfeited its alternative argument that each petitioner must independently establish venue. FDA is wrong anyway. Congress enacted the TCA's venue provision against a decades-long, uniform judicial interpretation holding that in cases challenging federal action, only one challenger need establish venue. When circuit courts have "'given a uniform interpretation'" to a statute, then "'a later version of that act perpetuating the wording is presumed to carry forward that interpretation.'" *Texas Dep't of Hous. & Cmty. Affs. v. Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 536–37 (2015) (quoting Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 322 (2012)). Joinder rules support such a reading because venue, like joinder, "goes to process rather than substantive rights." *Am. Dredging Co. v. Miller*, 510 U.S. 443, 453 (1994). Moreover, the longstanding interpretation makes sense because it avoids needless multiplicity of proceedings.

The Court should dismiss the petition or, in the alternative, affirm the order below.

ARGUMENT

I. THIS COURT LACKS JURISDICTION.

This Court lacks jurisdiction to review by certiorari before judgment an interlocutory ruling in a case originating in the court of appeals. At minimum, this jurisdictional question is sufficiently complicated and rare that discretionary review is not warranted in this interlocutory posture. This Court should therefore

dismiss the petition either for want of jurisdiction or as improvidently granted.

1. The Constitution gives this Court original jurisdiction over a small set of cases and appellate jurisdiction over other cases only "under such Regulations as the Congress shall make." U.S. Const. Art. III, § 2. This Court indisputably lacks original jurisdiction here because this case is not between states and does not involve ambassadors, ministers, or consuls. *See Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 152 (1803); *Ortiz v. United States*, 585 U.S. 427, 435 (2018). Nor has Congress authorized this Court to exercise appellate jurisdiction over the Fifth Circuit's interlocutory ruling in the posture of this case.

FDA (at 1) relies solely on the certiorari statute, which provides that "*[c]ases* in the courts of appeals may be reviewed … [b]y writ of certiorari granted … before or after rendition of judgment or decree." 28 U.S.C. § 1254(1) (emphasis added). The statute thus authorizes review of the entire "case[ ]," not particular pre-judgment rulings. *Id.* And review here is "before" rendition of judgment or decree because the Fifth Circuit has not rendered a "judgment or decree." It is undisputed that there is no "judgment." And the Fifth Circuit's order also was not a "decree" because a "decree" in this context is "similar to a judgment." *Decree*, Black's Law Dictionary (12th ed. 2024); *see Am. Constr. Co. v. Jacksonville, Tampa & Key W. Ry. Co.*, 148 U.S. 372, 378–79 (1893) ("No appeal, therefore, lay to this court from an … interlocutory order, until after final decree."). Indeed, venue rulings are not "final decisions" even under the collateral-order doctrine. *See, e.g.*, *Lauro Lines s.r.l. v. Chasser*, 490 U.S. 495, 501 (1989).

When, unlike here, a court of appeals issues a *final* judgment or decree, the statute authorizes the Court to exercise appellate jurisdiction over the case. *See, e.g.*, *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. 258 (2017). But, when "this Court grant[s] certiorari before judgment, [it] effectively stand[s] in the shoes of the Court of Appeals." *Whole Women's Health v. Jackson*, 595 U.S. 30, 38 (2021) (citing *United States v. Nixon*, 418 U.S. 683 (1974); S. Shapiro, et al., Supreme Court Practice 2-11 (11th ed. 2019)). This means this Court is exercising the same type of jurisdiction (original or appellate) as the court of appeals. This normally presents no constitutional concern, because in most "certiorari before judgment" cases, the court of appeals is exercising appellate review (pursuant to a statute) of district-court judgments or orders. *See, e.g.*, *Whole Women's Health*, 595 U.S. at 38; *Nixon*, 418 U.S. at 690–92; *Hohn v. United States*, 524 U.S. 236, 248–49 (1998); *Dart Cherokee Basin Op. Co. v. Owens*, 574 U.S. 81, 90–91 (2014).

For example, in *Whole Women's Health*, the district court denied motions to dismiss the complaint. The defendants pursued an interlocutory appeal in the Fifth Circuit under the collateral-order doctrine. Under *Cohen v. Beneficial Loan Co.*, 337 U.S. 541 (1949), the Fifth Circuit had appellate jurisdiction to review that order. Before the Fifth Circuit ruled, this Court granted certiorari before judgment. As the Court explained, "[b]ecause this Court granted certiorari before judgment, we effectively stand in the shoes of the Court of Appeals" and exercise appellate jurisdiction. *Whole Women's Health*, 595 U.S. at 38. In other words, this Court effectively *became* the court of

appeals and exercised *that court's* appellate jurisdiction over the district court. *See id.*

This Court took the same approach in *Nixon*, 418 U.S. at 690–92. There, the district court denied a motion to quash a subpoena issued to President Nixon. The President appealed to the D.C. Circuit. In granting certiorari before judgment, this Court concluded that the denial of the motion to quash was an appealable order because it had the hallmarks of finality—that is, it could be appealed to the circuit court. *Id.* at 691. This Court thus took over for the appeals court: "The appeal from that order was therefore properly 'in' the Court of Appeals, and the case is now properly before this Court on the writ of certiorari before judgment." *Id.* at 692.

Conversely, where, as here, a case originates in the Court of Appeals on a petition for review of an agency order, this Court cannot constitutionally "stand in the shoes of the Court of Appeals." That is because, in reviewing the agency's order, the court of appeals is exercising original, not appellate, jurisdiction. *See Ortiz*, 585 U.S. at 448 (reserving on "whether we could exercise appellate jurisdiction over cases from … administrative agencies"); *Verizon Md. Inc. v. Public Serv. Comm'n of Md.*, 535 U.S. 635, 644 & n.3 (2002) ("judicial review of executive action, including determinations made by [an] administrative agency," involves the exercise of federal court's "original jurisdiction" rather than its "appellate jurisdiction"); *see also Marbury*, 5 U.S. (1 Cranch) at 175. Reviewing such a "[c]ase" before judgment, 28 U.S.C. § 1254(1), would therefore mean exercising *original* jurisdiction over the underlying dispute, rather than appellate jurisdiction over a district court's order. *See Wheeler*

Lumber Bridge & Supply Co. v. United States, 281 U.S. 572, 577 (1930) (pre-judgment certification of "the whole cause" from court exercising original jurisdiction would unconstitutionally assume "original … jurisdiction"); *White v. Turk*, 37 U.S. 238, 239 (1838) (same).[8]

Commentators have recognized that exercising certiorari before judgment where the court of appeals is hearing a petition for review of agency action presents a constitutional "issue" because the "case" below "seek[s] review of an administrative ruling," not of any lower court. Shapiro, *supra*, 2-4. The Solicitor General raised the same "serious" jurisdictional issue in opposing certiorari before judgment in challenges to OSHA's COVID-19 vaccination mandate. Resp. to App., at 85–86 (No. 21A244).[9]

This constitutional problem likely explains why this Court has repeatedly declined to grant certiorari before judgment in cases in this posture. *See* Shapiro, *supra*, 2-4 at n.37 (collecting cases). And if this Court ever did review a case in this posture, *see* Shapiro, *supra*, 2-4, it would have been a "drive-by jurisdictional ruling[ ]" with "no precedential effect."

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[8] That is why the Court initially dismissed the certificates in *Wheeler*. *See* James Moore, *Present and Potential Role of Certification in Federal Appellate Procedure*, 35 Va. L. Rev. 1, 34–35 (1949).

[9] This Court did not grant certiorari before judgment, but appropriately exercised jurisdiction over the challengers' stay applications under the All Writs Act and/or 28 U.S.C. § 2101(f). *See NFIB v. Dep't of Labor*, 595 U.S. 109, 120–21 (2022) (per curiam).

Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 91 (1998).

The statute therefore does not permit this Court to grant certiorari here. The certiorari statute provides for review of "cases," not orders, and the writ has always entitled the issuing court to review "the entire case" (even if the Court reviews only certain aspects of the case). Shapiro, *supra*, 2-3 (collecting cases); *see, e.g.*, *Major League Baseball Players Ass'n v. Garvey*, 532 U.S. 504, 508 & n.1 (2001) (per curiam). Indeed, as originally understood, "the extraordinary writ of certiorari" applied only to "cases" in which *some* lower tribunal had made "findings and decisions [that], even though erroneous, had the quality of a final judgment, and there being no right of appeal or other method of review, the [writ] was … necess[ary] to afford a remedy where there would otherwise have been a denial of justice." *Degge v. Hitchcock*, 229 U.S. 162, 170, 172 (1913) (refusing to grant the "writ for the purpose of reviewing an administrative order").[10]

To be clear, Congress *could* give this Court the power to exercise appellate review of an interlocutory order in a case originating in the circuit courts, as it

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[10] This explains *International Union v. Scofield*, 382 U.S. 205 (1965). *Scofield* reviewed by certiorari the denial of a motion to intervene because the purported intervenor "would not have been entitled to file a petition to review a judgment on the merits by the Court of Appeals." *Id.* The intervenor had no other means of redress, making the denial an appealable collateral order (akin to a final decree). *See also Stringfellow v. Concerned Neighbors in Action*, 480 U.S. 370, 377 (1987). But venue rulings are not "final decisions" under the collateral-order doctrine, *see, e.g.*, *Lauro Lines*, 490 U.S. at 501, because nothing prevents FDA from seeking certiorari *after* judgment.

has done in other (inapplicable) circumstances. *See* 28 U.S.C. §§ 1254(2), 1651(a). But Congress has *not* done so in the *certiorari* statute. *See Coleman v. Paccar Inc.*, 424 U.S. 1301, 1303 (1976) (Rehnquist, J., in chambers) (noting that Congress has not enacted a "provision for appeal eo nomine from an interlocutory order of a court of appeals"). Instead, for cases originating in the circuit courts, Congress has only given this Court the authority to review the "case[ ]." So this Court's review of interlocutory orders issued by a court exercising original jurisdiction must await final judgment.

2. FDA notably does not rely on the two statutes that, unlike the certiorari statute, actually authorize this Court to review interlocutory rulings by courts of appeals. Neither applies here.

First, the All Writs Act authorizes this Court to "issue all writs necessary or appropriate in aid of [its] respective jurisdiction[ ]." 28 U.S.C. § 1651(a). In a rare case, the All Writs Act can serve as a mechanism for review of "an interlocutory order of a court of appeals." *Coleman*, 424 U.S. at 1303 (Rehnquist, J., in chambers). Here, FDA would need to seek a writ of mandamus. But FDA has not done so, much less satisfied the three necessary conditions for mandamus. FDA cannot argue that there are "no other adequate means to attain … relief," given its ability to seek certiorari after judgment. *See Cheney v. U.S. Dist. Ct.*, 542 U.S. 367, 380 (2004). Nor can FDA establish any "clear and indisputable" error. *Id.* at 381. And this is certainly not the rare case justifying such extraordinary relief. *Id.*; *see* Shapiro, *supra*, 11-2(b) (noting "policy against using the extraordinary

writs as a means of obtaining appellate review of unappealable interlocutory orders").

Second, 28 U.S.C. § 1254(2) authorizes this Court to accept review "of any question of law in any civil or criminal case" "[b]y certification at any time by a court of appeals." Here, the Fifth Circuit did not certify its ruling to this Court.

3. In sum, given constitutional and statutory limits, this Court cannot review the Fifth Circuit's interlocutory ruling now. At the very least, this rare and complicated jurisdictional question does not itself warrant this Court's review. Accordingly, the Court should dismiss the petition for want of jurisdiction or as improvidently granted.

II. RETAILERS ARE PROPER PETITIONERS.

A. Retailers are within the zone of interests, and may thus challenge marketing denials.

Retailers like Avail Texas and members of Mississippi Retailers plainly qualify as "any person adversely affected" by FDA's marketing denials; thus, they "may file a petition for review." Marketing denials directly prohibit retailers from selling a product and expose them to onerous penalties, including criminal sanctions, if they do. *See* 21 U.S.C. §§ 332(a), 333(a) & (f)(9)(A), 334(a) & (g). Under the plain language of the statute, "any person adversely affected" therefore covers retailers who wish to sell a denied product. *See id.* § 321(e) ("person" means "individual, partnership, corporation, and association."); *Webster's Third New Int'l Dictionary* 31 (1981) ("adverse" means "in opposition to one's interests").

This Court's zone-of-interests analysis confirms as much. As the Court has explained, phrases like "person adversely affected" are "term[s] of art" with a "long history in federal administrative law"; those phrases trigger the "zone-of-interests" test. *Director v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 126 (1995); *see Bank of Am.*, 581 U.S. at 197; Pet. Br. 11–12. And that test "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). It asks whether the interest asserted is "arguably within the zone of interests to be protected or regulated by the statute." *Id.* at 224. Challengers thus fail the test only when their "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." *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399–400 (1987).

This test was originally developed for the APA, but it plainly applies here. Not only does the TCA incorporate verbatim the APA standard, *compare* 5 U.S.C. § 702 ("[a] person … adversely affected or aggrieved") *with* 21 U.S.C. § 387*l*(a)(1) ("any person adversely affected"), but the TCA's review provision also governs challenges to agency action, as the APA does. Moreover, the TCA explicitly says that review of denials shall be conducted under the APA's standards, further signaling that the APA zone-of-interests test should apply. *See* 21 U.S.C. § 387*l*(b). And this Court has not limited the test to the APA. *See, e.g.*, *Bank of Am.*, 581 U.S. at 197 (applying the test to the Fair Housing Act ("FHA")); *Thompson v. N. Am. Stainless,*

LP, 562 U.S. 170, 177–78 (2011) (applying the test to Title VII).

Indeed, the whole point of the zone-of-interests test is to determine how far to extend the right of review *beyond* a directly regulated party. Thus, this Court's cases consistently hold that statutes using language like "any person adversely affected" entitle a broad class of persons to judicial review. For example:

- Citrus growers, marketers, and packers were "adversely affected" under the Food, Drug, & Cosmetic Act because the agency order deeming certain oranges adulterated had "practical effect[s]" on their businesses. *Flemming v. Fla. Citrus Exch.*, 358 U.S. 153, 163, 168 & n.5 (1958).
- A radio station was "aggrieved" under the Communications Act of 1934 because of "economic injury" from the grant of a license to a competitor. *FCC v. Sanders Bros. Radio Station*, 309 U.S. 470, 472–73 (1940).
- A stockholder was "aggrieved" under the Public Utility Holding Company Act because the agency's order governing accounting practices at a corporation could affect dividends. *Am. Power & Light Co. v. SEC*, 325 U.S. 385, 388–89 (1945).
- Farmers were "adversely affected" under the Line Item Veto Act because the veto canceled a tax-benefit program and thus revived a contingent liability. *Clinton v. City of New York*, 524 U.S. 417, 428 (1998).

In none of these cases were all of the plaintiffs directly subject to the challenged agency action. These

cases show that the zone extends to cover parties who are negatively affected by the challenged action unless Congress *plainly* indicates otherwise. Indeed, this case follows *a fortiori* from cases like *Sanders Brothers*, which recognize a right to challenge an agency action directed at a competitor. *See* 309 U.S. at 472–73. In those cases, the agency failed to properly regulate a party under a statute; a competitor sued because it was factually harmed by that regulatory failure; and the Court invariably held the zone-of-interests test satisfied. *See, e.g.*, *id.*; *FCC v. Nat'l Broad. Co.*, 319 U.S. 239, 246–47 (1943). As these cases show, agency action alleged to arbitrarily regulate (or fail to regulate) a party can have significant downstream effects on unregulated parties, and those effects are typically sufficient for the unregulated parties to fall within a statute's zone of interests, unless Congress indicates otherwise. The same reasoning applies with even more force here. Congress said retailers cannot sell an unauthorized product. FDA denied authorization for a product. That means retailers cannot sell it—either as a factual or legal matter. And if they do, they are subject to penalties and enforcement actions. Even if that effect is downstream in some sense, the retailers' interest is plainly covered.

This Court's decision in *Bank of America* vividly illustrates just how capacious the zone-of-interest test is. There, the City of Miami sued banks under the FHA's judicial-review provision, which is effectively identical to the TCA's provision. 42 U.S.C. § 3613(a)(1)(A) ("An aggrieved person may commence a civil action … under this subchapter."). Miami alleged that banks engaged in discriminatory lending

in the residential housing market, which "disproportionately caused foreclosures and vacancies in minority communities in Miami," which in turn "reduc[ed] [Miami's] property tax revenues." *Id.* at 194–95 (cleaned up). In concluding that Miami came within the FHA's zone of interests, the Court applied the same zone-of-interests test as the APA because, like the APA, "FHA's definition of 'aggrieved' reflects a congressional intent to confer standing broadly." *Id.* at 197. Because Miami claimed that the banks' practices indirectly caused Miami to lose tax revenue through downstream effects of intervening foreclosures and vacancies, the Court concluded that Miami was at least "arguably … within the FHA's zone of interests"—even though Miami itself did not suffer discrimination. *Id.* at 200–01.[11]

This is a *far easier* case than *Bank of America*. The connection between the retailers' injuries and the interests protected by the TCA is far more direct than the attenuated connection between Miami's lost tax revenue and the FHA's housing-discrimination provision. FDA (arbitrarily) denied authorization for menthol Alto under 21 U.S.C. § 387j, thus failing to "issue an order" allowing the product "into interstate commerce." *Id.* § 387j(c)(1)(A)(i). That provision is *not* about what may be manufactured. Instead, it explicitly governs what products may be *marketed*—that is, sold. Here, Avail Texas and members of Mississippi Retailers are market participants, directly regulated by the marketing denial at issue

[11] The government filed an *amicus* brief in support of the position this Court adopted. Br. for U.S. as *Amicus Curiae*, *Bank of Am.*, 2016 WL 5903233.

and undisputedly harmed (one of them potentially fatally) by it. FDA understood as much when it threatened retailers selling unauthorized Vuse e-cigarettes with potential enforcement action. *See supra* Statement Part C.

Notably, retailers would establish standing even under Justice Thomas's view in *Bank of America*. Justice Thomas concluded that Miami's lost revenues did not implicate the interests protected by the FHA. 581 U.S. at 207–09. (Thomas, J., concurring in part, dissenting in part). Here, in contrast, there is no question that the retailers' inability to sell a product on pain of criminal sanctions directly implicates the interests protected by the TCA. *See infra* Part II.B.

Again, the standard's breadth—sweeping in any interests even "arguably" related to the statute, *Match-E-Be-Nash-She-Wish*, 567 U.S. at 225, and excluding only those "so marginally related to or inconsistent with the purposes implicit in the statute," *Clarke* 479 U.S. at 399–400—makes this an easy case. There is no plausible argument that the interest of a retailer is "marginally related to or inconsistent with the purposes" of a statute requiring FDA to permit the manufacturer to sell the product to retailers. And if Congress was contemplating that anyone other than manufacturers can sue FDA for unlawfully preventing them from selling their products, re-sellers like retailers and distributors who are both factually and legally precluded from re-selling those products are next in line in terms of injury, by any "reasonabl[e]" measure. *See id.*

B. FDA is wrong that only applicants come within the zone of interests.

FDA does not dispute that retailers qualify under the ordinary zone-of-interests test. Instead, FDA says (at 12–13) that the ordinary test is simply a presumption, and that statutory text and structure can narrow the zone, *e.g.*, *Block v. Community Nutrition Institute*, 467 U.S. 340 (1984), or expand it, *e.g.*, *Bennett v. Spear*, 520 U.S. 154 (1997). *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130–32 (2014). Based on that principle, FDA contends (at 14) that only the applicant can challenge a denial. That runs headlong into the TCA's statutory text and structure.

1. Under *Lexmark*, the "lenient approach" applies unless the statute in question indicates otherwise. 572 U.S. at 130–32. Here, however, the statutory text forecloses FDA's interpretation twice over. Congress did not say only applicants could challenge denials. Instead, it intentionally used a broad phrase—"any person adversely affected." As noted, the TCA's review provision (i) incorporates the APA's review provision verbatim, (ii) explicitly references the APA, and (iii) governs challenges to agency action. The same test must therefore apply. Indeed, in both *Lexmark* and *Bank of America*, the Court applied the lenient approach to include a plaintiff within the zone of interests even though *no* agency action was involved. Here, where agency action is directly challenged, the APA test must apply.

But even if there were daylight between the APA and TCA, the TCA itself forecloses the FDA's argument that the phrase "any person adversely

affected" covers only the applicant. That is because for *withdrawals* of authorization, the TCA explicitly states that only "[t]he *holder of an application*"—that is, the applicant—can obtain review. 21 U.S.C. § 387j(d)(2) (emphasis added). In other words, "any person adversely affected" can challenge a denial, but only "[t]he holder of an application" can challenge a withdrawal. FDA's interpretation seeks to erase that clear textual distinction. But it is a cardinal rule of statutory construction that courts must "respect Congress' decision to use different terms to describe different categories of people or things." *Mohamad v. Palestinian Auth.*, 566 U.S. 449, 456, (2012). This express statutory distinction, moreover, bears special weight here because not only were the two parallel provisions enacted in the same statute, but one provision explicitly cross-references the other. 21 U.S.C. § 387j(d)(2) (specifying that review of an applicant's challenge to a withdrawal is "in accordance with section 387*l*"). As a result, they should be construed *in pari materia.*

Indeed, the only reason Congress would have used the capacious phrase "any person adversely affected" when referring to denials is to cover at least *some* entities *beyond* applicants, because otherwise Congress would have just said applicants, as it did elsewhere. W. Eskridge, *Interpreting Law* 415 (2016) (noting that courts cannot read "a specific concept into general words when precise language in other statutes reveals that Congress knew how to identify that concept"); *see also Jama v. ICE*, 543 U.S. 335, 341 (2005). And if that is so—if "any person adversely affected" extends to even one person beyond the applicant, as it must—then it necessarily covers

retailers, who, next to applicants, are the entities *most* directly impacted by denials.

Other federal statutes confirm that "any person adversely affected" must mean something more than an applicant. *See Newport News*, 514 U.S. at 129 (noting "significan[ce]" of "other provisions" to zone-of-interests analysis); *see also Bennett*, 520 U.S. at 165 (comparing other federal statutes). The U.S. Code teems with provisions limiting who may challenge agency action. Taking one example from this Term, the Government argues that the phrase "*party* aggrieved" in the Hobbs Act is *narrower* than "person adversely affected." *See* Brief for U.S. Nuclear Regulatory Comm'n 16–18, *NRC v. Texas*, No. 23-1300 (Dec. 2, 2024) (emphasis added). The Government specifically contrasts "party" in the Hobbs Act with the APA's "person … adversely affected," saying the phrases must mean different things. *Id.* (citing *Simmons v. ICC*, 716 F.2d 40, 43 (D.C. Cir. 1983) (Scalia, J.)). In particular, "parties" must have appeared before the agency, and "all others who may be affected by the suit, indirectly or consequentially, are persons interested." *Id.* (quoting Black's Law Dictionary 1278). By the Government's own admission, then, "any person adversely affected" in the TCA cannot be limited only to the parties before the agency—namely, the applicants.

Further examples abound. Like the Hobbs Act, some statutes limit review to "parties." 12 U.S.C. § 4634; 21 U.S.C. § 2344; 29 U.S.C. § 3247; 41 U.S.C. § 1327. Others limit the right to the "applicant." 21 U.S.C. § 1047; 42 U.S.C. § 6869. And others are even more specific. 42 U.S.C. § 5311 ("recipient"); 7 U.S.C. § 228b-3 ("live poultry dealer"); 8 U.S.C. § 1189

("designated organization"); 10 U.S.C. § 1508 ("primary next of kin"); 15 U.S.C. § 298(b) ("competitors, customers, or subsequent purchasers"); 31 U.S.C. § 7107 ("contractor"). None of these narrow review provisions looks anything like § 387*l*(a)(1)'s capacious text: "any person adversely affected."

This straightforward reading is confirmed by the structure of TCA's review provision. The phrase "any person adversely affected," after all, covers *both* "regulation[s]" and "denial[s]"—the provision applies to "any person adversely affected" by "a regulation … establishing, amending, or revoking a tobacco product standard." 21 U.S.C. § 387*l*(a)(1). But FDA's argument (that "any person adversely affected" means only the applicant) makes no sense for challenging a regulation (who is the applicant?), which is covered by the same exact same phrase in the exact same provision. FDA's position thus also runs headlong into the presumption of consistent usage in a single statute: the same term usually has the same meaning. *See Clark v. Martinez*, 543 U.S. 371, 378 (2005).

It is thus clear that "any person adversely affected" in the TCA *cannot* be synonymous with the applicant.

2. The TCA's larger structure also contradicts FDA's reading. Other provisions of the TCA, which FDA completely ignores, further prove that retailers come within the zone of interests of § 387j. The TCA is rife with provisions that regulate and protect retailers when reselling manufacturers' products. *See Calumet Indus., Inc. v. Brock*, 807 F.2d 225, 228 (D.C. Cir. 1986) (all that is required is "some indicia—however slight—that the litigant before the court was

intended to be protected … or regulated by the statute"—either suffices (citing *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970))).

Most specifically, the TCA prohibits retailers from selling unauthorized products, and violations can land retailers in jail. 21 U.S.C. §§ 331, 387b(6); *see also id.* § 334(a), (g); § 333(a), (f)(9)(A); § 332(a). Retailers are thus not just "indirectly" affected by a denial, as FDA argues (at 7). FDA's arbitrary denial means that retailers *themselves* are being *unlawfully prohibited* from re-selling products that they would legally be allowed to re-sell if FDA had complied with the law. FDA's own statements and enforcement efforts prove as much, as FDA has initiated enforcement actions against retailers for selling products subject to denials.[12] More broadly, the TCA prohibits retailers from selling products to anyone underage. *Id.* § 387f(d). It prohibits retailers from selling products with unauthorized "modified risk" claims. *Id.* § 387k(a). It also requires retailers to limit free samples. *Id.* § 387a-1(d). And it requires retailers to adhere to advertising requirements for cigarette and smokeless tobacco. 15 U.S.C. §§ 1333(b), 4402.

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[12] FDA, *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products*, https://tinyurl.com/mrxxt3ja (last updated Dec. 5, 2024); FDA, *Working with States, FDA Warns More than 100 Retailers for Illegal Sale of Youth Appealing E-Cigarettes* (Dec. 5, 2024), https://tinyurl.com/2332cfcu; Consent Decree of Permanent Injunction, *United States v. Lucky Convenience & Tobacco, LLC*, No. 6:22-cv-1237 (D. Kan. Jan. 26, 2023) (obtaining permanent injunction against retailer).

The TCA also protects retailers' interests. It provides retailers with procedural protections for certain alleged violations of the Act. 21 U.S.C. § 333 note; *id.* § 333(f)(8). It preserves retailers' ability to sell tobacco products. *Id.* § 387g(d)(3). And it creates safe harbors for retailers relating to certain disclosures. 15 U.S.C. § 1333(a)(4), (c)(4), (e)(4).

FDA does not dispute any of this. Instead, it says none of it matters because the zone-of-interests analysis is limited solely to analyzing a single provision, § 387j. Even if that were right, it would not matter, because as demonstrated above, retailers plainly fall with the zone of interests of § 387j considered entirely on its own terms.

But FDA's argument that the analysis must fixate solely on the provision upon which the claim is based is also wrong. In fact, FDA later admits (at 18), "Discerning which harms constitute adverse effects often involves inferences drawn from the nature of the 'statutory scheme.'" And this Court has repeatedly made clear that additional provisions of the law at issue—that is, the statutory *context—can* inform the proper zone of the specific provision invoked by the plaintiff.

For example, *Clarke* rejected the Government's attempts to "focus[ ] too narrowly" on a single provision without "adequately plac[ing] [it] in the overall context of the [relevant] Act" and understanding "the purposes implicit in the statute." 479 U.S. at 399, 401. Likewise, *Lexmark* looked to "the Lanham Act," including its "statement of the statute's purposes," not just the judicial review or false advertising provisions directly at issue, because the

purposes shed light on the relevant provisions. 572 U.S. at 131. Even when this Court has found Congress narrowed the zone, the Court still looked to provisions that "have any integral relationship" with those directly at issue. *Air Courier Conference of Am. v. Am. Postal Workers Union*, 498 U.S. 517, 530 (1991).

FDA also undercuts its own argument by pointing to a separate TCA provision—though that provision does not bear the weight assigned. According to FDA (at 18–20), the *only* other TCA provision that matters is § 387f(c), which limits public access to certain application information that FDA contends retailers would need to seek review. But § 387f(c) explicitly does *not* apply to, and therefore does not prevent disclosure of, information that is "relevant in any proceeding under this subchapter." The proceeding at issue here (and all challenges to denials) are "under this subchapter" (that is, they are authorized by 21 U.S.C. § 387*l*). So when a retailer challenges a denial, the "information may be disclosed" to the parties to the case (with appropriate safeguards, such as sealing portions of the record). And apart from that, FDA must furnish an administrative "record" for judicial "review." 5 U.S.C. § 706; *see Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971).

In any event, FDA overstates any practical difficulties. The agency publicly announces denial orders, as it did here. But even if retailers face difficulties obtaining the information prior to suing, that is no reason to foreclose *all* challenges by retailers. That would be true only if the Act *prohibited* retailers from obtaining the information, which it clearly does not do, even under FDA's reading.

3. The cases cited by FDA (at 12–13) do not change the zone-of-interests analysis.

FDA unsurprisingly leads with the *only* APA case (out of at least a dozen) in which this Court has ever found a party *not* to come within the zone of interests: *Air Courier*, 498 U.S. 517. But *Air Courier* is easily distinguishable. There, postal employees challenged the Postal Service's suspension of the Private Express Statutes (PES). *Id.* at 519, 521–22. This Court reviewed the statute and concluded that Congress was concerned "not with opportunities for postal workers but with the receipt of necessary revenues for the Postal Service." *Id.* at 525–26. The postal employees "argue[d] that the courts should look *beyond* the PES to the entire 1970 [Postal Reorganization Act]," which reenacted the PES. *Id.* at 528 (emphasis added). This Court rejected that contention, holding, "The only relationship between the PES, upon which the Unions rely for their claim on the merits, and the labor-management provisions of the PRA, upon which the Unions rely for their standing, is that both were included in the general codification of postal statutes embraced in the PRA." *Id.* at 529. An interpretation at such "level of generality … could deprive the zone-of-interests test of virtually all meaning." *Id.* at 529–30. That was because "none of the provisions of the PES have any integral relationship with the labor-management provisions of the PRA." *Id.* at 530.

Air Courier thus stands for the simple proposition that unrelated provisions that shed no light on the provision at issue do not bear on the provision's zone of interests. Here, by contrast, the TCA's provisions directly regulating and protecting retailers plainly confirm that retailers fall within the zone of § 387j.

And § 387j is the provision the retailers claim FDA arbitrarily applied in refusing to allow manufacturers to sell menthol Alto to them for resale. Thus, the retailers do not seek to "deprive the zone-of-interests test of virtually all meaning." *Air Courier*, 498 U.S. at 529–30.

FDA's reliance on *Bennett*—which, like *Lexmark,* was authored by Justice Scalia—is equally misplaced. 520 U.S. 154. FDA quotes *Bennett* (at 13) for the anodyne proposition that "what comes within the zone of interests … for purposes of … the 'generous review provisions' of the APA may not do so for other purposes." But *Bennett* actually concluded that the Endangered Species Act ("ESA") *broadened* the category of individuals entitled to sue because the statute's citizen-suit provision allowed "any person" to sue. 520 U.S. at 164. Here, in contrast, the TCA uses the *exact same statutory language* as the APA and specifically distinguishes between "the holder of an application" and "any person adversely affected." *See supra* at 17–20. The text thus both confirms that the TCA's "any person adversely affected" language is intended to incorporate the APA standard and demonstrates that, at the very least, it is broader than simply the applicant.

Moreover, *Bennett* itself applied the APA's zone-of-interests test in a later part of the opinion, and that holding further refutes FDA's position. In *Bennett*, irrigation districts and ranches invoked an ESA provision that required the government to use good science in biological opinions when determining a government project's impact on animals. 520 U.S. at 159. The Ninth Circuit had suggested the plaintiffs did not fall within the statute's zone because the

purpose of the *Act* was to protect *animals*, not *industry*. This Court unanimously rejected that, concluding instead that the plaintiffs came within the zone of "the substantive provisions of the ESA" governing the good-science requirement because, while the ESA had an "overall goal of species preservation," the substantive provision was aimed at "avoid[ing] needless economic dislocation." *Id.* at 175–77. *Bennett* did not hold that a court is *precluded* from considering overall statutory purpose. Indeed, the Court relied on a "readily apparent" statutory "objective": "avoid[ing] needless economic dislocation produced by agency officials zealously but unintelligently pursuing their environmental objectives." *Id.* at 176–77. Rather, *Bennett* held it was error for the appeals court to focus *solely* on statutory purpose divorced from the provision upon which the claim is based. That holding is no different than the argument Respondents now make—namely, that a party factually harmed by arbitrary over-regulation by an agency falls within the zone of the provision at issue, notwithstanding that a general purpose of the Act as a whole is to protect consumers.

That FDA is misreading Justice Scalia's opinion in *Bennett* is further confirmed by Justice Scalia's subsequent opinion in *Lexmark*, 572 U.S. 118, which makes clear that courts *do* look to the broader statutory context to inform the zone of the provision at issue. After all, *Lexmark* did not look solely at the provision that was the gravamen of the complaint. Instead, the Court looked to other provisions in the statute and the statute's purpose: "Identifying the interests protected by the Lanham Act … requires no guesswork, since the Act includes an unusual, and

extraordinarily helpful, detailed statement of the statute's purposes." *Id.* at 131. So too does the TCA. The TCA was enacted "to provide authority to [FDA] to regulate tobacco products … , by recognizing it as the primary Federal regulatory authority with respect to the manufacture, *marketing, and distribution* of tobacco products as provided for in this division." TCA § 3(1), 123 Stat. 1776, 1781 (codified at 21 U.S.C. § 387 note) (emphasis added). Congress also intended "to continue *to permit the sale* of tobacco products to adults." *Id.* § 3(7) & (8), 123 Stat. at 1782 (codified at 21 U.S.C. § 387 note) (emphasis added).

Finally, FDA's reliance (at 23–25) on *Block*, 467 U.S. 340, is also misplaced. In *Block*, this Court considered whether milk consumers could obtain judicial review of milk market orders under the Agricultural Marketing Agreement Act ("AMAA"). *Id.* at 341. Those orders set minimum prices that milk handlers must pay to milk producers. *Id.* at 343–43. The Court's holding that consumers could not challenge those orders was premised on the statute's administrative review requirements that would be upended if consumers (in addition to milk handlers) could file suit under the APA. *Id.* at 347–48. The Court noted that, for an order to become effective, a certain percentage of milk handlers and producers had to vote in favor of the orders. *See id.* at 342. And if handlers were unsatisfied after exhausting those administrative procedures, the AMAA authorized suit "in any district in which *such handler* is an inhabitant, or has his principal place of business." 7 U.S.C. § 608c(15)(B) (emphasis added).

In short, *Block* held that "[t]he structure of [the statute] indicates that Congress intended only

producers and handlers, and not consumers, to ensure that the statutory objectives would be realized." 467 U.S. at 347. Thus, "when a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded." *Id.* at 349.

The collaborative scheme and limited judicial-review provision at issue in *Block* is worlds apart from the TCA's provisions governing premarket tobacco product applications. The TCA's provisions contain "no administrative review requirements that would be 'end run' if targets of the orders were allowed to obtain judicial review thereof." *ACLU v. Clapper*, 785 F.3d 787, 806 (2d Cir. 2015) (discussing the Foreign Intelligence Surveillance Act). "Unlike the AMAA," the TCA "in no way contemplates a 'cooperative venture' that precedes the issuance of orders." *See id.* And the review provision is not limited to "handlers." 7 U.S.C. § 608c(15)(B). Instead, the TCA's only review provision for the denial of a premarket tobacco product application is § 387*l*—which expressly allows "any person adversely affected" to file suit. *Block* thus has no purchase here.

C. FDA's other arguments are wrong.

FDA's remaining counterarguments fare no better.

1. FDA argues (at 21) that sales of Alto "have violated the [Tobacco Control] Act all along …, and an interest in continuing to violate the law necessarily falls outside the zone of interests that the law seeks to protect." FDA's argument proves too much.

To begin, it would mean that RJRV, as the applicant, also could not sue. Like the retailers,

RJRV's interest is in marketing (*i.e.*, selling) the product. RJRV filed a *premarket* tobacco product application to secure the right to market the product—not to manufacture it. Manufacturing is not the interest at stake—after all, RJRV could manufacture the product even after a denial, for example, for export.[13] Instead, its interest is in selling the product in the United States. Thus, the retailers' and RJRV's interest is the same.

In addition, although FDA's enforcement policy *allowed* retailers to sell the products prior to FDA's denial, this case does not turn on that fact. Even if the products had never previously been on the market, a denial would still adversely affect retailers who want to sell them, because the wrongful denial has prevented the products' sale.

Indeed, the Act legally *requires* FDA to grant applications to sell products that meet statutory conditions. *See* 21 U.S.C. § 387j(c)(1)(A)(i). Here, Respondents' ultimate argument is that FDA acted unlawfully by denying the application even though it satisfied the statutory criteria. Thus, contrary to FDA's argument (at 22), Respondents are not asking this Court to "lend its aid" to an illegal act. Respondents are instead seeking to invalidate FDA's illegal act (the denial) that prevents them from selling products that, in their view, they have a lawful right to sell. This is no different from a licensing regime. If an agency unlawfully denies the license, a person denied the license (or someone who stands to benefit from that potential licensee) is not asking the court to

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[13] FDA, *Importing and Exporting*, https://tinyurl.com/y5ur7fp8 (last updated Aug. 15, 2024).

aid an illegal act; it is asking the court to *stop* an illegal act—the agency's denial.

Moreover, FDA's argument defies the real-world context here: the products at issue already *have* been on the market lawfully, pursuant to FDA's enforcement-discretion policy. *See supra* Statement Part B. For more than eight years, retailers like Avail Texas and members of Mississippi Retailers have been able to sell the products. Surely retailers must be able to challenge a denial that bars them from selling a product that FDA has allowed them to sell for years, where such order imposes direct and, for at least one Respondent, catastrophic financial injury.

2. FDA also argues (at 34) that the Fifth Circuit's decision "nullifies the Act's restrictions." According to FDA, an applicant can always find a retailer in a preferred circuit. Even if that were true, the remedy would lie with Congress; "[p]olicy arguments are properly addressed to Congress, not this Court." *SAS Inst. Inc. v. Iancu*, 584 U.S. 357, 368 (2018).

But FDA's argument is wrong. That an applicant and retailers may join in a single petition does not nullify the Act's venue restrictions. One petitioner must be in the relevant circuit unless it is the D.C. Circuit. And there are a number of reasons why an out-of-circuit applicant may not be able to find an in-circuit co-petitioner. For example, a Vermont applicant that sells its products directly to consumers cannot file a petition in the Fifth Circuit. Likewise, there will be cases where there is no retailer wishing to sell the denied product or motivated to pursue

litigation.[14] Indeed, at least one case has been transferred because the applicant could not find an in-circuit co-petitioner. *See* Order Granting Mot. to Transfer, *Shenzhen Yibo v. FDA*, No. 24-60191 (5th Cir. May 20, 2024). But the TCA does not 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.

* * *

For these reasons, the phrase "any person adversely affected" readily encompasses retailers like Avail Texas and members of Mississippi Retailers, since the denial means that they are not permitted (under threat of penalty) to sell the products at issue. Indeed, Avail Texas will go out of business if it can no longer sell Vuse e-cigarettes. *See* Pet.App.4a. The statutory text, this Court's precedent, and common sense all compel the conclusion that retailers are "adversely affected" and "may file a petition for judicial review of [the] denial." 21 U.S.C. § 387*l*.

III. ONLY ONE PETITIONER NEEDS TO ESTABLISH VENUE.

FDA argues (at 27) that even if Avail Texas and Mississippi Retailers are proper petitioners, RJRV "may not simply tag along" as an additional party. FDA did not present—and the Fifth Circuit did not pass on—this argument below, so the Court should not consider it. In any event, Congress enacted the

[14] Contrary to FDA's suggestion (at 18), allowing a retailer to challenge the denial order would not violate "the autonomy" of the applicant. The applicant is free to stop manufacturing the product.

TCA's review provisions against uniform and longstanding precedent holding that, in cases challenging federal action, only one challenger need establish venue. FDA's cases, in contrast, involve more restrictive and irrelevant diversity-jurisdiction statutes.

A. FDA failed to raise its venue-as-to-each-petitioner argument below.

FDA forfeited its venue-as-to-each-petitioner argument by failing to advance it below (a failure that FDA did not deny in its certiorari-stage reply (at 10–11)). In the Fifth Circuit, FDA argued that retailers could not sue under the TCA, and that without them venue was not proper. FDA did not argue that each petitioner needs to independently establish venue. Indeed, the relief that FDA sought below is inconsistent with its new argument. Below, FDA sought to have the entire "petition … dismissed or transferred," *Alto* C.A. Mot. to Dismiss or Transfer 6 (Oct. 18, 2023); in contrast, its argument here that RJRV cannot join the retailers' case would require dismissal or transfer of *only RJRV's* claims.

Because this argument "was never presented to any lower court," it is "forfeited." *OBB Personenverkehr AG v. Sachs*, 577 U.S. 27, 37 (2015). Regardless, this Court should not pass upon it in the first instance. *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005) ("[W]e are a court of review, not of first view."). Doing so would be particularly inappropriate given the constraints on this Court's jurisdiction. Raising a new argument not passed upon below confirms that FDA is invoking this Court's original, not appellate, jurisdiction. *See supra* Part I.

B. Congress clearly intended that only one petitioner needs to establish venue.

1. Congress enacted the TCA's venue provision against a decades-long, uniform judicial interpretation of near-identical venue provisions governing suits against the government. *See* Amicus Br. 4–15, U.S. Chamber of Comm., *FDA v. R.J. Reynolds Vapor Co.*, No. 23-1187 (U.S. Nov. 25, 2024). Courts have uniformly interpreted the language Congress chose for the TCA to mean that where one petitioner or plaintiff lays venue, other petitioners or plaintiffs may join the action. And because this Court "presume[s] that Congress is knowledgeable about existing law pertinent to the legislation it enacts," it follows that the interpretation of those other, similarly worded provisions will control, especially "[i]n the absence of affirmative evidence in the language or history of the statute" to the contrary. *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988); *see also Texas Dep't of Hous.*, 576 U.S. at 536–37 ("'If a word or phrase has been … given a uniform interpretation by inferior courts …, a later version of that act perpetuating the wording is presumed to carry forward that interpretation.'").

The TCA's review provision uses the language of the Hobbs Act, which governs review of many agency actions in the circuit courts. 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, the venue inquiry is at an end. *See,*

e.g., *Global Van Lines, Inc. v. ICC*, 691 F.2d 773, 774 n.1 (5th Cir. 1982); *Burlington Northern, Inc. v. United States*, 549 F.2d 83, 85–87 & n.1 (8th Cir. 1977); *Radio Relay Corp. v. FCC*, 409 F.2d 322, 324 n.1 (2d Cir. 1969); *Anglo Canadian Shipping Co. v. United States*, 238 F.2d 18, 20 (9th Cir. 1956).

Take *Burlington Northern*, 549 F.2d at 85–87. There, the Eighth Circuit permitted non-resident petitioners to participate because "[v]enue is proper in that Burlington Northern maintains its principal office in this Circuit." *Id.* at 85 n.1. Courts have uniformly reached the same conclusion for other similarly worded venue provisions.[15]

The general venue statute has the same meaning. That statute authorizes suits against the federal government (including under the APA) "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. *See Sidney Coal Co. v. Soc. Sec. Admin.*, 427 F.3d 336, 344–45 (6th Cir. 2005) ("[This] is not only the majority view—it is the only view adopted by the federal courts since 1971."). Indeed, the general venue statute was enacted specifically because "Congress intended to broaden the number of districts in which suits could be brought against government entities." *Id.* (citing cases). Even the government agrees. *See* U.S. Dep't of

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[15] *Nat'l Ass'n of Priv. Fund Managers v. SEC*, 103 F.4th 1097, 1109 (5th Cir. 2024) (Investment Advisers Act); *Fournier v. Johnson*, 677 F. Supp. 2d 1172, 1174 (D. Ariz. 2009) (Social Security Act); *Est. of Israel v. Comm'r*, 159 F.3d 593, 596 (D.C. Cir. 1998) (tax provision).

Justice, Civil Resource Manual 41 Venue ("Only one of the plaintiffs need reside in the district …."), https://tinyurl.com/58msjksk.

The TCA was enacted in 2009 against this backdrop of these longstanding and uniform judicial interpretations of nearly identical language governing judicial review of agency action. "When … 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 … judicial interpretations as well." *Bragdon*, 524 U.S. at 645. As Scalia and Garner explain, "If a statute uses words or phrases that have already received … uniform construction by inferior courts … they are to be understood according to that construction." Scalia & Garner, *supra*, at 322. Thus, Congress did not intend to require each petitioner 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.

2. Although FDA invokes the joinder rule to support its interpretation, that rule supports Respondents. It provides, "If their interests make joinder practicable, two or more persons may join in a petition to the same court to review the same order." Fed. R. App. P. 15(a)(1). Under the plain language, RJRV "may join" in the retailers' "petition to the [Fifth Circuit] to review the" denial. FDA is correct (at 29–30) that the rule cannot enlarge jurisdiction or affect substantive rights, but allowing RJRV to join a petition does neither. To the contrary, "venue is a matter that goes to process rather than substantive rights." *Am. Dredging Co. v. Miller*, 510 U.S. 443, 453 (1994).

Joinder likewise is a "procedural means of processing claims, not [a] font[] of judicial authority." *Alabama v. North Carolina*, 560 U.S. 330, 362 (2010) (Roberts, C.J., concurring in part and dissenting in part); *see also Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 408 (2010) (plurality opinion). It leaves everyone's rights "intact and the rules of decision unchanged." *Shady Grove*, 559 U.S. 393 at 408.

FDA's discussion of joinder proves the point. Nowhere therein does FDA mention "venue"; instead, FDA discusses *jurisdiction*. But there is no dispute the Fifth Circuit had jurisdiction. Nor does FDA get anywhere by arguing that "if multiple parties join in one complaint, 'each plaintiff's right of action remains distinct, as if it had been brought separately.'" Opening Br. at 30 (quoting 7 Wright & Miller, *Federal Practice and Procedure* § 1652, at 414 (4th ed. 2019)). FDA ignores that all Respondents make the same arguments in support of the same request for relief challenging the same order. In other words, their joinder does not expand the right of action of any petitioners. Moreover, the TCA expressly contemplates that an improper denial be "set[ ] aside." 21 U.S.C. § 387*l*(c). So even if an applicant and retailer were to file separate petitions, the result would be the same because they seek the same relief (which is not party-specific). Thus, Rule 15 authorizes RJRV's participation in the retailers' case.

3. Aside from being a longstanding and uniform interpretation, Respondents' rule makes sense. Otherwise, different petitioners would have to file separate lawsuits in separate courts challenging the same agency action. Sometimes, there could be a

petition in every regional circuit. Those petitions would be assigned to one circuit eventually. *See* 28 U.S.C. § 2112(a). So there is no reason to *force* litigants and the court system to engage in the meaningless kabuki dance of filing multiple cases in multiple courts just to have everything consolidated. Moreover, so long as only one petition were filed in the first ten days, all subsequent petitions would be transferred to the original circuit, *see id.*, meaning that multiple petitioners would still be able to coordinate to choose their forum.

When parties coordinate and file a single petition, it saves everyone time and resources (including FDA, which only has to respond to one petition and does not have to notify the Multidistrict Litigation Panel). Courts have emphasized this point in the context of the general venue statute—which was a precursor to the TCA. *See Sidney Coal Co.*, 427 F.3d at 344–45; *Exxon Corp. v. FTC*, 588 F.2d 895, 898–99 (3d Cir. 1978) ("[R]equiring every plaintiff … to independently meet section 1391(e)'s standards would result in an unnecessary multiplicity of litigation."), *overruled on other grounds*, *Reifer v. Westport Ins. Corp.*, 751 F.3d 129 (3d Cir. 2014); *Ry. Labor Execs.' Ass'n v. Interstate Com. Comm'n*, 958 F.2d 252, 256 (9th Cir. 1991); *Quarles v. Gen'l Inv. & Dev. Co.*, 260 F. Supp. 2d 1, 12 (D.D.C. 2003).

4. Ignoring this wall of authority and logic, FDA argues (at 27–29) that because the statute uses "singular nouns" and allows for an adversely affected party to petition for review where "such person resides or has their principal place of business," the Act requires venue to be analyzed on a petitioner-by-petitioner basis. But the TCA does not say that each

party to a joint petition needs to independently satisfy venue. It simply says the petition must be filed where a petitioner resides or has its principal place of business. And FDA's interpretation would contradict how other similarly worded statutes are uniformly interpreted, working a sea change in venue law.

FDA invokes (at 29) the *expressio unius* canon, arguing that the Act's "enumeration of" three venues "implies the exclusion of others." That is right to some extent: If no petitioner resides or has its principal place of business in the circuit, then venue is improper (other than for cases filed in the D.C. Circuit). But if FDA is offering a Latin reprisal of its argument that the Fifth Circuit's decision nullifies the Act's venue provision, Respondents have already explained why that is not true. *See supra* at 35–36.

5. Finally, FDA's interpretation would not even solve the purported problem. Assuming this Court finds retailers are "adversely affected," a retailer could challenge the denial of a product that it sells in its home circuit within ten days of the denial. Then, on day eleven, an applicant could challenge the same denial in its home circuit. The result: both petitions would be consolidated in *the retailer's* circuit. 28 U.S.C. § 2112(a). The same result could be obtained via an applicant's intervention in a retailer's case. *See* Fed. R. App. P. 15(d).

Indeed, FDA's rule would make no difference in this very case. If the Court ordered the RJRV entities dismissed, then the D.C. Circuit would transfer their protective petition to the Fifth Circuit, which would be consolidated with the retailers' earlier-filed Fifth Circuit petition, *see* Pet. for Rev., *R.J. Reynolds Vapor*

Co. v. FDA, No. 23-1298 (D.C. Cir. Oct. 27, 2023)—bringing us back to the starting point. 28 U.S.C. § 2112(a).

C. FDA's authorities are inapposite.

FDA relies on inapposite diversity cases, including two century-old cases. *See Smith v. Lyon*, 133 U.S. 315 (1890); *Camp v. Gress*, 250 U.S. 308 (1919). But none of FDA's authorities provide support.

1. None of FDA's cases are relevant.

First, *Smith* and *Camp* are inapposite because the statutory language in those cases is different from the TCA. 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 that restrictive language is not in the TCA's venue provision. *See Favereau v. United States*, 44 F. Supp. 2d 68, 69 (D. Me. 1999) (noting that "only" changes the venue calculus).

Moreover, the venue statute in *Smith* and *Camp* concerned diversity suits between private citizens, not against the federal government. *Smith* and *Camp* specifically looked to the line of cases stretching back to *Strawbridge v. Curtiss*, which established the complete-diversity rule—for diversity jurisdiction, no plaintiff can be from the same state as any defendant. 7 U.S. (3 Cranch) 267 (1806). Because Congress (in 1890) had not changed the relevant language interpreted by *Strawbridge*, *Smith* 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.

But for suits challenging federal action, there is a long history establishing that only one plaintiff needs to establish venue. "Thus, *Smith* has no bearing on this Court's interpretation of" venue provisions governing actions against the federal government. *Sidney Coal Co.*, 427 F.3d at 345 n.12.[16]

2. FDA's other cases suffer similar pitfalls. FDA (at 31) cites *Bankers Life & Casualty Co. v. Holland*, 346 U.S. 379 (1953), as an example of when this Court "analyzed venue one defendant at a time." But the Court "d[id] not pass upon" the lower court's venue decision. *Id.* at 382. Instead, the Court concluded that issuing a writ of mandamus (the requested relief) was improper. Nor was the case against the government.

FDA goes a step further (at 32) by citing *Geneva Furniture Manufacturing Co. v. S. Karpen & Bros.*, 238 U.S. 254, 259 (1915), for the proposition that courts "evaluate venue not just party by party, but claim by claim." Here, there is no difference in the claims brought by the parties. But more fundamentally, FDA confuses venue with jurisdiction. In *Geneva Furniture*, the Court held that the district court lacked *jurisdiction* over one of four claims. *Id.* at 258–59. But nowhere does the word "venue" appear in that case.

To the extent FDA is arguing that the Fifth Circuit lacks jurisdiction over this suit, the Agency's argument reflects a misunderstanding of the TCA's judicial-review provision. Like similar provisions, § 387*l* is a "two-fold" provision; it both confers

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[16] The same is true of FDA's other diversity-jurisdiction authorities: *Clark v. Paul Gray, Inc.*, 306 U.S. 583 (1983); *Zahn v. Int'l Paper Co.*, 414 U.S. 291 (1973).

jurisdiction on the federal courts of appeals and tells petitioners in which venue they may file. *Texas v. EPA*, 829 F.3d 405, 418 (5th Cir. 2016); *see also Harrison v. PPG Indus., Inc.*, 446 U.S. 578, 590–91 (1980) (discussing provisions that confer jurisdiction and determine venue). In other words, the TCA confers jurisdiction on all regional circuit courts to hear petitions for review of denials. In fact, the provision later provides, "Upon the filing of the petition …, the court shall have jurisdiction to review the … [denial] order." 21 U.S.C. § 387*l*(b). And the Act separately addresses venue by directing petitioners to file in certain circuits. The Fifth Circuit thus has jurisdiction to hear Respondents' petition apart from any venue issue.[17]

FDA does discuss (at 27) two lower-court opinions (one of which is a concurrence) addressing suits against the federal government. Neither helps. In *Amerada Petroleum Corp. v. Federal Power Commission*, the Federal Power Commission consolidated and then disposed of separate applications. 338 F.2d 808, 809–10 (10th Cir. 1964). The applicants then filed one petition for review of the order denying the applications, but only one applicant was in the Tenth Circuit. *Id.* at 810. Because the statute clearly contemplated a separate "order relating to [each] particular natural-gas company,"

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[17] FDA's reliance (at 32–33) on the defendant-unanimity rule for removal is immaterial. Regardless, the rule gives "deference to a plaintiff's choice of a state forum," *McManus v. Glassman's Wynnefield, Inc.*, 710 F. Supp. 1043, 1045 (E.D. Pa. 1989), and "prevent[s] the defendants from gaining an unfair tactical advantage by splitting the litigation." *Esposito v. Home Depot, USA, Inc.*, 436 F. Supp. 2d 343, 347 (D.R.I. 2006).

there needed to be a separate petition for each denied application, and venue had to be properly laid for each. *See id.* Here, by contrast, all Respondents are "adversely affected" by, and seek review of, FDA's *single* order on *one* application. 21 U.S.C. § 387*l*(a)(1).

FDA also cites Judge Nelson's concurrence in *National Family Farm Coalition v. EPA*, 966 F.3d 893 (9th Cir. 2020). But even under his opinion—which addresses a hypothetical—Respondents' case is properly in the Fifth Circuit. Judge Nelson asked, "What happens … if venue is proper as to some petitioners, but only a petitioner without proper venue satisfies the requirements for Article III standing?" *Id.* at 932 (Nelson, J., concurring). He answered, "the petition for review should be dismissed." *Id.* However, Judge Nelson agreed that when a co-petitioner has Article III (and statutory) standing and satisfies venue, the petition is properly before the court. *See id.* at 930. Here, the retailers have Article III standing (undisputed), satisfy venue (also undisputed), and have statutory standing (*see* Part II).

3. Even FDA's secondary sources do not support its argument. FDA argues (at 30–32 (quoting Wright & Miller, *supra* at § 3807)) that "[this] Court long ago held that venue must be proper as to each party" and that "venue must be proper as to each claim." But FDA ignores that this case is against the federal government. Just below FDA's selected quote, Wright & Miller addresses *this* situation: "in suits against the United States," courts permit "venue in 'any' district where 'the plaintiff' resides," which "is satisfied if only one of several plaintiffs resides in that district." *Id.* Indeed, in a section specifically about actions against

federal agencies, Wright & Miller explains, "[i]n cases involving multiple plaintiffs, venue is proper where *any one of them resides*." *Id.* § 3815 (emphasis added). It notes elsewhere that "[w]hen more than one petitioner seeks review of the same order, the venue opportunities may expand considerably." *Id.* § 3941 n.6. In short, FDA is without support.

4. Finally, FDA's claim (at 33) that "the purpose of statutorily specified venue is to protect the *defendant*" is backward. This Court has long observed that it is the "plaintiff's venue privilege," *not* the defendant's—and certainly not the federal government's, which is nationally omnipresent. *Atl. Marine Constr. Co. v. U.S. Dist. Ct. W. Dist. Tex.*, 571 U.S. 49, 63 (2013). Indeed, even in *Leroy v. Great Western United Corp.*, the case FDA cites for this proposition, the Court was careful to carve out suits against the federal government as the exception to the rule. While *Leroy* said that "Congress has generally not made the residence of the plaintiff a basis for venue in nondiversity cases," it then added a "*But cf.*" cite to the general venue statute governing suits against the government. 443 U.S. 173, 184 (1979). In other words, *Leroy* recognized that suits against the government are an *exception* to the rule.

CONCLUSION

The Court should dismiss the petition for want of jurisdiction or as improvidently granted or, in the alternative, affirm the order below.

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