

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*

REPLY BRIEF FOR THE PETITIONERS

ELIZABETH B. PRELOGAR
*Solicitor General
Counsel of Record
Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217*

TABLE OF CONTENTS

	Page
A. This Court has jurisdiction.....	1
B. A retailer may not challenge the denial of a manufacturer’s application for marketing authorization	4
C. A manufacturer may file a petition for review only in the D.C. Circuit or the circuit where it is based	12
D. Respondents’ interpretation effectively nullifies the Act’s venue restrictions	21

TABLE OF AUTHORITIES

Cases:

<i>Abbott Laboratories v. Celebrezze</i> , 228 F. Supp. 855 (D. Del. 1964), vacated on other grounds, 352 F.2d 286 (3d Cir. 1965), rev’d, 387 U.S. 136 (1967).....	17
<i>Abbott Laboratories v. Gardner</i> , 387 U.S. 136 (1967).....	2
<i>Allen v. Wright</i> , 468 U.S. 737 (1984).....	5
<i>Amerada Petroleum Corp. v. Federal Power Comm’n</i> , 338 F.2d 808 (10th Cir. 1964)	18, 19
<i>Atlantic Marine Construction Co. v. United States District Court</i> , 571 U.S. 49 (2013).....	21
<i>Bank of America Corp. v. City of Miami</i> , 581 U.S. 189 (2017).....	6
<i>Bankers Life & Casualty Co. v. Holland</i> , 346 U.S. 379 (1953).....	14, 20
<i>Bennett v. Spear</i> , 520 U.S. 154 (1997).....	9, 11
<i>Block v. Community Nutrition Institute</i> , 467 U.S. 340 (1984).....	10
<i>CBOCS West, Inc. v. Humphries</i> , 553 U.S. 442 (2008).....	19
<i>Clarke v. Securities Industry Ass’n</i> , 479 U.S. 388 (1987).....	10

II

Cases—Continued:	Page
<i>Clinton v. City of New York</i> , 524 U.S. 417 (1998)	8
<i>Davis & Farnum Manufacturing Co. v. Los Angeles</i> , 189 U.S. 207 (1903).....	8
<i>Department of State v. Muñoz</i> , 602 U.S. 899 (2024).....	3
<i>Devlin v. Scardelletti</i> , 536 U.S. (2002).....	5
<i>Director, Office of Workers’ Compensation Programs v. Newport News Shipbuilding & Dry Dock Co.</i> , 514 U.S. 122 (1995)	5, 6
<i>Estate of Israel v. Commissioner</i> , 159 F.3d 593 (D.C. Cir. 1986).....	18
<i>Exxon Corp. v. FTC</i> , 588 F.2d 895 (3d Cir. 1978)	16, 17
<i>FBI v. Fikre</i> , 601 U.S. 234 (2024)	3
<i>Hertz Corp. v. Friend</i> , 559 U.S. 77 (2010).....	15
<i>INS v. Legalization Assistance Project</i> , 510 U.S. 1301 (1993).....	7
<i>Lesnik v. Public Industrials Corp.</i> , 144 F.2d 968 (2d Cir. 1944)	13
<i>Lexmark International, Inc. v. Static Control Components, Inc.</i> , 572 U.S. 118 (2014)	5, 6
<i>Manchester Modes, Inc. v. Schuman</i> , 426 F.2d 629 (2d Cir. 1970)	17
<i>Marbury v. Madison</i> , 1 Cranch 137 (1803).....	4
<i>Mercantile National Bank v. Langdeau</i> , 371 U.S. 555 (1963).....	3
<i>Milner v. Department of the Navy</i> , 562 U.S. 562 (2011).....	19
<i>Minor v. Mechanics Bank</i> , 1 Pet. 46 (1828)	2
<i>Mississippi Publishing Corp. v. Murphree</i> , 326 U.S. 438 (1946).....	13
<i>Moody v. NetChoice, LLC</i> , 603 U.S. 707 (2024)	3
<i>Morrison v. National Australia Bank Ltd.</i> , 561 U.S. 247 (2010).....	15

III

Cases—Continued:	Page
<i>Murthy v. Missouri</i> , 603 U.S. 43 (2024).....	3
<i>National Ass’n of Manufacturers v. Department of Defense</i> , 583 U.S. 109 (2018).....	3
<i>National Ass’n of Private Fund Managers v. SEC</i> , 103 F.4th 1097 (5th Cir. 2024)	18
<i>National Family Farm Coalition v. EPA</i> , 966 F.3d 893 (9th Cir. 2020).....	20
<i>Romero v. International Terminal Operating Co.</i> , 358 U.S. 354 (1959).....	13
<i>Rubin v. Islamic Republic of Iran</i> , 583 U.S. 202 (2018).....	21
<i>Schenley Distillers Corp. v. United States</i> , 326 U.S. 432 (1946).....	8
<i>Sidney Coal Co. v. SSA</i> , 427 F.3d 336 (6th Cir. 2005), cert. denied, 547 U.S. 1020 (2006)	16
<i>Smith v. Lyon</i> , 133 U.S. 315 (1890).....	17
<i>Trump v. United States</i> , 603 U.S. 593 (2024)	3
<i>United States v. Williams</i> , 504 U.S. 36 (1992)	12
<i>Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.</i> , 454 U.S. 464 (1982).....	5
<i>Walters v. National Ass’n of Radiation Survivors</i> , 473 U.S. 305 (1985).....	2
 Constitution and statutes:	
U.S. Const. Art. III	2, 4
§ 2, Cl. 2.....	4
Administrative Orders Review Act, ch. 1189, 64 Stat. 1129 (1950).....	15
§ 3, 64 Stat. 1130.....	15
28 U.S.C. 2341(2)	15
28 U.S.C. 2343.....	15

IV

Statutes—Continued:	Page
28 U.S.C. 2343 note	16
Administrative Procedure Act, 5 U.S.C. 501 <i>et seq.</i> , 701 <i>et seq.</i>	5
5 U.S.C. 702.....	5
Fair Housing Act, 42 U.S.C. 3601 <i>et seq.</i> :	
42 U.S.C. 3602(i)	6
42 U.S.C. 3613(a)	6
False Claims Act, ch. 67, 12 Stat. 696 (1863)	14
§ 4, 12 Stat. 698.....	14
False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 6, 100 Stat. 3158	14
Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776 (2009).....	1
21 U.S.C. 387b(6)(A).....	7
21 U.S.C. 387f(e)	9
21 U.S.C. 387j	6
21 U.S.C. 387j(b)(2)(B).....	7
21 U.S.C. 387j(c)	6, 8, 9
21 U.S.C. 387j(c)(3).....	7
21 U.S.C. 387j(d)(2)	11
21 U.S.C. 387j(e)(2)	7, 9
21 U.S.C. 387l(a).....	11
21 U.S.C. 387l(a)(1)	4, 5, 11-13, 18, 20, 22
21 U.S.C. 387l(a)(1)(B).....	9
21 U.S.C. 387l(b).....	6
Investment Advisers Act of 1940, 15 U.S.C. 80b-13(a)	18
Natural Gas Act, 15 U.S.C. 717r(b)	18
15 U.S.C. 1333(b)	9
21 U.S.C. 331(c).....	7

Statutes—Continued:	Page
26 U.S.C. 7482(b)(1).....	18
28 U.S.C. 1254.....	3, 4
28 U.S.C. 1254(1).....	2, 3
28 U.S.C. 1257.....	3
28 U.S.C. 1257(a).....	3
28 U.S.C. 1391.....	15
28 U.S.C. 1391(e)(1)(A).....	16
28 U.S.C. 1391(e)(1)(C).....	16, 17
28 U.S.C. 2112.....	20
28 U.S.C. 2112(a).....	20
28 U.S.C. 2112(a)(5).....	21
Miscellaneous:	
<i>Black’s Law Dictionary</i> (4th ed. 1951).....	2
3 William Blackstone, <i>Commentaries on the Laws of England</i> (1768).....	2
Center for Tobacco Prods., FDA, U.S. Dep’t of Health & Human Servs., <i>Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market With- out Premarket Authorization (Revised)</i> (Apr. 2020).....	8
S. Rep. No. 345, 99th Cong., 2d Sess. (1986).....	14
Antonin Scalia & Bryan A. Garner, <i>Reading Law</i> (2012).....	19
Stephen M. Shapiro et al., <i>Supreme Court Practice</i> (11th ed. 2019).....	3
U.S. Dep’t of Justice, <i>Civil Resource Manual</i> , www.justice.gov/archives/jm/civil-resource- manual-41-venue-government-officers-and- agencies-defendants	17

VI

Miscellaneous—Continued:	Page
Charles Alan Wright et al., <i>Federal Practice and Procedure</i> :	
Vol. 7 (4th ed. 2019)	13
Vol. 16 (3d ed. 2012).....	21

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*

REPLY BRIEF FOR THE PETITIONERS

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776 (2009), requires a manufacturer to obtain authorization from the Food and Drug Administration (FDA) before marketing a new tobacco product. If FDA denies authorization, an adversely affected person may seek judicial review in either the D.C. Circuit or its home circuit. Yet in the decision below, the Fifth Circuit held that an out-of-circuit manufacturer may nonetheless seek review there, so long as it is joined by a local retailer. Respondents provide no meritorious defense of that decision, which effectively nullifies the Act's limits on venue. This Court should reverse.

A. This Court Has Jurisdiction

Respondents argued when opposing certiorari (Br. in Opp. 31-33) that this Court may review the decision below only by granting certiorari before judgment. And

although they did not previously cast that argument in jurisdictional terms, they now further contend (Br. 11-18) that granting certiorari before judgment would violate the certiorari statute and Article III. Those arguments lack merit.

1. This Court may review cases in the courts of appeals by granting certiorari “before or after rendition of judgment or decree.” 28 U.S.C. 1254(1). When Congress enacted that language in 1948, a “judgment” was understood to be an “official and authentic decision of a court of justice upon the respective rights and claims of the parties,” and a “decree” was a “judgment of a court of equity or admiralty.” *Black’s Law Dictionary* 498, 976-977 (4th ed. 1951) (capitalization omitted). Here, the Fifth Circuit’s order denying the government’s motion to dismiss or transfer is a judgment because it is the court’s official decision on respondents’ asserted right to litigate in the circuit. See Pet. App. 5a. And it is a decree because a judicial-review proceeding is a suit in equity. See *Abbott Laboratories v. Gardner*, 387 U.S. 136, 155 (1967). This case thus falls within the Court’s statutory jurisdiction to grant certiorari *after* judgment.

Respondents contend (Br. 13) that “judgment or decree” means “*final* judgment or decree” and that the decision below was not final. But it has long been recognized that “judgments are either interlocutory or final” and that an equitable “decree is either interlocutory or final.” 3 William Blackstone, *Commentaries on the Laws of England* 396, 452 (1768) (emphases omitted); see *Minor v. Mechanics Bank*, 1 Pet. 46, 79 (1828) (“interlocutory judgments”); *Walters v. National Ass’n of Radiation Survivors*, 473 U.S. 305, 319 (1985) (“interlocutory decrees”). This Court therefore has “unquestioned jurisdiction to review interlocutory judg-

ments of federal courts of appeals.” Stephen M. Shapiro et al., *Supreme Court Practice* § 4.18, at 4-54 (11th ed. 2019). Last Term, for example, the Court granted certiorari—not certiorari before judgment—to review multiple interlocutory judgments of the courts of appeals. See, e.g., *Moody v. NetChoice, LLC*, 603 U.S. 707, 723 (2024); *Trump v. United States*, 603 U.S. 593, 605 (2024); *Murthy v. Missouri*, 603 U.S. 43, 56 (2024); *Department of State v. Muñoz*, 602 U.S. 899, 907 (2024); *FBI v. Fikre*, 601 U.S. 234, 240 (2024).

When Congress means “final,” it says so. The state-court certiorari statute grants this Court jurisdiction to review “[f]inal judgments or decrees rendered by the highest court of a State.” 28 U.S.C. 1257(a). But the federal-court certiorari statute at issue here omits the modifier “final.” See 28 U.S.C. 1254(1). This Court has held, moreover, that a state supreme court’s denial of a motion to transfer a case to a venue where the defendant is located constitutes a final judgment for purposes of the state-court certiorari statute. See *Mercantile National Bank v. Langdeau*, 371 U.S. 555, 557-558 (1963). Respondents do not explain how the denial of a transfer motion could be a final judgment for purposes of Section 1257 but not a judgment at all for purposes of Section 1254.

This Court’s decision in *National Ass’n of Manufacturers v. Department of Defense*, 583 U.S. 109 (2018), confirms its jurisdiction to review this case. There, private parties filed petitions for review in the Sixth Circuit; that court denied motions to dismiss for lack of jurisdiction; and this Court granted certiorari to review the interlocutory order denying dismissal. See *id.* at 119-120. Similarly here, respondents filed a petition for review in the Fifth Circuit; that court denied a motion

to dismiss; and this Court granted certiorari to review the interlocutory order denying dismissal.

2. Reviewing this case also complies with Article III, which generally confines this Court to exercises of “appellate Jurisdiction.” U.S. Const. Art. III, § 2, Cl. 2. The “essential criterion of appellate jurisdiction” is that “it revises and corrects the proceedings in a cause already instituted.” *Marbury v. Madison*, 1 Cranch 137, 175 (1803). Here, the government asks this Court to revise and correct a lower court’s order denying a motion to dismiss or transfer. Reviewing that order is plainly an exercise of appellate jurisdiction.

To be sure, when a court of appeals is considering a petition for review, Article III may preclude a grant of certiorari before judgment to review the underlying agency action in the first instance. See Gov’t Resp. to Applications for a Stay at 85-86, *NFIB v. OSHA*, 595 U.S. 109 (2022) (No. 21A244). In this case, however, the Court has not granted certiorari before judgment to review FDA’s denial order in the first instance. It has instead granted certiorari to review the Fifth Circuit’s interlocutory judgment on venue. That exercise of jurisdiction complies with both Section 1254 and Article III.

B. A Retailer May Not Challenge The Denial Of A Manufacturer’s Application For Marketing Authorization

The Tobacco Control Act authorizes an “adversely affected” person to seek judicial review of an order denying an application for marketing authorization. 21 U.S.C. 387l(a)(1). Respondents fail to show that FDA’s denial of a *manufacturer’s* application adversely affects *retailers* of the manufacturer’s products.

1. Respondents agree (Br. 19) that “adversely affected” is a legal term of art that invokes the zone-of-interests test. That test requires a plaintiff to show that

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).

As respondents note (Br. 19), the zone-of-interests test is not meant to be especially demanding in suits under the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 701 *et seq.* But the “lenient approach” that this Court has applied “in the APA context” does not carry over to this non-APA case. *Lexmark*, 572 U.S. at 130. While the Court has required APA plaintiffs to show only that their interests “arguably” fall within the zone protected by the statute, it has omitted the adverb “arguably” in non-APA cases. *Ibid.* (citation omitted); see, e.g., *id.* at 126; *Devlin v. Scardelletti*, 536 U.S. 1, 7 (2002); *Allen v. Wright*, 468 U.S. 737, 751 (1984); *Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 475 (1982). Thus, “what comes within the zone of interests of a statute for purposes of * * * the APA may not do so for other purposes.” *Lexmark*, 572 U.S. at 130 (citation omitted).

Respondents provide (Br. 19) three reasons for applying the APA test here, but none is sound. First, they note the similarity between the term used in the Tobacco Control Act (“adversely affected”) and the term used in the APA (“adversely affected or aggrieved”). Resp. Br. 19 (quoting 21 U.S.C. 387l(a)(1) and 5 U.S.C. 702)). But the terms “adversely affected” and “aggrieved” predate the APA. See *Director, Office of Workers’ Compensation Programs v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 126 (1995). And they are highly context-dependent; “what consti-

tutes adverse effect or aggrievement varies from statute to statute.” *Id.* at 127 (emphasis omitted).

Second, respondents observe (Br. 19) that the Tobacco Control Act “governs challenges to agency action, as the APA does.” But this Court has adopted a “lenient approach” in APA cases in order to preserve “the flexibility of the APA’s omnibus judicial-review provision,” *Lexmark*, 572 U.S. at 130—not simply because the APA “governs challenges to agency action,” Resp. Br. 19.

Third, respondents cite (Br. 19) a provision of the Tobacco Control Act stating that, “upon the filing of the petition,” the court must review the denial “in accordance with” the APA. 21 U.S.C. 387l(b). But that provision, by its plain terms, comes into play only after the “filing of the petition.” *Ibid.* It incorporates only the APA’s standards for how a court must resolve a petition for review, not the APA’s standards for who may file a petition in the first place.

Respondents separately err in relying (Br. 21-23) on this Court’s decision in *Bank of America Corp. v. City of Miami*, 581 U.S. 189 (2017), a case that involved the scope of the term “aggrieved person” in the Fair Housing Act, 42 U.S.C. 3613(a). That Act defines “aggrieved person” more broadly than the customary legal meaning, 42 U.S.C. 3602(i), and this Court has interpreted that definition to extend the right to sue “as broadly as is permitted by Article III.” *Bank of America*, 581 U.S. at 197 (citation omitted). No such special definition appears in the Tobacco Control Act.

2. Respondents cannot show that retailers’ interests fall within the zone protected by 21 U.S.C. 387j(c), the provision directing FDA to adjudicate manufacturers’ applications for marketing authorization. Section 387j recognizes and protects only the applicant’s interests.

For example, it allows the “applicant” to ask FDA to refer the application to a scientific committee, 21 U.S.C. 387j(b)(2)(B); requires FDA to serve its order on “the applicant,” 21 U.S.C. 387j(e)(2); and directs FDA, when practicable, to inform “the applicant” of the steps that it could take to avoid denial, 21 U.S.C. 387j(e)(3). Respondents identify nothing in Section 387j that displays similar concern for the interests of non-applicant retailers. Cf. *INS v. Legalization Assistance Project*, 510 U.S. 1301, 1305 (1993) (O’Connor, J., in chambers) (concluding that an immigration statute protected only the interests of noncitizens, not those of employers, landlords, or non-profit organizations that were indirectly affected by immigration restrictions).

Respondents err in contending (Br. 18) that denials nonetheless adversely affect retailers because they “prohibit retailers from selling a product.” A denial is issued to the applicant alone, not to retailers. See 21 U.S.C. 387j(e)(2). Respondents also concede (Br. 5) that the Act forbids the sale of a new tobacco product until FDA authorizes it. A denial thus does not subject a retailer to a new legal prohibition; the sale of the unauthorized product was unlawful before the denial, and it remains unlawful after.

Respondents similarly err in contending (Br. 37) that, under FDA’s enforcement policy, a retailer may “lawfully” sell unauthorized products until FDA issues a denial. The Act itself prohibits the sale of an unauthorized product—regardless of whether an application for marketing authorization was denied, is still pending, or was never submitted. See 21 U.S.C. 331(c), 387b(6)(A). FDA thus warned private parties that its enforcement priorities did “not in any way alter the fact that it is illegal to market any new tobacco product

without premarket authorization.” 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)* 3 (Apr. 2020); *id.* at 27 (explaining that FDA would “exercise enforcement discretion for up to one year [*i.e.*, until September 9, 2021] pending FDA review, unless there [was] a negative action by FDA on such application”).

Respondents describe (Br. 36) the Act as a “licensing regime,” but that analogy cuts against their position. The proper party to challenge the denial of a license is normally the applicant—not, as respondents suggest (Br. 36), a bystander who would “benefit from that potential licensee.” See, *e.g.*, *Schenley Distillers Corp. v. United States*, 326 U.S. 432, 435 (1946) (*per curiam*) (holding that a parent corporation could not challenge the denial of a license application filed by its subsidiary); *Davis & Farnum Manufacturing Co. v. Los Angeles*, 189 U.S. 207, 218-220 (1903) (holding that a subcontractor could not challenge the revocation of a proprietor’s license for a construction project).

Respondents cite (Br. 20) decisions allowing litigants to challenge governmental action that did not directly regulate them, but those decisions rested on statutory provisions that evinced Congress’s intention to protect those litigants’ interests. See, *e.g.*, *Clinton v. City of New York*, 524 U.S. 417, 432 (1998) (explaining that Congress had enacted the statutory provision at issue “for the specific purpose of providing a benefit” to a class that included the litigants). Section 387j(c), by contrast, focuses on the applicant. It does not mention, let alone indicate Congress’s intent to protect, retailers.

Respondents cite (Br. 27-30) *other* provisions of the Tobacco Control Act that regulate or protect retailers. But the zone-of-interests test turns on the interests protected by “the particular provision of law” at issue, not on those protected by the statute “overall.” *Bennett v. Spear*, 520 U.S. 154, 175-176 (1997). That principle applies with added force here because the Act’s judicial-review provision refers specifically to denials “under section 387j(c).” 21 U.S.C. 387l(a)(1)(B). Respondents correctly note (Br. 29) that Section 387j(c) must be read in the context of surrounding provisions, but the provisions they cite do not support their case. For instance, the need for retailers to comply with “advertising requirements,” Resp. Br. 28 (citing 15 U.S.C. 1333(b)), shows at most that the Act’s advertising requirements may adversely affect retailers—not that denials of new tobacco product applications do.

If anything, context confirms that retailers’ interests fall outside the zone protected by Section 387j(c). While the Act requires FDA to serve denials on applicants, it does not require FDA to notify retailers about denials. See 21 U.S.C. 387j(e)(2). And under the Act’s confidentiality requirement, retailers usually lack access to the full administrative record underlying a denial and often will not know about the denial itself. See 21 U.S.C. 387f(c). It is implausible that Congress granted retailers the right to challenge denials, but not the right to know whether or why the denials had been issued.

Respondents argue (Br. 30) that, because the Act permits disclosures of confidential information during judicial-review proceedings, a retailer could gain access to the administrative record after filing a petition for review. See 21 U.S.C. 387f(c). But such a disclosure could occur only after the filing of a petition, and then

only with the applicant's consent or pursuant to a protective order. The retailer would still be required to initiate litigation in the dark. Worse, respondents' approach could enable a retailer to obtain a court order requiring the disclosure of a manufacturer's confidential information over the manufacturer's objection. A retailer affiliated with respondent R.J. Reynolds Vapor Co., for example, could announce plans to sell Philip Morris products, challenge an order denying a Philip Morris application, and (under respondents' theory) gain access to Philip Morris's trade secrets. Congress could not conceivably have intended that result.

Respondents, finally, fail to distinguish this case from *Block v. Community Nutrition Institute*, 467 U.S. 340 (1984), where this Court held that consumers lacked a right to challenge rules setting minimum prices to be paid by milk handlers to milk producers. Respondents note (Br. 34-35) that the statute in *Block* gave consumers no role in the underlying rulemaking process, but the Tobacco Control Act similarly gives retailers no role in the underlying application process. Respondents observe that allowing consumers to sue in *Block* would have enabled an "end run" around an exhaustion requirement, Br. 35 (citation omitted), but allowing retailers to sue here would facilitate a similar end run around the Act's venue restrictions, see pp. 21-22, *infra*. Respondents also emphasize (Br. 35) that the statute in *Block* contained a "limited judicial-review provision." But the consumers in *Block* did not sue under that provision; they invoked the generous review provisions of the APA. See 467 U.S. at 345; see also *Clarke v. Securities Industry Ass'n*, 479 U.S. 388, 399 (1987) (describing *Block* as "a useful reference point for understanding the 'zone of interest' test" under the APA).

3. Respondents contrast (Br. 24-25) the Act’s provision allowing a “person adversely affected” to challenge an order denying marketing authorization, 21 U.S.C. 387l(a)(1), with a separate provision allowing the “holder of an application” to challenge an order withdrawing authorization that was previously granted, 21 U.S.C. 387j(d)(2). They also contrast the Act with other statutes that permit suit by an “applicant” or a “party.” Resp. Br. 26 (citations omitted). But we have already explained that variation in language. See Gov’t Br. 26. The judicial-review provision at issue applies not only to denials of applications for new tobacco products, but also to regulations establishing, amending, or revoking tobacco product standards. See 21 U.S.C. 387l(a). Terms such as “party,” “applicant,” and “holder of an application” would not have fit the full range of agency actions covered by that judicial-review provision.

Contrary to respondents’ suggestion (Br. 27), the government is not interpreting “adversely affected” to mean one thing for denials and another for regulations. The term bears the same meaning for both: A plaintiff may challenge the action only if it satisfies the zone-of-interests test. But the “breadth of the zone of interests varies according to the provisions of law at issue.” *Bennett*, 520 U.S. at 163.

In the end, the provision concerning judicial review of withdrawal orders undermines rather than supports respondents’ position. See Gov’t Br. 22-23. Withdrawals affect retailers’ interests much more directly than do denials. Withdrawals force retailers to stop previously lawful sales, while denials leave retailers’ legal rights unchanged. Respondents do not explain why Congress would have allowed retailers to challenge denials but not withdrawals.

**C. 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 in holding that an out-of-circuit manufacturer may sue in a circuit simply because it is joined by a retailer that is located there. Respondents' defenses of that holding lack merit.*

1. The Act authorizes an adversely affected person to challenge a denial in the D.C. Circuit or “the circuit in which *such person* resides or has their principal place of business.” 21 U.S.C. 387l(a)(1) (emphasis added). The term “such person” makes clear that a person may sue in a circuit only if *that person* is based there. Party *A* may not lay venue based on Party *B*'s residence or principal place of business.

Respondents contend (Br. 42-43) that, even when a manufacturer cannot file its own petition in a circuit, it may still join a retailer's petition in that circuit. That contention is flawed. As respondents concede (Br. 43), joinder is simply a procedural tool for aggregating claims; “each plaintiff's right of action remains distinct,

* Respondents renew (Br. 39) the contention, which they raised when opposing certiorari (Br. in Opp. 18), that the government failed to preserve its argument that venue must be proper as to each party. “In granting certiorari,” this Court “necessarily considered and rejected that contention as a basis for denying review.” *United States v. Williams*, 504 U.S. 36, 40 (1992). In any event, as we have explained (Cert. Reply Br. 10-11), that contention is wrong because (1) parties must preserve claims and defenses rather than individual arguments, and FDA preserved its venue defense below; (2) this Court may consider a question that was pressed *or* passed upon below, and the Fifth Circuit passed upon the question whether venue must be proper for each party; and (3) the Fifth Circuit had held in a published opinion that only a single petitioner need satisfy the venue requirements, making it futile for FDA to argue otherwise below.

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). Thus, even when an out-of-circuit manufacturer and a local retailer file a joint petition, the government may properly assert a venue defense to the manufacturer’s suit.

Respondents argue (Br. 42) that, although joinder under the Federal Rules cannot enlarge jurisdiction, it can extend venue. But venue restrictions, no less than jurisdictional limits, derive from Acts of Congress. It is thus a “settled principle that procedural rules cannot be used to extend federal jurisdiction *or venue*.” *Lesnik v. Public Industrials Corp.*, 144 F.2d 968, 973 (2d Cir. 1944) (emphasis added); see *Mississippi Publishing Corp. v. Murphree*, 326 U.S. 438, 445 (1946) (“Rule 4(f) does not enlarge or diminish the venue of the district court.”). And this Court has recognized that “venue provisions” can “prevent the joinder” of parties in a federal case. *Romero v. International Terminal Operating Co.*, 358 U.S. 354, 377 n.47 (1959).

Respondents’ contrary interpretation of the Act and the joinder rule is internally inconsistent. Respondents accept (Br. 18-38) that, when multiple petitioners file a joint petition, each petitioner must independently show that it is a “person adversely affected.” 21 U.S.C. 387l(a)(1). They do not suggest that, once one person satisfies the adverse-effect requirement, the joinder rule allows anyone else to join that person’s petition even it is not adversely affected. The Act’s text, however, draws no distinction between the requirement that a person be “adversely affected” and the requirement that the person sue in the D.C. Circuit or its home circuit. *Ibid.* Respondents do not explain why every

petitioner needs to satisfy the former requirement but only one needs to satisfy the latter.

Respondents' theory, moreover, conflicts with this Court's precedents, under which venue must be proper as to each party unless Congress provides otherwise. See Gov't Br. 30-34. Respondents seek (Br. 46-47 & n.16) to confine that principle to diversity cases, but that attempted distinction is unsound. In *Bankers Life & Casualty Co. v. Holland*, 346 U.S. 379 (1953), for example, the Court interpreted an antitrust venue statute to require courts to analyze venue one party at a time. See *id.* at 384. Respondents assert (Br. 47) that the Court did not pass upon venue in that case, but the Court's opinion makes plain that it did. See *Holland*, 346 U.S. at 384 ("Congress * * * placed definite limits on venue in treble damage actions. Certainly Congress realized in so doing that many such cases would not lie in one district as to all defendants.").

To take another example, the False Claims Act, ch. 67, 12 Stat. 696 (1863), originally authorized suit in any district where "the" defendant could be found. § 4, 12 Stat. 698. Congress understood that, if the defendants in a multi-defendant case could not all "be 'found' in any one district," the government would be compelled "to file multiple suits" in different districts. S. Rep. No. 345, 99th Cong., 2d Sess. 32 (1986). Congress therefore amended the statute to authorize suit where "any one defendant" could be found. False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 6, 100 Stat. 3158. That amendment confirms that, even in non-diversity cases, Congress legislates against the backdrop of the default rule that venue must be proper as to each party.

Respondents would replace (Br. 46-47) that clear default rule with a jumble of conflicting presumptions:

one for “diversity suits,” another for “suits challenging federal action,” and still others for other types of cases. Respondents’ approach would deprive Congress of a “stable background against which [it] can legislate with predictable effects.” *Morrison v. National Australia Bank Ltd.*, 561 U.S. 247, 261 (2010). It would also inject needless complexity into the resolution of a threshold issue, “eating up time and money as the parties litigate, not the merits of their claims, but which court is the right court to decide those claims.” *Hertz Corp. v. Friend*, 559 U.S. 77, 94 (2010).

2. Respondents emphasize (Br. 40-42) that lower courts have construed other venue statutes—including the Administrative Orders Review Act (Hobbs Act), ch. 1189, 64 Stat. 1129 (1950), and the general venue statute, 28 U.S.C. 1391—to allow multiple litigants to challenge agency action in a venue where only one litigant resides. But those decisions do not support respondents’ interpretation of the distinct statute at issue here.

a. The Hobbs Act, which governs judicial review of certain agency orders, provides that venue lies in the D.C. Circuit or the circuit where “the petitioner resides or has its principal office.” 28 U.S.C. 2343. The statute defines “petitioner” to mean “the party *or parties*” who petition for review, 28 U.S.C. 2341(2) (emphasis added)—suggesting that a court must analyze venue for all petitioners collectively rather than one at a time. As first enacted in 1950, moreover, the statute authorized suit in the circuit where “the party *or any of the parties* filing the petition” was based. Hobbs Act § 3, 64 Stat. 1130 (emphasis added). In 1966, Congress amended the statute to its current form “for clarity and conciseness”; “[t]he word ‘petitioner’ [wa]s substituted for ‘party or any of the parties filing the petition for review’ in view

of the definition of ‘petitioner’ in section 2341.” 28 U.S.C. 2343 note.

Consistent with the Hobbs Act’s text and history, many courts of appeals have determined—in our view, correctly—that multiple petitioners may sue in a circuit where any one petitioner is based. See Resp. Br. 41 (collecting cases). The Tobacco Control Act, however, does not share the Hobbs Act’s text and history. It does not define “petitioner” to include multiple petitioners, and its history does not suggest that Congress intended to authorize multiple petitioners to lay venue based on a single petitioner’s residence. Decisions interpreting the Hobbs Act are therefore inapposite.

b. The general venue statute authorizes a person to sue the government in a district where “a defendant” or “the plaintiff” resides. 28 U.S.C. 1391(e)(1)(A) and (C) (emphasis added). Naturally read, that provision allows venue in multi-party cases based on the residence of a single defendant, but not based on the residence of a single plaintiff.

Despite the textual distinction between defendants and plaintiffs, two courts of appeals have held—in our view, incorrectly—that multiple plaintiffs may sue the government in a district where any one plaintiff resides. See *Sidney Coal Co. v. SSA*, 427 F.3d 336, 344-346 (6th Cir. 2005), cert. denied, 547 U.S. 1020 (2006); *Exxon Corp. v. FTC*, 588 F.2d 895, 898-899 (3d Cir. 1978). One court relied on “the hearing transcripts of the House Committee on the Judiciary,” which purportedly show that Congress legislated with the “purpose of easing plaintiffs’ burdens when suing government entities.” *Sidney Coal*, 427 F.3d at 344. The other court asserted that a plaintiff-by-plaintiff approach to venue “would result in an unnecessary multiplicity of litigation.”

Exxon, 588 F.2d at 898. Those decisions improperly subordinate statutory text to legislative history and generic policy concerns.

Respondents assert (Br. 41) that lower federal courts have “uniformly” adopted that interpretation of the general venue statute, but they overstate the degree of consensus. Respondents and their amici identify only two court of appeals decisions that adopt that reading; the remaining decisions they cite were issued by district courts. See, e.g., *ibid.*; Chamber of Commerce Amicus Br. 9. Respondents also ignore other decisions in which courts understood the statute to require each plaintiff to establish venue separately. See *Manchester Modes, Inc. v. Schuman*, 426 F.2d 629, 633 n.7 (2d Cir. 1970) (Friendly, J.); *Abbott Laboratories v. Celebrezze*, 228 F. Supp. 855, 858-860 (D. Del. 1964), vacated on other grounds, 352 F.2d 286 (3d Cir. 1965), rev’d, 387 U.S. 136 (1967). The government has long shared the same understanding. See Gov’t Br. at 62-65, *Abbott Laboratories, supra* (S. Ct. No. 39). Respondents cite (Br. 41-42) an archival Department of Justice manual stating that venue need be proper only as to one plaintiff, but that manual simply summarized decisions of the lower courts; it did not separately set forth the Department’s own view. See U.S. Dep’t of Justice, *Civil Resource Manual* § 41, www.justice.gov/archives/jm/civil-resource-manual-41-venue-government-officers-and-agencies-defendants.

In any event, the general venue statute’s text differs from the Tobacco Control Act’s. The general venue statute allows a plaintiff to sue in the district where “the plaintiff” resides. 28 U.S.C. 1391(e)(1)(C). Although this Court has traditionally interpreted that term to mean “every plaintiff,” it has recognized the plausibility of the contrary reading. See *Smith v. Lyon*, 133 U.S.

315, 317 (1890). The Tobacco Control Act, by contrast, does not refer to “the plaintiff” or “the petitioner.” It instead authorizes an adversely affected person to sue in “the circuit in which such person resides or has their principal place of business.” 21 U.S.C. 387l(a)(1). The term “such person” makes clear that one person may not lay venue in a different person’s home circuit.

c. Respondents cite (Br. 41 n.15) two more court-of-appeals decisions, but those decisions do not support their argument either. In one, the D.C. Circuit interpreted a statute to require “a petitioner-by-petitioner determination” of venue—consistent with the government’s position here. *Estate of Israel v. Commissioner*, 159 F.3d 593, 595 (1986). The court went on to allow petitioners from different circuits to join in a single petition, but that aspect of its decision rested on a special clause permitting suit in the D.C. Circuit. See *id.* at 596 (citing 26 U.S.C. 7482(b)(1)).

In the other case, the Fifth Circuit concluded that the venue provision of the Investment Advisers Act of 1940, 15 U.S.C. 80b–13(a)—which is worded like the provision here—allows multiple litigants to sue in a venue where one litigant resides. See *National Ass’n of Private Fund Managers v. SEC*, 103 F.4th 1097, 1109 (2024). But that decision shows only that the Fifth Circuit has repeated in another recent case the same error it committed here.

Moreover, the Tenth Circuit has held that the venue provision of the Natural Gas Act, 15 U.S.C. 717r(b)—which is also worded like the provision here—does *not* allow multiple litigants to sue in a venue where only one litigant resides. See *Amerada Petroleum Corp. v. Federal Power Commission*, 338 F.2d 808, 809-810 (1964). Respondents seek (Br. 48) to distinguish that case on

the ground that it involved “separate applications,” but the agency had consolidated the applications and issued a single order resolving them. See 338 F.2d at 809-810. And respondents’ theory—that “only one party” needs to satisfy the applicable venue requirements “in cases against the government,” Br. 3—does not differentiate between an order denying separate applications and one denying a single application.

d. Respondents’ argument suffers from a further flaw: It attaches too much importance to the lower courts’ decisions and too little to this Court’s. This Court has “no warrant” to depart from the best reading of a statute “on the ground that other courts have done so.” *Milner v. Department of the Navy*, 562 U.S. 562, 576 (2011); see *CBOCS West, Inc. v. Humphries*, 553 U.S. 442, 471 (2008) (Thomas, J., dissenting) (collecting cases in which this Court has “decided a question differently than every court of appeals to have considered it”). By contrast, the Court is generally bound by its own precedents, and those precedents analyze venue one party at a time. See Gov’t Br. 30-34.

Respondents invoke (Br. 40) the prior-construction canon—the principle that, “[i]f a word or phrase * * * has been given a uniform interpretation by inferior courts,” later statutes that use “the same wording” are “presumed to carry forward that interpretation.” Antonin Scalia & Bryan A. Garner, *Reading Law* § 54, at 322 (2012). But that canon does not apply here. The Tobacco Control Act’s venue provision does not use “the same wording” that was construed in the lower-court decisions cited by respondents; rather, the relevant statutory texts differ in material ways. See pp. 16-18, *supra*. Nor have the lower-court decisions been “uniform.” See *ibid*.

3. Finally, respondents complain (Br. 43) that the government’s interpretation would force litigants “to file separate lawsuits in separate courts challenging the same agency action.” Even if that were true, it would not justify departing from the default rule that venue must be proper as to each party. See, e.g., *Holland*, 346 U.S. at 384 (requiring an antitrust plaintiff to establish venue as to each defendant, even though that approach would require trying different members of an antitrust conspiracy in different districts).

Congress has in any event addressed respondents’ concern in two ways. First, the Tobacco Control Act allows an adversely affected person to sue in the D.C. Circuit regardless of whether the person is based there. See 21 U.S.C. 387l(a)(1). Thus, adversely affected persons from different circuits who wish to file a joint petition can readily do so in the D.C. Circuit. Second, a general statute provides for the consolidation of petitions for review that are filed in different circuits and challenge the same agency order. See 28 U.S.C. 2112. If more than one petition is filed within ten days after the order, all petitions must be consolidated in a single court chosen by lottery; and if only one petition is filed within ten days, later petitions must be consolidated in the court that received the first-filed petition. See 28 U.S.C. 2112(a). “This process would be circumvented if all petitioners could join a single petition in the same circuit, regardless of whether each petitioner had proper venue.” *National Family Farm Coalition v. EPA*, 966 F.3d 893, 931 (9th Cir. 2020) (Nelson, J., concurring).

Respondents contend (Br. 45) that, if a retailer files a petition for review in its home circuit within ten days, and a manufacturer files a petition elsewhere on day

eleven, the petitions will end up consolidated in the retailer's circuit anyway. But that argument overlooks the separate provision that authorizes the court of appeals in which the petitions are consolidated to transfer the cases "[f]or the convenience of the parties in the interest of justice." 28 U.S.C. 2112(a)(5). "[T]ransfer may be ordered without compunction to combat" the type of gamesmanship that respondents hypothesize. 16 Wright & Miller § 3944, at 1035 (3d ed. 2012).

D. Respondents' Interpretation Effectively Nullifies The Act's Venue Restrictions

The Fifth Circuit erred by holding that retailers may challenge the denial of manufacturers' applications, and it erred again by holding that manufacturers may lay venue based on retailers' locations. The combination of those errors deprives the Act's venue restrictions of any practical effect, enabling manufacturers to sue anywhere in the country. It also undermines the Act's designation of the D.C. Circuit as the sole circuit with nationwide authority, enabling every other regional court of appeals to hear petitions for review filed by out-of-circuit manufacturers.

Respondents wrongly dismiss those concerns as "policy arguments" that are "properly addressed to Congress." Br. 37 (brackets and citation omitted). "[O]ne of the most basic interpretive canons" directs courts to construe a statute "so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Rubin v. Islamic Republic of Iran*, 583 U.S. 202, 213 (2018) (citation omitted). Courts also have traditionally interpreted venue statutes in a manner that avoids encouraging forum shopping. See *Atlantic Marine Construction Co. v. United States District Court*, 571 U.S. 49, 65 (2013).

Respondents argue (Br. 37-38) that the venue limits still do some work in cases where products are sold in only one circuit. In other words, respondents suggest that Congress affirmatively enabled forum shopping by large manufacturers whose products are sold nationwide, though not by small manufacturers whose products are sold in only one region.

If Congress meant to allow a manufacturer to sue wherever its products are sold, it would have said so. Instead, Congress authorized a person to seek judicial review only where it “resides” or has its “principal place of business.” 21 U.S.C. 387l(a)(1). Respondents’ interpretation negates that congressional choice.

* * * * *

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.

ELIZABETH B. PRELOGAR
Solicitor General

JANUARY 2025