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 ELECTRONIC NICOTINE DELIVERY SYSTEM TRADE ASSOCIATIONS AND SMALL BUSINESSES AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*

Amici are national and state trade associations, as well as small businesses, who represent manufacturers, distributors, and retailers of Electronic Nicotine Delivery Systems ("ENDS") (commonly known as "e-cigarettes").[1] Millions of addicted smokers in the U.S. have used ENDS to transition away from more dangerous conventional cigarettes. Indeed, many of these companies were started by individuals who themselves relied on ENDS to successfully move on from their own smoking habits. *Amici* therefore share a common goal in advocating for a reasonably regulated marketplace that gives consumers access to less risky tobacco products.

Amici also have a substantial interest in this litigation. FDA argues that retailers do not have standing to challenge an FDA marketing denial order ("MDO") rejecting a manufacturer's application seeking authorization to market and sell a given product. FDA takes this position even though the TCA's venue provision states that "any person adversely affected" by an MDO may challenge the order in either the D.C. Circuit or their home circuit. Despite this seemingly expansive language, FDA maintains that only the manufacturer who filed the application may seek judicial review of a denial order. According to FDA, retailers are too far removed from the "zone of interests" protected under the TCA section governing premarket applications and thus under this Court's precedent do not fall under the statute's venue

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[1] This brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for preparing or submitting this brief; and no one other than *amici* and their counsel have contributed money for preparing or submitting this brief. *Amici* are listed in the attached appendix.

provision. All of this stems from FDA's concerns that an out-of-circuit manufacturer will be able to defeat the venue provision by joining with a retailer located in any circuit of its choice. FDA cites eight instances, in addition to the instant case, where manufacturers allegedly took this approach when filing petitions in the Fifth Circuit. These include *amici* retailers Wood Creek Vapory, Texas Wholesale, Max & Zach's Vapor Shops, and Jail Puff Max.

Under FDA's reading of the statute, retailers would be unable to vindicate on their own any legal rights and other interests in the face of an unlawful MDO. That cannot be. Retailers must comply with the MDO and, at a minimum, will not be able to legally market and sell the ENDS products in the future. As active participants in the ENDS marketplace, retailers will clearly be impacted by a denial of marketing authorization. In this brief, *amici* therefore reflect on the grounds underlying their own Fifth Circuit petitions, and demonstrate why they, as well as retailers like them, fall squarely within the TCA's "zone of interests" and venue provision.

SUMMARY OF ARGUMENT

Under the TCA, ENDS manufacturers must submit to FDA premarket tobacco product applications ("PMTAs") to obtain authorization before marketing their products. The TCA's plain language requires FDA to evaluate all information and data submitted by a manufacturer when determining whether a given product is "appropriate for the protection of the public health" ("APPH"). The APPH standard is set forth in Section 387j of the TCA, which essentially obligates FDA to consider whether the benefits of an ENDS product outweigh its risks with respect to the population as a whole, including whether the product

will help smokers quit (cessation) or entice non-smokers to start (initiation). 21 U.S.C. § 387j(c).

Unfortunately, FDA has not reviewed PMTAs on a case-by-case basis; instead, it has applied a generic, across-the-board scheme resulting in the denial of virtually all non-tobacco flavored (e.g., mint and fruit) ENDS products. FDA adopted this strategy following a deluge of PMTAs filed prior to a court-imposed deadline, expressly designed to quickly deny marketing authorization for as many non-tobacco flavored ENDS as possible. Agency staff were instructed to engage in a simple box-checking exercise and issue a marketing denial if the PMTA failed to contain a single study indicating whether the manufacturer's non-tobacco flavored ENDS products are more effective at helping adult smokers quit when compared to its tobacco flavored ENDS products (what is referred to below as the "comparative efficacy study" requirement). Since 2021, based on this approach, FDA has issued virtually identical MDOs for over one million non-tobacco flavored ENDS products.[2]

Not surprisingly, manufacturers and other affected stakeholders raced to federal circuit courts across the country to challenge the MDOs. Petitions for review were filed under the TCA's venue provision, which is broad in scope; it permits "*any person* adversely affected" by a marketing denial to file a petition in either the D.C. Circuit or where their principal place of business is located within 30 days of the denial order. 21 U.S.C. § 387*l*(a)(1)(B) (emphasis added). One would think, given the provision's plain language, that "any person" would include retailers

[2] *See* https://tinyurl.com/2sdcmtr2 (FDA tracker indicating MDOs have been issued for over 1.2 million ENDS).

who had previously sold ENDS products now subject to a denial order. Indeed, they are undoubtedly impacted by an MDO—at a minimum, they are legally barred from selling the subject ENDS products going forward. They will also lose substantial revenues and incur other damages, such as lost goodwill and compliance costs.

FDA, however, sees it differently. Notwithstanding the TCA's expansive venue provision, FDA maintains that retailers do not have standing because their interests fall outside those protected by the statute's "zone of interests." A party satisfies the zone of interests test if the statute either protects or regulates its interests. But in FDA's eyes, if retailers are allowed to file a petition for review and challenge an MDO, that would nullify the venue limitations set forth in Section 387*l*. Specifically, FDA worries that a manufacturer who is located in a circuit with unfavorable precedent could gain entry into a more advantageous forum by pairing with a retailer who is located there. In fact, that is what FDA contends various *amici* manufacturers and retailers did in filing petitions in the Fifth Circuit. FDA therefore argues that retailers are not affected by Section 387j and the APPH standard. It characterizes retailers as mere bystanders or third parties, with no involvement in the PMTA process or relevance to the APPH determination. Yet nothing could be further from the truth.

As *amici* demonstrate below: (i) FDA ignores two provisions in Section 387j that regulate and protect retailer interests as part of the APPH analysis, particularly with regard to the impact of marketing and access restrictions implemented by retailers themselves; (ii) retailers play a key role in the PMTA process, gathering data regarding consumer use and

intentions that manufacturers include in the PMTA, which are relevant to the APPH determination and whether a product will lead to smoking initiation or cessation in adult consumers; (iii) an MDO will significantly impact a retailer's legal and business-related interests, including damages going beyond just barring the sale of a given ENDS product; and (iv) the TCA's confidentiality provisions do not prevent retailers from effectively challenging an MDO, especially where FDA itself provides public notice every time an MDO is issued, including through press releases, and has otherwise publicly disclosed its rationale underlying the cookie-cutter MDOs for virtually every non-tobacco flavored ENDS.

ARGUMENT

I. Retailers Fall Within the Zone Of Interests Protected Or Regulated By The TCA, Including Section 387j And The APPH Standard

Whether a petitioner meets the zone of interests test "is not meant to be especially demanding." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012). A party has statutory standing if it asserts an interest that is "arguably" protected or regulated by the statute. *Id.* at 225-26. The zone of interests test "forecloses suit only when 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." *Id.* All that is required is "some indicia—however slight—that the litigant before the court was intended to be protected…or regulated by the statute." *Calumet Indus., Inc. v. Brock*, 807 F.2d 225, 228 (D.C. Cir. 1986). Either scenario will suffice. Resp. Br. at 8-9.

FDA argues in its opening brief, however, that the "zone of interests" test only looks to the specific statutory provision at issue, not other sections or the statute's overall purpose. FDA Br. at 13. FDA then maintains that Section 387j does not "consider [retailers'] substantive interests." *Id.* at 17; *see also id.* at 16 ("Section 387j(c) does not seek to protect retailers"); ("Section 387j…reveals no concern for retailers' particular interests"). This is so, according to FDA, because the APPH standard set forth in Section 387j(c) "does not direct the agency to weigh any interests of potential retailers, such as the product's effects on their revenues." *Id.* at 17. "The statutory text and context thus strongly suggest that retailers' interests fall outside the zone of interests that Section 387j(c) protects." *Id.* at 17; *see also id*. at 17 ("In fact, Section 387j does not mention retailers at all."). FDA's arguments fail on multiple grounds.

To begin, even if FDA is correct that this Court should focus solely on Section 387j and the APPH standard, FDA still mischaracterizes the zone of interests test. As noted above, the relevant question is whether retailers fall "within the zone of interests to be protected or *regulated* by the statute." *Patchak*, 567 U.S. at 224 (emphasis added) (citation omitted). FDA therefore impermissibly narrows the inquiry when it only asks if the provision protects retailers' substantive interests, like revenue generation. The zone of interest test is much broader in scope. Here, it would also consider whether Section 387j and the APPH standard implicate the regulation of retailer conduct. Yet FDA conspicuously ignores that side of the equation. Indeed, there are at least two provisions in Section 387j(c) that explicitly incorporate issues involving retailers in the APPH determination but go unmentioned in FDA's opening brief.

First, when deciding whether to grant marketing authorization, FDA must consider whether imposing further restrictions on the sale and distribution of a given product would mean that it is APPH. 21 U.S.C. § 387j(c)(1)(B). That provision, in turn, incorporates by reference Section 387f(d), which provides examples of restrictions that directly regulate retail operations going to access, advertising and promotion, and online sales. 21 U.S.C. § 387f(d). Significantly, a restriction may only be imposed if it is APPH—the same standard set forth in Section 387j(c). Conversely, if FDA finds that such restrictions would not help a product satisfy the APPH standard, then that increases the likelihood that an MDO will be issued. 21 U.S.C. § 387j(c)(2)(A) (requiring an MDO if the product is not found to be APPH). And Section 387f(d) not only regulates retailers, it also explicitly protects them. It bars restrictions under the APPH standard that "prohibit the sale of any tobacco product in face-to-face transactions by a specific category of *retail* outlets." 21 U.S.C. § 387f(d)(3)(A)(i) (emphasis added).

Second, Section 387j(b) requires a manufacturer to include certain information in a PMTA, including whether any "tobacco product standard" promulgated by FDA applies to the given product and whether the product satisfies such standard. 21 U.S.C. § 387j(b)(1)(D). FDA is then directed to consider all information contained in a PMTA, including that related to tobacco product standards, when deciding whether the product is APPH. 21 U.S.C. § 387j(c)(2). Section 387j(b) cross-references Section 387g, which permits FDA to adopt tobacco product standards provided they are APPH—again, the same standard found in Section 387j(c). Importantly, such standards may regulate retailer conduct, including sale and distribution restrictions, which must be consistent with Section 387f(d). 21

U.S.C. § 387g(a)(4)(B)(v). And Section 387g is also designed to protect retailers' interests. Any tobacco product standard that is eventually considered by FDA as part of an APPH analysis under Section 387j(c) must have gone through public notice and comment rulemaking. 21 U.S.C. § 387g(c)-(d). As such, FDA must have evaluated comments submitted by "interested persons," including retailers. *Id.*

Tellingly, FDA itself has repeatedly stated that compliance by retailers with underage marketing and access restrictions would be key to obtaining an APPH finding, thus all but conceding that retailers' interests fall within Section 387j's zone of interests. In June 2019 guidance regarding PMTA submissions, FDA stated applicants should:

> propose specific restrictions on the sale and distribution that can help support a showing that permitting the marketing of the product would be APPH (e.g., a restriction that decreases the likelihood that those who do not use tobacco products will start using tobacco products).[3]

Likewise, in a proposed PMTA rule issued in 2019, FDA noted that the "applicant's marketing plans…will provide input that is *critical* to FDA's determination of the likelihood of changes in tobacco product use behavior, especially when considered in conjunction

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[3] FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry*, at 12 (June 2019) ("2019 PMTA Guidance"), https://tinyurl.com/2s33cz3h; *see also id.* at 21 (requesting applicants to submit "any restrictions on the sales and distribution of the new tobacco product that you propose to be included as part of a marketing order under section 910(c)(1)(B) to help support a showing that the marketing of the product would be APPH").

with other information contained in the application."[4] FDA then reiterated in the final rule that marketing plans are a "*critical* factor in…FDA's statutorily required determination."[5] In fact, FDA's failure to review relevant evidence in the form of marketing and access restrictions was the basis for the Eleventh Circuit's holding in *Bidi Vapor, LLC v. FDA*, 47 F.4th 1191 (11th Cir. 2022), in which it vacated and remanded MDOs issued to *amici* Bidi Vapor, LLC ("Bidi Vapor") for further APPH review.

FDA also highlighted the importance of retailer compliance in 2020 enforcement guidance.[6] FDA warned that it would prioritize enforcement against manufacturers and retailers where "adequate measures" had not been taken to "prevent minors' access." *Id.* at 10. FDA then listed steps manufacturers should take that would directly impact retailer operations, including: (i) monitoring retailer compliance with age-verification and sales restrictions; (ii) screening retailers based on the strength of their age-verification policies; (iii) requiring use of technology that tracks age-verification practices; (iv) establishing an anonymous hotline for reporting noncompliant sales; (v) implementing a mystery shopper program; (vi) enforcing penalties against retailers that fail to comply with marketing and access restrictions; (vii) implementing a policy of notifying FDA of retailer violations; and (viii) restricting the quantity of ENDS products that a

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[4] 84 Fed. Reg. 50566, 50581 (Sept. 25, 2019) (emphasis added).

[5] 86 Fed. Reg. 55300, 55324 (Oct. 5, 2021) (emphasis added).

[6] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (April 2020), https://tinyurl.com/4dbe9uup.

retailer may sell to a customer within a given period of time. *Id.* at 22.

Not surprisingly, manufacturers who FDA now complain ran afoul of the TCA's venue provision by joining with retailers who operate within the Fifth Circuit, *see* FDA Br. at 11 n.2, pointed out that their marketing and access restrictions are working and there is no evidence retailers are selling ENDS products to underage consumers. For example, *amici* NicQuid, LLC and Vertigo Vapor, Inc. (d/b/a Baton Vapor) outlined restrictions imposed on their respective retailers that comply with many of the "adequate measures" outlined by FDA in the 2020 guidance.[7] Both companies then noted FDA's own National Youth Tobacco Survey ("NYTS") between 2021-23 indicated that no high school or middle school respondents had used their products.[8] NicQuid and Vertigo Vapor further demonstrated that this information, going to retailer compliance, should have been fully considered by FDA during its APPH analysis.[9]

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[7] *See NicQuid, LLC, et al. v. FDA*, No. 24-60272 (5th Cir.), NicQuid Mot. for Stay (ECF 14-2) at A102-A103 (e.g., monitoring retailers' marketing efforts, requiring retailers to use age-verification software, establishing an anonymous hotline to report noncompliant sales, establishing an internal auditing program (like a mystery shopping program), and restricting the quantity of ENDS per sale); *Vertigo Vapor, Inc., et al. v. FDA*, No. 24-60332 (5th Cir.), Vertigo Vapor Mot. for Stay (ECF 18-2) at A102 (e.g., requiring retailers to employ adequate age-verification software, obligating retailers to sign retailer agreements outlining sales and access restrictions, and limiting retail sales to a quantity that is reasonable to purchase in a single transaction).

[8] *See supra* note 7, NicQuid Mot. for Stay at A104; *supra* note 7, Vertigo Vapor Mot. for Stay at A102-A103.

[9] *See supra* note 7, NicQuid Mot. for Stay (ECF 14-1) at 16; *supra* note 7, Vertigo Vapor Mot. for Stay (ECF 18-1) at 15-16.

And it is no wonder, given Section 387j's emphasis on marketing and sales restrictions, that the TCA generally regulates retailer activity and protects their interests. Examples abound. *See*, *e.g.*, 21 U.S.C. §§ 387g (preserving retailers' ability to sell tobacco products by prohibiting bans on all cigarettes and other tobacco products); 333(f)(8) (providing hearing rights to retailers before a no-tobacco-sale order is enforced); 387f(d) (prohibiting retailers from selling ENDS to underage individuals); and 387a-1(d) (limiting the use of free samples). The statute's purposes section also acknowledges retailer interests when it directs FDA "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure" they are not sold to underage consumers. Pub. L. No. 111-31, § 3(7), 125 Stat. 1776, 1782 (2009).

Retailers are the driving force behind the ENDS distribution and sales chain, and therefore play a significant role in whether an ENDS product is APPH. This reality is reflected throughout the TCA, including Section 387j. Consequently, retailers fall within the TCA's zone of interests; FDA cannot fairly argue otherwise.

II. Manufacturers Rely On Retailers During The PMTA Process To Gather Information Required Under Section 387j And Relevant To The APPH Standard

Not giving up the fight, FDA next contends that Section 387j "does not give retailers any role in [the PMTA] process." FDA Br. at 16. FDA notes it is the manufacturer who files the application and that Section 387j does not otherwise authorize retailers, among other things, to "submit additional evidence, or to comment on the agency's proposed action." *Id.* In doing so, however, FDA ignores key contributions that

retailers often make as PMTAs are assembled, including the submission of information pertinent to the APPH determination.

In particular, FDA requested in its 2019 PMTA Guidance that, for products already in the marketplace, manufacturers submit sales data to "better understand potential consumer demographic[s]."[10] FDA was especially interested in "sales data broken down by population demographics and tobacco use status." *Id.* Moreover, the guidance asked that manufacturers submit consumer perception and intention studies that, in part, address how consumers intend to use a particular product, including among current ENDS users. *Id.* at 38. And FDA sought data regarding "cessation among current tobacco users" through "perception" and "actual use" observational studies. *Id.* All of this goes directly to APPH. *See*, *e.g.*, 21 U.S.C. § 387j(c)(4) (e.g., requiring FDA to assess potential initiation and cessation).

As a result, manufacturers often rely on retailers to collect such information in order to submit robust and complete PMTAs. For instance, the PMTAs submitted by *amici* Bidi Vapor are instructive.[11] First, in section 2.4.2.5 of the PMTAs, Bidi Vapor summarized extensive purchaser demographics and sales data collected from retailers between 2019-20. As requested by FDA, this included information regarding age identification checks, age and gender distribution, consumer buying frequency, and U.S. regional distribution. Second, in a PMTA amendment submitted in 2021, Bidi Vapor furnished results of a Patterns of Use study, which was designed to assess, in part, whether consumers are

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[10] 2019 PMTA Guidance at 39.

[11] *See generally, Bidi Vapor*, 47 F.4th 1191.

using Bidi Vapor products to reduce or quit their smoking habits. As this involved a survey of current adult users (i.e., persons who had used Bidi Vapor's ENDS products within the past 30 days), Bidi Vapor and its consultant required the help of retailers to recruit potential respondents. Specifically, the consultant sent postcards with accessible QR codes to retail stores that led to the survey landing page. Each store had a code for tracking participation by its respective customers.[12]

Similarly, JUUL relied on retail outlets to complete a published Longitudinal Cohort Study ("LCS") that was used to support its PMTAs.[13] These involved online surveys of thousands of adult conventional cigarette smokers who had started using JUUL ENDS products. The surveys, conducted between 2018-19, were designed to assess the odds of cigarette smoking cessation at 3 and 6 months after initiating use of JUUL devices. Many of these participants were recruited with the help of 10,000 brick-and-mortar retail stores across the country. JUUL inserted business card-sized invitations in JUUL Starter Kits with a unique six-digit alphanumeric code through which a retailer customer could access the online

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[12] *See Bidi Vapor, LLC v. FDA*, No. 21-13340 (11th Cir.), Bidi Vapor Principal Br., App. Vol. II at FDA-BIDIVAPOR-5317 (Dec. 3, 2021).

[13] Russell, et al., *Factors associated with past 30-day abstinence from cigarette smoking in adult established smokers who used a JUUL vaporizer for 6 months*, Harm Reduction Journal, (2019) 16:59, https://tinyurl.com/8f42mrje; Russell, et al., *Factors associated with past 30-day abstinence from cigarette smoking in a non-probabilistic sample of 15,456 adult established current smokers in the United States who used JUUL vapor products for three months*, Harm Reduction Journal, (2019) 16:22, https://tinyurl.com/3n9b2erw.

survey. As such, the availability of JUUL ENDS products at retail and the cooperation of retailers were essential to completing the LCS.

FDA again blinks reality when it claims Congress did not envision retailers playing some role in the PMTA process. It would be extremely difficult for applicants to provide FDA with all data required under Section 387j and the APPH standard absent retailer participation.

III. An MDO Significantly Impacts The Legal Rights And Business-Related Interests Of Retailers Selling Products Subject To The Denial Order

Continuing to overreach, FDA then argues that an MDO has "no effect on a retailer's legal rights and duties." FDA Br. at 20-21. How can that be? Once an MDO is in place, a retailer is barred from selling the ENDS going forward. Continuing to offer the product at retail would violate the adulteration provisions of the TCA, and risk, *inter alia*, civil and criminal penalties. *See* 21 U.S.C. §§ 331(c), 333, 387b(6)(A) (providing that a product that does not have a marketing granted order under Section 387j is considered adulterated). The MDOs issued to the *amici* retailers in Fifth Circuit proceedings say so themselves.[14] In

[14] *See*, *e.g.*, *Breeze Smoke, LLC, et al. v. FDA*, No. 24-60304 (5th Cir.), Pet. for Review (ECF 1-1) at Ex. A (June 11, 2024); *Lead by Sales LLC, et al. v. FDA*, No. 24-60424 (5th Cir.), Pet. for Review (ECF 1-2) at Ex. A (Aug. 20, 2024) (both MDOs stating "You cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA. These actions may include, but are

fact, FDA has issued at least 175 civil money penalty orders to date, which are adjudicated by administrative law judges, to retailers across the country over the past several years, in part, because their products lacked a PMTA marketing granted order.[15]

FDA complains that a retailer "has no legal right to sell the unauthorized product before the denial order, and it still lacks that right after the order." FDA Br. at 21. But FDA misses the point. What if the MDO was issued unlawfully? That is precisely what the *amici* retailers have alleged in their petitions for review—that FDA acted in an arbitrary and capricious manner and otherwise violated the law when issuing the MDOs. As retailers clearly fall within the TCA's and Section 387j's zone of interests, *supra*, it makes sense Congress at a minimum intended to grant retailers the right to seek judicial review under the TCA's broad venue provision allowing "any person adversely affected" to challenge an MDO. 21 U.S.C. § 387*l*(a).

Indeed, there are circumstances under which a retailer will have a strong incentive to challenge a potentially illegal MDO. Take *amici* retailer JP-MAXX (d/b/a "Jail Puff Max") as an example. Jail Puff Max was founded in 2016 to provide adult smokers who are currently incarcerated with a less harmful alternative to conventional combustible cigarettes. The company is the exclusive distributor for a disposable menthol ENDS product manufactured by *amici* Lead by Sales

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not limited to, civil money penalties, including an enhanced civil money penalty under FD&C Act section 333(f)(9)(B)(i), seizure, and/or injunction.").

[15] FDA, *FDA Seeks Fines Against 18 Retailers that Continue to Sell Unauthorized E-Cigarettes* (Nov. 26, 2024), https://tinyurl.com/32xhj6xu.

specifically for law enforcement agencies in twelve states, including the Fifth Circuit. The inmates purchase the device in the commissaries of correctional facilities. While Lead by Sales produces other ENDS subject to the challenged MDO, the menthol product alone makes up a substantial portion of Jail Puff Max's business. Between 2021-24, it comprised between 30%-45% of the company's annual sales, with an average of over $500,000 in annual revenues. Jail Puff Max will lose many dedicated customers who are responsible for purchasing the product and stocking the commissaries. Seeking judicial review of the MDO is the most effective way for Jail Puff Max to ensure its own substantial interests will be protected.[16]

And retailers stand to lose more than thousands of dollars in annual revenue. For example, *amici* retailers Wood Creek Vapory and Max & Zach's Vapor Shops noted in their Fifth Circuit stay motions that they will also suffer extensive damage to their business goodwill, as customers loyal to the particular ENDS product or brand will not only stop buying other related products, such as device parts and batteries, but also cease doing business with them altogether. They may also incur thousands of dollars in compliance costs to properly dispose of now worthless inventory according to federal, state, and local environmental laws.[17]

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[16] *See supra* note 14, Lead by Sales Mot. for Stay (ECF 25-1) at A117-A120 (declaration of John Hemphill, CEO of Jail Puff Max).

[17] *See supra* note 7, Vertigo Vapor Mot. for Stay (ECF 18-2) at A62-A64 (declaration of Zachary Jones, CEO of Max & Zach's Vapor Shops); *supra* note 7, NicQuid Mot. for Stay (ECF 14-2) at A060-A063 (declaration of Josh Wood, Operations Manager of Wood Creek Vapory).

Collectively, the immediate downstream effects resulting from an MDO are real and can have a devastating impact on retailers who have no choice but to obey FDA's denial of marketing authority. It is easy to see, therefore, why Congress intended for the TCA's venue provision to apply to both manufacturers and their retailers.[18]

IV. The TCA's Confidentiality Provision Does Not Preclude Retailers From Effectively Challenging An MDO

FDA also contends that the TCA's confidentiality provision, *see* 21 U.S.C. § 387f(c), means that retailers will not necessarily know that an MDO has been issued for a particular ENDS product. FDA Br. at 18-19.[19] FDA makes much of the fact that it only publicly discloses the name of an ENDS manufacturer who has received an MDO if its products are currently on the market. *Id.* at 19. In other words, per the confidentiality provision, FDA cannot disclose that an MDO has been issued for products where a manufacturer only intends to market them in the future. *Id.* FDA then concludes from this latter scenario that Congress did

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[18] FDA also argues that allowing retailers to challenge an MDO "nullifies the Act's [venue] restrictions." FDA Br. at 34. FDA believes that out-of-circuit manufacturers can always find an in-circuit retailer. FDA Br. at 35. Not so. There are certainly instances where ENDS manufacturers would not be able to find an in-circuit retailer. For example, *amici* ECIG Charleston produces its own e-liquid products, but only sells them at its 14 brick-and-mortar stores in South Carolina. *See* https://tinyurl.com/yn2pnuv9.

[19] Under Section 387f(c), FDA treats information contained in a PMTA as confidential consistent with the Freedom of Information Act at 5 U.S.C. § 552.

not give retailers a right to seek judicial review under *any* circumstances. *Id.* at 20.

Yet as FDA concedes, the TCA's confidentiality protections do not prohibit public notice when the products are already being sold at retail—the very scenario in which a retailer's incentive to challenge the MDO will be at its highest. In fact, FDA publishes a spreadsheet listing companies whose products have been denied marketing authorization and thus must be removed from the marketplace.[20] For instance, that was the case for *amici* retailers Wood Creek Vapory, Texas Wholesale, Max & Zach's Vapor Shops, and Jail Puff Max, all of whom were already selling ENDS products that were denied marketing authorization. *Id.*

Once a manufacturer is included on the spreadsheet, it is a simple matter for the retailer to contact the manufacturer to confirm which products are covered by the order and obtain a copy of the MDO. And practically speaking, even if the retailer selling a product does not realize that the manufacturer has been listed, it is likely the manufacturer will contact its retailers to inform them that it will stop distributing the covered ENDS, that they need to destroy any remaining inventory, and that there is now an increased chance of an FDA enforcement action if the retailer continues to sell the products. For example, that is what happened to Jail Puff Max. It was in the midst of negotiating a new contract with

[20] FDA, *Tobacco Products Marketing Orders*, https://tinyurl.com/2dmf2jba.

Lead by Sales when the MDO was issued. Those negotiations were then placed on hold.[21]

FDA also conspicuously leaves out the fact that for some MDOs it immediately issues a press release not only announcing the order, but also identifying the company and products denied marketing authorization. Since 2021, FDA has issued no less than 20 such press releases covering tens of thousands of ENDS products.[22] FDA clearly does not believe that the TCA's confidentiality restrictions prevent such press releases, which are intended to put retailers on notice that they can no longer sell the targeted products, with some releases explicitly instructing retailers to contact the manufacturer for further direction.[23]

Finally, FDA maintains that the confidentiality provision prevents retailers from accessing the full administrative record and thus they would not be able to prosecute a "record-intensive" challenge to an MDO under the APA's arbitrary and capricious standard, which is incorporated by reference into the TCA's

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[21] *See supra* note 14, Lead by Sales Mot. for Stay (ECF 25-1) at A119 (declaration of John Hemphill, CEO of Jail Puff Max).

[22] *See supra* note 20; *see also* FDA, CTP Newsroom, https://tinyurl.com/9mzebze8; FDA, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products For Failing to Provide Evidence They Appropriately Protect Public Health* (Aug. 26, 2021), https://tinyurl.com/4ymndkdh.

[23] *See*, *e.g.*, FDA, *FDA Denies Marketing for 65 "MNGO Disposable Stick" E-Cigarettes* (Apr. 15, 2024), https://tinyurl.com/4yhr85ux ("Retailers should contact the manufacturer, Shenzhen Yibo Technology Co. Ltd., with any questions about MNGO Disposable Stick products in their inventory. Manufacturers, distributors, and retailers who do sell, or distribute, these products in interstate commerce are violating the law and are at risk of enforcement action.").

judicial review section. FDA Br. at 20 (citing 21 U.S.C. § 387*l*(b) and 5 U.S.C. § 706(2)(A)). According to FDA, this again indicates Congress did not intend for retailers to seek judicial review. *Id.* Never mind the fact that FDA would be required to produce an unredacted version of the entire administrative record, subject to a confidentiality order, after a retailer files a petition for review (*see* Fed. R. App. P. 17). It will also be the case that there are purely legal grounds upon which a petition can be based that do not require a detailed working knowledge of the PMTA or FDA's underlying APPH analysis.

Indeed, while the TCA provides that a petition shall be reviewed under the APA's arbitrary and capricious standard, it also states that "remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law." 21 U.S.C. § 387*l*(d). This would necessarily include a court holding unlawful and setting aside an MDO under the APA that is found to be: (i) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or (ii) without observance of procedure required by law. 5 U.S.C. § 706(2)(C)-(D). Thus, a retailer could file a petition for review based not on the underlying facts of the case, but rather FDA's readily apparent violation of statutory requirements. And that is what *amici* retailers did in the Fifth Circuit.

For example, by the time Wood Creek Vapory, Texas Wholesale, Max & Zach's Vapor Shops, and Jail Puff Max filed their petitions for review, it was obvious to all in the marketplace that FDA had essentially achieved a *de facto* ban on over one million non-tobacco flavored ENDS products by virtue of the cookie-cutter MDOs. In their respective stay motions and opening briefs in the Fifth Circuit, the retailers argued that a

restriction or ban on flavors amounts to a "tobacco product standard" that the TCA requires to go through notice-and-comment rulemaking. *See* 21 U.S.C. § 387g(c)-(d). They pointed out that FDA staff reviewing PMTAs had no choice but to deny a PMTA if it did not include a comparative efficacy study. As FDA failed to adhere to these procedural requirements, the retailers requested their respective MDOs be vacated and remanded.[24] But there is nothing about this argument or form of relief that required the retailers to have access to an administrative record. They are wholly legal in nature.[25]

In any event, as a practical matter, retailers had more than enough publicly available information to challenge MDOs issued for non-tobacco flavored ENDS as arbitrary and capricious, notwithstanding the confidentiality restrictions. As noted above, the vast majority of these MDOs were virtually identical and were based on the absence of a comparative efficacy study. In September 2021, FDA publicly released a "Sample Decision Summary Document"—a 20-page, single-spaced template of what is called a Technical Project Lead ("TPL") Review, which was issued in support of each MDO. Specifically, it seeks to justify

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[24] *See supra* note 7, NicQuid Pet. Br. (ECF 62) at 42-45; *supra* note 14, Breeze Smoke Pet. Br. (ECF 27) at 20-23; *supra* note 7, Vertigo Vapor Mot. to Stay (ECF 18-1) at 18-20; *supra* note 14, Lead by Sales Mot. to Stay (ECF 25-1) at 18-20.

[25] *See Wages and White Lion Invs., LLC v. FDA*, 90 F.4th 357, 384 n.5 (5th Cir. 2024) ("FDA unquestionably failed to follow § 387g's notice-and-comment obligations before imposing its *de facto* ban on flavored cigarettes). Although FDA recently approved four menthol-flavored ENDS manufactured by NJOY, https://tinyurl.com/m6d846d3, those ENDS constitute a mere 0.000333% of the total number of products denied marketing authorization pursuant to the comparative efficacy test requirement.

the comparative efficacy study requirement, and actually contains the explanatory language to be inserted into each MDO. That template is still available on FDA's website today.[26] Thus, even in the unlikely event that a retailer does not have complete access to the administrative record after filing a petition for review, it would still have information regarding FDA's rationale sufficient to mount a vigorous challenge to an MDO based on the arbitrary and capricious standard.

CONCLUSION

Based on the foregoing, it is clear that retailers, including *amici*, easily fall within the TCA's and Section 387j's "zone of interests" and therefore qualify under the statute's expansive venue provision as "any person adversely affected" by an MDO. Accordingly, this Court should affirm the order of the Fifth Circuit below.

Respectfully submitted,

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December 23, 2024

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[26] FDA, *Tobacco Products Marketing Orders: FDA Sample Decision Summary Document*, https://tinyurl.com/npn2x4ec.

APPENDIX

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LIST OF *AMICI CURIAE*

American Vape Company, LLC d/b/a Ludicrous Distro (TX)

Bidi Vapor, LLC (FL)

Breeze Smoke, LLC (MI)

Capella Flavors, Inc. (NJ)

ECIG Charleston (SC)

Flavour Art North American (Canada)

FLV USA d/b/a Flavorah (WA)

JP-MAXX, LLC d/b/a Jail Puff Max (TX)

Lead by Sales, LLC d/b/a White Cloud Cigarettes (FL)

Lotus Vaping Technologies, LLC (ID)

Magellan Technology, Inc. (NY)

Matrix Minds, LLC (TX)

Max and Zach's Vapor Shops Inc. (TX)

NicQuid, LLC (OH)

Ohio Vapor Trade Association, Inc. (OH)

Pastel Cartel, LLC (TX)

Smoke-free Alternatives Trade Association (DC)

SS Vape Brands (FL)

Streamline Group/MH Global (CA)

SV3, LLC (CA)

Texas Wholesale (TX)

Vape Element LLC d/b/a BLVK E-Liquid (CA)

Vapermate LLC (OH)

Vape Away LLC (TX)

Vertigo Vapor, Inc. d/b/a Baton Vapor (WA)

Wood Creek Vapory (TX)

YLSN Distribution LLC d/b/a Happy Distro (AZ)