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 FOREIGN ENDS MANUFACTURERS AND DOMESTIC RESELLERS OF THEIR PRODUCTS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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December 23, 2024

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Miscellaneous

INTEREST OF THE AMICI CURIAE[1]

Amici Curiae Shenzhen IVPS Technology Co., Ltd. ("IVPS") and Shenzhen Youme Information Technology Co., Ltd. ("Youme") are Shenzhen, China-based manufacturers of electronic nicotine delivery system ("ENDS"), or electronic cigarette, devices. Modern ENDS were first developed in China more than 20 years ago and these foreign *Amici* have been in the business of developing, manufacturing, and selling ENDS devices to global markets, including to businesses based in the United States, for fourteen and ten years, respectively. Additional *Amici Curiae* ECIGRUSA, LLC, which does business as Worldwide Vape Distribution ("Worldwide"), and Frendz Trading, Inc., which does business as Vape-E-Way ("Vape-E-Way"), are Texas-based small businesses that are resellers of IVPS's and Youme's refillable, open-system ENDS devices.

As required by the Family Smoking Prevention and Tobacco Control Act ("TCA" or "Act"), IVPS and Youme have each submitted multiple applications for premarket review of their ENDS devices to the Food and Drug Administration ("FDA"), and both received marketing denial orders for some of their refillable, open-system ENDS devices in January 2024. Because these *Amici* do not have a principal place of business in the United States, they timely filed petitions for review of their marketing denial orders in the United

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[1] Pursuant to Supreme Court Rule 37, *Amici Curiae* state that no counsel for a party authored this brief in whole or in part, and no party or counsel other than the *Amici Curiae* and their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

States Court of Appeals for the Fifth Circuit. IVPS filed its petition for review as a co-petitioner to Worldwide Distribution, while Youme filed its petition for review as a co-petitioner to Vape-E-Way.

As long-established foreign manufacturers of ENDS and domestic small businesses that have been "adversely affected" by FDA's denial of applications for premarket authorization and which have petitioned for judicial review in the circuit in which the resellers are based, *Amici* have a strong interest in the interpretation of 21 U.S.C. § 387*l*(a)(1). For the reasons explained herein, *Amici* respectfully submit that the Court should affirm the Fifth Circuit's order finding venue to be properly laid where each of multiple petitioners has been adversely affected by an order denying an application for premarket authorization under 21 U.S.C. § 387j(c) and the principal place of business of at least one of those petitioners is in the circuit where the petition for review is filed.

SUMMARY OF ARGUMENT

The Court should dismiss Petitioners' petition for writ of certiorari for lack of jurisdiction or as improvidently granted. Although both Petitioners and their supporting *amici* voice concerns about the Fifth Circuit's order creating incentives for "forum shopping," any practical concerns regarding those incentives should not prevent the Court from dismissing the petition, as Petitioners overstate them and they are likely to be transitory with respect to premarket applications for ENDS products in any event.

The Court should also find that resellers are within the "zone of interests" that judicial review under 21 U.S.C. § 387*l*(a)(1) is intended to protect. The determination at issue is a marketing denial order, which equally prohibits resellers from selling the subject ENDS products as it does the applicant manufacturer. That resellers undoubtedly fall within the zone of interests is underscored by the extent of FDA's efforts to pursue civil money penalties against and seize unauthorized ENDS products from such resellers.

Finally, only a single applicant need establish venue in a circuit court for a joint petition. In addition to the arguments advanced by Respondents and other *amici*, the incongruity of FDA's position on the proper venue for judicial review of lesser adverse agency actions taken against premarket applications earlier in the review process with the agency's position on the proper venue for judicial review of major adverse agency actions taken against such applications later in the process underscores that Petitioners' positions regarding venue and joinder are untenable.

ARGUMENT

I. Practical Concerns About "Forum Shopping" Should Not Prevent the Court From Dismissing the Petition for Lack of Jurisdiction or as Improvidently Granted

Respondents present compelling arguments that the Court should dismiss the petition for certiorari for lack of jurisdiction or as improvidently granted because 28 U.S.C. § 1254(1) does not grant the Court jurisdiction to review by certiorari before judgment an

interlocutory ruling in a case originating in a court of appeals, as is the case here. Resp. Br. at 11-18. Petitioners, for their part, claim that the decision below "invites unchecked forum shopping," Pet. Br. at 35, while *amici* supporting Petitioners claim that manufacturers "seek[] to avoid the seven circuits that have upheld [denial orders] for flavored e-cigarettes, [and] flock[] to the Fifth Circuit to obtain stays of FDA's decisions and then to challenge FDA's adverse marketing denial orders." Public Health, Medical, and Community Grps. Br. at 6. But—as the circumstances of *Amici*'s petitions for review suggest—to the extent such concerns exist, FDA overstates them and they are likely temporary in any event. FDA's concerns about forum shopping should not prevent the Court from dismissing the petition for certiorari.

Both Petitioners and *amici* in support of Petitioners suggest that IVPS and Youme are among petitioners in the Fifth Circuit that have engaged in forum shopping for judicial review of their denial orders. Pet. Br. at 10-11 n.2; Public Health, Medical, and Community Grps. Br. at 15-16. Both IVPS and Youme are incorporated and maintain their principal places of business in Shenzhen, China, and do not have any factories, offices, or employees in the United States. Because they do not "reside" and their principal places of business are not located in *any* circuit, IVPS and Youme both joined petitions for review in the circuit where significant resellers of their subject ENDS products are located. For the reasons addressed in II., below, the resellers were no doubt "adversely affected" by the denials of IVPS's and Youme's petitions, and so had statutory standing

under 21 U.S.C. § 387*l*(a)(1) to join with IVPS and Youme to file their respective petitions for review.

Indeed, *Amici*'s lack of intent to "forum shop" is underscored by the fact that both petitions—which do not involve flavor at all because the subject products consist solely of open-system devices—rely heavily not on the Fifth Circuit's decision in *Wages & White Lion Investments, L.L.C. v. FDA*, 90 F.4th 357 (5th Cir. 2024), cert. granted, No. 23-1038 (argued Dec. 2, 2024), but rather on the *D.C. Circuit's* decision in *Fontem US, LLC v. FDA*, 82 F.4th 1207 (D.C. Cir. 2023).[2]

Under FDA's interpretation of 21 U.S.C. § 387*l*(a)(1), the *only* venue available to IVPS and Youme—or, for that matter, any foreign applicant—would be the D.C. Circuit, meaning that, unlike for most domestic applicants, many foreign applicants would not even have the opportunity to seek review in a circuit in which their products are sold.[3] In any

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[2] Indeed, contrary to the suggestion on page 15 of the brief filed by *amici* supporting Petitioners that the D.C. Circuit has "repeatedly upheld similar [denial orders]" as that issued to IVPS, the D.C. Circuit actually *vacated* the denial order most analogous to that of IVPS. *Fontem*, 82 F.4th at 1217-22. *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022), has little relevance to IVPS's petition for review since IVPS's subject products do not contain any e-liquid, flavored or unflavored.

[3] While the products that are the subject of IVPS's and Youme's petitions for review are refillable, open-system devices that do not contain any e-liquid of any flavor, *Amici* anticipate that the circuit courts will continue to see more petitions for review of marketing denial orders for non-tobacco-flavored ENDS going forward. The District of Columbia prohibits the purchase, sale, and distribution of tobacco products, including ENDS, that

event, the supposed incentive to forum shop can be expected to be short-lived. Regardless of whether this Court ultimately affirms or reverses the Fifth Circuit's order regarding applications for flavored ENDS in *FDA v. Wages & White Lion Investments, L.L.C.*, No. 23-1038, presumably all of the circuits will consistently follow this Court's reasoning in resolving petitions for review involving flavored ENDS going forward, giving petitioners no strong incentive to favor the Fifth Circuit (or any other circuit) over the others.

As IVPS's and Youme's circumstances demonstrate, FDA's concerns about the prevalence of forum shopping are overstated and ignore other good faith reasons why petitioners may have filed in the Fifth Circuit. In any event, the Court's forthcoming decision in *Wages* should render such concerns temporary. Alleged incentives to engage in forum shopping should not prevent the Court from dismissing FDA's petition for lack of jurisdiction or as improvidently granted.

II. The Significant Civil and Criminal Penalties that Threaten Resellers of ENDS Subject to a Marketing Denial Order Underscore that Resellers Are Within the Zone of Interests

Title 21 U.S.C. § 387*l*(a)(1) provides, in relevant part, that:

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impart a "distinguishable taste or aroma other than tobacco." D.C. Code §§ 7-1721.08(a)(1), -1721.01(1), (1)(B).

> Not later than 30 days after . . . a denial of an application under section 387j(c) of this title, any person adversely affected by such . . . denial may file a petition for judicial review of such . . . denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

The term "adversely affected" echoes the language of the Administrative Procedure Act, which gives a right of review to a person "adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702.

Terms like "adversely affected" trigger a "zone-of-interests" test where a reviewing court must determine whether the party's injury falls within the "zone of interests sought to be protected by the statutory provision whose violation forms the legal basis" for the challenge. *Lujan v. Defenders of Wildlife*, 497 U.S. 871, 883 (1990). This test is "not especially demanding" and "lenient"; "the benefit of any doubt goes to the plaintiff." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130 (2014) (cleaned up). Indeed, the only way a plaintiff or petitioner fails to satisfy the zone-of-interests test is when its "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." *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399-400 (1987). This "zone-of-interests" test is effectively incorporated into judicial review under 21 U.S.C. § 387*l*(a)(1) by subsection (b)

of that statute, which provides in relevant part that "[u]pon the filing of the petition under subsection (a) for judicial review of a[n] . . . order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief . . . ."

While Petitioners contend that Respondents' view of the zone of interests for purposes of judicial review under 21 U.S.C. § 387*l*(a)(1) is limitless, Pet. Br. at 17-18, Petitioners' view is exaggerated. Because resellers *who have actually sold the products* are subject to potential penalties for reselling unauthorized tobacco products in violation of a marketing denial order, they undoubtedly fall within the proper bounds of the "zone of interests" of 21 U.S.C. § 387j(c), which governs the issuance of marketing granted orders and marketing denial orders. And even if resellers have not yet sold the subject products but desire to do so, they still have an interest that is adversely affected by FDA's arbitrary and capricious denial of a marketing application.

Under the TCA, a tobacco product—including an ENDS product—sold without a marketing granted order under 21 U.S.C. § 387j is considered "adulterated." 21 U.S.C. § 387b(6)(A). The introduction or delivery for introduction into interstate commerce of an "adulterated" tobacco product is a prohibited act. 21 U.S.C. § 331(a). Penalties for violations include imprisonment for a term of not more than one year and/or civil monetary penalties of up to $1,423,220. 21 U.S.C. § 333(a)(1),

(f)(9).[4] FDA and the Department of Justice can also seek civil injunctions against persons that sell adulterated tobacco products, 21 U.S.C. § 332(a), or seize their inventories, 21 U.S.C. § 334(a).

While, to date, *Amici* are unaware of the United States bringing a criminal prosecution for the sale of adulterated tobacco products, FDA and the Department of Justice have made liberal use of the civil monetary penalty provisions of the Federal Food, Drug, and Cosmetic Act to punish retailers and distributors engaged in sales of unauthorized ENDS products[5] and have also seized unauthorized ENDS products.[6] Moreover, in issuing marketing denial orders on ENDS products that were subject to FDA's deferred enforcement policy while the premarket applications were pending, FDA has from time to time

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[4] *See also* HHS, Annual Civil Monetary Penalties Inflation Adjustment, 89 Fed. Reg. 64815, 64817 (Aug. 8, 2024).

[5] *See* FDA, Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products, available at https://tinyurl.com/29t6k9cz (last visited Dec. 22, 2024) (observing that, to date, FDA "has issued [civil money penalty] complaints against 140 brick and mortar and 37 online retailers for selling unauthorized tobacco products for the maximum statutory amount"). Multiple district court lawsuits are pending challenging these civil money penalty complaints decided by an administrative law judge under *SEC v. Jarkesy*, __ U.S. ___, 144 S. Ct. 2117 (2024). *See*, *e.g.*, *Vape Central Group, LLC v. FDA*, Case No. 1:24-cv-03354 (D.D.C.) (filed Nov. 27, 2024).

[6] FDA, Press Release, FDA, DOJ Seize Over $700,000 Worth of Unauthorized E-Cigarettes (Apr. 30, 2024), available at https://tinyurl.com/bdf8sckv (describing seizure of unauthorized ENDS from California distributors).

underscored that retailers are prohibited from selling the unauthorized products and explicitly threatened enforcement actions.[7]

In support of their argument that resellers fall outside the zone of interests that Congress intended 21 U.S.C. § 387j(c) to protect, Petitioners contend that the type of "order" referenced therein "regulates only the applicant." Pet. Br. at 14. But, as the foregoing discussion demonstrates, this could not be further from the truth; if a marketing denial order did not "regulate" resellers, FDA would have no basis to, *inter alia*, threaten to "ensure compliance by distributors and retailers" when announcing a marketing denial order. *See* n.7, *supra*. Just as a marketing denial order grants resellers the legal right to sell the subject tobacco products, given FDA's deferred enforcement scheme governing ENDS products, the issuance of a marketing denial order also strips them of that ability—at least in fact, even if not in law.[8] Nor are resellers' interests "adequately protected" by a

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[7] *See*, *e.g.*, FDA, Press Release, FDA Denies Authorization to Market JUUL Products (June 23, 2022), available at https://tinyurl.com/4vezsaeu ("In addition to ensuring that JUUL complies with this order, as with unauthorized products generally, the FDA intends to ensure compliance by distributors and retailers.").

[8] While FDA suggests that resellers' lack of a *legal* right to sell unauthorized ENDS products is fatal to Respondents' proposed construction of 21 U.S.C. § 387*l*(a)(1), Pet. Br. at 22, FDA overlooks that one of the principal reasons for its policy of deferred enforcement is the agency's own failure to have *ever* complied with the TCA's requirement that FDA render a marketing determination within 180 days of receipt of the application. *See* 21 U.S.C. § 387j(c)(1)(A).

manufacturer—particularly a foreign one; no manufacturer can substitute itself in for a reseller when FDA filed a complaint for civil money penalties, seeks a civil injunction, or pursues criminal charges for selling unauthorized tobacco products.

The very fact of FDA's deferred enforcement policy and the existence of unauthorized ENDS already on the market without marketing granted orders undercuts FDA's concern that retailers may not necessarily know about the existence of an application. Pet. Br. at 19. Manufacturers have every incentive to communicate to resellers when their ENDS products fall within the parameters of FDA's deferred enforcement policy so as to maximize sales, not keep that information close to the vest.

Resellers are within the zone of interests sought to be protected through the judicial review mechanism provided by 21 U.S.C. § 387*l*(a)(1).

III. Only a Single Petitioner Must Establish Venue for a Joint Petition

On the issue of whether only a single petitioner, as opposed to all petitioners, need establish venue for a joint petition, *Amici* will not rehash Respondents' and *amicus* Chamber of Commerce's extensive presentation of relevant authorities. *Amici* do, however, wish to draw the Court's attention to a patent incongruity in FDA's position regarding venue for joint petitions.

Title 21 U.S.C. § 387j(c)(1) creates only two possible outcomes of an application for premarket authorization: either FDA will "issue an order that the new product may be introduced or delivered for

introduction into interstate commerce" or FDA will "issue an order that the new product may not be introduced or delivered for introduction into interstate commerce."

Despite the clear statutory mandate to issue an "order" in either event, in its final regulation governing premarket applications for tobacco products, FDA created for itself two other options for denying premarket applications prior to their entering substantive scientific review: a so-called "refuse to accept" letter and a so-called "refuse to file" letter. *See* 21 C.F.R. § 1114.27(a)(3), (b)(2).

Upon receiving a "refuse to accept" letter that it believed to be arbitrary and capricious, an applicant filed a petition for review under 21 U.S.C. § 387*l*(a)(1) with the Fifth Circuit in 2022. *See Boomtown Vapor, L.L.C. v. FDA*, No. 22-60467 (5th Cir. filed Aug. 22, 2022). FDA moved to dismiss the petition on the ground that the agency's "refuse to accept" letter was not a "denial of an application under section 387j(c)" as required to vest jurisdiction in the circuit court pursuant to 21 U.S.C. § 387*l*(a)(1)(B). The Fifth Circuit agreed and dismissed the case for lack of jurisdiction shortly thereafter. *See* Doc. No. 33 in *Boomtown Vapor, L.L.C. v. FDA*, No. 22-60467 (5th Cir. Nov. 1, 2022). The upshot of that order is that persons "adversely affected or aggrieved" by such "refuse to accept" or "refuse to file" letters must bring civil actions in district court under the Administrative Procedure Act to obtain judicial review of such determinations.

However, as Respondents emphasize, Resp. Br. at 41, federal courts have uniformly held for decades

that under the general venue statute governing district court actions against the federal government, 28 U.S.C. § 1391(e)(1)(C), venue can be established by any plaintiff. *Sidney Coal Co. v. Soc. Sec. Admin.*, 427 F.3d 336, 344-45 (6th Cir. 2005). Thus, a manufacturer that receives a "refuse to accept" or "refuse to file" letter can join with a reseller of the subject products to file suit against FDA in the district court corresponding to the reseller's location and venue will properly lay in that district under Section 1391(e)(1)(C). But, under FDA's interpretation of 21 U.S.C. § 387*l*(a)(1), venue will not properly lay in the circuit court corresponding to the reseller's principal place of business in the event that the application proceeds further in the FDA review process and results in a marketing denial order under 21 U.S.C. § 387j(c)(1)(A)(ii). The incongruity of this result reflects the incongruity of FDA's position both with the statutory scheme and with the agency's own regulations.

To the extent it does not find that FDA waived the issue, the Court should conclude that, consistent with the Hobbs Act, 28 U.S.C. § 2343 and the general venue statute, 28 U.S.C. § 1391(e)(1)(C), only a single petitioner need establish venue in a circuit for a joint petition to proceed under 21 U.S.C. § 387*l*(a)(1).

CONCLUSION

The Court should dismiss the petition for certiorari for lack of jurisdiction or as improvidently granted. In the event the Court finds that it properly has jurisdiction, the Court should affirm the Fifth Circuit's order denying dismissal or transfer.

Respectfully submitted.

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