No. 23-1187

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION; ET AL.,
Petitioners,

v.

R.J. REYNOLDS VAPOR COMPANY; RJR VAPOR COMPANY, L.L.C.; AVAIL VAPOR TEXAS, L.L.C.; AND MISSISSIPPI PETROLEUM MARKETERS AND CONVENIENCE STORES ASSOCIATION,
Respondents.

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

BRIEF *AMICUS CURIAE* OF THE NEW CIVIL LIBERTIES ALLIANCE IN SUPPORT OF RESPONDENTS

Andrew J. Morris
Counsel of Record
Daniel Kelly
Mark Chenoweth
NEW CIVIL LIBERTIES ALLIANCE
4250 N. Fairfax Dr., Suite 300
Arlington, VA 22203
Phone: (202) 869-5210
andrew.morris@ncla.legal
Counsel for Amicus Curiae

TABLE OF CONTENTS

TABLE OF CONTENTS i
TABLE OF AUTHORITIES ii
INTEREST OF *AMICUS CURIAE* 1
INTRODUCTION AND SUMMARY 2
STATEMENT 5
ARGUMENT 6
I. FDA'S DENIAL ORDERS "ADVERSELY AFFECT" THE RETAILER RESPONDENTS 6
II. FDA'S ARGUMENTS CONTRADICT THE STATUTE'S TEXT AND THE COURT'S ZONE-OF-INTERESTS TEST 13
A. FDA's Arguments Dodge Rather Than Explain the Governing Phrase "Any Person Adversely Affected" 14
B. FDA's Arguments Attempt to Narrow the Review Provision by Rewriting This Court's Zone-of-Interests Test 18
III. FDA'S ARGUMENTS WOULD NARROW THE SCOPE OF JUDICIAL REVIEW PROVISIONS IN MANY OTHER STATUTES 21
A. FDA's Categorical "Party" Requirement 22
B. The Danger of Unintended Consequences 25
CONCLUSION 31

TABLE OF AUTHORITIES

Page(s)

Cases

Abbott Lab'y v. Gardner,
387 U.S. 136 (1967) 9, 15

Bank of Am. Corp. v. City of Miami,
581 U.S. 189 (2017) 6, 8, 18

Bd. of Trade of Chicago v. SEC,
883 F.2d 525 (7th Cir. 1989) 28

Center for Reproductive Law & Policy v. Bush,
304 F.3d 183 (2d Cir. 2002) 20

Clarke v. Sec. Indus. Ass'n,
479 U.S. 388 (1987) 7, 11, 18, 19

Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.,
603 U.S. 799 (2024) 9, 15

Darby v. Cisneros,
509 U.S. 137 (1993) 16

Dep't of State v. *Muñoz*,
602 U.S. 899 (2024) 20

Dir., Off. of Workers' Comp. Programs v. Newport News Shipbuilding & Dry Dock Co.,
514 U.S. 122 (1995) 8, 26

Horizons Int'l, Inc. v. Baldrige,
811 F.2d 154 (3d Cir. 1987) 28, 29

Kucana v. Holder,
558 U.S. 233 (2010) 9

Lexmark Int'l, Inc. v. Static Control Components, Inc.,
572 U.S. 118 (2014).....7, 8, 9, 10, 20

Lujan v. Defs. of Wildlife,
504 U.S. 555 (1992)..... 20

Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak,
567 U.S. 209 (2012)..... 19

Nat'l Credit Union Admin. v. First Nat'l Bank & Tr. Co.,
522 U.S. 479 (1998)..... 7, 18, 19

O'Bannon v. Town Court Nursing Center,
447 U.S. 773 (1980)..... 19

Russello v. United States,
464 U.S. 16 (1983)..... 16

SAS Inst., Inc. v. Iancu,
584 U.S. 357 (2018)..... 9

Thompson v. N. Am. Stainless, LP,
562 U.S. 170 (2011)..... 8, 15

United States v. Soul Vapor, LLC,
No. CV 1:22-00458, 2024 WL 3258211
(S.D. W. Va. July 1, 2024)..... 12

Statutes

05 U.S.C. § 702..... 8, 28

07 U.S.C. § 136n..... 30

07 U.S.C. § 3804..... 27

07 U.S.C. § 6912..... 15

15 U.S.C. § 1710..... 27

15 U.S.C. § 2615 30
15 U.S.C. § 4015 ..... 27, 29
15 U.S.C. § 6762 27
15 U.S.C. § 77i 27
15 U.S.C. § 78y 27, 28
16 U.S.C. § 824k 27
16 U.S.C. § 825l 30
20 U.S.C. § 7905 27
21 U.S.C. § 331 .....5, 6, 10, 19
21 U.S.C. § 333 11
21 U.S.C. § 360g 27
21 U.S.C. § 387 3
21 U.S.C. § 387b 5, 6, 19
21 U.S.C. § 387f 24
21 U.S.C. § 387j 5, 10, 13, 16, 17, 23, 30
21 U.S.C. § 387l 3, 5, 6, 9, 13, 14, 18, 21, 26, 29
21 U.S.C. § 877 27
28 U.S.C. § 2344 15
30 U.S.C. § 816 27
33 U.S.C. § 1516 30
42 U.S.C. § 5405 27
42 U.S.C. § 6306 27
42 U.S.C. § 7622 27
47 U.S.C. § 252 27

49 U.S.C. § 5127 27

52 U.S.C. § 30109 17

Regulations

81 Fed. Reg. 28,974 (May 10, 2016)..... 6, 10

Other Authorities

Jonathan R. Siegel,
2022 Sourcebook of Federal Judicial Review Statutes, Administrative Conference of the United States 25

INTEREST OF *AMICUS CURIAE*

The New Civil Liberties Alliance ("NCLA") is a nonpartisan, nonprofit civil rights organization and public-interest law firm devoted to defending constitutional freedoms from the administrative state's depredations. Professor Philip Hamburger founded NCLA to challenge multiple constitutional defects in the modern administrative state through original litigation, *amicus curiae* briefs, and other advocacy.[1]

The "civil liberties" of the organization's name include rights at least as old as the U.S. Constitution itself, such as jury trial, due process of law, and the right to have laws made by the nation's elected lawmakers through constitutionally prescribed channels (*i.e.*, the right to self-government). These selfsame civil rights are also very contemporary—and in dire need of renewed vindication—precisely because Congress, the President, federal agencies, and even sometimes the Judiciary, have neglected them for so long.

NCLA aims to defend civil liberties—primarily by asserting constitutional constraints on the administrative state. Although the American People still enjoy the shell of their Republic, there has

---

[1] No counsel for any party to this case authored this brief in whole or part, and no party or counsel other than *amicus curiae* and its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amicus curiae* notified the parties of its intention to file this brief on December 12 , 2024.

developed within it a very different sort of government—a type, in fact, that the Constitution was designed to prevent. This unconstitutional state within the Constitution's United States is the focus of NCLA's concern.

NCLA therefore has a strong interest in the first question presented and the judicial review provision it addresses. NCLA believes it can assist the Court by discussing the effect a decision for the FDA would have on judicial review provisions in many statutes. The key language, "adversely affected," appears in many judicial review provisions. FDA asks this Court to give that language a vanishingly narrow reading that disregards the language chosen by Congress. But NCLA has a strong interest in ensuring that Courts apply all judicial review provisions as Congress wrote them, to give effect to these important checks on agencies and to provide parties access to the courts to challenge unlawful agency actions.

INTRODUCTION AND SUMMARY

Amicus submits this brief to highlight the damage FDA's arguments would do to many judicial review provisions across the United States Code. Congress has enacted hundreds of such provisions, typically using the same "adversely affected" language at issue here. In this case, FDA attempts to narrow a typical provision to a fraction of the scope Congress enacted. FDA's arguments, if successful, would narrow similar provisions in other statutes. But Congress enacts these provisions precisely to place a check on agencies' compliance with the law. These provisions also codify the important principle that citizens

injured by agency action are entitled to their day in court. So, it is important that courts respect Congress's legislative authority by giving these provisions the broad scope Congress chose to give them.

FDA seeks to narrow the judicial review provision in the Family Smoking Prevention and Tobacco Control Act ("TCA"), 21 U.S.C. § 387 *et seq*. The TCA makes it illegal to sell certain tobacco products unless FDA authorizes their sale. It also subjects FDA's denial of an application to judicial review upon the petition of "any person adversely affected" by the denial order. 21 U.S.C. § 387l(a)(1). FDA contends that Congress chose that broad phrase to *limit* the right of review to only one "person"—the manufacturer whose application was denied. FDA argues that retailers who also want to sell the covered products—the same goal as the applicant manufacturer—are not adversely affected by the denial order.

FDA's narrow reading cannot be reconciled with the statute, either with the broad review provision itself or with other provisions that directly contradict FDA's arguments. FDA's reading also conflicts with this Court's zone-of-interests test. This Court describes the test as "lenient," reflecting the strong presumption that citizens injured by agency action should have access to a court to challenge that action. Applying the test here shows that the retailers fall well within the TCA's zone of interests. Like the manufacturer whose application FDA denied,

retailers want to sell products the FDA has approved, and they want to refrain from selling products it has declined to approve. If they act in violation of a denial order, they can be prosecuted. Indeed, even if FDA isn't willing to *say* retailers are within the TCA's zone of interests, it *acts* as though they are; it has compiled a substantial record of vigorous enforcement against many retailers for selling unauthorized products in violation of the TCA.

FDA's arguments would transform this lenient zone-of-interests test into a roadblock that bars relief for many persons injured by agency actions. In particular, FDA's argument construes this test as a requirement to exhaust administrative remedies before petitioning for judicial review, a requirement not imposed by this Court's precedents nor the TCA. Because the zone-of-interests test is a background principle for interpreting *all* judicial review provisions, such a newly stringent test could also narrow the scope of hundreds of other judicial review provisions. That change would insulate many agencies from judicial scrutiny Congress directed them to face, and it would bar many citizens and small businesses injured by agency actions from obtaining the day in court that Congress instructed them to have.

The Fifth Circuit properly avoided these damaging consequences by rejecting FDA's arguments, ruling that retailers were "adversely affected" by the FDA denial orders. This Court should affirm.

STATEMENT

This case arises from a petition to the Fifth Circuit for review of FDA's denial of applications by R.J. Reynolds Vapor Co. ("Reynolds") for authorization to sell certain e-cigarette products. *See* C.A. Pet. for Review (Oct. 12, 2023). In addition to Reynolds, Respondents include retailers RJR Vapor Company, LLC, Avail Vapor Texas, LLC, and an association that includes retailers, the Mississippi Petroleum Marketers and Convenience Stores Association. These retailers wish to continue selling products addressed by the denial orders

Reynolds submitted the applications to comply with the TCA. Enacted in 2009, this statute requires manufacturers to obtain FDA authorization before introducing certain products to market. *See* 21 U.S.C. § 387j(a)(2). If FDA denies an application, the TCA prohibits sale of the product by the applicant or anyone else. 21 U.S.C. §§ 331(a), 387b(6). The TCA also provides that, if FDA denies an application, "any person adversely affected by" the denial has the right to petition for judicial review. 21 U.S.C. § 387l(a)(1).

After FDA denied Reynolds's applications, Pet. App. 9a–23a, Reynolds and the retailers petitioned for review by the Fifth Circuit, Pet. App. 3a. Since before Reynolds submitted its application, the retailers have been selling products now covered by FDA's denial. Pet. App. 3a-4a. (FDA has permitted sales of certain

products while their manufacturers were applying for FDA approval. *See* 81 Fed. Reg. 28,974, 28,977, 29,001 (May 10, 2016)). The denial order currently is stayed, Pet. Br. 7, but if it takes effect the retailers will be prohibited from selling those products. *See* 21 U.S.C. §§ 331(a), 387b(6).

In response to the petition, FDA moved to dismiss or transfer. It contended (among other arguments) that the retailers lacked standing because they were not "adversely affected" by the denial orders. Pet. App. 2a–3a. The court denied FDA's motion, correctly holding that the Respondents are "adversely affected" by the denial. Pet. App. 3a–5a. This Court then granted interlocutory review of the court's order denying FDA's motion.

ARGUMENT

I. FDA'S DENIAL ORDERS "ADVERSELY AFFECT" THE RETAILER RESPONDENTS

The TCA says "any person adversely affected" by a marketing denial order "may file a petition for judicial review." 21 U.S.C. § 387l(a)(1). This provision does not specifically state whom it includes, but the Court's zone-of-interests test shows that it encompasses the applicant manufacturer and the retailers who want to sell products covered by a denial order. *See Bank of Am. Corp. v. City of Miami*, 581 U.S. 189, 194, 197 (2017) (stating that this Court applies the zone-of-interests test to determine whether a person is "adversely affected"). This test is

a background limitation that, this Court assumes, Congress incorporates into judicial review provisions. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129, 130 n.5 (2014). The test is rooted in the venerable "harm within the risk" principle, *id.* at 130 n.5, and it focuses on whether an injured person's interests "arguably" align with the interests the statute advances, *Nat'l Credit Union Admin. v. First Nat'l Bank & Tr. Co.*, 522 U.S. 479, 492 (1998).

The test has two steps. The first "discern[s] the interests 'arguably ... to be protected' by the statutory provision at issue," and the second "inquire[s] whether the plaintiff's interests affected by the agency action in question are among them." *Nat'l Credit Union Admin.,* 522 U.S. at 492. This Court has "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 (cleaned up). Because it gives plaintiffs the benefit of any doubt, the test does not "foreclose[] suit" unless "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 authorized that plaintiff to sue." *Id.* (cleaned up). *See also Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 403 (1987) (requiring only a "plausible relationship" between the statute's zone of interests and the complainant's asserted interest).

This lenient "benefit of the doubt" approach is not limited to cases decided under the Administrative

Procedure Act, as FDA contends. This Court has applied the same approach to challenges arising under other statutes, including the Fair Housing Act, *Bank of Am. Corp.*, 581 U.S. at 194 (stating that it suffices if the plaintiff's interest is "arguably within the zone of interests"), the Lanham Act, *Lexmark*, 572 U.S. at 130–31, 137–38 (applying the "lenient approach" developed in APA cases), and the Civil Rights Act of 1964, *Thompson v. N. Am. Stainless, LP*, 562 U.S. 170, 178 (2011) (stating that the plaintiff is within the zone of interests unless "the 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").

The same lenient approach applies here. *Lexmark* states that this approach depends on "the provisions of law at issue," 572 U.S. at 130. TCA's review provision uses the same language as the APA, referring to "any person adversely affected." *See* 5 U.S.C. § 702 (granting a right of judicial review to "a person … adversely affected or aggrieved by agency action").[2] Nothing suggests Congress meant this

---

[2] This Court also has equated "adversely affected" and "aggrieved." *See Dir., Off. of Workers' Comp. Programs v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 126 (1995) (stating that "[t]he phrase 'person adversely affected or aggrieved' is a term of art used in many statutes to designate those who have standing to challenge or appeal an agency decision," and "'adversely affected' and 'aggrieved,' alone or in combination, have a long history in federal administrative law").

language to describe a different category in the TCA than in the APA. In fact, the TCA expressly incorporates the APA's review standards, 21 U.S.C. § 387l(b) (referencing U.S. Code Title 5, Ch. 7).

This lenient approach also reflects the presumption that everyone directly injured by agency action should have access to judicial review. *See, e.g., Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 824 (2024); *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967). This presumption is strong, governing absent "'clear and convincing indications' that Congress meant to foreclose review." *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 370 (2018). This "presumption favoring judicial review of administrative action" is a "familiar principle of statutory construction." *Kucana v. Holder*, 558 U.S. 233, 251 (2010). Because of it, "[w]hen a statute is reasonably susceptible to divergent interpretation, [courts] adopt[] the reading that accords with … basic principles: that executive determinations generally are subject to judicial review." *Id.* (citation omitted). Nothing in the TCA provides any basis to overcome this strong presumption.

The zone-of-interests test identifies those who may bring a claim by comparing the challenger's interests to the interests protected by the statute. *Lexmark* illustrates its application. There, a company sued a competitor under the Lanham Act, alleging that the competitor's false advertising had caused the plaintiff to lose sales. 572 U.S. at 122. The Court identified the "interests protected by the Lanham Act"

as "protecting persons engaged in commerce against unfair competition." *Id.* at 131 (cleaned up). It held that the plaintiff was in the statute's zone of interests because it had "allege[d] an injury to a commercial interest in reputation or sales." *Id.* at 131–32; *see also id.* at 137. But, the Court noted, this statutory zone of interests did not extend beyond the injured competitor, for example to "a consumer who is hoodwinked into purchasing a disappointing product." *Id.* at 132.

Like the *Lexmark* plaintiff who had lost sales, the retailers in this case lie well inside the zone of protected interests. The TCA permits the sale of products that meet its public-health standard, and prohibits the sale of products FDA has concluded do not. 21 U.S.C. § 331(a). The TCA requires FDA to approve products that meet the statutory standards. 21 U.S.C. § 387j(c)(a)(A)(i). These statutory provisions directly affect an e-cigarette retailer's interests every bit as much as those of a manufacturer—they are both interested in selling permitted products and in complying with the TCA by not selling products the TCA prohibits. Retailers and the manufacturer were already selling the very products that FDA's denial orders would take off the market. (As noted above, FDA has permitted sales of certain products while their manufacturers were applying for FDA approval. 81 Fed. Reg. at 28,977, 29,001). The denial order would put one of the retailers out of business altogether. Pet. App. 4a. The close match between the interests the TCA protects

and the retailers' interests easily satisfies the lenient "plausible relationships" threshold set by the zone-of-interests test. *Clarke*, 479 U.S. at 403.

FDA's own actions confirm this conclusion. Its extensive efforts to enforce the TCA against retailers establish that, in its view, retailers are near the bullseye of the TCA's zone of interests. The TCA subjects retailers to severe sanctions for violations. Retailers that sell unauthorized products can be penalized as much as $1 million per "proceeding." 21 U.S.C. § 333(f)(9)(A). They can be criminally prosecuted and imprisoned for years. 21 U.S.C. § 333(a) (authorizing imprisonment of one year for the first violation and three years for every subsequent violation).

Against this background of stiff regulatory penalties, FDA maintains a vigorous program of enforcement against tobacco retailers. FDA specifically provides retailers extensive guidance about compliance with the TCA.[3] It conducts routine physical inspections of retailers' stores, checking for violations.[4] It sends warning letters to many retailers

---

[3] *See* FDA, *Retailer Regulations and Guidance*, *available at* https://tinyurl.com/5b2926dx.

[4] *See* FDA, *About Warning and Close-Out Letters*, "Tobacco Retail Warning Letters" *available at* https://tinyurl.com/5fuad8t2.

it believes have violated the TCA.[5] So far this month alone, it has issued letters warning more than 100 "brick-and-mortar retailers" to comply with the TCA.[6] FDA has sought civil money penalties against at least 177 retailers, in each case seeking the "maximum statutory amount."[7] It also has obtained injunctive relief against retailers. *E.g.*, *United States v. Soul Vapor,* LLC, No. CV 1:22-00458, 2024 WL 3258211, *2–7, *14–16 (S.D.W. Va. July 1, 2024) (entering injunction against retailer for selling unapproved e-cigarette and other products in violation of the TCA). Actions speak louder than words. FDA's history of enforcement actions, if not its brief, demonstrates that it believes the retailers fall within the TCA's zone of interests.

The conclusion that the TCA's zone of interests encompasses retailers does not, as FDA contends, expand the zone of interests without a "stopping point." Pet. Br. 17–18. It would not, for example,

---

[5] *See* FDA, *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products*, *available at* https://tinyurl.com/3sru29nw.

[6] *See* FDA, *Working with States, FDA Warns More than 100 Retailers for Illegal Sale of Youth Appealing E-Cigarettes,* Dec. 5, 2024, *available at* https://tinyurl.com/yex52kes.

[7] *See* FDA, *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products*, "Which Retailers Have Received CMP Complaints for Violations Related to Unauthorized Tobacco Products?" *available at* https://tinyurl.com/3sru29nw.

extend the zone of interests to include retail customers. Unlike the retailers, those customers do not sell vaping products, do not suffer an economic injury from FDA's application denials, and are not targets of FDA warnings or enforcement actions. This distinction between, on one hand, retail businesses that lost revenue because of the denial order and, on the other, customers who had no such losses, draws the same kind of line the Court drew in *Lexmark*. There, the zone of interests included companies that had lost sales because of the legal violation, but it did not extend to their consumers. 572 U.S. at 132.

II. FDA'S ARGUMENTS CONTRADICT THE STATUTE'S TEXT AND THE COURT'S ZONE-OF-INTERESTS TEST

FDA argues that the review provision's phrase "any person adversely affected," 21 U.S.C. § 387l(a)(1), despite its apparent breadth, in fact refers to only one "person": the applicant whose application FDA denied. Pet. Br. 7. The key to FDA's argument is its effort to avoid this governing broad language altogether. Rather than address the meaning of "any person adversely affected," FDA shifts the focus away from that language to a different statutory subsection, "Action on application," which describes the intra-agency procedure for marketing applications and denials, 21 U.S.C. § 387j(c). Pet. Br. 14. Then, having shifted the focus, FDA points out that *this* subsection refers only to the applicant. 21 U.S.C. § 387j(c). And, FDA also notes, this subsection "does not grant [retailers] any procedural rights," Pet.

Br. 7–8; *see also id.* at 14–15, nor does it "require FDA to account for their substantive interests," Pet. Br. 8. "In fact," FDA summarizes, this "Action on application" subsection "does not mention retailers at all." Pet. Br. 17. FDA then concludes with an abrupt *non sequitur*, stating that only the applicant referred to in the "Action on application" subsection can be a "person adversely affected" by a denial order. Pet. Br. 7, 14.

FDA does acknowledge, though briefly, that denial orders affect retailers. It concedes that the orders prevent retailers from selling products, but it assures the Court that this effect is only "indirect." Pet. Br. 7, 14–15. In FDA's view, this means that the retailers were not "adversely affected" under the judicial review section.

A. FDA's Arguments Dodge Rather Than Explain the Governing Phrase "Any Person Adversely Affected"

FDA's arguments never confront the key statutory language and conflict with other textual evidence. FDA also distorts the zone-of-interests test beyond recognition. From the start, FDA's attempt to shift the focus away from the governing language misreads the text.

Nothing in the judicial review provision, 21 U.S.C. § 387l(a)(1), suggests that "any person adversely affected" refers only to the applicant in the underlying agency proceeding. To the contrary, Congress chose the broad adjective "any." It then

chose "person," not "party," which is the term used in some other review provisions. *See, e.g.*, Hobbs Act, 28 U.S.C. § 2344 (referring to "any party aggrieved"). Congress again expanded the scope of the review provision beyond the party to the order by referring to a person "affected," not just to the party participating in the agency proceeding. If the "artificially narrow meaning" proposed by FDA "is what Congress intended[,] it would more naturally have said" person who was a party to the marketing application, rather than the person adversely affected. *Thompson*, 562 U.S. at 177 (rejecting an effort to insert a scope limitation Congress had not inserted). Congress chose the broader language, not the narrower, and FDA does not even try to explain why.

FDA's efforts to narrow this provision also collide with the strong presumption in favor of judicial review of final agency actions. *Corner Post, Inc.*, 603 U.S. at 799; *Abbott Labs.*, 387 U.S. at 140. FDA tries to brush that key presumption aside but cannot reconcile its novel arguments with that presumption.

At bottom, FDA's argument attempts to read an administrative exhaustion requirement into the TCA's review provision. Under FDA's reading of the review provision, a potential challenger must intervene in the agency proceeding to secure the right to subsequently petition for review. But Congress inserted no such requirement in the statute, and it obviously knows how to do so. *See, e.g.*, 7 U.S.C. § 6912(e) (requiring that "a person shall exhaust all administrative appeal procedures" before bringing an

action against the Secretary or Department of Agriculture). Nor has the zone-of-interests test ever been understood to include it. And it is not given to courts to create such prerequisites when Congress has chosen not to impose them. *See Darby v. Cisneros*, 509 U.S. 137, 154 (1993) (where judicial review provision did not require it, agency could not require plaintiff to exhaust administrative remedies before seeking judicial review).

FDA's arguments conflict more directly with other textual evidence, which rules out its proposed narrow reading of the judicial review provision. The TCA contains a separate review provision that addresses FDA orders withdrawing previously approved applications, 21 U.S.C. § 387j(d)(2), one that contains precisely the limitation FDA wants to read into the review provision for denial orders. With respect to withdrawal orders, only the "holder of" the previously approved "application" may file a petition for review. 21 U.S.C. § 387j(d)(2). The different language in these two provisions shows that, when Congress meant to limit the right to seek review to the person who made the marketing application, it said so. "Where 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." *Russello v. United States*, 464 U.S. 16, 23 (1983). That presumption dictates that, in contrast with the review provision for withdrawal orders, Congress did not

limit the right to petition for review of denial orders to the applicant.

Comparing the TCA judicial review provision for denial orders with judicial review provisions in various other statutes further confirms this textual conclusion. In certain review provisions, Congress did include specific limitations on the persons who could seek judicial review, even limiting the right of review to the party to the agency proceeding. *See, e.g.*, 52 U.S.C. § 30109(a)(4)(C)(iii) (Federal Campaign Finance Enforcement) (providing the right to seek judicial review to "Any person against whom an adverse determination is made under this subparagraph"). Congress knows how to limit the scope of a judicial review provision when it wants to.

FDA's argument offers one final conflict with the relevant text. FDA misdescribes the application process as an "adjudication," Pet. Br. 7 (citing 21 U.S.C. § 387j(c)), *see also id.* at 14, and it even equates the process with a "*court* proceeding[]," Pet. Br. 14 (emphasis added). FDA then notes that "only the parties to an adjudication may challenge its outcome in court." *Id.* at 25. But the subsection FDA cites does not use the word "adjudicate" or anything like it. 21 U.S.C. § 387j(c). The marketing application process is a simple paper review. There are no competing evidentiary submissions, no hearings, and no resulting findings of fact or conclusions of law. The FDA just reviews the application and either grants or denies it. 21 U.S.C. §§ 387j(c)(1)–(2); *see also* Pet. App. 10a (denial order stating that it is "[b]ased on our review of your" applications). Because there is no

hearing to which a person could be a party, it makes perfect sense for § 387l(a)(1) to make judicial review available to those who are "adversely affected" by a denial order.

B. FDA's Arguments Attempt to Narrow the Review Provision by Rewriting This Court's Zone-of-Interests Test

FDA's attempt to direct the focus solely to the party to the underlying agency proceeding brings us to its misreading of the zone-of-interests test. This test provides the proper framework to determine whether the retailers were "adversely affected" by the denial order. *See Bank of Am. Corp.*, 581 U.S. at 194, 197. As summarized above, the test focuses on the substantive "interests" advanced by the relevant statute and by the challenger. *See Nat'l Credit Union Admin.*, 522 U.S. at 492. The test does not, as FDA contends, limit the statutory zone of interests to the person named in the agency order at issue, nor to those whom the statute permitted to participate in the underlying agency proceeding.

One leading zone-of-interests case illustrates FDA's error. *Clarke*, 479 U.S. at 390–92, 403. There, the Comptroller of the Currency had granted applications by certain banks for authority to provide brokerage services. *Id.* at 390–91, 399. A group of securities brokers and similar entities challenged the order. *Id.* at 392–93. Like the retailers in this case, they had played no role in the agency application process that had led to the order they were challenging. *Id.* Yet, the Court held that they were in

the zone of interests of the governing National Bank Act and thus could challenge the order granting the banks' applications. 479 U.S. at 390–94, 397. (*See also id.* at 403, concluding that the securities brokers' "interest … has a plausible relationship to the policies underlying" the National Bank Act.)

Similarly, the zone-of-interests test does not require a showing that the relevant statute expressly protects the challenger. To the contrary, this Court already has rejected that argument: "We do not require any indication of congressional purpose to benefit the would-be plaintiff." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (cleaned up). *See also Clarke*, 479 U.S. at 399 (same); *Nat'l Credit Union Admin.*, 522 U.S. at 492 (same).

Finally, FDA's assertion that the denial order "affects retailers only indirectly," Pet. Br. 7, ignores the direct effects that denial orders have on them. Most obviously, they lose sales as a direct effect of the denial order. And as documented above, FDA penalizes retailers for selling unauthorized tobacco products. *See*, *e.g.*, 21 U.S.C. §§ 331(a), 387b(6). FDA cites no authority suggesting these tangible economic effects do not satisfy the zone-of-interests test.[8]

---

[8] FDA cites authorities addressing takings and other due process claims, but those cases do not discuss proximate cause or even any judicial review statute. *See* Pet. Br. 15. *O'Bannon v. Town Court Nursing Center*, 447 U.S. 773, 788 (1980), addresses a due process claim based on an asserted property interest in remaining in a nursing home. *Department of State v. Muñoz*,

Equally telling, FDA does not challenge the retailers' standing under Article III—which it surely would have done if it could show that the effect on retailers was only "indirect." *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (stating that Article III standing requires "a causal connection between the injury and the conduct complained of"). But FDA has not advanced that argument.

Overall, FDA attempts to transform the zone-of-interests test into an arbitrary barrier that would narrow the scope of judicial review provisions. This Court's test inquires into the "interests" of the petitioner and those protected by the governing statute, but FDA substitutes a test that asks only whether (i) the petitioner participated in the underlying agency proceeding, or (ii) the statute specifically identifies the plaintiffs as a beneficiary. FDA's proposed alternative test bears no resemblance to the Court's zone-of-interests test. *See, e.g.*, *Lexmark*, 572 U.S. at 129–30; *see also id.* at 130 n.5 (discussing the harm-within-the-risk).

By reducing the scope of persons who are "adversely affected," FDA would eliminate the ability of many "adversely affected" persons to seek

---

602 U.S. 899, 917–919 (2024), addresses a wife's assertion of a liberty interest in her husband's visa application. Similarly, *Center for Reproductive Law & Policy v. Bush*, 304 F.3d 183, 186 (2d Cir. 2002), holds that the "plaintiffs' alleged harm does not fall within the zone of interests protected by the Due Process Clause."

redress for the FDA's injurious actions. If successful, FDA's arguments also would generate significant new uncertainty about the content of the well-established zone-of-interests test. This uncertainty would, in turn, cast doubt on the meaning of the many judicial review provisions that authorize those who are "adversely affected" to obtain judicial review of agency actions.

III. FDA'S ARGUMENTS WOULD NARROW THE SCOPE OF JUDICIAL REVIEW PROVISIONS IN MANY OTHER STATUTES

In some instances, the Venn diagram of those who are both "adversely affected" and "parties" to an agency proceeding could, given the right circumstances and statutory language, completely overlap. But that is not the argument FDA is making. FDA says an entity that was not a party to an agency proceeding may not, as a categorical matter, be "adversely affected." That cannot be correct. Congress regularly addresses itself to the question of whether "party" status should be a prerequisite to seeking judicial review. Sometimes it says it's necessary, quite often it doesn't. FDA, impatient with these prudential judgments, asks the Court to make uniform what Congress did not. But judicially imposing a "party" status requirement in this case would affect not just 21 U.S.C. § 387l(a), but all statutes that condition the right to judicial review on being "adversely affected" or "aggrieved."

A. FDA's Categorical "Party" Requirement

Although couching its proposition in terms of the zone-of- interests test, FDA focuses almost exclusively on factors that relate to what it means to be a party to an agency proceeding. Here is FDA's own summary of its argument:

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

Pet. Br. 7–8.

According to FDA, unless an entity partakes of the listed characteristics, it cannot qualify as "adversely affected" for purposes of filing a petition for review. All but two of those characteristics (more about the exceptions in a moment) describe attributes associated with "party" status in the agency proceeding. Thus, the fact that the FDA's order addresses the applicant and no one else is not only to

be expected but could hardly be otherwise. An administrative agency has no authority to adjudicate the rights of anyone not a party to the proceeding, so there would be no reason for FDA to address itself to anyone else. Similarly, "procedural rights" have no meaning outside the context of participation in the agency proceeding. And, naturally, FDA's observation that 21 U.S.C. § 387j contains no mechanism for retailers to participate in the application process is just another way of saying retailers cannot be parties.

The two characteristics *not* addressing party attributes do not detract from the categorical nature of FDA's argument. First, whether the retailers are "indirectly" affected is simply a conclusory characterization by which FDA tries to drive a wedge between the retailers' and Reynolds's interests. But there's little light between them. Reynolds's interest is in selling its product at wholesale, while the retailers' interest is selling that same product at retail. The effect of FDA's order doesn't differentiate between the retailers' and Reynolds's interests: They are all prohibited from selling the product. The retailers may be downstream in the supply chain, but the order's impact on their interests is every bit as direct as it is on Reynolds's.

The second non-party characteristic is as inapplicable to parties as it is to retailers. FDA says the statute indicates Congress did not allow retailers to file petitions for review because it "does not require FDA to account for their substantive interests." Pet. Br. 8. Perhaps there are circumstances in which that

is relevant, but here, the Act doesn't account for any of the *applicant's* substantive interests either. Unless, that is, FDA is referring to its duty not to broadcast proprietary information used in the application process. 21 U.S.C. § 387f(c). And, if that is the interest to which FDA adverts, it's merely incidental to the only substantive question the statutory application process addresses, to wit, whether the product may be offered for sale.

Because the two extraneous characteristics do nothing to distinguish the retailers from Reynolds, they can be dropped without affecting the substance of FDA's argument. With that adjustment, FDA's ultimate position boils down to this: An entity cannot be "adversely affected" unless it was a party to the agency proceeding. FDA helpfully said that very thing in the tightest summary of its argument: "[T]his case involves judicial review of an adjudication. It is particularly natural to infer that only the parties to an adjudication may challenge its outcome in court." Pet. Br. 25.

Congress, however, did not include the categorical restriction the FDA wants the Court to impose, even though it has been legislatively included in many other statutory programs. Accepting the FDA's argument would thus require the Court to supplant Congress's prudential judgment with its own and venture into the legislative realm. Moreover, the likely unintended consequences attendant on such a venture are far-reaching. So, there is more than

adequate reason to leave this question in Congress's hands where it belongs.

B. The Danger of Unintended Consequences

Although FDA may be asking the Court to impose a categorical "party" requirement on just one judicial review provision, it offers no limiting principle to prevent it from becoming instantly applicable to all other statutes that use similar language. If the Court were to grant FDA's request, the risk of unintended consequences with respect to the scope of a host of other judicial review statutes would be enormous.

The Administrative Conference of the United States ("ACUS") counts 652 statutes that grant a right to judicial review of agency actions.[9] At least that was true upon completion of the research that went into the 2022 Sourcebook of Federal Judicial Review Statutes.[10] The number might be, and likely is, higher today. As part of its study, ACUS examined who the statutes' text authorizes to file such petitions. It found that Congress uses at least four different categories to identify authorized petitioners, including the following:

---

[9] The Administrative Conference compiled a list of the statutes into a spreadsheet (the "ACUS Spreadsheet"), which is available here: https://tinyurl.com/4kvfyz47.

[10] Jonathan R. Siegel, *2022 Sourcebook of Federal Judicial Review Statutes*, Administrative Conference of the United States, *available at* https://tinyurl.com/2ptp6tdz.

1. Aggrieved or adversely affected;[11]

2. Those against whom the agency has acted;[12]

3. Any interested person;[13] and

4. States or political subdivisions.[14]

ACUS also noted that some statutes grant a right to judicial review to specifically named agencies or entities, while others contain no textually defined category of proper petitioners at all. ACUS's study is instructive at the most general level because it reveals the multiplicity of approaches Congress has taken in expressing who should have a right to file a petition for judicial review.

Of all these categories, the first is of greatest interest here, of course, inasmuch as such statutes use the same phrase (or an indistinguishable cognate) as 21 U.S.C. § 387l(a). ACUS identified 124 statutory

---

[11] *See* ACUS Spreadsheet, column W ("Who May Seek Review"). ACUS coded the statutes according to the language describing who has the right to petition for review. Those coded as "B.1" through "B.3" use the term "aggrieved" or "adversely affected." There has been no suggestion that these terms identify materially different groups of people. *See, e.g., Dir., Off. of Workers' Comp. Programs*, 514 U.S. at 126 ("'adversely affected' and 'aggrieved,' alone or in combination, have a long history in federal administrative law").

[12] *Id.* ACUS coded the statutes falling into this category as "C.1" through "C.5."

[13] *Id.* Statutes in this category are coded "A."

[14] *Id.* Statutes in this category are coded "F."

provisions that use that language, alone or in combination with other descriptors, to identify the class of people who may file a petition for review. With respect to those using "aggrieved" or "adversely affected" as the *only* descriptor, the following is just a representative sample: 7 U.S.C. § 3804(b) ("[a]ny person aggrieved by an order"); 15 U.S.C. § 77i(a) ("[a]ny person aggrieved by an order"); 15 U.S.C. § 78y(a) & (b)(1) ("[a] person aggrieved by a final order"; "[a] person adversely affected by a rule"); 15 U.S.C. § 1710(a) ([a]ny person, aggrieved by an order or determination"); 15 U.S.C. § 4015(a) ("any person aggrieved by such determination"); 15 U.S.C. § 6762(a) ("[a]ny person aggrieved by a decision or action"); 16 U.S.C. § 824k(f)(1) ("any aggrieved person"); 20 U.S.C. § 7905(c)(3) ("[a]ny person aggrieved by the action"); 21 U.S.C. § 360g(a) ("any person adversely affected by such regulation or order"); 21 U.S.C. § 877 ("any person aggrieved by a final decision"); 30 U.S.C. § 816(a)(1) ("[a]ny person adversely affected or aggrieved by an order"); 42 U.S.C. § 5405(a)(1) ("any person who may be adversely affected by such order"); 42 U.S.C. § 6306(b)(1) ("[a]ny person who will be adversely affected by a rule"); 42 U.S.C. § 7622(c)(1) ("[a]ny person adversely affected or aggrieved by an order"); 47 U.S.C. § 252(e)(6) ("any party aggrieved by such determination"); 49 U.S.C. § 5127(a) ("a person adversely affected or aggrieved by a final action"). And, of course, there is the APA provision making review available to any person who is "adversely

affected or aggrieved by agency action within the meaning of a relevant statute ...." 5 U.S.C. § 702.

Not all of these statutes have received judicial treatment on the question of whether a petitioner must first have been a party to the agency proceeding. But some have. As mentioned above, this Court in the *Clarke* case did not require "party" status in an agency proceeding as a prerequisite to being "adversely affected" within the meaning of the APA's judicial review provision. 479 U.S. at 390-93. Other courts have come to the same conclusion when addressing the same language in the context of non-APA judicial review statutes.

For example, in *Bd. of Trade of Chicago v. SEC*, 883 F.2d 525 (7th Cir. 1989), business rivals of a newly-authorized clearing house filed a petition to review the SEC's authorization under a provision that granted such right to "person[s] aggrieved by a final order of the Commission." 15 U.S.C. § 78y(a)(1). The question was whether business competitors fell within the statute's zone of interests governing the authorization process. Notwithstanding the fact that the rivals had not been parties to the clearing house's application process before the SEC, the court concluded the competitors were "aggrieved" and entitled to file their petition.

Nor were the petitioners in *Horizons Int'l, Inc. v. Baldrige*, 811 F.2d 154 (3d Cir. 1987), stymied by the fact they had not participated in the agency proceeding. The case addressed "certificates of

review" that give applicants "limited antitrust immunity to engage in specified concerted export activity" if "the proposed activity meets statutory requirements." *Id.* at 156. The application process requires publication in the Federal Register so that interested parties may file comments. A consortium of interests filed an application for such a certificate, which the Commerce Secretary granted. The relevant review statute says "any person aggrieved by such determination" may file a petition for review. 15 U.S.C. § 4015. The petitioners, who were business competitors of the applicants, petitioned for review of the certificate without first filing comments during the agency application process. The court concluded that "failure to comment did not affect plaintiffs' standing to seek judicial review." 811 F.2d at 168.

FDA does not account for the effect of its argument on these opinions, nor on all the other statutes that use "aggrieved" or "adversely affected" to identify those who are entitled to file a petition for review. But if the Court accepts FDA's contra-textual argument that "party" status in the agency proceeding is a *sine qua non* to being "adversely affected" for purposes of 21 U.S.C. § 387l(a), there is no limiting factor that would preclude imposition of this restriction across this entire category of statutes.

Not only would FDA's argument, if accepted, represent the imposition of a condition Congress did not adopt, but the rejection of a distinction Congress must be presumed to have deliberately created. Even as it rejected "party" status in the category of statutes

identified above, it affirmatively *required* that status in others. So, when Congress considered it was not enough to be "aggrieved" or "adversely affected," it added the further requirement that the petitioner must have been a party to the agency proceedings. *See, e.g.*, 7 U.S.C. § 136n(b) ("any person who will be adversely affected by such order and who had been a party to the proceedings"); 15 U.S.C. § 2615(a)(3) ("Any person who requested in accordance with paragraph (2)(A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order"); 16 U.S.C. § 825l(a) ("Any person, electric utility, State, municipality, or State commission aggrieved by an order issued by the Commission in a proceeding under this chapter to which such person, electric utility, State, municipality, or State commission is a party"); 33 U.S.C. § 1516 ("A person shall be deemed to be aggrieved by the Secretary's decision within the meaning of this chapter if he—(A) has participated in the administrative proceedings before the Secretary …."). And then, of course, there is the judicial review provision governing an FDA order that withdraws a prior approval of an application. Congress saw fit to limit review in such circumstances to the applicant alone. 21 U.S.C. § 387j(d)(2).

The Court should reject FDA's argument not just because it finds no support in statutory text or the history of the zone-of-interests test, but also because it would unsettle the meaning of a distressingly large number of judicial review provisions, impose requirements that Congress did not create, and erase

distinctions that it did. The U.S. Code's array of judicial review provisions may not create the uniform "party" requirement FDA wants, but it does reflect Congress's prudential judgment about when that status should be a prerequisite to judicial review. And that is a judgment the Constitution reserves to the first branch of government.

CONCLUSION

The Court should hold that the retailer Respondents are persons "adversely affected" by FDA's denial order within the meaning of 21 U.S.C. § 387l(a)(1).

December 23, 2024

Respectfully submitted,

/s/ *Andrew J. Morris*
Andrew J. Morris
Counsel of Record
Daniel Kelly
Mark Chenoweth
NEW CIVIL LIBERTIES ALLIANCE
4250 N. Fairfax Dr., Suite 300
Arlington, VA 22203
Phone: (202) 869-5210
andrew.morris@ncla.legal

Counsel for Amicus Curiae
New Civil Liberties Alliance