No. 23-1187

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONERS

v.

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

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

BRIEF FOR THE PETITIONERS

SAMUEL R. BAGENSTOS
General Counsel
Department of Health and Human Services
Washington, D.C. 20201

MARK RAZA
Chief Counsel
WENDY S. VICENTE
Deputy Chief Counsel for Litigation
WILLIAM H. RAWSON
Associate Chief Counsel
SARAH E. ROSENBERG
Assistant Chief Counsel
Food and Drug Administration
Silver Spring, MD 20993

ELIZABETH B. PRELOGAR
Solicitor General
Counsel of Record
BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
CURTIS E. GANNON
Deputy Solicitor General
VIVEK SURI
Assistant to the Solicitor General
LINDSEY POWELL
JOSHUA M. KOPPEL
CATHERINE PADHI
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776, requires a person to obtain authorization from the Food and Drug Administration (FDA) before introducing a new tobacco product into interstate commerce. If FDA denies an application for authorization, "any person adversely affected by such * * * denial 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). The question presented is:

Whether a manufacturer may file a petition for review in a circuit (other than the D.C. Circuit) where it neither resides nor has its principal place of business, if the petition is joined by a seller of the manufacturer's products that is located within that circuit.

TABLE OF CONTENTS

Table of Contents—Continued: Page

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Cases—Continued: Page

Cases—Continued: Page

Constitution, statutes, regulations, and rules:

Statutes, regulations, and rules—Continued: Page

Miscellaneous—Continued: Page

In the Supreme Court of the United States

No. 23-1187

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONERS

v.

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

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

BRIEF FOR THE PETITIONERS

OPINION BELOW

The order of the court of appeals (Pet. App. 1a-8a) is unreported.

JURISDICTION

The order of the court of appeals was entered on February 2, 2024. The petition for a writ of certiorari was filed on May 2, 2024, and granted on October 4, 2024. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The pertinent statutory provisions are reprinted in the appendix. App., *infra*, 1a-15a.

STATEMENT

A. Legal Background

1. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control

Act or Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776. The Act empowers the Secretary of Health and Human Services, acting through the Food and Drug Administration (FDA), to regulate tobacco products. See 21 U.S.C. 393(d)(2). The Act applies automatically to some tobacco products, such as cigarettes, but other products become subject to it only once FDA issues a rule that "deems" the product "to be subject to" the Act. 21 U.S.C. 387a(b).

As relevant here, the Act restricts the marketing of "new tobacco product[s]"—that is, tobacco products that were not commercially marketed in the United States as of February 15, 2007. 21 U.S.C. 387j(a)(1). A manufacturer may introduce a new tobacco product into interstate commerce only if it obtains authorization from FDA. See 21 U.S.C. 387j(a)(2).

A manufacturer seeking marketing authorization must file an application with FDA. See 21 U.S.C. 387j(b). After reviewing the application, FDA must issue either an "order that the new product may be introduced" or an "order that the new product may not be introduced" into interstate commerce. 21 U.S.C. 387j(c)(1)(A). The agency must deny an application unless the applicant shows that the product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A).

The Act provides that "any person adversely affected" by the "denial of an application" for marketing authorization "may file a petition for judicial review" within 30 days after the denial. 21 U.S.C. 387*l*(a)(1)(B). The petition must be filed "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). The court must review the denial in accordance with the Administrative

Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 701 *et seq.* See 21 U.S.C. 387*l*(b).

2. This case involves the application of the Act to electronic nicotine delivery systems, which are commonly known as e-cigarettes or vapes. See Office of the Surgeon General, U.S. Public Health Serv., U.S. Dep't of Health & Human Servs., *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* 3 (2016). An e-cigarette is a battery-powered device that heats a nicotine solution, or "e-liquid," converting the solution into an aerosol (a suspension of small airborne droplets) that the user then inhales. See *id.* at 11.

Because Congress did not list e-cigarettes among the products to which the Act automatically applied, they were not at first subject to regulation under the Act. See 21 U.S.C. 387a(b). But in 2016, FDA issued a rule deeming e-cigarettes and e-liquids to be subject to the Act. See 81 Fed. Reg. 28,974, 29,028-29,044 (May 10, 2016). Because e-cigarettes had generally not been on the market as of February 15, 2007, they are new tobacco products under the Act, and FDA's deeming rule meant that they could lawfully be marketed only after receiving agency authorization. See *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 414 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023).

In 2020, FDA issued an enforcement policy regarding certain e-cigarettes. See Center for Tobacco Prods., FDA, U.S. Dep't of Health & Human Servs., *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (Apr. 2020). FDA stated that it intended to prioritize enforcement action against certain categories of products: certain flavored products, products for which the manufac-

turer failed to take adequate measures to prevent minors' access, products targeted to minors, and products for which the manufacturer failed to submit an application by September 9, 2020. See *id.* at 3. For other e-cigarettes, FDA stated that it would "exercise enforcement discretion for up to one year pending FDA review, unless there is a negative action by FDA on such application." *Id.* at 27. FDA warned, however, that its guidance "does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization." *Id.* at 3.

B. Facts And Proceedings Below

1. Respondent R.J. Reynolds Vapor Co. (Reynolds) manufactures e-cigarette products. See Pet. App. 13a. Reynolds is incorporated, and thus resides, in North Carolina, and it maintains its principal place of business in Winston-Salem, North Carolina. See R.J. Reynolds Vapor Co., *Business Corporation Annual Report, F.Y. 2022*, at 1 (Jan. 30, 2023).

Reynolds applied for authorization to market berry- and menthol-flavored e-cigarette products under the brand name Vuse Alto. See Pet. App. 3a. FDA denied the applications, finding that Reynolds had failed to show that the products would be appropriate for the protection of the public health. See *id.* at 9a-23a.

2. Reynolds sought judicial review. See Pet. App. 3a. Under the Act, Reynolds could have filed a petition for review in either the Fourth Circuit (where it is based) or the D.C. Circuit. See *id.* at 7a (Higginson, J., dissenting). But those courts had already rejected the principal legal theory on which Reynolds relies here. See *ibid.* Specifically, Reynolds claims that FDA acted arbitrarily and capriciously by changing the evidentiary standards for flavored e-cigarette products after manu-

facturers had submitted their applications. See *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182, 189 (5th Cir. 2023). The Fourth and D.C. Circuits previously rejected similar claims. See *Avail Vapor*, 55 F.4th at 422 (4th Cir.); *Prohibition Juice Co.* v. *FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022).

Reynolds sought judicial review in the Fifth Circuit instead. See Pet. App. 3a. A panel of that court had rejected a claim similar to that brought by Reynolds, see *Wages & White Lion Investments, L.L.C.* v. *FDA*, 41 F.4th 427, 439 (5th Cir. 2022), but by the time Reynolds filed its petition for review, the court had vacated that decision and granted rehearing en banc, see *Wages & White Lion Investments, L.L.C.* v. *FDA*, 58 F.4th 233 (5th Cir. 2023). The en banc court would eventually rule in favor of the e-cigarette manufacturers. See *Wages & White Lion Investments, L.L.C.* v. *FDA*, 90 F.4th 357, 386 (5th Cir. 2024), cert. granted, No. 23-1038 (oral argument scheduled for Dec. 2, 2024).

Three other entities joined Reynolds' Fifth Circuit petition: RJR Vapor Co., LLC; Avail Vapor Texas, LLC; and the Mississippi Petroleum Marketers and Convenience Stores Association. See C.A. Pet. for Review 1-4 (Oct. 12, 2023). The first entity (a corporate affiliate of Reynolds) is based in North Carolina and sells Vuse Alto products online. See Pet. 5. The second entity is a Texas company that runs a retail store that sells Vuse Alto products. See C.A. Pet. for Review 3. The third entity is a Mississippi trade association of gas stations and convenience stores, which has members that sell Vuse Alto products. See *ibid.*

Reynolds and the other three entities (respondents in this Court) alleged that Avail and the Association's members "will no longer be able to sell" Vuse products

and "will have to dispose of [their] existing inventory" now that FDA has denied Reynolds' application. C.A. Pet. for Review 3. Respondents argued that venue lies in the Fifth Circuit because Avail and the Association are both based there. See *ibid.* "Out of an abundance of caution," however, respondents later filed a "protective petition" in the D.C. Circuit. Pet. for Review at 3, *R.J. Reynolds Vapor Co.* v. *FDA*, No. 23-1298 (Oct. 27, 2023).

3. FDA moved to dismiss the petition for review or to transfer it to the D.C. Circuit or the Fourth Circuit. See C.A. Doc. 43, at 23 (Oct. 18, 2023). The Fifth Circuit denied the motion in an unpublished order. See Pet. App. 1a-8a.

The Fifth Circuit had previously held, in considering another petition for review filed by Reynolds and joined by the remaining respondents, that "venue is proper in this circuit." *Reynolds*, 65 F.4th at 188. In the decision below, the court stated that it was bound by that holding. See Pet. App. 4a. Elaborating on the earlier decision's reasoning, the court stated that, because the Tobacco Control Act allows "any person adversely affected" to challenge the denial of an application for marketing authorization, e-cigarette sellers may "challenge FDA decisions that affect them." *Ibid.* (citation and emphasis omitted). The court also concluded that, because "two of the [four] Petitioners" "have their principal places of business here in the Fifth Circuit," all four could file a petition for review there. *Id.* at 3a.

Judge Higginson dissented. See Pet. App. 6a-8a. He observed that the court of appeals' interpretation of the Act effectively nullifies its venue limitations. See *id.* at 6a-7a. He also stated that the court's "expansive read-

ing of venue cannot seem to be reconciled with the other provisions of the [Act]." *Id.* at 7a.

In a separate order, the court of appeals granted respondents' motion to stay FDA's denial order pending resolution of the petition for review. See C.A. Doc. 133, at 1-3 (Feb. 2, 2024). Judge Higginson dissented from that order as well. See *id.* at 3 n.*.

SUMMARY OF ARGUMENT

The Fifth Circuit erred in holding that a retailer may challenge the denial of a manufacturer's application. It erred again in holding that the out-of-circuit manufacturer may ride the local retailer's coattails to establish venue. The combination of those errors deprives the Tobacco Control Act's venue restrictions of meaningful effect.

A. Under the Tobacco Control Act, an "adversely affected" person may seek judicial review of an FDA order denying an application for marketing authorization. 21 U.S.C. 387*l*(a)(1). "Adversely affected" is a term of art in administrative law. It invokes the zone-of-interests test, under which an entity may seek judicial review only if the interest it asserts falls within the zone of interests protected by the statutory provision at issue.

A retailer's interests fall outside the zone of interests protected by the provision at issue—the provision that requires FDA to adjudicate an application for marketing authorization. See 21 U.S.C. 387j(c). The order that FDA issues at the end of that adjudication speaks to the applicant alone (always or nearly always a manufacturer of the product) and affects retailers only indirectly. And while the provision grants procedural rights to the applicant itself, it shows no similar solicitude for retailers. It does not allow retailers to participate in the proceedings, does not grant them any proce-

dural rights, and does not require FDA to account for their substantive interests.

The statute's structure confirms that non-applicant retailers lack the right to challenge denial orders. The Act contains a confidentiality provision that shields trade secrets and other sensitive information submitted as part of the application process. Because of that provision, retailers will not necessarily know that a manufacturer has filed an application or that the agency has denied it. Congress would not have granted retailers the right to challenge denial orders in court while denying them the right to know that such orders had been entered and the right to see the information necessary to mount an effective challenge to FDA's conclusion that the applicant failed to show that the product at issue would be appropriate for the protection of public health.

The Act, moreover, forbids the sale of a new tobacco product unless and until FDA authorizes the marketing of the product. An order denying a manufacturer's application thus leaves a retailer's legal rights unchanged: The retailer has no right to sell the product before the denial, and it still lacks that right after the denial. The retailers in this case unlawfully sold Reynolds' Vuse Alto products before FDA had acted on Reynolds' applications, but their unlawful conduct cannot generate a right to judicial review that they would otherwise lack.

B. The Fifth Circuit also erred in holding that an out-of-circuit manufacturer may join a local retailer who seeks judicial review in the circuit. The Act provides that a person may file a petition for review in a circuit (other than the D.C. Circuit) only if "such person" resides or has its principal place of business there. 21 U.S.C. 387*l*(a)(1). The text thus makes clear that a person may sue in a circuit only if *that person* is based

there. A manufacturer may not sue based on a retailer's residence.

Traditional principles of joinder confirm that reading. Joinder is a procedural device that enables suits that could have been brought separately to be brought and processed together, not a tool for expanding the parties' rights or the court's power. Because Reynolds had no right to file its own petition in the Fifth Circuit, it also had no right to join someone else's petition there.

The same result follows from traditional principles of venue. This Court has long held that, except when Congress provides otherwise, venue must be proper as to each party in a multi-party case. "[E]ach plaintiff must be competent to sue" and "each defendant must be liable to be sued" in the chosen forum. *Smith* v. *Lyon*, 133 U.S. 315, 319 (1890). Nothing in the language of the Act departs from that default rule.

C. The Fifth Circuit's interpretation deprives the Act's venue restrictions of meaningful effect and enables their ready evasion. Congress specified three venues where a person may sue. But under the decision below, an applicant may sue in any regional circuit anywhere in the country so long as it finds a local retailer willing to join its petition. This Court should not adopt such a self-defeating interpretation of the statute.

ARGUMENT

The Tobacco Control Act provides as follows:

> Not later than 30 days after—
>
> (A) the promulgation of a regulation under [21 U.S.C. 387g] establishing, amending, or revoking a tobacco product standard; or
>
> (B) a denial of an application under [21 U.S.C. 387j(c)],

> any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or 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). That provision allows a person to file a petition for review of an FDA denial order in one of three circuits: the D.C. Circuit, the circuit where it resides, or the circuit where it maintains its principal place of business. When, as here, a venue statute does not define what counts as a residence, this Court usually holds that a domestic corporation resides in the State of its incorporation. See, *e.g.*, *TC Heartland LLC* v. *Kraft Foods Group Brands LLC*, 581 U.S. 258, 262 (2017); *Shaw* v. *Quincy Mining Co.*, 145 U.S. 444, 449 (1892).

The Fifth Circuit, however, has read the Tobacco Control Act's venue provision to mean that a manufacturer that neither resides nor maintains its principal place of business in the circuit may nonetheless file a petition for review there, so long as the petition is joined by a local seller of the manufacturer's products. See Pet. App. 3a. Reynolds, a manufacturer based in the Fourth Circuit, has invoked that theory to file three petitions for review, including the petition at issue here, in the Fifth Circuit.[1] At least eight other out-of-circuit manufacturers—based in China, California, Florida, Michigan, North Carolina, Ohio, and Washington—

---

[1] See p. 5, *supra*; Pet. for Review at 3, *R.J. Reynolds Vapor Co.* v. *FDA*, No. 23-60037 (5th Cir. Jan. 24, 2023); Pet. for Review at 3, *R.J. Reynolds Vapor Co.* v. *FDA*, No. 23-60128 (5th Cir. Mar. 17, 2023).

have since relied on the same tactic to seek judicial review in the Fifth Circuit.[2]

The Fifth Circuit's reading of the Act rests on two independent errors. First, the court erred in holding that a retail seller may seek judicial review of an FDA order denying a manufacturer's application. Second, the court erred in holding that venue need be proper only as to one party, rather than all the parties. Those two errors, in combination, effectively nullify the Act's limits on venue. This Court should reverse the court of appeals' order and remand with instructions to transfer the case to the D.C. Circuit. See C.A. Doc. 80, at 38 (Oct. 30, 2023) (stating that respondents prefer the D.C. Circuit to the Fourth Circuit).

A. A Retailer May Not File A Petition For Review Of An FDA Order Denying A Manufacturer's Application For Marketing Authorization

The Tobacco Control Act provides that an "adversely affected" person may seek judicial review of an FDA order denying an application for marketing authorization. 21 U.S.C. 387*l*(a)(1). The term "adversely affected," like its cousin "aggrieved," is a "term of art" with a

---

[2] See Pet. for Review at 1-3, *Shenzhen IVPS Technology Co.* v. *FDA*, No. 24-60032 (5th Cir. Jan. 19, 2024) (China); Pet. for Review at 1-3, *Shenzhen Youme Information Technology Co.* v. *FDA*, No. 24-60060 (5th Cir. Feb. 5, 2024) (China); Pet. for Review at 1-3, *Corr-Williams Co.* v. *FDA*, No. 24-60068 (5th Cir. Feb. 8, 2024) (North Carolina); Pet. for Review at 1-2, *NicQuid, LLC* v. *FDA*, No. 24-60272 (5th Cir. June 3, 2024) (Ohio); Pet. for Review at 1-2, *Breeze Smoke, LLC* v. *FDA*, No. 24-60304 (5th Cir. June 14, 2024) (Michigan); Pet. for Review at 1-2, *Vertigo Vapor LLC* v. *FDA*, No. 24-60332 (5th Cir. June 28, 2024) (Washington); Pet. for Review at 2, *Lead by Sales LLC* v. *FDA*, No. 24-60424 (5th Cir. Aug. 20, 2024) (Florida); Pet. for Review at 1-3, *VDX Distro, Inc.* v. *FDA*, No. 24-60537 (5th Cir. Oct. 18, 2024) (California).

"long history in federal administrative law." *Director, Office of Workers' Compensation Programs* v. *Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 126 (1995). The APA authorizes judicial review at the behest of an "adversely affected or aggrieved" person. 5 U.S.C. 702. Many agency-specific statutes likewise use the terms "adversely affected" and "aggrieved," alone or in combination, to designate those who may challenge agency action. See *Newport News*, 514 U.S. at 126.

The terms "adversely affected" and "aggrieved" invoke the zone-of-interests test. See, *e.g.*, *Thompson* v. *North American Stainless, LP*, 562 U.S. 170, 178 (2011); *Lujan* v. *National Wildlife Federation*, 497 U.S. 871, 886 (1990). Under that test, a plaintiff may seek judicial review only if its interests "fall within the zone of interests protected by the law invoked." *Lexmark International, Inc.* v. *Static Control Components, Inc.*, 572 U.S. 118, 129 (2014) (citation omitted).

"[T]he breadth of the zone of interests varies according to the provisions of law at issue." *Bennett* v. *Spear*, 520 U.S. 154, 163 (1997); see *Newport News*, 514 U.S. at 126 ("[W]hat constitutes adverse effect or aggrievement varies from statute to statute.") (citation and emphasis omitted). In APA cases, the zone-of-interests test is not "especially demanding." *Lexmark*, 572 U.S. at 130 (citation omitted). In that context, the Court has "conspicuously included the word 'arguably' in the test to indicate that the benefit of any doubt goes to the plaintiff." *Ibid.* (citation omitted). That "lenient approach" preserves "the flexibility of the APA's omnibus judicial-review provision, which permits suits for violations of numerous statutes of varying character." *Ibid.*

That lenient approach does not, however, carry over to other statutes. See *Lexmark*, 572 U.S. at 130. In

non-APA cases, a court should generally ask whether the interest asserted by the plaintiff actually (rather than just arguably) falls within the zone protected by the statute. See *id.* at 129. As a result, "what comes within the zone of interests * * * for purposes of * * * the 'generous review provisions' of the APA may not do so for other purposes." *Bennett*, 520 U.S. at 163 (citation omitted).

A court should discern the breadth of the zone of interests—or, said otherwise, identify the types of harms that qualify as adverse effects—using the normal tools of statutory interpretation, including text, structure, and precedent. See *Newport News*, 514 U.S. at 127-136. In this case, those tools show that a retailer may not challenge an order denying a manufacturer's application for marketing authorization.

1. A retailer's interests fall outside the zone of interests protected by the statutory provision at issue

In applying the zone-of-interests test, a court should focus on "the particular provision of law upon which the plaintiff relies," not on the "overall purpose of the Act." *Bennett*, 520 U.S. at 175-176. The plaintiff must show that its interest falls within the zone protected by "the statutory provision whose violation forms the legal basis for [the] complaint." *National Wildlife Federation*, 497 U.S. at 883. Applying the test at a higher "level of generality" risks depriving it "of virtually all meaning." *Air Courier Conference of America* v. *American Postal Workers Union*, 498 U.S. 517, 529-530 (1991).

Respondents claim that FDA acted arbitrarily and capriciously in applying 21 U.S.C. 387j(c), the provision of the Tobacco Control Act directing the agency to act on applications for marketing authorization. See pp. 4-5, *supra*. The judicial-review provision that they invoke

authorizes courts to review "a denial of an application *under section 387j(c) of this title*." 21 U.S.C. 387*l*(a)(1)(B) (emphasis added). Respondents must therefore show that Section 387j(c) protects not only the interests of the applicant itself, but also the interests of retail sellers of the applicant's products. Respondents cannot make that showing.

a. Section 387j(c) directs FDA to issue an "order" after adjudicating an application. 21 U.S.C. 387j(c)(1)(A); see 5 U.S.C. 551(6) (APA's definition of "order"). Congress modeled administrative adjudications on court proceedings. See *Sims* v. *Apfel*, 530 U.S. 103, 110 (2000). Like a court order, an agency order ordinarily addresses particular parties, not the "world at large." *Radiofone, Inc.* v. *FCC*, 759 F.2d 936, 938 (D.C. Cir. 1985) (opinion of Scalia, J.). Under Section 387j(c), after evaluating an application, FDA must issue either "an order that the new product may be introduced" or "an order that the new product may not be introduced" into interstate commerce. 21 U.S.C. 387j(c)(1)(A). That order is issued to the applicant alone. Because the order regulates only the applicant, the prohibition upon arbitrary and capricious decision-making in the issuance of the order seeks to protect only the applicant. It does not seek to protect retailers, who are strangers to the adjudication.

To be sure, denial orders may have indirect consequences for retailers: If a manufacturer lacks authorization to sell a product, retailers cannot lawfully obtain and resell it. But that indirect effect does not entitle retailers to judicial review of FDA's decision on a manufacturer's application. Our legal system has long distinguished between "action that directly affects a citizen's legal rights" and "action that is directed against a

third party and affects the citizen only indirectly or incidentally." *O'Bannon* v. *Town Court Nursing Center*, 447 U.S. 773, 788 (1980); see *Department of State* v. *Muñoz*, 602 U.S. 899, 917-919 (2024); *Legal Tender Cases*, 12 Wall. 457, 551 (1871). When agency action "directly affects" one person and "causes only a consequential detriment" to a bystander, the bystander has a weak claim to judicial review—especially when (as here) its interests can be "adequately protected by the person directly affected." *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U.S. 123, 153-154 (1951) (Frankfurter, J., concurring). Indeed, a claim based on a "derivative" harm is "precisely the sort of claim that the prudential standing doctrine" (as the zone-of-interests test is sometimes known) "is designed to foreclose." *Center for Reproductive Law & Policy* v. *Bush*, 304 F.3d 183, 196 (2d Cir. 2002) (Sotomayor, J.).

This case, in addition, differs meaningfully from cases where this Court has held that a bystander may challenge an agency order. Although the Act provides for review only of denials of applications, see 21 U.S.C. 387*l*(a)(1)(B), some other statutes authorize adversely affected or aggrieved persons to seek review of both grants and denials of applications, see, *e.g.*, 47 U.S.C. 402(b)(6). Such statutes may even allow "persons with interests adverse to the winning party," such as "competitors," to challenge an agency order granting an application. *Radiofone*, 759 F.2d at 939 (opinion of Scalia, J.); see, *e.g.*, *FCC* v. *Sanders Brothers Radio Station*, 309 U.S. 470, 476-477 (1940). Unlike competitors, however, the retailers here are not adverse to the manufacturer. Their interests, rather, derive from the manufacturer's and are "adequately protected" by the manufacturer's own ability to seek review of the denial of its ap-

plication. *Joint Anti-Fascist Refugee Committee*, 341 U.S. at 154 (Frankfurter, J., concurring).

b. The rest of Section 387j—the section establishing the process for applying for marketing authorization—confirms that Section 387j(c) does not seek to protect retailers. Section 387j authorizes an applicant to file an application with FDA, see 21 U.S.C. 387j(b), and then directs FDA to issue a decision after considering "the information submitted to [it] as part of the application," 21 U.S.C. 387j(c)(2). Section 387j does not give retailers any role in that process. It does not authorize them to intervene, to submit additional evidence, or to comment on the agency's proposed action.

Section 387j also confers various procedural rights upon the applicant alone. For example, "an applicant" may ask FDA to refer the application to a special scientific committee. 21 U.S.C. 387j(b)(2)(B). FDA must serve its order on "the applicant." 21 U.S.C. 387j(e)(2). And if FDA denies an application, it must, to the extent practicable, provide a "statement informing the applicant of the measures required to remove such application from deniable form"—measures that may include "further research by the applicant." 21 U.S.C. 387j(c)(3). Section 387j, by contrast, grants no procedural rights to retailers. Retailers have no right to make requests about the processing of the application, no right to notice of the agency's order, no right to know the reasons for a denial, and no right to know what changes could be made to make the application grantable.

The substantive standard that Section 387j requires FDA to apply likewise reveals no concern for retailers' particular interests. The agency may authorize the marketing of a new tobacco product only if the applicant shows that authorization would be "appropriate for the

protection of the public health." 21 U.S.C. 387j(c)(2)(A). The Act requires the agency, in applying that test, to weigh (1) the likelihood that the new product will help existing smokers "stop using" tobacco products and (2) the risk that the new product will prompt non-smokers to "start using" tobacco products. 21 U.S.C. 387j(c)(4). But the Act does not direct the agency to weigh any interests of potential retailers, such as the new product's effects on their revenues.

In sum, Section 387j requires FDA to issue an order directed to the applicant, not to retailers. It does not give retailers a role in the agency process, does not grant them any procedural protections, and does not require the agency to consider their substantive interests. In fact, Section 387j does not mention retailers at all. The statutory text and context thus strongly suggest that retailers' interests fall outside the zone of interests that Section 387j(c) protects.

c. The contrary reading of the Act lacks an obvious stopping point. This case involves retailers that have previously sold the product at issue, but respondents' reasoning would seem to extend even further. Taken to its logical conclusion, it would permit judicial review at the behest of a retailer that has never sold the product but would like to do so once the product is authorized. It would also permit review at the behest of a consumer who uses the product—or, for that matter, a consumer who does not yet use it but would like to do so. A court should not lightly infer that an agency order directed to a specific applicant may be challenged by such a broad class of bystanders.

The contrary reading would also allow a retailer (and perhaps a consumer) to file a petition for review without regard to the wishes of the unsuccessful applicant. A

retailer could seek judicial review even if the applicant prefers to drop the case (*e.g.*, in favor of filing a new application). Or a retailer could insist on litigating in one circuit even if the applicant prefers another one where it is permitted to file. Allowing retailers and other bystanders to file their own challenges would thus undermine "the autonomy of those persons likely to be most directly affected by [the agency's] order." *Valley Forge Christian College* v. *Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 473 (1982).

2. The structure of the statutory scheme confirms that a retailer may not challenge an FDA order denying a manufacturer's application

A court should always seek to interpret a statute "as a symmetrical and coherent regulatory scheme" and to "fit, if possible, all parts into an harmonious whole." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citations omitted); see Antonin Scalia & Bryan A. Garner, *Reading Law* 167 (2012). Statutory structure is especially relevant to the interpretation of the term "adversely affected." Discerning which harms constitute adverse effects often involves inferences drawn from the nature of the "statutory scheme." *Newport News*, 514 U.S. at 127 (citation omitted). Here, several features of the statutory framework confirm that a retailer lacks the right to challenge the denial of a manufacturer's application.

a. The Tobacco Control Act includes a provision that protects "privileged or confidential" "trade secrets and commercial or financial information" submitted by an applicant as part of the application process. 5 U.S.C. 552(b)(4); see 21 U.S.C. 387f(c) (cross-referencing 5 U.S.C. 552(b)(4)). The Act provides that such information "shall be considered confidential and shall not

be disclosed," except in specified circumstances. 21 U.S.C. 387f(c).

Because of the confidentiality provision, retailers and other members of the public will not necessarily know that a manufacturer has applied for authorization to market a new tobacco product. "[T]he intent to market a tobacco product that is not currently marketed is often considered confidential commercial information." 86 Fed. Reg. 55,300, 55,398 (Oct. 5, 2021). FDA thus generally "will not publicly disclose the existence of an application." 21 C.F.R. 1114.47(b)(1).

Retailers and other members of the public likewise will not necessarily know that FDA has denied a particular manufacturer's application or what particular product was subject to agency adjudication. "Even after receipt of a marketing denial order," "the intent to market may still constitute confidential commercial information." 86 Fed. Reg. at 55,398. When FDA denies an application, therefore, it limits public disclosures to non-confidential information, such as the "tobacco product category (*e.g.*, cigarette)," the "tobacco product subcategory (*e.g.*, filtered, combusted cigarette)," and the "characterizing flavor." 21 C.F.R. 1114.47(d). Unless the manufacturer has disclosed its intent to market the product, the agency does not identify the specific product for which marketing authorization was denied.

Even when the public knows that a manufacturer has applied for marketing authorization and that FDA has denied the application, the confidentiality provision precludes full disclosure of the contents of the application, denial order, and agency record. Here, for example, Reynolds successfully moved to seal its filings in the court of appeals in order to protect "confidential and proprietary information concerning Vuse products' de-

sign, components, and other highly sensitive technical details that have not been made available to the public." C.A. Doc. 59, at 3. It observed that "FDA has repeatedly recognized the need to prevent public disclosure of confidential and sensitive information contained in submissions like the Vuse applications." *Id.* at 9.

The confidentiality provision reinforces retailers' lack of any right to seek judicial review. See Pet. App. 7a (Higginson, J., dissenting). A person can seek judicial review only if it knows that a manufacturer has filed an application and that FDA has denied it. There is no reason to think that Congress wanted a non-applicant retailer to be able to obtain judicial review if it could somehow learn the non-public fact that an application had been filed by someone else and had been denied in the 30 days preceding the retailer's petition for review. See 21 U.S.C. 387*l*(a)(1)(B).

A person, moreover, can "make a considered decision whether to seek judicial review" only if it knows the agency's "reasons for the denial." *T-Mobile South, LLC* v. *City of Roswell*, 574 U.S. 293, 304 (2015). That is particularly true under the Tobacco Control Act, which instructs courts to review denials under the arbitrary-and-capricious standard. See 21 U.S.C. 387*l*(b) (citing 5 U.S.C. 706(2)(A)). It is implausible that Congress granted retailers a right to litigate record-intensive arbitrary-and-capricious challenges while denying them the right to see the administrative record.

b. The Tobacco Control Act's separate provisions governing sales of tobacco products support the conclusion that denial orders do not adversely affect retailers. Those provisions make it unlawful to sell a new tobacco product unless and until FDA authorizes its marketing. See 21 U.S.C. 331(c), 387b(6)(A). Given those provi-

sions, an order denying a manufacturer's application has no effect on a retailer's legal rights or duties. The retailer has no legal right to sell the unauthorized product before the denial order, and it still lacks that right after the order. Because a denial order leaves the retailer's legal position unchanged, the order does not "adversely affect" the retailer.

A denial order, at most, affects a retailer's expectations about the likelihood of FDA enforcement action. Under the enforcement policy in effect when Reynolds submitted its applications, FDA's enforcement priorities included products for which marketing applications had been denied. See p. 4, *supra*. But an increase in the likelihood that FDA will enforce the law is not an "adverse effect." The scope of the term "adversely affected" depends on the statute's meaning when enacted, not on FDA's post-enactment enforcement choices. Treating a change in the odds of enforcement as a judicially cognizable harm would undermine the Executive Branch's exclusive Article II power to decide "how to prioritize and how aggressively to pursue legal actions against defendants who violate the law." *United States* v. *Texas*, 599 U.S. 670, 678 (2023) (citation omitted).

In this case, the retailers explain that they have been selling Reynolds' Vuse Alto products since before FDA resolved Reynolds' applications. See C.A. Pet. for Review 3. They fear that, now that FDA has denied the applications, it will enforce the Act against them, so that they "will no longer be able to sell" the products. *Ibid.* But those sales have violated the Act all along (even if they were not identified as priorities for FDA enforcement), and an interest in continuing to violate the law necessarily falls outside the zone of interests that the law seeks to protect. A retailer that has started unlaw-

fully selling an unauthorized product may not seek judicial review on the ground that a denial order reduces the chances that FDA will continue to refrain from taking action against those violations. Respondents' contrary argument runs up against "the basic notion that no court will lend its aid to one who founds a cause of action upon an * * * illegal act." *Paperworkers* v. *Misco, Inc.*, 484 U.S. 29, 42 (1987); see *Holman* v. *Johnson*, 98 Eng. Rep. 1120, 1121 (K.B. 1775) (Lord Mansfield, L.C.J.) ("If, from the plaintiff's own stating or otherwise, the cause of action appears to arise * * * [from] the transgression of a positive law of this country, there the Court says he has no right to be assisted.").

c. Finally, the Act empowers FDA to withdraw a grant of marketing authorization in some circumstances —for instance, if it finds that "the continued marketing of [the] tobacco product no longer is appropriate for the protection of the public health." 21 U.S.C. 387j(d)(1)(A). The Act provides that the "holder of an application" may obtain review of a withdrawal order "in accordance with section 387*l*," the judicial-review provision at issue here. 21 U.S.C. 387j(d)(2).

The statutory text makes plain, and respondents agree (Br. in Opp. 11), that the Act does not allow a retailer to challenge an order withdrawing authorization. But a withdrawal order, which forces a retailer to stop previously lawful sales, affects a retailer's interests far more directly than a denial order. See Pet. App. 7a (Higginson, J., dissenting). Respondents have proffered no persuasive reason why Congress would have wanted to allow retailers to challenge the denial of authorization to market a new tobacco product at the outset, but not to challenge the agency's withdrawal of a previous authorization.

Reinforcing that point, Congress required FDA to follow more robust procedures when issuing withdrawal orders than when issuing denial orders. Before the agency issues a withdrawal order, it must provide the applicant with a hearing, see 21 U.S.C. 387j(d)(1), in which the applicant enjoys specified procedural rights, see 21 U.S.C. 321(x). It would have been strange for Congress to conclude that granting additional procedural rights to *the applicant* somehow compensated for denying judicial review to entities other than the applicant.

3. Precedent confirms that retailers lack the right to seek judicial review

The interpretive issue presented in this case closely resembles the interpretive issue resolved in *Block* v. *Community Nutrition Institute*, 467 U.S. 340 (1984). The statute in *Block* empowered an agency to issue market orders setting minimum prices to be paid by milk handlers to milk producers. See *id.* at 341-342. It authorized handlers to seek judicial review of market orders, but only after exhausting administrative remedies. See *id.* at 346. A handler tried to bypass that exhaustion requirement by joining a group of milk *consumers* to challenge a market order under the APA. See *id.* at 344-345.

The D.C. Circuit held that the consumers could sue, but then-Judge Scalia dissented from that aspect of its decision. See *Community Nutrition Institute* v. *Block*, 698 F.2d 1239, 1256-1258 (1983) (Scalia, J., concurring in part and dissenting in part), rev'd, 467 U.S. 340 (1984). Judge Scalia emphasized that the market orders had a "direct and immediate" effect on handlers, but only an "indirect" effect on consumers. *Id.* at 1257. He reasoned that, because the "immediately affected" group

(handlers) was "readily identifiable" and could be "relied upon to challenge agency disregard of the law," the "more remote" group (consumers) could not be "found to meet the zone of interests test." *Ibid.*

This Court agreed with Judge Scalia that consumers lacked the right to challenge milk market orders. See *Block*, 467 U.S. at 346-348. The Court emphasized that, although the statute authorized handlers "to participate in the adoption and retention of market orders," it contained no "express provision for participation by consumers." *Id.* at 346-347. The Court inferred that, because Congress had excluded consumers from the "regulatory process," it "intended a similar restriction of judicial review." *Id.* at 347. The Court added that allowing consumer suits "would provide handlers with a convenient device for evading the statutory [exhaustion] requirement"; a handler "would need only to find a consumer who is willing to join in or initiate an action in the district court." *Id.* at 348. Because that result would "effectively nullify" the exhaustion requirement, the Court found it "clear that Congress intended that judicial review of market orders * * * ordinarily be confined to suits brought by handlers." *Ibid.*

Most of this Court's and Judge Scalia's reasoning in *Block* also applies here. An FDA order denying an application for marketing authorization has a direct and immediate effect on the applicant itself, but only an indirect and incidental effect on retail sellers of the applicant's products. The Act authorizes the applicant itself to participate in the regulatory process, but it contains no provision for participation by retailers. And allowing retailer suits could hand applicants a convenient device for evading the Act's venue restrictions; unless this Court rejects the court of appeals' rule that venue need

be proper only as to one party, a disappointed applicant could simply find a retailer that is willing to join in a petition for review in a preferred circuit. Those features of the statutory scheme all indicate that only applicants, not retailers, may seek judicial review of orders denying applications.

In some respects, this case follows *a fortiori* from *Block*. *Block* involved a suit under the APA, see 467 U.S. at 345, while this case involves a petition for review under the Tobacco Control Act. The Court has applied the zone-of-interests test more stringently in non-APA cases than in APA cases. See *Lexmark*, 572 U.S. at 130. *Block* also involved judicial review of a rulemaking, see 467 U.S. at 342, while this case involves judicial review of an adjudication. It is particularly natural to infer that only the parties to an adjudication may challenge its outcome in court. See p. 14, *supra*.

4. The court of appeals' reasoning is flawed

The court of appeals reasoned that a retail seller may seek judicial review of a denial order because such an order "affect[s]" the seller by reducing its sales. Pet. App. 4a. But as explained above, the phrase "adversely affected" is a term of art in administrative law. See pp. 11-12, *supra*. The critical question is not whether a denial order harms the seller in some way; it is whether that harm "constitutes adverse effect" within the meaning of the Act. *Newport News*, 514 U.S. at 126 (emphasis omitted). For the reasons given above, the Act's structure shows that it does not.

The court of appeals also emphasized that the statute refers to "*any* person adversely affected." Pet. App. 4a (quoting 21 U.S.C. 387*l*(a)(1)). But "the word 'any' cannot expand the phrase" that follows. *National Ass'n of Manufacturers* v. *Department of Defense*, 583 U.S. 109,

123 (2018). Despite the inclusion of the word "any," the term "any person adversely affected" still requires a showing that the person has been "adversely affected," which in turn requires a showing that the person falls within the zone of interests protected by the statutory provision at issue. See, *e.g.*, *Newport News*, 514 U.S. at 126 (interpreting 33 U.S.C. 921(c), which referred to "any person adversely affected or aggrieved") (brackets omitted).

The court of appeals next contrasted the provision at issue here—under which an "adversely affected" person may challenge a denial order, 21 U.S.C. 387*l*(a)(1)—with the provision under which the "holder of an application" may challenge a withdrawal order, 21 U.S.C. 387j(d)(2). See Pet. App. 4a-5a. The court read too much into that contrast. The provision at issue authorizes judicial review not only of a "denial" of an application, but also of a "regulation" establishing, amending, or revoking a tobacco product standard. 21 U.S.C. 387*l*(a)(1). The term "holder of an application," used in the narrower provision specifically addressing judicial review of withdrawal orders, would have been a poor fit for the full range of agency actions covered by the provision here. If anything, the provision concerning judicial review of withdrawal orders cuts against the court of appeals' reading. It would have been incongruous for Congress to allow retailers to challenge denial orders, but not to challenge withdrawal orders. See pp. 22-23, *supra*.

Finally, the court of appeals stated that concerns about petitions for review filed by retailers should be "directed to Congress," not to the courts. Pet. App. 5a. But that suggestion rests on the mistaken premise that the statute, as written, allows retailers to seek judicial review. The term "adversely affected" requires "the

courts" to infer, "in the context of * * * the particular statutory pattern," "who is entitled to judicial review." U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 96 (1947); see *Newport News*, 514 U.S. at 126-127 (quoting the *Attorney General's Manual*). Courts must carry out the function that Congress entrusted to them. And as discussed above, the statutory pattern here shows that retailers may not challenge an FDA order denying a manufacturer's application.

B. A Manufacturer May File A Petition For Review Only In The D.C. Circuit Or The Circuit Where It Is Based

The Fifth Circuit further erred by holding that a group of petitioners may file a petition for review in a circuit so long as "*a* petitioner" resides or maintains its principal place of business within that circuit. *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182, 188 (5th Cir. 2023) (emphasis added); see Pet. App. 5a. Unless Congress provides otherwise, courts must evaluate venue party by party, and venue must be proper as to each party. A petitioner for whom venue is improper may not simply tag along with one for whom it is proper. See *Amerada Petroleum Corp.* v. *Federal Power Commission*, 338 F.2d 808, 809-810 (10th Cir. 1964) (interpreting a similarly worded venue statute to mean that an out-of-circuit petitioner could not join a local petitioner); *National Family Farm Coalition* v. *EPA*, 966 F.3d 893, 930-932 (9th Cir. 2020) (Nelson, J., concurring) (same).

1. The Act does not authorize one person to lay venue based on a different person's residence or principal place of business

In general, a party may bring a suit only if a statute authorizes it to do so. See *Alexander* v. *Sandoval*, 532

U.S. 275, 286-287 (2001). That authorization ordinarily must be explicit; Congress usually does not create new remedies by implication. See *Cummings* v. *Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 226 (2022). The government thus does not bear the burden of showing that the Tobacco Control Act prohibits Reynolds from seeking judicial review in the Fifth Circuit. Instead, respondents bear the burden of proving that the Act affirmatively authorizes Reynolds to do so. They cannot make that showing.

The Act states that "any person adversely affected by [a] regulation or denial may file a petition for judicial review of such regulation or 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) (emphasis added). The word "such," when used to modify a noun, refers back to something "previously spoken of." *United States* v. *Gooding*, 12 Wheat. 460, 477 (1827). The term "such person" thus makes clear that a person may seek judicial review in a circuit (other than the D.C. Circuit) only if *that person* is based in that circuit. Party *A* may not sue in a circuit just because party *B* lives there. The court of appeals effectively rewrote the statute to allow a person to sue in "the circuit in which such person [*or a retail seller of such person's products*] resides or has their principal place of business." 21 U.S.C. 387*l*(a)(1).

The Act also uses singular rather than plural nouns, authorizing a "person" to file "a petition" in the circuit where the "person" resides or has its principal place of business. 21 U.S.C. 387*l*(a)(1). That matters because the use of the singular or the plural can illuminate a statute's meaning. See *Niz-Chavez* v. *Garland*, 593

U.S. 155, 161-164 (2021); *Life Technologies Corp.* v. *Promega Corp.*, 580 U.S. 140, 149-151 (2017). Here, the "use of the singular noun 'person' * * * suggests venue should be analyzed on a petitioner-by-petitioner basis." *National Family Farm Coalition*, 966 F.3d at 930 (Nelson, J., concurring).

Finally, the Act lists three venues in which a person may seek judicial review: the D.C. Circuit, the circuit where the person resides, and the circuit in which the person has its principal place of business. See 21 U.S.C. 387*l*(a)(1). The Act's enumeration of those three options implies the exclusion of others, such as the circuit where a co-petitioner resides. *Expressio unius est exclusio alterius*. See *Jennings* v. *Rodriguez*, 583 U.S. 281, 300 (2018); Scalia & Garner 107.

2. Traditional principles of joinder confirm that an out-of-circuit manufacturer does not acquire a right to sue in a circuit by joining a local retailer

Although the Act does not address the filing of joint petitions, the Federal Rules of Appellate Procedure provide that "two or more persons may join in a petition to the same court to review the same order" if "their interests make joinder practicable." Fed. R. App. P. 15(a)(1). The Federal Rules of Civil Procedure similarly allow multiple plaintiffs to join in one complaint. See Fed. R. Civ. P. 20(a)(1). Joinder, however, just allows suits that could have been brought separately to be brought together; it does not allow an out-of-circuit manufacturer to piggyback on a local retailer's claims.

Joinder is a device for the "aggregation of claims." *Sprint Communications Co.* v. *APCC Services, Inc.*, 554 U.S. 269, 291 (2008). Although it "enables a federal court to adjudicate claims of multiple parties at once, instead of in separate suits," it "leaves the parties' legal

rights and duties intact and the rules of decision unchanged." *Shady Grove Orthopedic Assocs., P.A.* v. *Allstate Insurance Co.*, 559 U.S. 393, 408 (2010) (plurality opinion). Said otherwise, joinder rules "are procedural means of processing claims, not fonts of judicial authority." *Alabama* v. *North Carolina*, 560 U.S. 330, 362 (2010) (Roberts, C.J., concurring in part and dissenting in part).

Thus, if multiple plaintiffs join in one complaint, "each plaintiff's right of action remains distinct, as if it had been brought separately." 7 Charles Alan Wright et al., *Federal Practice and Procedure* § 1652, at 414 (4th ed. 2019) (Wright & Miller). Joinder cannot "rescue claims that would have been doomed * * * if they had been asserted in a separate action"; conversely, it does not require "dismissal of claims that would have otherwise survived." *Rockwell International Corp.* v. *United States*, 549 U.S. 457, 476 (2007) (quoting *United States ex rel. Merena* v. *SmithKline Beecham Corp.*, 205 F.3d 97, 103 (3d Cir. 2000) (Alito, J.)).

The Tobacco Control Act plainly would not allow Reynolds to file its own petition for review in the Fifth Circuit. Under ordinary principles of joinder, it follows that Reynolds is equally unable to join someone else's petition in that circuit.

3. Traditional principles of venue confirm that venue must be proper as to each petitioner

The Fifth Circuit's interpretation of the Act conflicts not only with statutory text and traditional principles of joinder, but also with traditional principles of venue. "Faced with multi-party cases," this Court "long ago held that venue must be proper as to each party." 14D Wright & Miller § 3807, at 204 (4th ed. 2013). Today, "it is common for courts to say that venue must be proper

as to each claim and as to each party." *Id.* at 206-207. Treatise writers agree that, "when a special venue statute allows venue where the plaintiff resides," "venue would not be proper for [multiple] plaintiffs in a district in which only one of them resides." *Id.* at 206.

This Court first applied that party-specific approach in interpreting a 19th-century statute authorizing a plaintiff to bring a diversity suit "in the district of the residence of either the plaintiff or the defend[a]nt." Act of Mar. 3, 1887, ch. 373, § 1, 24 Stat. 552-553. In *Smith* v. *Lyon*, 133 U.S. 315 (1890), the Court held that the statute's reference to "the plaintiff" meant every plaintiff, not just one plaintiff. See *id.* at 317-320. And in *Camp* v. *Gress*, 250 U.S. 308 (1919), the Court held that the term "the defendant" in a similarly worded successor statute meant every defendant, not just one defendant. See *id.* at 311-316. Those decisions establish that, in a multi-party case, "each plaintiff must be competent to sue" and "each defendant must be liable to be sued" in the chosen forum. *Smith*, 133 U.S. at 319 (citation omitted); see *Camp*, 250 U.S. at 312 (requiring "each" party to be "competent to sue, or liable to be sued," in the chosen court) (citation omitted).

This Court adhered to that approach in *Bankers Life & Casualty Co.* v. *Holland*, 346 U.S. 379 (1953). The venue statute there allowed an antitrust plaintiff to sue "in the district in which the defendant resides or is found or has an agent." 15 U.S.C. 15(a). Even though antitrust cases routinely involve conspiracies among multiple defendants, the Court analyzed venue one defendant at a time. See *Holland*, 346 U.S. at 384. It explained that, when venue does not "lie in one district as to all defendants," proceedings would need to be "severed and transferred or filed in separate districts origi-

nally." *Ibid.* The plaintiff had argued that each antitrust defendant could be regarded as an "agent" of his co-conspirators, enabling all of them to be sued where any one of them lived. See *id.* at 380-381. But the Court rejected that theory, stating that it had "all the earmarks of a frivolous albeit ingenious attempt to expand the statute," which had "placed definite limits on venue." *Id.* at 384. The Court thus explained that "many such cases would not lie in one district as to all defendants, unless venue was waived" as a defense. *Ibid.*

In fact, other precedents of this Court require courts to evaluate venue not just party by party, but claim by claim. See *Geneva Furniture Manufacturing Co.* v. *S. Karpen & Bros.*, 238 U.S. 254, 258-259 (1915). In other words, "if the plaintiff asserts multiple claims against the defendant, venue must be proper for each claim." 14D Wright & Miller § 3808, at 213. That rule confirms the broader principle that venue "cannot be enlarged or extended by uniting [different causes of action] in a single suit." *Geneva*, 238 U.S. at 259.

This Court's party-by-party approach to venue is consistent with its party-by-party approach to other threshold statutory requirements. For example, the Court has long interpreted the diversity-jurisdiction statute to require complete diversity; each plaintiff must be diverse from each defendant. See *Strawbridge* v. *Curtiss*, 3 Cranch 267, 267-268 (1806). The Court has read amount-in-controversy requirements, in the diversity statute as well as in other jurisdictional grants, to mean that "each of several plaintiffs is bound to establish the jurisdictional amount with respect to his own claim." *Clark* v. *Paul Gray, Inc.*, 306 U.S. 583, 590 (1939); see *Zahn* v. *International Paper Co.*, 414 U.S.

291, 294-295 & n.3 (1973) (collecting cases). And the Court has interpreted the removal statute to mean that, when "there is more than one defendant, all the defendants must join" in removing the case from state to federal court. *Gableman* v. *Peoria, Decatur, & Evansville Ry. Co.*, 179 U.S. 335, 337 (1900); see *Chicago, Rock Island, & Pacific Ry. Co.* v. *Martin*, 178 U.S. 245, 248 (1900).

The party-by-party approach to venue vindicates the general purpose of such provisions. The plaintiff, as master of its complaint, controls which co-plaintiffs and co-defendants it will name. But "the purpose of statutorily specified venue is to protect the *defendant*." *Leroy* v. *Great Western United Corp.*, 443 U.S. 173, 183-184 (1979). Venue restrictions would not serve that purpose if a plaintiff could evade them simply by adding more parties to its complaint.

The principle that venue must be proper as to each party is, of course, simply a default rule. Congress is free to adopt a different approach in a particular statute. Congress has thus enacted special venue statutes that authorize suit where "any party resides," 49 U.S.C. 44309(d)(1); where "any plaintiff resides," 18 U.S.C. 2334(a); where "any defendant resides," 43 U.S.C. 1349(b)(1); where "a defendant in the action resides," 28 U.S.C. 1391(e)(1)(A); or where "any one defendant can be found," 31 U.S.C. 3732(a). It has also provided that, in certain cases, a "joinder of * * * a defendant shall be disregarded in determining where the action may be brought with respect to the other defendants." 28 U.S.C. 1391(c)(3).

The statute at issue here, however, does not allow an adversely affected person to seek judicial review in a circuit where "any petitioner" resides. Nor does it state

that a joinder may be disregarded in analyzing venue. To the contrary, by authorizing an adversely affected person to sue in the circuit where "such person resides or has their principal place of business," 21 U.S.C. 387*l*(a)(1), the Act makes clear that a person may seek review in a circuit (other than the D.C. Circuit) only if *that person* is based in the circuit. See pp. 28-29, *supra*.

C. The Fifth Circuit's Interpretation Effectively Nullifies The Act's Restrictions On Venue

The Fifth Circuit's errors—allowing retailers to sue and requiring venue to be proper as to only one party—combine to produce a result that defies elementary principles of statutory interpretation. A court should read a statute "so that effect is given to all provisions, so that no part will be inoperative or superfluous, void or insignificant." *Ysleta del sur Pueblo* v. *Texas*, 596 U.S. 685, 698-699 (2022) (citation omitted). Courts should avoid readings that would facilitate a statute's "evasion" or would enable parties "to elude its provisions in the most easy manner." *The Emily*, 9 Wheat. 381, 389-390 (1824); see Scalia & Garner 63.

Those principles apply to venue statutes no less than to other statutes. This Court has resisted reading venue statutes in a way that would, in practice, "give the plaintiff an unrestrained choice of venues." *Leroy*, 443 U.S. at 186-187 & n.23. The Court has likewise avoided interpretations that would "encourage gamesmanship" or "'create or multiply opportunities for forum shopping.'" *Atlantic Marine Construction Co.* v. *United States District Court*, 571 U.S. 49, 65 (2013) (citation omitted); see, *e.g.*, *Rumsfeld* v. *Padilla*, 542 U.S. 426, 447 (2004) (rejecting interpretation that would allow "rampant forum shopping").

Contrary to those fundamental principles, the Fifth Circuit's approach drains the Act's venue restrictions of meaning, facilitates their ready circumvention, and invites unchecked forum shopping. Even though the Act specifies only three venues where a person may seek judicial review, see 21 U.S.C. 387*l*(a)(1), the Fifth Circuit's reading allows an applicant to seek review in *any* regional circuit through the simple expedient of enlisting a local retailer that is interested in selling (or a local consumer who is interested in using) its products. This Court should not lightly conclude that Congress enacted such a "self-defeating statute." *Pugin* v. *Garland*, 599 U.S. 600, 607 (2023) (citation omitted); see *Citizens Bank of Maryland* v. *Strumpf*, 516 U.S. 16, 20 (1995) ("It is an elementary rule of construction that 'the act cannot be held to destroy itself.'") (citation omitted).

The Fifth Circuit's interpretation undermines the Act's venue framework in additional ways. By authorizing each adversely affected person to seek judicial review in that person's home circuit, the Act spreads out the work of reviewing denial orders across all the regional circuits. That is no small matter given the volume of work involved; FDA has received more than 27 million applications for marketing authorization since 2024. See Testimony of Brian A. King, Dir., Center for Tobacco Products, FDA, *Evaluating FDA Human Foods and Tobacco Programs* (Sept. 10, 2024). Under the decision below, however, applicants throughout the country—indeed, throughout the world—could all head to a single circuit for judicial review. That concern is not hypothetical; as discussed above, applicants from China, California, Florida, Michigan, North Carolina, Ohio, and Washington have all flocked to the Fifth Cir-

cuit. See pp. 10-11, *supra*. That result thwarts Congress's effort to allocate cases among the circuits in an orderly and sensible way. Cf. Pet. Br. at 15, *TC Heartland LLC* v. *Kraft Foods Group Brands LLC*, 581 U.S. 258 (2017) (No. 16-341) (noting that plaintiffs had exploited an expansive reading of the patent venue statute —which this Court ultimately reversed—to file roughly 40% of the Nation's patent cases in a single district).

The Act, moreover, designates the D.C. Circuit as the sole circuit where a person may seek judicial review regardless of residence or principal place of business. See 21 U.S.C. 387*l*(a)(1). That provision reflects the D.C. Circuit's "unique character" as a "national court" with "special responsibility to review legal challenges to the conduct of the national government," irrespective of where the challenger lives. John G. Roberts, Jr., *What Makes the D.C. Circuit Different? A Historical View*, 92 Va. L. Rev. 375, 389 (2006). Yet the decision below would transform every regional court of appeals into another national court. It would allow every circuit to hear cases brought there by manufacturers from around the country (and the world), defeating Congress's decision to vest such nationwide responsibility in the D.C. Circuit alone.

If Congress had meant to allow an applicant to seek judicial review in any circuit, it would have said so. Some federal statutes authorize suit in "any United States district court," 15 U.S.C. 1640(e), or "any United States Court of Appeals," 26 U.S.C. 7482(b)(2). The Tobacco Control Act, however, contains no such provision. The Fifth Circuit nonetheless held that an applicant may file a petition for review anywhere in the country, so long as it can find a local retailer willing to join its petition. But the court "offered no reason for Congress

to have constructed such an obscure path to such a simple result." *Kloeckner* v. *Solis*, 568 U.S. 41, 52 (2012).

The potential consequences of the court of appeals' approach extend beyond the Tobacco Control Act. Many federal statutes authorize an adversely affected or aggrieved person to challenge an agency order in the D.C. Circuit or the circuit where the person is based.[3] But the logic of the decision below would make it easy for challengers to avoid those restrictions: A challenger need only (1) find someone who lives in the preferred circuit and is indirectly affected by the order and (2) seek review alongside that person.

The forum shopping invited by the decision below not only violates the Act, but also harms the Judiciary. When parties throughout the country deploy complex procedural stratagems to channel their cases to a single circuit, even when they have no meaningful ties to that circuit, they erode the perception that judicial decisions rest on universally applicable rules of law. This Court should avoid that harm by correcting the court of appeals' erroneous interpretation of the Act's venue provision.

---

[3] See, *e.g.*, 5 U.S.C. 7123(a); 15 U.S.C. 77i(a), 80a–42(a), 80b–13(a), 1710(a); 20 U.S.C. 6083(f)(5), 7973(e)(5); 21 U.S.C. 346a(h)(1), 348(g)(1), 360g(a), 457(d), 607(e), 1036(b); 22 U.S.C. 6761(a)(5); 29 U.S.C. 160(f), 210(a), 660(a); 49 U.S.C. 5127(a), 47106(d)(3), 47111(d)(3).

CONCLUSION

This Court should reverse the order of the court of appeals and remand with instructions to transfer the case to the D.C. Circuit.

Respectfully submitted.

SAMUEL R. BAGENSTOS
General Counsel
Department of Health and Human Services

MARK RAZA
Chief Counsel

WENDY S. VICENTE
Deputy Chief Counsel for Litigation

WILLIAM H. RAWSON
Associate Chief Counsel

SARAH E. ROSENBERG
Assistant Chief Counsel
Food and Drug Administration

ELIZABETH B. PRELOGAR
Solicitor General

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

CURTIS E. GANNON
Deputy Solicitor General

VIVEK SURI
Assistant to the Solicitor General

LINDSEY POWELL
JOSHUA M. KOPPEL
CATHERINE PADHI
Attorneys

NOVEMBER 2024

APPENDIX

TABLE OF CONTENTS

APPENDIX

1. 21 U.S.C. 387j provides:

Application for review of certain tobacco products

(a) In general

(1) New tobacco product defined

For purposes of this section the term "new tobacco product" means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other

than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general

In this section and section 387e(j) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate to-

bacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) Health information

(A) Summary

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco

product or state that such information will be made available upon request by any person.

(B) Required information

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

(b) Application

(1) Contents

An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title

which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) Referral to Tobacco Products Scientific Advisory Committee

Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may, on the Secretary's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) Action on application

(1) Deadline

(A) In general

As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the infor-

mation submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

(3) Denial information

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) Basis for finding

For purposes of this section, the finding as to whether the marketing of a tobacco product for which

an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

(A) Investigations

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) Other evidence

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

(d) Withdrawal and temporary suspension

(1) In general

The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 387i of this title;

(ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title; or

(iii) has not complied with the requirements of section 387e of this title;

(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed,

that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 387f(e) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 387g of this title, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) Appeal

The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date

upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 387*l* of this title.

(3) Temporary suspension

If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) Service of order

An order issued by the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(f) Records

(1) Additional information

In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records,

and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) Access to records

Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) Investigational tobacco product exemption for investigational use

The Secretary may exempt tobacco products intended for investigational use from the provisions of this subchapter under such conditions as the Secretary may by regulation prescribe.

2. 21 U.S.C. 387*l* provides:

Judicial review

(a) Right to review

(1) In general

Not later than 30 days after—

(A) the promulgation of a regulation under section 387g of this title establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 387j(c) of this title,

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or 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.

(2) Requirements

(A) Copy of petition

A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

(B) Record of proceedings

On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed—

(i) the record of the proceedings on which the regulation or order was based; and

(ii) a statement of the reasons for the issuance of such a regulation or order.

(C) Definition of record

In this section, the term "record" means—

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Secretary with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

(iv) any hearing held with respect to such regulation or order; and

(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) Standard of review

Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5.

(c) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

(d) Other remedies

The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(e) Regulations and orders must recite basis in record

To facilitate judicial review, a regulation or order issued under section 387f, 387g, 387h, 387i, 387j, or 387p of this title shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.