No. 23-1187

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,

Petitioner,

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 VAPING INDUSTRY STAKEHOLDERS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICI CURIAE*

Amici are national and state trade associations, which represent thousands of small businesses consisting of flavored vaping product manufacturers, distributors, and retailers, including individual member distributors and retailers.[1] Millions of smokers have used flavored vaping products to transition away from cigarettes. Many of the *amici* businesses exist because of their owners' individual success in using vaping products to quit smoking. *Amici* therefore share a common interest to ensure the Family Smoking and Tobacco Control Act (TCA), 21 U.S.C. §§ 301, *et seq*. is properly interpreted and applied by both FDA and the courts.

Amici thus have a substantial interest in the outcome of this litigation because vaping industry stakeholders have chosen to challenge the serial marketing denials issued by the Food and Drug Administration (FDA) in the Fifth Circuit. These stakeholders did so based upon the plain language of the TCA's venue provision, 21 U.S.C. § 387*l*, by partnering with distributors or retailers of their products located in Mississippi, Louisiana, or Texas. These manufacturers, distributors, and retailers are all persons "adversely affected" by an FDA marketing denial because of a common impact upon the stream of commerce. How this Court interprets the phrase "person adversely affected" in 21 U.S.C. § 387*l* in the

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[1] Pursuant to SUP. CT. R. 37.6, counsel for *amici curiae* state that no counsel for any party authored this brief in whole or in part or made any monetary contribution. Pursuant to SUP. CT. R 37.2, notice of intent to file was provided to counsel for all parties more than 10 days in advance of the filing deadline. *Amici* are listed in the attached appendix.

context of an FDA marketing denial order impacts the interests of the *Amici* whose members occupy the vape product manufacturing, distribution and retail channels.

INTRODUCTION

Words matter and this Court has repeatedly told litigants that words especially matter when interpreting a statute. *See e.g., Public Citizen v. U.S. Dept. of Justice*, 491 U.S. 440, 454 (1989) ("the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing"); *Watt v. Alaska*, 451 U.S. 259, 266 n.9 (1981) (same). At issue here is the scope of who Congress contemplated as having the right to judicial review when crafting the phrase "person adversely affected" in 21 U.S.C. § 387*l vis-a-vis* the venue of petitions for review of an FDA tobacco marketing denial order (MDO). *Amici* argue the phrase "person adversely affected" includes vaping product manufacturers, distributors and retailers on equal par.

21 U.S.C. § 387*l* provides a right to judicial review, identifies who is entitled to review, and specifies the appropriate venue for such proceedings. Congress, defined the term "person," 21 U.S.C. § 321(e), for purposes of identifying who is entitled to review, but it did not define the phrase "adversely affected" in 21 U.S.C. § 387*l* when crafting the TCA. Vape industry stakeholders, the *amici* included, understand what Congress understood when crafting the TCA: an MDO impacts the entirety of the stream of commerce—from manufacturer to retailer—because federal law, and some state laws bar impacted vaping products from entering the stream and being marketed in that stream. Ignoring an MDO carries the possibility of significant civil and criminal penalties at both the

federal and state levels for all participants in the stream of commerce.

Vaping product distributors and retailers must thus be viewed as standing in the same shoes as manufacturers for purposes of determining who has a right to review and fixing the venue of a challenge to an MDO whether the Court affords the phrase "person adversely affected" its ordinary meaning or views the question through the prism of its existing standing jurisprudence. The Respondents, *amici* and the Fifth Circuit have correctly read 21 U.S.C. § 387*l*.

SUMMARY OF THE ARGUMENT

First, *Amici* address the plain language of 21 U.S.C. § 387*l* in discerning the ordinary meaning of the phrase "adversely affected" for purposes of defining who has a right of judicial review and determining the venue for that review. *Amici* conclude that Congress intended the phrase to include not only vaping product manufacturers but also downstream participants (*i.e.* distributors and retailers) for purposes of fixing the venue of petitions for review. The Fifth Circuit therefore did not err in upholding the propriety of the Respondents and similarly situated distributors and retailers joining with manufacturers to challenge an MDO based upon the plain language of 21 U.S.C. § 387*l*.

Second, *Amici* demonstrate how vaping product distributors and retailers are "adversely affected" by an MDO for purposes of vesting venue based upon the Court's existing standing jurisprudence. *Amici* analyze that existing jurisprudence and demonstrate that vaping product distributors and retailers satisfy the requirements of *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992) because they suffer: (1) an actual,

concrete and particularized injury; (2) an injury which is fairly traceable to the challenged action; and (3) judicial relief is likely to redress the injury. *Amici* demonstrate that vaping product distributors and retailers satisfy the *Lujan* standing test because the TCA equally bars them from marketing and selling vaping products subject to an MDO and subjects them to possible penalties for doing so under both federal and state law.

ARGUMENT

I. THIS COURT'S RULES OF STATUTORY INTERPRETATION COUNTENANCE THE FIFTH CIRCUIT'S INTERPRETATION OF 28 U.S.C. § 387*l*

The Administrative Procedure Act (APA), 5 U.S.C. § 301, *et seq*., applies to judicial review of agency actions except where "statutes preclude judicial review," *id*., at § 701(a)(1). In turn, 5 U.S.C. § 702 defines the availability of review to any:

> "person suffering a legal wrong because of agency action, or *adversely affected or aggrieved* by agency action withing the meaning of a relevant statute."

5 U.S.C. § 702 (emphasis added). The TCA articulates a nearly identical standard by conferring a right of review to any person who is "adversely affected" by an MDO. 21 U.S.C. § 387*l*.

This Court has interpreted the APA to presume reviewability of an adverse agency decision absent Congress expressing a clear and convincing intent. *Japan Whaling Ass'n v. American Cetacean Soc.*, 478 U.S. 221 (1986). The question this Court must answer is whether Congress intended to confer the broad right of review equally upon manufacturers, distributors

and retailers when FDA issues an MDO, or intended to limit such right solely to manufactures.

A. THE TCA'S PLAIN LANGUAGE REFLECTS A BROAD RIGHT OF REVIEW.

Congress provided a means for seeking judicial review of an MDO when crafting the TCA's regulatory framework. 21 U.S.C. § 387*l*(b) provides in relevant part that:

> "any *person adversely affected* by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business."

21 U.S.C. § 387*l*(b) (Emphasis added).

Congress answered the first part of the inquiry by defining the term "person" in 21 U.S.C. § 321(e) to include an "individual, partnership, corporation, and association." The plain meaning of such term would equally include vaping product manufacturers, distributors and retailers regardless of whether they operate as an individual or through a limited liability entity (*e.g.* corporation or limited liability company). The APA applies a parallel definition. 5 U.S.C. § 551(2).

Congress, however, did not define the phrase "adversely affected" in either the APA, 5 U.S.C. § 702, or when crafting 21 U.S.C. § 387*l*. The Court therefore must reach into its statutory interpretation toolbox and apply specific rules to discern what Congress meant. One of the tools in that toolbox is that the proper starting point lies in a court seeking to accord the term's "ordinary or natural meaning" when

Congress does not furnish a statutory definition. *HollyFrontier Cheyenne Ref., LLC v. Renewable Fuels Ass'n*, 594 U.S. 382, 388 (2021). Courts must discern a statute's ordinary meaning from its words which cannot be read in isolation but "must be read" and interpreted "in their context," *Southwest Airlines Co. v. Saxon*, 596 U.S. 450, 455 (2022), with an eye to the "structure of the law itself," *Food Mktg. Inst. v. Argus Leader Media*, 588 U.S. 427, 435 (2019).

The Cambridge Dictionary defines the collocation "adversely affected" to mean "influenced or changed in a negative way."[2] Burton's Legal Thesaurus casts a broad net in defining "adversely affected" to mean:

> "aggrieved, damaged, endangered, endamaged, harmed, hurt, ill-treated, impaired, inflicted with injury, injured, seriously injured, threatened, wronged."[3]

Black's Law Dictionary uses the phrase "person adversely affected" in defining the synonym "aggrieved party" as being "a party whose personal, pecuniary, or property rights have been adversely affected…."[4] These examples of what it means to be "adversely affected" evidence an ordinary and natural meaning within the context Congress used such phrase.

This Court has countenanced the resort to dictionary definitions when seeking to discern the

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[2] Cambridge Online Dictionary, Adversely Affected. https://dictionary.cambridge.org/us/dictionary/english/adversely-affected

[3] Burton's Legal Thesaurus, 6th Ed., Adversely Affected.

[4] Black's Law Dictionary 1297 (10th ed. 2014).

plain meaning of a statutory term or phrase in the absence of Congress providing a definition. *Kouichi Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560 (2012). The above dictionary definitions are common and were understood to have the same meanings when Congress crafted 21 U.S.C. § 387*l*. Congress used plain, readily-understood, and broad language when telling vaping industry stakeholders where they must venue petitions for review from adverse FDA marketing decisions.[5] Congress could have easily limited the availability of relief solely to vaping product manufacturers by using more narrow language which limited the availability of judicial review.

Instead, Congress used broad, expansive, and encompassing language which evidences an intention to make judicial review available to all participants in the stream of commerce, recognizing that MDOs adversely affect the entirety of the stream of commerce for vaping products. Congress, after all, does not "hide elephants in mouseholes." *Sackett v. EPA*, 598 U.S. 651, 677 (2023). It would surely not have used broad language like "person adversely affected" if intending a narrow interpretation which constrained the right of review solely to vaping product manufacturers. The Fifth Circuit correctly recognized such fact, and the Court should affirm its interpretation of 21 U.S.C. § 387*l*.

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[5] The TCA's legislative history is of no help in the search for Congressional intent because it does not appear to address the scope of 21 U.S.C. § 387*l* concerning the meaning of who is a "person adversely affected" by an FDA marketing denial.

B. THE PLAIN LANGUAGE OF 21 U.S.C. § 387*l* INCLUDES DISTRIBUTORS AND RETAILERS.

This Court's jurisprudence concerning the regulation of products under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 301, *et seq*., of which the TCA is a part, confirms that congressional power to regulate interstate commerce applies to misbranded and adulterated products. *U.S. v. Sullivan*, 332 U.S. 689 (1948). Indeed, Congress contemplated that vaping products subject to an MDO are considered "adulterated" and "misbranded" under the TCA, 21 U.S.C. §§ 387b(6)(A) and 387c(a)(6). The FFDCA prohibits the introduction and marketing of adulterated and misbranded vaping products in interstate commerce, *id.*, at § 331(a), (c), (k).

The sample Technical Project Lead document which FDA transmits with every MDO reflects the above facts in stating that an impacted manufacturer is prohibited from "introduc[ing] or deliver[ing]" the impacted products into commerce and that "[d]oing so is a prohibited act" under the FFDCA "which could result in enforcement action.[6] It is axiomatic that any prohibition against manufacturers introducing or delivering a vaping product into the stream of commerce adversely affects not only them but the downstream distributors and retailers because the negation of their right to continue selling the impacted products results in the loss of business revenues.

Aside from financial impacts, manufacturers, distributors and retailers equally face federal criminal penalties for marketing vaping products subject to an MDO. *See* 21 U.S.C. § 333(a)(1) which provides for

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[6] *See* FDA, Sample Technical Project Lead at 14. https://www.fda.gov/media/152504/download?attachment

imprisonment for a period not to exceed 1 year for a first violation and 21 U.S.C. § 333(a)(2) which provides for imprisonment for a period not to exceed 3 years for subsequent violations.

Manufacturers, distributors and retailers also face significant civil penalties for selling vaping products subject to an MDO. 21 U.S.C. § 333(f)(9) provides for the imposition of civil monetary penalties ranging from $15,000.00 to $1,000,000.00, and enhanced penalties for certain intentional violations. FDA has employed this avenue of redress in numerous instances to target vape industry stakeholders beyond the manufacturing tier.[7] FDA has conducted numerous such proceedings before administrative law judges without jury trials contrary to *SEC v. Jarksey*, ___ U.S. ___, 144 S.Ct. 2117 (2024).

Alternatively, 21 U.S.C. § 332 authorizes FDA to initiate civil actions for injunctive relief beyond the manufacturing tier of the stream of commerce. FDA has employed this avenue of relief in numerous instances as to vaping product distributors and retailers across the nation.[8] FDA continues to place

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[7] *See e.g.*, FDA, *FDA Files Another Round of Actions Seeking Fines Against Retailers for Selling Illegal E-Cigarette Products*, Dec. 5, 2023; FDA, *FDA Seeks Civil Money Penalties Against 11 Retailers Selling Unauthorized E-Cigarettes* (Sept. 23, 2024). (itemizing examples of FDA's imposition of civil monetary penalties against retailers in administrative proceedings).

[8] *See e.g.*, *U.S. v. Morin Enterprises Inc.*, No. 2022-cv-02592 (D. Minn); *U.S. v. Soul Vapor LLC*, No. 2022-cv-00458 (S.D. W.Va.); *U.S. v. Super Vape'z LLC*, No. 22-cv-05789 (W.D. Wa.); *U.S. v. Vapor Craft LLC*, No. 22-cv-00160 (M.D. Ga.); *U.S. v. Lucky's Convenience & Tobacco LLC*, No. 22-cv-01237 (D. Kan.); *U.S. v. Seditious Vapours LLC*, No. 22-cv-01777 (D. Ariz.); *U.S. v. Fitzgerald, et al.*, No. 2023-

vaping product distributors and retailers at risk of being adversely affected even as this case progresses.[9]

The adverse impacts which manufacturers, distributors and retailers mutually experience from an MDO do not stop with federal enforcement efforts. Recent years have seen state legislatures adopt cigarette-manufacturer driven "registry" laws[10] which predicate the right of manufacturers, distributors and retailers to market and sell vaping products upon them having FDA market authorization.[11]

ALA. CODE. § 28-11-17 is one such enactment which provides that:

> "[i]t is unlawful to distribute, sell, or offer for sale any electronic nicotine delivery system or alternative nicotine product that cannot be legally marketed under federal law or FDA rule, regulation, or guidance."

ALA. CODE. § 28-11-17(a). A violation of this provision is a Class C misdemeanor, punishable by 3 months of

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cv-01130 (M.D. Fla.) and *U.S. v. Boosted LLC*, 1:24-cv-01582 (D. Colo).

[9] FDA, *Working with States, FDA Warns More than 100 Retailers for Illegal Sale of Youth Appealing E-Cigarettes, including Geek Bar*, Dec. 5, 2024.

[10] Katz, M., *et al., State E-Cigarette Registry Bills and What to Make of Them*, Public Health Law Center (Feb. 1, 2024).

[11] Cigarettes manufacturers turned to this strategy after attempts to utilize unfair trade practices laws proved unsuccessful. *See Court Dismisses Njoy Lawsuits, Allows Elf Bar*, Tobacco Reporter, Jan. 24, 2024. https://tobaccoreporter.com/2024/01/24/most-defendants-dropped-from-njoy-vape-suit/

incarceration ALA. CODE. § 13A-5-7(a)(3). Another example is 2024 KY. ACT. CH. 111, codified in KY. REV. STAT. ANN. CH. 438, which imposes significant fines upon manufacturers, distributors and retailers who sell vaping products subject to an MDO. KY. REV. STAT. ANN. § 438.308(4) imposes fines of $25,000.00 to $75,000.00 for manufacturers; KY. REV. STAT. ANN. § 438.309(2) imposes fines of $5,000.00 to $15,000.00 upon distributors; and KY. REV. STAT. ANN. § 438.316(4) imposes fines of $1,000.00 to $5,000.00 upon retailers plus a revocation of its right to sell vape products for a year after a third or subsequent offense within 2 years.[12]

It defies logic to say the aforementioned prohibitions and possible penalties imposed against distributors and retailers do not make them adversely affected by an FDA marketing denial for purposes of 21 U.S.C. § 387*l*. Congress articulated a clear understanding that an MDO carries a broad and substantial effect on the marketplace. The Constitution "does not permit this Court to rewrite [a] statute that Congress has enacted." *Nat'l Ass'n of Mfrs. v. DOD*, 583 U.S. 109, 124 (2018). It is thus incumbent upon Congress to amend 21 U.S.C. § 387*l* if it does not like the way vaping industry stakeholders are availing themselves of venue in the Fifth Circuit. The Court should thus affirm the Fifth Circuit's interpretation of 21 U.S.C. § 387*l*.

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[12] Iowa and Louisiana have similarly passed registry laws which prohibit the distribution and retail sale of vaping products absent an FDA marketing authorization. *See* IOWA CODE ANN. §§ 453.52, .52A and .53B; LA. REV. STAT. ANN. § 26:916.1.

II. VAPING PRODUCT DISTRIBUTORS AND RETAILERS SATISFY THE COURT'S STANDING JURISPRUDENCE.

Article III of the Constitution confines federal judicial power to "Cases" and "Controversies." U.S. CONST., Art. III, § 2. The right to access federal relief exists only if a plaintiff has standing to sue—a bedrock constitutional requirement this Court has applied to all manner of important disputes. *U.S. v. Texas*, 599 U.S. 670, 675 (2023). Standing, after all, is:

> "not merely a troublesome hurdle to be overcome if possible so as to reach the 'merits' of a lawsuit which a party desires to have adjudicated; it is a part of the basic charter promulgated by the Framers of the Constitution at Philadelphia in 1787."

Valley Forge Christian College v. Americans United for Separation of Church and State, Inc., 454 U. S. 464, 476 (1982).

In *Sierra Club v. Morton,* 405 U.S. 727 (1972), this Court viewed the question of Article III standing through the prism of 5 U.S.C. § 702 when considering whether a party was "adversely affected" by an agency action. This Court reasoned that Section 702 only confers a right of review to parties who can show "the challenged action had caused them 'injury in fact'." *Id.* at 733. The Court broadly interpreted the phrase "injury in fact" for purposes of Section 702 in *U.S. v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 686 (1973) when holding it is not "confined to those who could show 'economic harm'," or the fact that "many persons shared the same injury" is not a disqualifying factor.

Relying upon the above precedent, this Court in *Lujan*, *supra*., articulated its seminal standing jurisprudence by requiring a:

> "personal injury fairly traceable to the defendant's allegedly unlawful conduct which is likely to be redressed by the requested relief."

Allen v. Wright, 468 U.S. 737, 751 (1984), overruled on other grounds by *Lexmark Intern., Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014). Thus, *Lujan* requires the existence of "a concrete and particularized injury that is either actual or imminent . . ." *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007), citing *Lujan*, at 578. The injury must be "distinct and palpable" as opposed to "abstract," "conjectural" or "hypothetical." *Allen*, at 751. The alleged injury must also be "fairly traceable to the challenged action" such that "relief from the injury must be 'likely' to follow from a favorable decision." *Id*. Monetary costs are of course an injury. *Texas*, at 676.

Further, this court's existing standing jurisprudence extends to the right of distributors and retailers to bring legal challenges to regulatory regimes which also impact manufacturers. In *Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263 (1984), this Court upheld the standing of in-state liquor wholesalers to challenge a state tax regime exempting certain in-state products from taxes. *Bacchus* is noteworthy because wholesalers were not among the class burdened by the challenged tax but nevertheless suffered an economic injury because they were directly liable and any resulting price increase to reflect the price increase which accompanied the tax for imported products relative to the exempted in-state beverages. *Id.*, at 267.

In *Craig v. Boren*, 429 U.S. 190, 193 (1976), this Court noted that a party being subjected to sanctions and loss of a license for violation of a statute was sufficient to confer Article III standing. The downstream effects of a regulation of commercial activity thus adversely impacts stakeholders at the manufacturing, distribution and retail tiers of the stream of commerce. KY. REV. STAT. ANN. § 438.316(4), cited *supra*., is an example of a circumstance which results in the loss of a license as contemplated by *Craig* sufficient to confer Article III standing.

Congress did not confine the prohibition against selling adulterated or misbranded vaping products to manufacturers when crafting the TCA. It likewise did not limit the imposition of the penalties for such sales to manufacturers. FDA can hardly dispute the imposition of sanctions provided by the FFDCA results in the type of concrete injury contemplated by *Lujan*. The fact that states have enacted laws which impose both civil and criminal penalties ups the ante of that concrete injury. The result is that vaping product distributors and retailers are "persons adversely affected" by an FDA marketing denial for purposes of challenges to such denials on equal par with manufacturers. The Court can thus affirm the Fifth Circuit's interpretation of what it means to be "adversely affected" under existing standing jurisprudence.

CONCLUSION

Based on the foregoing, this Court should affirm the Fifth Circuit's Opinion in its entirety.

December 12, 2025

Respectfully submitted,

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APPENDIX

APPENDIX
LIST OF *AMICI CURIAE*

723VAPE, INC. (KY)

AMERICAN VAPOR MANUFACTURERS ASSOCIATION (AZ)

BREATHE EASY ALLIANCE OF ALABAMA

DERBECIGS LLC (KY)

DERBECIGS INDIANA LLC (IN)

FLORIDA SMOKE FREE ASSOCIATION, INC.

FREEDOM VAPES LLC (MT)

GEORGIA SMOKE FREE ASSOCIATION, INC.

KANSAS SMOKE FREE ASSOCIATION

KENTUCKY VAPING RETAILERS ASSOCIATION, INC. D/B/A KENTUCKY SMOKE FREE ASSOCIATION

IOWANS FOR ALTERNATIVES TO SMOKE AND TOBACCO, INC.

IOWA VAPE ASSOCIATION, INC.

J-VAPOR LLC, D/B/A NORTH SHORE VAPOR (MA)

LIQUID LABS LLC (NJ)

LOUISIANA VAPING ASSOCIATION, INC.

MARYLAND VAPOR ALLIANCE

MICHIGAN VAPE SHOP OWNERS, INC.

MIDWEST VAPE COALITION, INC.

MISSISSIPPI VAPING ADVOCACY ASSOCIATION, INC.

MISSOURI SMOKE FREE, INC.

MONTANA SMOKE FREE ASSOCIATION, INC.

NEBRASKA VAPE VENDORS ASSOCIATION, INC.

NEVADA VAPING ASSOCIATION, INC.

NEW MEXICO SMOKE FREE ALLIANCE, INC.

NEW YORK STATE VAPOR ASSOCIATION, INC.

NORTH CAROLINA VAPING COUNCIL, INC.
OP MURSE HOLDINGS, LLC, D/B/A OPMH PROJECT (KY)
SOUTH CAROLINA VAPOR ASSOCIATION, INC.
VIRGINIA SMOKE FREE ASSOCIATION, INC.
WASHINGTON SMOKE FREE ASSOCIATION, INC.
WEST VIRGINIA SMOKE FREE ASSOCIATION, INC.
UNITED VAPERS ALLIANCE, INC.
VAPOR STOCKROOM, L.L.C. (KY)
VAPOR UNLIMITED, LLC (FL)