Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

FOOD AND DRUG ADMINISTRATION ET AL. *v.* R. J. REYNOLDS VAPOR CO. ET AL.

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

No. 23–1187. Argued January 21, 2025—Decided June 20, 2025

The Family Smoking Prevention and Tobacco Control Act (TCA) requires manufacturers to apply for and receive approval from the Food and Drug Administration (FDA) before marketing any "new tobacco product." 21 U. S. C. §387j. In 2016, the FDA decided that e-cigarettes and related products were new tobacco products subject to the TCA. Given the size of the existing e-cigarette market, the FDA announced that it would defer enforcement of the TCA against e-cigarette manufacturers and retailers while the manufacturers sought FDA approval. R. J. Reynolds Vapor Co. (RJR Vapor)—a manufacturer of e-cigarettes—sought FDA approval to continue marketing its popular Vuse Alto products. The FDA denied the applications, finding that RJR Vapor had failed to demonstrate that marketing Vuse Alto products would be "appropriate for the protection of the public health" as required by the TCA. §387j(c)(2)(A). The FDA's order sounded the death knell for a significant portion of the e-cigarette market, and RJR Vapor sought to challenge it.

The TCA provides that "any person adversely affected" by an FDA denial order can petition for judicial review in either the D. C. Circuit or "the circuit in which such person resides or has their principal place of business." §387*l*(a)(1). Had RJR Vapor sought judicial review on its own, it could have filed a petition in the D. C. Circuit (the statutory default) or the Fourth Circuit (which includes North Carolina, RJR Vapor's state of incorporation and principal place of business). RJR Vapor instead combined forces with a Texas-based retailer and a Mis-

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sissippi-based trade association of retailers to challenge the FDA's denial order in the Fifth Circuit (which includes both Texas and Mississippi). In response, the FDA asked the court to either dismiss the joint petition for lack of venue or transfer it to the D. C. Circuit or Fourth Circuit. The FDA argued that only a disappointed applicant—in this case, RJR Vapor—is "adversely affected" by an FDA denial order within the meaning of the TCA. Because the retailers had no right to seek review, the FDA argued, the petition had no basis for being in the Fifth Circuit. A divided Fifth Circuit panel concluded venue was proper and denied the FDA's motion.

Held: Retailers who would sell a new tobacco product if not for the FDA's denial order may seek judicial review of that order under §387*l*(a)(1). Pp. 3–12.

(a) To invoke a statutory cause of action, a plaintiff must be within the "zone of interests" that the statute protects. *Lexmark Int'l, Inc.* v. *Static Control Components, Inc.*, 572 U. S. 118, 129. That means a plaintiff must belong to the class of persons to which the statute grants a right to sue, which under the TCA is "any person adversely affected" by the FDA's "denial." §387*l*(a)(1).

"Adversely affected" (and its variations like "adversely affected or aggrieved") is a term of art with a "long history in federal administrative law." *Director, Office of Workers' Compensation Programs* v. *Newport News Shipbuilding & Dry Dock Co.*, 514 U. S. 122, 126. Many statutes use the term, most notably the Administrative Procedure Act (APA), which entitles anyone "adversely affected or aggrieved by agency action within the meaning of a relevant statute . . . to judicial review." 5 U. S. C. §702. The Court has interpreted "adversely affected" broadly, as covering anyone even "*arguably* within the zone of interests to be protected or regulated by the statute . . . in question." *Association of Data Processing Service Organizations, Inc.* v. *Camp*, 397 U. S. 150, 153 (emphasis added).

The FDA insists that the capacious understanding of "adversely affected" is unique to the APA, and that other statutes require a person to "actually"—not "arguably"—fall within the statute's zone of interests. And, as the FDA sees it, under the TCA the only person *actually* aggrieved by the denial of permission to market a tobacco product is the one with the closest relationship to the application—the applicant. But the Court has not drawn the distinction the FDA proposes. Instead, the Court has borrowed from its APA cases, including their broad formulation of the zone-of-interests test, when it has interpreted variations of the phrase "adversely affected or aggrieved" in other statutes. See, *e.g., Bank of America Corp.* v. *Miami*, 581 U. S. 189, 193 (interpreting "aggrieved person" in the Fair Housing Act); *Thompson*

v. *North American Stainless, LP*, 562 U. S. 170, 177 (interpreting "person claiming to be aggrieved" in Title VII); *Newport News*, 514 U. S., at 123 (interpreting "person adversely affected or aggrieved" in the Longshore and Harbor Workers' Compensation Act). Taken together, these cases reflect a presumption that "adversely affected" carries the same meaning outside the APA as in it.

The Court interprets "adversely affected" in the TCA against this backdrop. Echoing the APA, the TCA provides that "any person adversely affected by [the FDA's] denial" may petition for judicial review. §387*l*(a)(1). The retailers fit the bill. If the FDA denies an application, the retailers lose the opportunity to profit from the sale of the new tobacco product—or, if they sell the product anyway, risk imprisonment and other sanctions. See §§331, 333(a), 387b(6)(A), 387j(a)–(c). Accordingly, the retailers are "adversely affected" by a denial order and are therefore proper petitioners under §387*l*(a)(1). Pp. 3–8.

(b) The FDA argues that the TCA's text and structure reflect Congress's choice to offer judicial review only to manufacturers denied permission to market a tobacco product. The FDA's arguments, which focus almost entirely on §387j, cannot be squared with §387*l*(a)(1)—the provision that creates the cause of action. Start with the textual oddity of using the phrase "*any* person adversely affected" to describe a cause of action that only one person—the applicant manufacturer—could use. Congress's use of "any" suggests that a denial order can adversely affect multiple persons.

Even without the word "any," the phrase "person adversely affected" suggests an intent to cover more than one party. If Congress intended to convey the FDA's reading, it would more naturally have said "applicant." And there is "no basis in text or prior practice" for limiting "person adversely affected" to mean "the applicant." Cf. *Thompson*, 562 U. S. 170 (rejecting analogous argument that Title VII's use of "person claiming to be aggrieved" refers to a single person). Congress knows how to limit the scope of a cause of action—in fact, it did so elsewhere in the TCA. When the FDA withdraws an existing approval of an application to market a new tobacco product, only the "holder of [the] application" may challenge the withdrawal order. §387j(d)(2). Congress's use of materially different terms in the TCA—"holder of [the] application" in §387j(d)(2) and "any person adversely affected" in §387*l*(a)(1)—raises the presumption that the different terms mean different things. This principle is fatal to the FDA's reading of §387*l*(a)(1). The FDA's other structural and policy arguments likewise cannot be squared with Congress's use of the phrase "any person adversely affected."

The retailers had the right to petition for review under the TCA, and

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the Fifth Circuit denied the FDA's motion to dismiss or transfer because it correctly concluded that at least one proper petitioner had venue. Pp. 8–12.

(c) The FDA now argues that each petitioner in a joint petition for review must independently establish venue. The FDA did not make that argument in the Fifth Circuit. The Court rarely addresses an argument raised first to the Court, see *OBB Personenverkehr AG* v. *Sachs*, 577 U. S. 27, 38, and prudence counsels against doing so here. Pp. 12–13.

Affirmed and remanded.

BARRETT, J., delivered the opinion of the Court, in which ROBERTS, C. J., and THOMAS, ALITO, KAGAN, GORSUCH, and KAVANAUGH, JJ., joined. JACKSON, J., filed a dissenting opinion, in which SOTOMAYOR, J., joined.

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

[June 20, 2025]

JUSTICE BARRETT delivered the opinion of the Court.

The Family Smoking Prevention and Tobacco Control Act (TCA) requires manufacturers to apply for and receive approval from the Food and Drug Administration (FDA) before marketing any "new tobacco product." 123 Stat. 1807, 21 U. S. C. §387j. Companies that manufacture or sell new tobacco products without the FDA's approval face significant penalties. See §§331, 333(a), 387b(6)(A), 387j(a)–(c). If the FDA denies an application, the TCA authorizes "any person adversely affected" by the denial order to petition for judicial review under the standards of the Administrative Procedure Act (APA). §§387*l*(a)–(b). We must decide whether retailers who would sell a new tobacco product if not for the FDA's denial order have the right to seek judicial review. We hold that they do.

I

When modern e-cigarettes made their American debut, the FDA did not treat them as "new tobacco products" for purposes of the TCA. See *FDA* v. *Wages & White Lion Investments, LLC*, 604 U. S. ___, ___–___ (2025) (slip op., at

6–9). They could therefore be sold without the FDA's approval, and over the years, a large market developed. See *ibid*. But in 2016, the FDA changed direction: It announced that e-cigarettes and related products are subject to the TCA after all. 81 Fed. Reg. 29028–29044 (2016). Given the size of the e-cigarette market, pulling products from the shelves while manufacturers sought "premarket" authorization to sell them would have been disruptive. To mitigate the disruption, the FDA announced that it would defer enforcement of the TCA against e-cigarette manufacturers and retailers while the manufacturers sought FDA approval. *Id*., at 29009–29015.

R. J. Reynolds Vapor Co. (RJR Vapor) manufactures e-cigarettes, including the popular menthol- and mixed-berry-flavored Vuse Alto products. It timely applied for authorization to market its Vuse Alto products, but three years later, the FDA denied the applications. According to the FDA, RJR Vapor had failed to demonstrate that marketing Vuse Alto products would be "appropriate for the protection of the public health." §387j(c)(2)(A). This order sounded the death knell for a significant portion of the e-cigarette market.

When the FDA denies premarket authorization, "any person adversely affected" by the denial may petition for judicial review in either the D. C. Circuit or "the circuit in which such person resides or has their principal place of business." §387*l*(a)(1). RJR Vapor is incorporated and has its principal place of business in North Carolina; thus, had it filed alone, its options were the D. C. Circuit and the Fourth Circuit. Rather than filing alone, however, RJR Vapor combined forces with retailers of Vuse Alto products: Avail Vapor Texas, L.L.C., a Texas company that owns and operates the "Vuse Inspiration Store" in Houston; the Mississippi Petroleum Marketers and Convenience Stores Association, a trade association of gas stations and convenience stores; and another North Carolina-based RJR

corporate affiliate that sold Vuse products online. RJR Vapor and the retailers filed a joint petition in the Fifth Circuit, where Avail Vapor and the trade association are located.

The FDA asked the court to either dismiss the joint petition for lack of venue or transfer it to the D. C. Circuit or Fourth Circuit. It pointed out that under the TCA, only those "adversely affected" by the denial of premarket authorization may petition for review of the FDA's order. And in the FDA's view, only a disappointed applicant—in this case, RJR Vapor—is "adversely affected" within the meaning of the TCA. Because the retailers had no right to seek review, the FDA argued, the petition had no basis for being in the Fifth Circuit. RJR Vapor could file in the D. C. Circuit (the default) or the Fourth Circuit (its home).

A divided Fifth Circuit panel denied the FDA's motion and concluded that venue was proper over the joint petition to review the FDA's denial order.[1] The FDA sought this Court's review of the Fifth Circuit's order, and we granted certiorari.[2] 603 U. S. ___ (2024).

II

A

To invoke a statutory cause of action, a plaintiff must be within the "zone of interests" that the statute protects.

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[1] In a separate order, the Fifth Circuit also stayed the FDA's denial order. The Fifth Circuit's stay order is not before us.

[2] The respondents argue that we lack jurisdiction to decide this case. Outside of limited circumstances, Article III allows this Court to exercise only "appellate jurisdiction," not "original jurisdiction." *Marbury* v. *Madison*, 1 Cranch 137, 175 (1803). The respondents argue that we are unconstitutionally exercising original jurisdiction because the Court of Appeals has not yet adjudicated the merits of their petition. This argument is clever but misguided. We are reviewing the Fifth Circuit's order denying a motion to transfer venue. So, as with any other case in which we review a lower court order, we are exercising appellate jurisdiction over that order—not deciding the motion in the first instance.

Lexmark Int'l, Inc. v. *Static Control Components, Inc.*, 572 U. S. 118, 129 (2014).[3] Put differently, a plaintiff must belong to the class of persons to whom the statute grants a right to sue. *Id.*, at 127. Under the TCA, the relevant class is "any person adversely affected" by the FDA's "denial." 21 U. S. C. §387*l*(a)(1).

"Adversely affected" (and its variations like "adversely affected or aggrieved") is a term of art with a "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); see also Brief for New Civil Liberties Alliance as *Amicus Curiae* 26–27 (claiming that 124 statutes use variations of "adversely affected"). Most notably, the term appears in the APA, which entitles anyone "adversely affected or aggrieved by agency action within the meaning of a relevant statute . . . to judicial review."[4] 5 U. S. C. §702. We have interpreted "adversely affected" broadly, as covering anyone even "*arguably* within the zone of interests to be protected or regulated by the statute . . . in question." *Association of Data Processing Service Organizations, Inc.* v. *Camp*, 397 U. S. 150, 153 (1970) (emphasis added). A plaintiff may sue under the APA unless her "interests are so marginally related to or inconsistent with the purposes implicit in the statute that

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[3] Though we once applied the zone-of-interests test as part of a "prudential standing" doctrine, we have abandoned that label as "misleading." *Bank of America Corp.* v. *Miami*, 581 U. S. 189, 196–197 (2017). As we have explained, the question is not one of standing, but of "whether the statute grants the plaintiff the cause of action that he asserts." *Ibid.* The zone-of-interests test is part of the ordinary statutory interpretation analysis that courts employ to answer that question. *Lexmark,* 572 U. S., at 127.

[4] Because the APA provides an omnibus cause of action for violations of other statutes, the "relevant statute" for an APA zone-of-interests analysis is not the APA itself, but the statute under which the relevant agency acted. See *Association of Data Processing Service Organizations, Inc.* v. *Camp*, 397 U. S. 150, 153 (1970).

it cannot reasonably be assumed that Congress intended to permit the suit." *Clarke* v. *Securities Industry Assn.*, 479 U. S. 388, 399 (1987). The inquiry is "not especially demanding." *Lexmark*, 572 U. S., at 130 (internal quotation marks omitted).

The FDA, however, attempts to ratchet up the standard. It insists that the capacious understanding of "adversely affected" is unique to the APA, whose "omnibus judicial-review provision . . . permits suit for violations of numerous statutes of varying character that do not themselves include causes of action for judicial review." *Ibid.*; see also, *e.g.*, *Bennett* v. *Spear*, 520 U. S. 154, 163 (1997). For statutes other than the APA, the FDA argues, a person must "actually"—not "arguably"—fall within the statute's zone of interests. Brief for Petitioners 12–13. And as the FDA sees it, the person *actually* aggrieved by the denial of permission to market a tobacco product is the one with the closest relationship to the application—the applicant.

We have not drawn the distinction that the FDA proposes. On the contrary, when we have interpreted variations of the phrase "adversely affected or aggrieved" outside the context of the APA, we have borrowed from our APA cases, including their broad formulation of the zone-of-interests test. For instance, in *Bank of America Corp.* v. *Miami*, we interpreted the Fair Housing Act's (FHA) cause of action—which permits any "aggrieved person" to sue. 581 U. S. 189, 193 (2017); 42 U. S. C. §3613(a)(1)(A). Citing our canonical articulation of the APA's broad zone-of-interests test in *Data Processing*, we held that Miami could sue under the FHA because the city "arguably" fell within the interests that the FHA sought to protect. 581 U. S., at 197–201.

Thompson v. *North American Stainless, LP*, runs in the same vein. 562 U. S. 170 (2011). There, we interpreted the scope of Title VII's cause of action, which permits a "person claiming to be aggrieved" to sue. 42 U. S. C. §2000e–5(f)(1). We held that this cause of action is neither so narrow as to

include only the person claiming to be the victim of discrimination nor so broad as to encompass every person with Article III standing. *Thompson*, 562 U. S., at 177. Instead, interpreting the term "aggrieved" consistently with its "common usage" in the APA context, we held that Title VII authorized suit by "any plaintiff with an interest 'arguably [sought] to be protected by the statute.'" *Id.*, at 177–178 (quoting *National Credit Union Admin.* v. *First Nat. Bank & Trust Co.*, 522 U. S. 479, 495 (1998)). Under this test, an employee who had allegedly been fired in retaliation for the protected activity of his fiancée (who was also his coworker) was "aggrieved" and could sue. *Thompson*, 562 U. S., at 178.

Finally, in *Newport News*, we had to decide whether the Director of the Office of Workers' Compensation Programs in the Department of Labor was "[a] person adversely affected or aggrieved by a final order" under the Longshore and Harbor Workers' Compensation Act. 514 U. S., at 123; 44 Stat. 1436, 33 U. S. C. §921(c). To answer this question, we considered the history of this "term of art" across administrative law, including our canonical interpretation of it under the APA: "[A] litigant [must] show . . . that the interest he seeks to vindicate is *arguably* within the 'zone of interests to be protected or regulated by the statute.'" *Newport News*, 514 U. S., at 126–127 (quoting *Data Processing*, 397 U. S., at 153; emphasis added). Considering the "long lineage" of this language, we found it telling that neither we nor any court of appeals had ever held, under the APA or otherwise, that "an agency, in its regulatory or policymaking capacity, is 'adversely affected' or 'aggrieved.'" *Newport News*, 514 U. S., at 127.

Taken together, these cases reflect a presumption that the term "adversely affected" carries the same meaning outside the APA as in it.[5] The Fair Housing Act, Title VII, and

[5] The FDA invokes *Bennett* and *Lexmark* for support, but the statutes

the Longshore and Harbor Workers' Compensation Act have different histories, scopes, and purposes. Yet in interpreting each statute, we borrowed principles from cases describing the APA's cause of action. The FDA cannot explain why—repeatedly and without regard for their differing statutory purposes—we have interpreted other causes of action with variations of "adversely affected or aggrieved" consistently with the APA's cause of action.[6]

We interpret the phrase "adversely affected" in the TCA against this backdrop. Echoing the APA, the TCA provides that "any person adversely affected by [the FDA's] denial" may petition for judicial review. 21 U. S. C. §387*l*(a)(1); see also 5 U. S. C. §702 ("[a] person . . . adversely affected or aggrieved by agency action"). The TCA's cause of action thus extends to any petitioner "with an interest 'arguably sought to be protected by the statute.'" *Thompson*, 562 U. S., at 178 (quoting *National Credit Union Admin.*, 522 U. S., at 495; alterations omitted). The retailers fit the bill. If the FDA denies an application, the retailers, like the manufacturer, lose the opportunity to profit from the sale

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at issue in those cases did not use variations of the phrase "adversely affected" to create a cause of action. See 16 U. S. C. §1540(g) (*Bennett* v. *Spear*, 520 U. S. 154 (1997)); 15 U. S. C. §1125(a)(1) (*Lexmark Int'l, Inc.* v. *Static Control Components, Inc.*, 572 U. S. 118 (2014)). So neither case sheds light on whether "adversely affected" has a unique meaning in the context of the APA.

[6]The FDA notes that the phrase "adversely affected or aggrieved" predates the APA. *Director, Office of Workers' Compensation Programs* v. *Newport News Shipbuilding & Dry Dock Co.*, 514 U. S. 122, 126 (1995). But the FDA has not shown that the pre-APA definition of "adversely affected or aggrieved" was meaningfully narrower than the version of the zone-of-interests test articulated in modern APA cases, not to mention *Bank of America* and *Thompson* v. *North American Stainless, LP*, 562 U. S. 170 (2011). Even our pre-APA construction of "adversely affected" was quite broad. See, *e.g.*, *FCC* v. *Sanders Brothers Radio Station*, 309 U. S. 470, 475–477 (1940) (holding that competitors of FCC licensees are "adversely affected" by an order granting a license within the meaning of §402(b)(2) of the Communications Act of 1934).

of the new tobacco product—or, if they sell the product anyway, risk imprisonment and other sanctions. See 21 U. S. C. §§331, 333(a), 387b(6)(A), 387j(a)–(c). Given this significant, direct impact on retailers, their interests are not "so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Clarke*, 479 U. S., at 399. Accordingly, the retailers are "adversely affected" by a denial order and are therefore proper petitioners under §387*l*(a)(1).[7]

B

Resisting this conclusion, the FDA (followed by the dissent) argues that the TCA's text and structure reflect Congress's choice to offer judicial review only to manufacturers denied permission to market a tobacco product. The FDA emphasizes that TCA applications result in an "order," §387j(c)(1)(A), and that "orders" may normally be challenged only by the participants in the proceeding that led to the order. It also asserts that other provisions of the stat-

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[7]The dissent argues that the zone-of-interests inquiry turns exclusively on §387j(c), which governs the FDA's response to a marketing application. See *post*, at 6 (opinion of JACKSON, J.) This myopic approach is inconsistent with *Clarke* v. *Securities Industry Assn.*, which explains that the zone-of-interests analysis must not "focu[s] too narrowly" on the basis for the violation, but must also consider that provision "in the overall context" of the relevant Act. 479 U. S. 388, 401 (1987). Here, the relevant context includes not only the application process outlined in §387j(c), but also the legal consequences if that process ends with a denial order—namely, the threat of criminal penalties for retailers who sell the denied products. According to the dissent, this threat is irrelevant because §387j(c) does not enable the retailers to "weigh in on" the FDA's consideration of an application for premarket authorization. *Post*, at 8, n. 1 (opinion of JACKSON, J.). But the TCA does not authorize suit only for those permitted to "weigh in on" the agency's disposition of an application—it authorizes suit for those "adversely affected" by the denial of an application. The retailers meet that description.

ute reflect an overriding concern with the applicant manufacturer: Only the manufacturer may ask the FDA to refer its application to a scientific committee, receive notice of a denial order, or receive a statement about why the application was denied. §§387j(b)(2)(B), (e)(2), (c)(3). And, the FDA observes, only the manufacturer is positioned to demonstrate that a product is "appropriate for the protection of the public health." §387j(c)(2)(A). Putting these provisions together, the FDA says that the TCA is concerned exclusively with the interests of the manufacturer. Retailers are outside the TCA's zone of interests.

These arguments, which focus almost entirely on §387j, cannot be squared with §387*l*(a)(1)—the provision that creates the cause of action. Start with the textual oddity of using the phrase "*any* person adversely affected" to describe a cause of action that only one person—the applicant manufacturer—could use. "Read naturally, the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind.'" *United States* v. *Gonzales*, 520 U. S. 1, 5 (1997) (quoting Webster's Third New International Dictionary 97 (1976)). Congress's use of "any" suggests that a denial order can adversely affect multiple persons.

Even without the word "any," the phrase "person adversely affected" suggests an intent to cover more than one party. *Thompson* is probative. In that case, the respondent similarly argued that the phrase "person aggrieved" referred to only the person who engaged in statutorily protected activity. 562 U. S., at 177. We said that "[w]e know of no other context in which the words carry this artificially narrow meaning, and if that is what Congress intended," then "it would more naturally have said 'person claiming to have been discriminated against' rather than 'person claiming to be aggrieved.'" *Ibid*. We saw "no basis in text or prior practice for limiting the latter phrase" to the single person who engaged in protected conduct. *Ibid*. So too here. If

Congress intended to convey the FDA's reading, it would more naturally have said "applicant" rather than "person adversely affected." And there is "no basis in text or prior practice" for limiting "person adversely affected" to mean "the applicant"—or, for that matter, the "party" with whom the agency dealt. See *NRC* v. *Texas*, 605 U. S. ___, ___ (2025) (slip op., at 9) (distinguishing between statutes that grant a cause of action to a "party" aggrieved, as opposed to the broader any "person" aggrieved).

The FDA tries to explain away the breadth of §387*l*(a)(1) by stressing that it applies not only to denial orders under §387j(c), but also to regulations promulgated under §387g. See also *post*, at 11–12 (JACKSON, J., dissenting). The provision's breadth, the FDA says, accommodates the latter context: Regulations affect more than one person, even if a denial order affects only the applicant. So, the FDA stresses, its interpretation does not read the phrase "any person" out of the provision. Fair enough. But it does read the phrase "an applicant" *into* the provision. Congress did not enact a narrow cause of action for denial orders and a broader one for regulations. Instead, it brought them under the same umbrella, using the same language—"any person adversely affected"—to cover both contexts. The FDA's spin on the provision proposes to undo that choice.

Congress knows how to limit the scope of a cause of action—in fact, it did so elsewhere in the TCA. When the FDA issues an order withdrawing an existing approval of an application to market a new tobacco product, only the "holder of [the] application" may challenge the order. §387j(d)(2). The difference between "holder of [the] application" and "any person adversely affected" is conspicuous. When Congress uses "one term in one place, and a materially different term in another, the presumption is that the different term denotes a different idea." A. Scalia & B. Garner, Reading Law 170 (2012); see also, *e.g.*, *Southwest Airlines Co.* v.

Saxon, 596 U. S. 450, 457–458 (2022). That principle is fatal to the FDA's reading of §387*l*(a)(1).

The FDA tries to turn this liability into an asset. See also *post*, at 9–10 (JACKSON, J., dissenting). It argues that Congress would not have allowed retailers to challenge denial orders (in which they normally have no reliance interests) but not withdrawal orders (in which they usually have significant reliance interests). Yet Congress made this very choice by using different language for the two types of challenges. Plainly, the FDA wishes that Congress had written the review provision differently. As we have explained before, however, "[w]e do not ask whether in our judgment Congress *should* have authorized" this lawsuit, "but whether Congress in fact did so." *Lexmark*, 572 U. S., at 128.

The FDA's other structural and policy arguments similarly fail. See also *post*, at 6–8 (JACKSON, J., dissenting). It claims that §387j's statutory structure suggests that only the applicant has a protected stake in the application process. In particular, it highlights the confidentiality protections, arguing that they could prevent a retailer from obtaining the information necessary to mount a successful challenge. See §387f(c) (applying protection to information obtained by the FDA through §387j's application process). Maybe—though the confidentiality provisions did not frustrate this lawsuit. In any event, §387*l*(a)(1) asks whether a petitioner is "adversely affected" by the denial order, not whether a petitioner is the person best positioned to challenge a denial order. If Congress had wanted only those with the most information to be able to bring these challenges, it would have said so.[8]

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[8]The FDA relies heavily on *Block* v. *Community Nutrition Institute*, 467 U. S. 340 (1984). See also *post*, at 12–14 (JACKSON, J., dissenting). But *Block* is readily distinguishable. The question in *Block* was whether the Act at issue "preclude[d] judicial review" within the meaning of 5 U. S. C. §701(a)(1), such that milk consumers could not invoke the APA's

The retailers had the right to petition for review under the TCA. Because Avail Vapor and the trade association have their principal places of business in Texas and Mississippi, respectively, they could both file in the Fifth Circuit. So when it denied the FDA's motion to dismiss or transfer, the Fifth Circuit correctly concluded that at least one proper petitioner had venue.

III

In addition to contending that the retailers are not "adversely affected," the FDA advances an argument in this Court that it failed to make in the Fifth Circuit: It maintains that each petitioner in a joint petition for review must independently establish venue. RJR Vapor and the RJR-affiliated retailer, standing alone, could not file in the Fifth Circuit. Thus, the FDA says, the Fifth Circuit must dismiss the RJR petitions even if the other retailers may petition for review there.

No court, including the Fifth Circuit in this case, has analyzed whether every petitioner in a joint petition must independently satisfy the TCA's venue provisions. We rarely address an argument raised for the first time in this Court. *OBB Personenverkehr AG* v. *Sachs*, 577 U. S. 27, 38 (2015). In the ordinary course, "[p]rudence . . . dictates awaiting a case in which the issue was fully litigated below, so that we will have the benefit of developed arguments on both sides and lower court opinions squarely addressing the question."

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omnibus cause of action to challenge the Secretary of Agriculture's milk market orders. *Block*, 467 U. S., at 341, 345. We held that consumers could not sue under the APA, primarily because the Act itself included a separate cause of action enabling dairy handlers (and not consumers) to seek judicial review of the orders after first exhausting administrative remedies. See *id.*, at 345–347 (citing 7 U. S. C. §608c(15)). Allowing consumers to sue under the APA would have frustrated that scheme. *Block*, 467 U. S., at 345–347. This case—which involves a single cause of action and no administrative exhaustion requirement—is not analogous.

Yee v. *Escondido*, 503 U. S. 519, 538 (1992). Prudence counsels that course here, because anything we say about the TCA's venue provisions would inevitably inform debates about similar statutes—including 28 U. S. C. §1391(e)(1), the general venue statute for lawsuits against the Government.

* * *

We affirm the Fifth Circuit's denial of the FDA's motion and remand the case for further proceedings consistent with this opinion.

It is so ordered.

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

[June 20, 2025]

JUSTICE JACKSON, with whom JUSTICE SOTOMAYOR joins, dissenting.

The statute at issue in this case requires tobacco manufacturers to receive permission from the Food and Drug Administration (FDA) before new tobacco products may be marketed or sold. 21 U. S. C. §387j. In deciding who falls within the zone of interest of that statute, the Court largely ignores this context. Instead, the Court directs all attention to the language of the statute's cause of action—and then essentially nullifies the zone-of-interest test by reducing it to the near-meaningless proposition that anyone affected, or even *arguably* affected, by the FDA's marketing denial can sue.

The actual zone-of-interest inquiry, however, requires us to examine exactly whom Congress intended to protect under the relevant statutory provisions. And, here, all the usual tools of statutory interpretation point in the same direction: Congress established a detailed scheme for manufacturers to obtain authorization to market new tobacco products—a scheme within which retailers have no rights and play no role—and, in the context of that scheme, Congress provided a cause of action for the protection of the manufacturers' statutorily created interests. Because noth-

ing in this statute suggests that Congress meant to authorize retailers to sue to challenge the FDA's denial of a manufacturer's marketing application, much less bring that legal challenge in a venue that is otherwise unavailable, I respectfully dissent.

I

The Family Smoking Prevention and Tobacco Control Act empowers the Secretary of Health and Human Services, acting through the FDA, to regulate tobacco products. See 21 U. S. C. §§387a, 393(d)(2). The Act expressly applies to many tobacco products that were popular when the Act was enacted in 2009, such as cigarettes. See §387a(b). But recognizing that markets evolve, Congress provided that the Act would also apply to "any other tobacco products" that the FDA "by regulation deems to be subject to" the Act. *Ibid.* Within that covered-product category, the Tobacco Control Act prohibits manufacturers from marketing without FDA authorization any "new tobacco product," defined as a product not generally available on the market as of February 15, 2007. §§387j(a)(1), (a)(2)(A). The statute also prohibits any retailer from selling a "new tobacco product" unless that product has been authorized by the FDA. See §§387b(6)(A), 331(a).

When a manufacturer seeks FDA authorization to market a new tobacco product, it must submit an application to the agency. See *FDA* v. *Wages & White Lion Investments, LLC*, 604 U. S. ___, ___ (2025) (slip op., at 5); §387j(b). That application must include "full reports of all information" the manufacturer is (or should be) aware of "concerning investigations which have been made to show the health risks of" the product. §387j(b)(1)(A). It must also include a list of the product's "components, ingredients, additives, and properties," along with a description of the manufacturing methods and facilities. §§387j(b)(1)(B), (C). And the man-

ufacturer must produce any "samples of such tobacco product" that the agency "may reasonably require." §387j(b)(1)(E).

"There are many reasons why the FDA may deny marketing authorization to a 'new tobacco product,'" but it *must* do so if the manufacturer fails to show "that the product 'would be appropriate for the protection of the public health.'" *Id.*, at ___ (slip op., at 5) (quoting §387j(c)(2)(A)). Congress has thus placed the burden on the applicant (the manufacturer) to persuade the FDA that its product would help—not hurt—public health.

If the agency denies a manufacturer's application for failure to make this showing, or if the application is denied for any other reason, the statute further authorizes judicial review of that FDA decision. The Act specifically provides that "any person adversely affected" by the FDA's 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." §387*l*(a)(1).

The question before us today is what "any person adversely affected" by the FDA's denial means in the context of this statute.

II

A

"Read literally," the "broad language" of the Tobacco Control Act's judicial-review provision "might suggest that an action is available to anyone who can satisfy the minimum requirements of Article III." *Lexmark Int'l, Inc.* v. *Static Control Components, Inc.*, 572 U. S. 118, 129 (2014). But, as the majority acknowledges, this Court has not read this or similar wording for all it is worth when interpreting causes of action. See *ante*, at 4. In the administrative-law context, we have long recognized that "adversely affected" is a term of art that can be far more cabined than its literal

meaning suggests. Indeed, we have consistently eschewed reading the "adversely affected" word formulation to apply to anyone in the world who might be affected by an agency's action, and have instead interpreted this language to refer "only to plaintiffs whose interests 'fall within the zone of interests protected by the law invoked.'" *Lexmark*, 572 U. S., at 129 (quoting *Allen* v. *Wright*, 468 U. S. 737, 751 (1984)).

We call this the zone-of-interest test—and it is, by now, well established. Simply stated, the test "is a guide for deciding whether . . . a particular plaintiff should be heard to complain of a particular agency decision." *Clarke* v. *Securities Industry Assn.*, 479 U. S. 388, 399 (1987). "The essential inquiry is whether Congress 'intended for [this particular] class [of plaintiffs] to be relied upon to challenge agency disregard of the law.'" *Ibid.* (quoting *Block* v. *Community Nutrition Institute*, 467 U. S. 340, 347 (1984); some alterations in original). We have also explained that, at bottom, "the reviewability question turns on congressional intent, and all indicators helpful in discerning that intent must be weighed." *Clarke*, 479 U. S., at 400. In short: "Whether a plaintiff comes within 'the "zone of interests"' is an issue that requires us to determine, using traditional tools of statutory interpretation, whether a legislatively conferred cause of action encompasses a particular plaintiff's claim." *Lexmark*, 572 U. S., at 127.

Our decision in *Lexmark* illustrates how the zone-of-interest test works in practice. The statute at issue there authorized a suit brought by "'any person who believes that he or she is likely to be damaged' by a defendant's false advertising." *Id.*, at 129 (quoting 15 U. S. C. §1125(a)(1)). Applying the zone-of-interest test, we held that, despite the statute's broad "any person" language, contextual clues—including the statute's expressed purpose—demonstrated that Congress intended to permit suit only by persons who suffered a particular type of injury (specifically, "an injury

to a commercial interest in reputation or sales"). 572 U. S., at 131–132.

The Administrative Procedure Act (APA) is on the other side of the spectrum of outcomes when the zone-of-interest test is applied. We have long recognized that the APA's judicial-review provision is particularly capacious. See *ante*, at 5. Notably, we have observed that such breadth is necessary in the context of *that* statute in order to "preserv[e] the flexibility" of the APA's provisions, which apply in a range of contexts. *Lexmark*, 572 U. S., at 130.

The majority accepts that the zone-of-interest test is the proper legal framework for assessing the breadth of the cause of action at issue. See *ante*, at 4. It also goes to great lengths to emphasize that the zone-of-interest test operates identically across all statutes that permit aggrieved persons to sue—be it the APA or a more specific provision. See *ante*, at 5–7. I wholeheartedly agree. Whatever the underlying statute, our task is "to determine the meaning of the congressionally enacted provision creating a cause of action," which we do by "apply[ing] traditional principles of statutory interpretation." *Lexmark*, 572 U. S., at 128. Sometimes, as with the APA, those contextual clues demonstrate a cause of action's breadth. Other times, as was the case in *Lexmark*, those clues suggest a narrower scope. In each case, the question is one of Congress's intent.

B

To properly discern congressional intent about the breadth of a particular cause of action, it is crucial to know where to look. And, unlike the majority's opinion here, our precedents do not merely look to the words of the cause-of-action provision that prompted the need to inquire further about what Congress intended. Doing so would be, of course, entirely circular. Instead, because the zone-of-interest test is premised on the idea that interpreting a seemingly unbounded cause of action requires exploration

into what Congress wanted in the context of that particular statute, we look to "the particular provision of law upon which the plaintiff relies" for his legal claim—that is, "'the statutory provision whose violation forms the legal basis for his complaint.'" *Bennett* v. *Spear*, 520 U. S. 154, 175–176 (1997) (quoting *Lujan* v. *National Wildlife Federation*, 497 U. S. 871, 883 (1990); emphasis deleted). Although one would not know it from reading the majority's opinion, this is blackletter law. See, *e.g.*, *Clarke*, 479 U. S., at 396–397; *Air Courier Conference* v. *Postal Workers*, 498 U. S. 517, 523–524 (1991); *Thompson* v. *North American Stainless, LP*, 562 U. S. 170, 178 (2011).

Respondents here allege that the FDA improperly denied a marketing application filed by R. J. Reynolds Vapor Co. (RJR Vapor) in violation of 21 U. S. C. §387j(c). So, it is *that* statutory provision, not the cause of action itself, that is the proper focus of the zone-of-interest inquiry.

Analyzing that provision (as the majority fails to do) reveals that §387j(c) is part of a statutory scheme that establishes an adjudicatory process between a manufacturer and the FDA—and no one else. Per that process, after the FDA receives a manufacturer's marketing application and reviews it, the statute requires a particular agency response: The FDA "shall" "issue an order that the new product" either may be, or may not be, "introduced . . . into interstate commerce." §387j(c)(1)(A).

The FDA makes this marketing-approval decision in accordance with the statute's directives, by considering the manufacturer's marketing application in all of its particulars. See §§387j(b), (c). I touched on those details above, see *supra*, at 2, but it bears repeating here that, by law, a manufacturer's application must contain a "full statement of the components, ingredients, additives, and properties" of the proposed tobacco product; a "description of the methods used in, and the facilities and controls used for, the manufacture, processing, and . . . packing" of the product;

and, in some instances, samples of the product itself. §387j(b)(1). The manufacturer gathers all of that information and submits it directly to the FDA. That is it—the agency does not solicit any information from interested third parties, such as potential consumers or retailers who wish to sell the product, and manufacturers are not required to submit any information to the FDA on their behalf.

Nor do retailers, in particular, have any procedural rights whatsoever after a manufacturer submits its marketing application. Indeed, in many circumstances, the FDA is required to *deny* an application without regard to the impact that doing so might have on retailers. For example, the FDA must deny an application if the manufacturer's production, processing, or packing facilities fail to conform to regulatory standards. See §387j(c)(2)(B). The FDA must also deny an application if the manufacturer fails to show "that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." §387j(c)(2)(A).

This all means that, under the premarketing-approval scheme that Congress has crafted, the interests of tobacco retailers are entirely beside the point—they do not factor in at all. It is the manufacturers that have to make the requisite showings, and if they do a poor job, the retailers are simply out of luck. There is no mechanism by which *any* interested third party (including a retailer excited by the prospect of being able to sell the relevant product) can supplement a manufacturer's marketing application. There are also no third-party notice requirements, and Congress has emphasized the importance of confidentiality, so third-party retailers may not even *know* that an application for the marketing of a particular new tobacco product has been submitted to the FDA at all, let alone that one was denied. See §387j(e)(2) (requiring the FDA to serve denial notices on applicants, but not retailers); see also §387f(c) (providing

that the agency may not disclose confidential information to nonapplicants); 86 Fed. Reg. 55398 (2021) (recognizing that "the intent to market a tobacco product that is not currently marketed is often considered confidential commercial information").[1]

Thus, the text of the statutory provisions that create the premarketing-approval scheme Congress adopted does not support the conclusion that Congress promulgated this statute with retailers' interests in mind.

C

Nor does the purpose of the Tobacco Control Act's premarketing-approval or judicial-review provisions. Instead, the statute's judicial-review mechanism operates to ensure that those most invested in a new product's authorization can enlist a court to double check the FDA's work. Manufacturers plainly fall within that category: At the time a manufacturer applies for authorization to market a new tobacco product, it has already expended considerable time, money, and effort to develop that product.

But retailers are differently situated. As a general mat-

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[1] Contrary to the majority's assertion (*ante*, at 8, n. 7), the fact that retailers can face criminal penalties for selling a tobacco product that lacks FDA approval tells us nothing about the scope of the statute's zone of interest related to the FDA's denial of a manufacturer's marketing application. After all, it is not Congress's decision to deny a manufacturer's marketing application that subjects a retailer to criminal penalties; a retailer *never* has a legal right to sell an unauthorized product—before or after an application is submitted. See *infra*, at 9. So, although retailers may hope that the FDA will grant a particular application, the FDA's failure to do so does not impact the retailer's rights. What is more, the zone-of-interest inquiry asks us to consider who Congress intended to weigh in on the FDA's decision to deny the manufacturer authorization to market the product. Neither Congress's general prohibition on the sale of unauthorized tobacco products nor the mechanisms it has provided for the enforcement of that prohibition speaks to the threshold authorization issue.

ter, when a manufacturer applies for authorization to market a new product, retailers are mere bystanders—they do not yet have any skin in the game. Cf. §§331(c), 387b(6)(A) (clarifying that a new tobacco product may not be sold before the FDA approves it). A retailer may *desire* to sell an upcoming (not-yet-approved) product—it may even expect to profit handsomely, if the manufacturer's application were to be approved and the product deemed marketable. But that kind of forward-looking interest is different in kind from the manufacturer's backward-looking one. If the FDA denies a manufacturer's marketing application, a retailer might well be disappointed, but it will not lose an investment; it can stock its shelves with something else. Thus, Congress could have rationally intended to protect manufacturers' reliance interests by affording them a layer of judicial review if the FDA denies a marketing application, while feeling no need to extend similar protection to retailers.

The intuition that Congress reasonably intended to draw a distinction between the interests of manufacturers and retailers—and protected only the former in the instant context—is confirmed by a provision of §387j that enables the FDA to withdraw its prior approval of a tobacco product in certain situations. See §387j(d). That provision states that the agency's decision to withdraw its approval of a tobacco product may be challenged in court by *only* the "holder of [the] application subject to" the withdrawal order—in other words, the manufacturer alone. §387j(d)(2). To me, this is the single most significant piece of textual evidence bearing on Congress's intent regarding the protection of retailers.

Under the majority's view, even though a retailer *cannot* challenge the FDA's decision to withdraw its prior approval per §387j(d), it *can* file a lawsuit to challenge the FDA's denial of a manufacturer's application in the first instance due to the "any person adversely affected" language of the cause of action. But as I see it, the fact that a retailer cannot

challenge a withdrawal order makes it much more likely that Congress did not intend to permit it to challenge the agency's initial denial of an application either—a consistent and reasonable result since, as I have explained, retailers generally lack any financial stake or reliance interests in the application's approval.

Indeed, in my view, the provision prohibiting retailers from challenging the withdrawal of an approved application puts the nail in the proverbial coffin of the contention that retailers' interests are being protected by this statute. When the FDA withdraws its marketing approval, retailers may well have already invested considerably in the new tobacco product—*e.g.*, by purchasing inventory, setting up store displays, or attracting new customers. But Congress did not seem to care; the statute states plainly that only manufacturers can file suit to challenge such withdrawal. *Why* would Congress have wanted retailers to be able to seek judicial review of the agency's initial denial (at which point they generally lack reliance interests), but not when the agency withdraws its approval (at which point they generally *will* have such interests)?

The majority offers no explanation, stating only that this differential treatment was Congress's "choice." *Ante*, at 10. But "[t]he illogic of the majority's interpretation strongly signals that what the majority believes Congress 'chose' is not actually what Congress intended or accomplished." *Advocate Christ Medical Center* v. *Kennedy*, 605 U. S. ___, ___ (2025) (JACKSON, J., dissenting) (slip op., at 10). The more logical inference by far is that Congress excluded retailers from protecting their interests in the withdrawal context precisely because retailers are not within the zone of interest of this statutory scheme.

III

A

Ignoring our past edicts regarding how the zone-of-

interest test works, the majority spends very little time evaluating the substantive provisions of the Tobacco Control Act's marketing scheme. Instead, it zeroes in on the language of the provision supplying the cause of action: §387*l*(a)(1). In its view, retailers fit within that provision's scope because, by permitting suit by "'*any* person adversely affected,'" the statute's text "suggests an intent to cover more than one party." *Ante*, at 9. But as I have already noted, fixating on the broad text of a judicial-review provision substantially similar to the ones that prompted us to birth the zone-of-interest test gets us nowhere—at least, nowhere remotely resembling the traditional inquiry and what it was designed to do. This observation is fundamental; as our foundational zone-of-interest precedents recognized, a literal reading of capacious cause-of-action language renders the provision far broader than it is typically reasonable to conclude Congress intended. Cf. *Thompson*, 562 U. S., at 176–177 (observing that "absurd consequences" about who was entitled to sue would follow if the Court were to interpret literally a similarly worded cause of action).

In any event, even pure textualists would have to acknowledge that §387*l*(a)(1)'s seemingly infinite terminology can be adequately explained by a linguistic quirk that has little to do with Congress's "choice" to allow any arguably affected person to sue. Carefully examined, the text of this provision permits suit by "any person adversely affected by" *either* "the promulgation of a regulation" *or* the "denial of an application." §387*l*(a)(1). One way to use a single subject to describe two different types of plaintiffs (those who may seek to challenge an FDA regulation *and also* those who may seek to challenge the FDA's denial of a manufacturer's application) is to use a generic term, such as "any person." By design, that generic phrasing relates to "more than one party" and does not explain or suggest

who is included in either category. *Ante*, at 9. So, ultimately, the "any person" phrasing the majority puts so much stock in might just be a product of Congress's desire to use a single statutory provision to cover both situations.

Another noteworthy problem with the majority's interpretation is that it draws almost exclusively from what this Court has said about the breadth of the cause of action in an entirely different statute (the APA). It is certainly true that, in the APA context, the zone-of-interest test is "not especially demanding." *Ante*, at 5 (internal quotation marks omitted). But, again, we have explained that Congress intended this language to be broadly interpreted as it appears in the APA precisely because of the breadth of the APA itself. See *supra*, at 5. By contrast, as I have shown, the Tobacco Control Act's premarketing-approval scheme is narrow: It involves an exchange between tobacco manufacturers and the FDA that occurs when said manufacturers wish to market a new tobacco product. Third parties are entirely excluded from that back-and-forth. And, notably, that is so even when circumstances develop that do, in fact, implicate third-party interests (such as when a retailer has already begun marketing the product). There really is no material similarity between the premarketing-approval scheme Congress has constructed in the Tobacco Control Act, on the one hand, and the various interests that the APA protects, on the other. Consequently, the zones of interest those two statutes create are completely different, making it difficult to understand why the majority finds the APA parallel so persuasive.

B

The majority's take on the scope of §387*l*(a)(1)'s cause of action also fails to fully appreciate the reasoning of our zone-of-interest precedents. The zone-of-interest analysis here is substantially similar to that of *Block*, 467 U. S. 340. There, the Court held that the Agricultural Marketing

Agreement Act of 1937 permitted only milk handlers and producers—not consumers—to seek judicial review of the Secretary of Agriculture's milk pricing orders, even though the orders affected (indeed, harmed) consumers by increasing the price of milk. Consumers were not in the zone of interest (and thus were not "adversely affected" persons under the relevant cause of action, *id.*, at 345), the Court reasoned, because of the structure of the underlying administrative scheme. Milk market orders were promulgated via a "cooperative venture" between the agency, milk handlers, and milk producers; "[n]owhere in the Act" was there any "provision for participation by consumers." *Id.*, at 346–347. The Court recognized that "[i]n a complex scheme of this type, the omission of such a provision is sufficient reason to believe that Congress intended to foreclose consumer participation in the regulatory process." *Ibid.*

In the same way that the Agricultural Marketing Agreement Act contemplated collaboration between the agency, milk handlers, and milk producers—but not consumers—the Tobacco Control Act's premarket-authorization program contemplates collaboration between the agency and manufacturers—but not retailers. Therefore, here, just as in *Block*, the absence of any mechanism for retailers to participate in that collaborative premarketing-approval process on the front end is a strong signal that Congress did not intend to protect any interests retailers may have on the back end, if premarketing approval is denied.

Moreover, as with the would-be plaintiff-consumers in *Block*, "preclusion of [retailer] suits will not threaten realization of the fundamental objectives of the statute." *Id.*, at 352. After all, a retailer's interest generally will be aligned with a manufacturer's—both want the FDA to approve the application. Manufacturers, then, can "be expected to challenge unlawful agency action and to ensure that the statute's objectives will not be frustrated." *Ibid.*; cf. *Joint Anti-Fascist Refugee Comm.* v. *McGrath*, 341 U. S. 123, 153

(1951) (Frankfurter, J., concurring) (recognizing that the likelihood that a person would be "adequately protected" by the party who is able to challenge the underlying Government action is a "relevant consideration" when determining the scope of judicial review).

The majority dismisses *Block* in a footnote, arguing that it is "readily distinguishable" because the statute provided that certain industry participants could seek judicial review only "after first exhausting administrative remedies." *Ante*, at 11–12, n. 8. But *Block* is not an exhaustion case. Rather, the Court held that consumers' inability to participate in the administrative process was in and of itself a "sufficient reason" to believe that Congress intended to exclude consumers from using the statutory cause of action to seek judicial review of the relevant agency action. 467 U. S., at 347.[2]

Applying the plainly analogous reasoning of *Block* to the question presented in this case gets us to the most straightforward answer: Like the consumers in *Block*, the retailers here are beyond the zone of interest and thus cannot invoke the cause of action. But instead of just applying *Block*, the majority opts to rely on a number of cases interpreting causes of action that are far less similar to the statute at

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[2] In any event, permitting retailers to sue *would* "frustrat[e]" the statutory scheme at issue here, too. *Ante*, at 11–12, n. 8. When the FDA denies a manufacturer's application, the manufacturer faces a choice. It can (1) stand on its initial application and challenge the FDA's denial in court; (2) attempt to address its application's shortcomings (by, for example, fixing the part of its manufacturing or processing facilities that the FDA deemed insufficient, see 21 U. S. C. §387j(c)(2)(B)); or (3) give up on the product. Allowing retailers to challenge the denial in court deprives the manufacturer of agency over its own application, and risks manufacturers and retailers taking inconsistent actions after an application is denied. Of course, there may be times in which a retailer and a manufacturer are in lockstep. But, in that situation, one wonders why a retailer needs to be able to sue at all—beyond, of course, its desire to bring a legal challenge in a venue unavailable to the manufacturer. See *infra*, at 17–18.

issue here. *Ante*, at 4–8.

Those cases are really of no help because, in each of them, the plaintiff was expressly protected by the statute at issue, and thus fit well within the zone of interest. In *Thompson*, for example, we had no trouble concluding that an employee injured by his employer's unlawful retaliation fell within the zone of interests of a statute whose purpose was "to protect employees from their employers' unlawful actions." 562 U. S., at 178. And in *Bank of America Corp.* v. *Miami*, 581 U. S. 189 (2017), the statute had specifically defined "'aggrieved person'" to include "'any person who . . . claims to have been injured by a discriminatory housing practice,'" when the plaintiff there had made that claim. *Id.*, at 193.

The majority makes much of the Court's statements in those cases that the statutes at issue permitted suit by anyone whose interests were at least "'"*arguably* . . . protected by the statute."'" *Ante*, at 7 (quoting *Thompson*, 562 U. S., at 178; emphasis added). But the retailers here cannot even satisfy *that* formulation of the standard. The majority explains how retailers may be *affected* by §387j but never articulates how retailers are *protected* by this statute—not arguably, and certainly not actually. See *ante*, at 8, and n. 7, 9. That's because they can't. No matter how long you stare at §387j, you will not find anything looking out for retailers. They are simply not protected by the provision at all.

IV

Finally, when evaluating Congress's intent regarding the scope of the cause of action it established in §387*l*(a)(1), we should keep in mind, too, that this provision does not merely authorize judicial review of agency determinations at the behest of "any person adversely affected." Congress also specifically prescribed *where* that review must be sought. Again, the text states that "any person adversely affected" by the FDA's 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." §387*l*(a)(1).

No one disputes that RJR Vapor itself qualifies as a "person adversely affected" by the FDA's denial of its marketing application. Therefore, it is not as though RJR Vapor had no options—it most certainly could have brought a lawsuit challenging the FDA's denial in the D.C. Circuit or in the Fourth Circuit, where it has its principal place of business.[3] So, stepping back, one wonders: Why does it even matter whether the tobacco retailers RJR Vapor has chosen to pair up with have the ability to sue?

The above-quoted statutory text provides the answer. As it turns out, at the time RJR Vapor filed its application, the D. C. Circuit and the Fourth Circuit had each already rejected on the merits similar challenges that other flavored e-cigarette manufacturers had filed. See *Avail Vapor, LLC* v. *FDA*, 55 F. 4th 409, 413, 422 (CA4 2022); *Prohibition Juice Co.* v. *FDA*, 45 F. 4th 8, 12, 20–21 (CADC 2022). It thus became (perhaps) imperative from RJR Vapor's perspective that its own lawsuit challenging the FDA's denial of its flavored e-cigarette marketing applications be filed somewhere else. To accomplish *that* objective—*i.e.,* to facilitate RJR Vapor's end run around §387*l*(a)(1)'s venue restrictions—RJR Vapor needed another party to bring its legal challenge to court.

It is not hard to see where this is going. RJR Vapor teamed up with a Texas-based retailer that sold the relevant e-cigarettes—respondent Avail Vapor Texas, LLC—and, together, they filed a joint petition in the Fifth Circuit, challenging the FDA's denial of RJR Vapor's application.[4]

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[3] RJR Vapor is incorporated in North Carolina and maintains its principal place of business there too.

[4] Two other parties were also included on the petition: the Mississippi Petroleum Marketers and Convenience Stores Association and an RJR Vapor corporate affiliate that sold the relevant product. The presence of

The possibility that the courts would allow venue to be established based on Avail Vapor's presence on the petition gave RJR Vapor hope that its substantive legal challenge would move forward in a more applicant-friendly venue.[5]

From RJR Vapor's strategic litigating standpoint, neither Congress's intent concerning the scope of the cause of action, nor the fact that retailers were not front of mind for Congress when it crafted the premarketing-approval provisions of the Tobacco Control Act (see Part II, *supra*) mattered much. Regardless, it was critical for the retailers to participate as plaintiffs if RJR Vapor was going to successfully skirt §387*l*(a)(1)'s venue restrictions and steer this case to the preferred—but unauthorized—forum.

This is, of course, precisely the kind of manipulation that the pesky zone-of-interest test operates to prevent, insofar as it requires §387*l*(a)(1) to be interpreted consistent with what Congress cared about when it crafted that statute (including, presumably, its venue-related policies), rather than with undue adherence to whatever might be necessary to advance a party's litigating interests. And, ultimately, for present purposes, the distinction between what Congress wanted when it enacted §387*l*(a)(1) and what some tobacco manufacturers want to do now is particularly acute.

As we consider who can sue under §387*l*(a)(1), it is important to acknowledge that the statute Congress enacted

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these parties does not affect the legal analysis.

[5]Although a Fifth Circuit panel had rejected a similar arbitrary-and-capricious challenge levied against the FDA's denial of a similar application, see *Wages & White Lion Investments, L.L.C.* v. *FDA*, 41 F. 4th 427, 430, 436–439 (2022), the Circuit had vacated that decision and granted rehearing en banc at the point in which RJR Vapor and Avail Vapor filed their joint action, see 58 F. 4th 233, 234 (2023). That vacatur strongly suggested that the full Fifth Circuit would come out against the FDA—as, indeed, it eventually did. See 90 F. 4th 357, 362, 371 (2024) (en banc). We later vacated the Fifth Circuit's en banc decision, disagreeing with its primary holding. See *FDA* v. *Wages & White Lion Investments, LLC*, 604 U. S. ___, ___ (2025) (slip op., at 46).

also articulates a clear venue mandate: Thwarted tobacco manufacturers have a cause of action to challenge the FDA's denial of their marketing applications in court, but they must litigate their interests in the designated venues and, presumably, not elsewhere—including through proxy suits that third parties file in other places on their behalf.

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The majority correctly acknowledges that the disputed "any person adversely affected" language in §387*l*(a)(1) of the Tobacco Control Act implicates our well-established zone-of-interest test. All agree, too, that, under the zone-of-interest test, the watchword is congressional intent. But I would proceed to determine Congress's intent as normal, by applying the traditional tools of statutory interpretation to investigate the scope of §387j(c)—the provision that respondents argue the FDA violated. Every available indicator reveals that Congress intended to permit manufacturers—not retailers—to challenge the denial of a manufacturers' marketing application (and to do so only in the designated courts). In concluding otherwise, the majority not only opens up an avenue for judicial review that Congress did not intend, it also allows manufacturers like RJR Vapor to evade the statute's venue requirements.