No. 23-1187

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,

Petitioners,

v.

R.J. REYNOLDS VAPOR CO., *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF ATLANTIC LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICUS CURIAE* [1]

Established in 1977, the Atlantic Legal Foundation (ALF) is a national, nonprofit, nonpartisan, public interest law firm. ALF's mission is to advance the rule of law and civil justice by advocating for individual liberty, free enterprise, property rights, limited and responsible government, sound science in judicial and regulatory proceedings, and effective education, including parental rights and school choice. With the benefit of guidance from the distinguished legal scholars, corporate legal officers, private practitioners, business executives, and prominent scientists who serve on its Board of Directors and Advisory Council, ALF pursues its mission by participating as *amicus curiae* in carefully selected appeals before the Supreme Court, federal courts of appeals, and state supreme courts. *See* atlanticlegal.org.

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This appeal concerns the ability of the manufacturer and retailers of a federally regulated product to jointly challenge, in a single federal court of appeals, a final agency action that directly and indisputably impairs their shared commercial interests. Petitioner Food and Drug Administration's

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[1] No counsel for a party authored this brief in whole or part, and no party or counsel other than the *amicus curiae* and its counsel made a monetary contribution intended to fund preparation or submission of this brief.

persistent efforts to block the Fifth Circuit from reviewing the regulatory action at issue—denial of "premarket" authorization that would allow Respondents to continue selling Vuse "Alto" e-cigarettes—trigger ALF's missions of advocating for civil justice, responsible government, and free enterprise.

ALF takes no position on the merits of Respondents' challenge to FDA's denial of marketing authorization for Vuse Alto e-cigarettes. Instead, this amicus brief focuses on the question of whether a Vuse e-cigarette retailer has statutory standing to obtain judicial review of FDA's denial. At least one retailer, Respondent Avail Vapor Texas, L.L.C., has been selling Vuse e-cigarettes since before FDA decided to deny authorization to market them as "new tobacco products" under the Family Smoking Prevention and Tobacco Control Act ("TCA"), 21 U.S.C. § 387 *et seq.*[2] Avail has stated that it "would 'cease business operations' if the FDA's denial order went into effect." App. 5a.[3]

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[2] The TCA was enacted in 2009 as subchapter IX of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* In 2016 FDA deemed e-cigarettes to be "new tobacco products" subject to the TCA. *See* 21 U.S.C. § 387j; 81 Fed. Reg. 28,974 (May 10, 2016).

[3] The Fifth Circuit has stayed FDA's marketing denial pending disposition of this appeal. *See* Brief for the Petitioners ("FDA Br.") at 7.

In its Order denying FDA's Motion to Dismiss or Transfer, the Fifth Circuit held—not surprisingly—that the TCA "grants the Petitioners [Respondents here] statutory standing to challenge FDA decisions that affect them." App. 4a. "All the Petitioners have statutory standing as 'person[s] adversely affected' under the [TCA]." *Id.* 5a (quoting 21 U.S.C. § 387*l*(a)(1)).

This Court should affirm the Fifth Circuit's Order. Indeed, ALF believes that the question of statutory standing presented in this case transcends § 387*l*(a)(1), the TCA judicial review provision at issue. Having granted certiorari, the Court now has an important opportunity to reaffirm, or at least clarify, the breadth of a statute-specific right to judicial review that encompasses "any person adversely affected" by a final agency action.[4]

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[4] ALF defers to Respondents as to why the Court also should affirm the Fifth Circuit's ruling on the equally important question of whether venue under § 387*l*(a)(1) must be satisfied independently by each joint petitioner for judicial review of an FDA tobacco product marketing denial. In a related appeal involving Vuse e-cigarettes and two of the same Respondents as here—R.J. Reynolds Vapor Co. ("RJRV") and Mississippi Petroleum Marketers and Convenience Stores Association—the Fifth Circuit held that "venue is proper in this circuit." *R.J. Reynolds Vapor Co. v. FDA* ("*RJRV*"), 65 F.4th 182, 188 (5th Cir. 2023); *see also* App. 4a ("Stare decisis governs venue

SUMMARY OF ARGUMENT

This Court, like the Fifth Circuit, should reject FDA's narrow and self-serving interpretation of the TCA judicial review provision at issue, 21 U.S.C. § 387*l*(a)(1). That plainly and broadly worded provision entitles "*any* person adversely affected" by an FDA "new tobacco product" (e.g., e-cigarette) marketing authorization denial to file a petition for judicial review (emphasis added). But FDA argues that § 387*l*(a)(1) applies only to manufacturers. Placing form over substance, FDA contends that e-cigarette retailers are excluded because despite the economic consequences they suffer where, as here, the agency denies an e-cigarette marketing authorization, it is the manufacturer that submits the application for marketing approval and that is the addressee on FDA's denial order.

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here so long as the distributors have standing, which they do.").

FDA's elaborate but strained arguments that Respondent retailers lack statutory standing are part of its attempt to keep this appeal (and related Vuse e-cigarette appeals) out of the Fifth Circuit. The agency's effort to compel RJRV to pursue its challenge to FDA's Vuse e-cigarette marketing denials in either the D.C. Circuit or the Fourth Circuit—which FDA claims already have rejected the principal legal theory on which RJRV's challenge relies—is no less a type of "forum shopping" than what FDA accuses the Fifth Circuit of condoning. *See* FDA Br. at 4-5; *see also* App. 5a.

FDA's convoluted arguments about statutory standing defy common sense, as well as the text of § 387*l*(a)(1), which refers to judicial review of a "denial," not of a denial "order." The Court should view the zone of interests for determining who is "adversely affected" by a marketing denial, and thus has the right to judicial review, as leniently for § 387*l*(a)(1) as it does for the Administrative Procedure Act's almost identically worded judicial review provision, 5 U.S.C. § 702. The Court's precedents establish that the benefit of any doubt should go to the plaintiff, here the Respondents, including the retailers.

There are many additional federal statutes containing judicial review provisions that expressly apply to any person adversely affected by a final agency action. If this Court were to adopt FDA's narrow, superficial, and inflexible approach for identifying the zone of interests for statutory standing purposes, a great variety of businesses subject to other federal statutes may be deprived of the opportunity to challenge agency actions that are detrimental to their economic, reputational, and/or other interests. Instead, the Court should affirm the Fifth Circuit's holding that the Respondent retailers, as well as Respondent RJRV, have statutory standing to challenge FDA's e-cigarette marketing denial.

ARGUMENT

Respondent E-Cigarette Retailers Have Statutory Standing

A. The judicial review provision should be construed broadly

Section § 387*l*(a)(1) states in part that "any person adversely affected by . . . denial [of a "new tobacco product" marketing application] may file a petition for judicial review of such . . . denial." FDA argues that this broadly worded judicial review provision is limited to manufacturers. The agency's contrived contention that § 387*l*(a)(1) excludes e-cigarette retailers is wrong. It is an advocacy position calculated to prevent the Fifth Circuit—where venue unquestionably is proper for the Respondent retailers—from addressing the merits of FDA's Vuse e-cigarette marketing denials. In a related appeal involving Vuse e-cigarettes, the Fifth Circuit not only has held that venue is proper, *see supra* n. 4, but also that success on the merits is likely. *See RJRV*, 65 F.4th at 188, 189-94.

1. According to FDA, § 387*l*(a)(1) "shows no . . . solicitude for retailers." FDA Br. at 7. FDA argues that the marketing denial "*order* that FDA issues . . . speaks to the applicant alone (always or nearly always a manufacturer of the product) and affects retailers only indirectly." *Id.* (emphasis added). The term "order," however, does not appear in § 387*l*(a)(1), which instead twice refers more broadly to judicial review of a "denial." Other subsections of § 387*l* do

refer to a denial "order." *See, e.g.*, § 387*l*(a)(2)(B) (Record of proceedings); 387*l*(b) (Standard of review). But unlike § 387*l*(a)(1), these and other subsections that facilitate judicial review of marketing denial orders do not specify *who* is entitled to file a petition for review of such an order.

If Congress had wanted to limit the right to judicial review of denials to *applicants* for marketing authorization, it would have said so in § 387*l*(a)(1), as it did in connection with FDA withdrawals of marketing authorization. *See* 21 U.S.C. § 387j(d)(2) (referring to "[t]he holder of an application subject to [a withdrawal] order"). Instead, § 387*l*(a)(1) expressly authorizes a petition for judicial review of a marketing denial to be filed by "*any* person adversely affected by such . . . denial" (emphasis added). This is "an authorization of remarkable breadth." *Bennett v. Spear*, 520 U.S. 154, 164 (1997). As the Fifth Circuit observed in its Order here, "'[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'" App. 4a (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

2. Turning a blind eye to the plain text of § 387*l*(a)(1), FDA invokes the "zone of interests" test for statutory standing to sue. FDA Br. at 12. In so doing, FDA glosses over the broad, unambiguous language of § 387*l*(a)(1)—language that is virtually identical to the omnibus Administrative Procedure

Act (APA) judicial review provision, which states that "[a] person . . . adversely affected or aggrieved by agency action. . . is entitled to judicial review." 5 U.S.C. § 702. The Court repeatedly has explained that in the APA context the zone of interests test "is not especially demanding . . . the benefit of any doubt goes to the plaintiff." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130 (2014) (internal quotation marks omitted); *see also Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak,* 567 U.S. 209, 225 (2012). Given the close similarity in statutory language, the same "lenient approach" that this Court affords to the APA's judicial review provision, *Lexmark*, 572 U.S. at 130, should apply to the right to judicial review under § 387*l*(a)(1).

B. FDA's marketing denial adversely affects Respondent retailers

1. Unable to avoid the fact that § 387*l*(a)(1) expressly refers to "*any* person"—not merely to an applicant for marketing authorization—FDA argues that the zone of interests test governs the meaning of "adversely affected" in § 387*l*(a)(1) and precludes retailers from "challeng[ing] an order denying a manufacturer's application for marketing authorization." FDA Br. at 13. Under the zone of interests test, courts "presume that a statutory cause of action extends only to plaintiffs whose interests fall within the zone of interests protected by the law invoked." *Lexmark*, 572 U.S. at 129 (internal quotation marks omitted); *see also Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 883 (1990) ("[T]o be

'adversely affected or aggrieved . . . within the meaning' of a statute, the plaintiff must establish that the injury he complains of (*his* aggrievement, or the adverse effect *upon him*) falls within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for his complaint.").

Because the "breadth of the zone of interests varies according to the provisions of law at issue . . . what comes within the zone of interests of a statute for purposes of obtaining judicial review of administrative action under the generous review provisions of the APA may not do so for other purposes." *Bennett*, 520 U.S. at 163 (internal quotation marks omitted). FDA is mistaken this *potential* distinction between the APA and a statute-specific judicial review provision means that the lenient approach afforded to the zone of interests test in APA judicial review cases "does not . . . carry over to other statutes." FDA Br. at 12. Nonetheless, seizing upon what it erroneously asserts is a categorical difference between APA and non-APA cases, FDA argues that for purposes of seeking judicial review of a marketing denial under § 387*l*(a)(1), "[a] retailer's interests fall outside the zone of interests protected by the statutory provision at issue." FDA Br. at 13.

2. FDA points to 21 U.S.C. § 387j(c) as the TCA provision whose zone of interests supposedly governs the right of any adversely affected person to obtain judicial review of marketing denials. That section, titled "Action on application," establishes procedures

and standards for FDA's review of a manufacturer's application for a "new tobacco product" marketing authorization, including for e-cigarettes. *See RJRV*, 65 F.4th at 187-88 (summarizing TCA statutory and regulatory background); *Wages & White Lion Invests., LLC v. FDA*, 90 F.4th 357, 363 (5th Cir. 2024) (en banc) (same).

According to FDA, § 387j(c) "protects . . . only the interests of the applicant itself," not "the interests of retail sellers of the applicant's products." FDA Br. at 14. Elevating form over substance, FDA asserts that because a marketing approval or denial order under § 387j(c) is "issued to the applicant alone," *id.*, retail sellers of the product are not encompassed by § 387j(c)'s zone of interests.

Even assuming that the right to judicial review under § 387*l*(a)(1) is limited to the zone of interests circumscribed by § 387j(c), Respondent retailers' interests squarely fit within that zone. This is not a case where "a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Lexmark*, 572 U.S. at 130 (internal quotation marks omitted).

FDA simply is wrong that because a marketing denial order is facially directed to the applicant (i.e., manufacturer), it "regulates only the applicant." FDA Br. at 14. FDA's October 12, 2023 marketing denial letter (i.e., order), App. 9a, declares that the Vuse e-cigarette products at issue are both "misbranded"

and "adulterated," and are prohibited from being "introduce[d] or delivered for introduction into interstate commerce." *Id.* 10a, 14a. FDA acknowledges that "[i]f a manufacturer lacks authorization to sell a product, retailers cannot lawfully obtain and resell it." FDA Br. at 14; *see* 21 U.S.C. § 331(a) (prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any . . . tobacco product . . . that is adulterated or misbranded"). What FDA refers to as an "indirect effect" of a marketing denial order, FDA Br. at 14, can have direct and serious consequences for noncompliant retailers. *See, e.g.*, 21 U.S.C. § 333 (Penalties); *id.* § 333(a)(1) (criminal penalties for "*[a]ny* person who violates a provision of section 331") (emphasis added); *id.* § 333(f)(9) (civil monetary penalties for violation of tobacco product requirements by "*[a]ny* person") (emphasis added); *see also* 21 U.S.C. § 334(a)(2)(E) (seizure of "[a]ny adulterated or misbranded tobacco product").

FDA's brief alleges that Respondent retailers engaged in "unlawful conduct" by selling e-cigarettes both before and after denial of marketing authorization. FDA Br. at 8. This assertion not only is unfounded, but also disingenuous in light of FDA's publicly announced compliance/enforcement policy allowing certain preexisting e-cigarettes to remain on the market pending submission and review of marketing authorization applications. *See* 81 Fed. Reg. at 28,977. Nonetheless, FDA's insinuation that Respondent retailers may be in legal jeopardy in light

of the marketing denial order underscores why they are adversely affected by the denial.

3. As the Fifth Circuit's Order denying FDA's Motion to Dismiss or Transfer reflects, the agency's arguments that Respondent retailers are not adversely affected by the marketing authorization denial for purposes of seeking judicial review under § 387*l*(a)(1) are "unavailing." App. 4a. Indeed, FDA's contention that Respondent retailers lack statutory standing defies common sense, especially in view of the undisputed evidence that Respondent Avail Vapor Texas would go out of business if the denial order goes into effect. *Id.*

The Court held in *Lexmark,* a frequently cited case on statutory standing, that "alleg[ing] an injury to a commercial interest in reputation or sales" was enough to satisfy the zone of interests for the false advertising statute involved in that case. 572 U.S. at 132; *cf. TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021) (a plaintiff must have a "personal stake" in a case to satisfy Article III standing requirements). Given the injury to their commercial interests, *i.e.*, sales, and possibly reputational harm, that they will suffer if FDA's marketing denial goes into effect, Respondent retailers have enough of a personal stake

in this case, *i.e.*, statutory as well as Article III standing, to challenge FDA's denial order.[5]

4. The Court should take a broader view of the applicable zone of interests than the § 387j(c) marketing denial procedures on which FDA predicates it superficial statutory standing arguments. Section 387j(c) also contains a statutory standard for granting or denying new tobacco product, including e-cigarette, marketing applications: "protection of the public health." 21 U.S.C. §§ 387j(c)(2)(A), 387j(c)(4), 387j(c)(5)(A).

As indicated above, FDA determined that retail sales of certain preexisting e-cigarette products could continue pending submission and review of marketing authorization applications. FDA's stated rationale for this carefully considered compliance/enforcement

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[5] In *Lexmark* the Court criticized use of the term "prudential standing" as "misleading" because "declin[ing] to adjudicate [a] claim on grounds that are 'prudential,' rather than constitutional" where a plaintiff has Article III standing (as Respondents do here) "is in some tension with [the Court's] reaffirmation of the principle that a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging." 572 U.S. at 125-26; *see also Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1302 (2017) ("In *Lexmark* we said that the label 'prudential standing' was misleading, for the requirement at issue is in reality is tied to a particular statute. The question is whether the statute grants the plaintiff the cause of action that he asserts."). Thus, referring to "statutory standing" in connection with a statute's zone of interests is more apt. *Id.* at 1302-03.

policy was in part protection of public health—specifically, continuing to make certain e-cigarette products available to adults who want "to transition away from combusted tobacco use." 81 Fed. Reg. at 28,977. Retailers' commercial interests in continuing to make such e-cigarette products available to combusted-tobacco transitioning adults align with the public health-related interests identified by FDA and expressly incorporated into § 387j(c). In other words, by making e-cigarettes available to the adult public, Respondent retailers facilitate the public health interests that FDA has identified. FDA's public health rationale is another reason why Respondent retailers' interests are adversely affected by FDA's marketing authorization denial, and thus, why the retailers have statutory standing to seek judicial review. *Cf. Env't Def. Fund v. Hardin*, 428 F.2d 1093, 1096 (D.C. Cir. 1970) ("The 'zone of interests' sought to be protected by the [pesticide registration] statute includes not only the economic interest of the registrant but also the interest of the public in safety.").

5. In short, this Court, like the court of appeals, should follow a common-sense approach and affirm that the Respondent retailers have statutory standing to challenge FDA's marketing denial.

C. This Court's ruling may affect the availability of judicial review under numerous other statutes

According to a recent survey conducted for the Administrative Conference of the United States, there

are "over 650 specific judicial review provisions in the *United States Code*." Jonathan R. Siegel, The ACUS Sourcebook of Federal Judicial Review Statutes, Admin. Conf. of the U.S. 37 (Jan. 2022). Dozens of them, in addition to the APA and § 387*l*(a)(1), afford judicial review to *any* person adversely affected by an agency action. *See, e.g.*, 21 U.S.C. § 360g(a)(9) (medical devices); 21 U.S.C. § 348(g) (food additives); 7 U.S.C. § 136n(b) (pesticides); 15 U.S.C. §§ 2060(a) & 2064(j)(2) (Consumer Product Safety Commission rules); 29 U.S.C. § 660(a) (Occupational Safety and Health Review Commission citations).

If adopted by this Court, the constricted, form-over-substance zone of interests interpretation that FDA is advocating here as a way of avoiding review in the Fifth Circuit may have repercussions for judicial-review-seeking adversely affected businesses and individuals far beyond the world of e-cigarettes. Although the "breadth of the zone of interests varies according to the provisions of law at issue," *Bennett*, 520 U.S. at 163, the Court should adopt and apply the same "lenient approach" for statute-specific judicial review provisions as it has for judicial review under the APA. *Lexmark*, 572 U.S. at 130. At the very least the Court should do so for judicial review provisions which, like § 387*l*(a)(1), use language that is identical or nearly identical to "the APA's omnibus judicial-review provision," 5 U.S.C. § 702, "as an appropriate means of preserving the flexibility" of such broad entitlements to judicial review. *Lexmark*, 572 U.S. at 130.

More specifically, the Court should hold, at least for judicial review provisions that expressly apply to any person adversely affected by an agency action, that the zone of interests test is whether "the interest sought to be protected by the complainant is *arguably* within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Bennett*, 520 U.S. at 163 (internal quotation marks omitted) (emphasis added). The Court has "often 'conspicuously included the word "arguably" in the test to indicate that the benefit of any doubt goes to the plaintiff.'" *Lexmark*, 572 U.S. at 130 (quoting *Patchak*, 567 U.S. at 225).

The Court did exactly that in *Bank of America Corp. v. City of Miami*, which involved Fair Housing Act statute-specific judicial review provisions that "allow[] any 'aggrieved person' to file a civil action seeking damages for a violation of the statute." 137 S. Ct. at 1300. Plaintiff City of Miami filed suit against two banks for allegedly violating the Act. This Court held that "the City's claimed injuries fall within the zone of interests that the FHA *arguably* protects." *Id.* at 1301 (emphasis added).

As Justice Scalia recognized in *Bennett*, finding statutory standing where a plaintiff's interests are at least "arguably" within a statute's zone of interests is appropriate because a plaintiff (or petitioner in a court of appeals) still must satisfy the "immutable requirements of Article III," 520 U.S. at 162, which FDA apparently recognizes Respondents satisfy here. There is no principled reason why plaintiffs (or court

of appeals petitioners) that invoke statute-specific judicial review provisions should be deprived of the same broad view that is applied in challenges arising under the APA. For the reasons already discussed, the retailers' interests in challenging FDA's marketing denial are not merely arguably, but squarely, within the TCA's zone of interests. Holding that they have statutory standing "requires no guesswork." *Lexmark*, 572 U.S. at 131.

CONCLUSION

The Fifth Circuit's Order denying dismissal or transfer should be affirmed.

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December 2024