APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 23-60037

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

v.

FOOD & DRUG ADMINISTRATION; ROBERT CALIFF, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE UNITED STATES FOOD & DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENTS

CONSOLIDATED WITH

No. 23-60128

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

v.

UNITED STATES FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, COMMISSIONER OF FOOD AND DRUGS; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENTS

CONSOLIDATED WITH

No. 23-60545

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

v.

FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, COMMISSIONER OF FOOD AND DRUGS; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENTS

Filed: Feb. 2, 2024

Petition for Review from an Order of the Food & Drug Administration
Agency No. PM0000973
Agency No. PM0000637
Agency No. PM0000713

UNPUBLISHED ORDER

Before JONES, HIGGINSON, and HO, *Circuit Judges*.

PER CURIAM:

In its latest Motion to Dismiss or Transfer, the Food and Drug Administration ("FDA") argues that Petitioners R.J. Reynolds Vapor Co. et al. do not meet the requirements of the Family Smoking Prevention and Tobacco Control Act for filing their petition here in the Fifth Circuit. This Act provides that "any person ad-

versely 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*(a)(1). We DENY the Motion. All the Petitioners are "person[s] adversely affected" under the Act, and two of the Petitioners, Avail Vapor Texas and the Mississippi Petroleum Marketers and Convenience Stores Association, have their principal places of business here in the Fifth Circuit.

I.

This Motion is the latest stage in an ongoing saga between the R.J. Reynolds's vape devices manufacturing and the FDA. The FDA has denied R.J. Reynolds's applications to market various e-cigarettes. *See* 21 U.S.C. § 387j(a)(1)-(2). At issue in this case, No. 23-60545, are menthol- and berry-flavored "Alto" e-cigarettes. Only the menthol flavor is currently on the market. Previous stay orders in the lead case, No. 23-60037, have concerned menthol-flavored "Vibe" and "Solo" e-cigarettes. This case was consolidated with No. 23-60037 in an unpublished order on October 19, 2023. In this Motion, the FDA renews arguments it raised in its previous motion to transfer, which this court denied in a one-sentence, unpublished per curiam opinion on June 27, 2023. This court has also already held that venue is proper. *R.J. Reynolds Vapor Co. v.* FDA, 65 F.4th 182, 188 (5th Cir. 2023).

II.

This court remains bound by our holding in the published opinion that venue is proper in this circuit. *R.J. Reynolds Vapor Co*, 65 F.4th at 188. The only differences between that earlier case and this one is that another R.J. Reynolds product was involved, and at least one different distributor. The FDA did not make its present statutory arguments at that time. Stare decisis governs venue here so long as the distributors have standing, which they do.

The FDA's arguments to the contrary are unavailing. Its arguments that the retail Petitioners could not lawfully have been selling the e-cigarettes without prior approval does not show that the Petitioners lose standing. The Tobacco Control Act gives standing to "*any* person adversely affected." 21 U.S.C. § 387*l*(a)(1) (emphasis added). Retail Petitioner Avail Vapor Texas submitted a declaration that "[i]f Avail were not allowed to sell Vuse products, Vuse Inspiration Store would have to close, and Avail would cease its business operations." The Tobacco Control Act grants the Petitioners statutory standing to challenge FDA decisions that affect them.

Similarly, the FDA's argument that the Act states elsewhere that only the "holder of [the] application" can challenge a marketing *withdrawal* order, 21 U.S.C. § 387j(d)(2), has no bearing on who can challenge a *denial* order. "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, 104 S. Ct. 296 (1983). Here, Congress

did not limit access to the courts for those challenging a *denial* order in the same way it did for those challenging a *withdrawal* order. If the FDA disagrees with Congress's policy choice in so drafting the Tobacco Control Act, its concerns are better directed to Congress than to this court. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 462, 122 S. Ct. 941 (2002) ("We will not alter the text in order to satisfy the policy preferences of the Commissioner. These are battles that should be fought among the political branches and the industry.").

The FDA's accusation of forum shopping fails because the retail entities are undisputedly in this circuit, and they provided declarations that they would "cease business operations" if the FDA's denial order went into effect. Its arguments relating to the confidentiality provisions are not probative of the meaning of the phrase "adversely affected" in a different portion of the Act. And its argument that the Tobacco Control Act should be read to favor the protection of the public from tobacco over the interests of the retail Petitioners fails in light of the statutory purpose of "continu[ing] to permit the sale of tobacco products to adults." *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776, 1782.

III.

All the Petitioners have statutory standing as "person[s] adversely affected" under the Tobacco Control Act, and both Avail Vapor Texas and the Mississippi Petroleum Marketers and Convenience Stores Association have their principal place of business in the Fifth Circuit. We therefore DENY the FDA's Motion to Transfer or Dismiss.

STEPHEN A. HIGGINSON, *Circuit Judge*:

In the above-captioned consolidated cases before us —Case Nos. 23-60037, 23-60128, and 23-60545—are three pending motions: (1) R.J. Reynolds Vapor Company's (Reynolds) motion for stay pending review in Case No. 23-60545 (concerning Reynolds's premarket application for its "Alto" product); (2) the FDA's motion to dismiss or transfer Case No. 23-60545; and (3) the FDA's motion to lift the previously-granted stays of proceedings in Case Nos. 23-60037 and 23-60128 (concerning Reynolds's premarket application for its "Vibe" and "Solo" products, respectively).

A motions panel of this court previously accepted that venue was proper in Case Nos. 23-60037 and 23-60128 because "*a* petitioner"—Mississippi Petroleum Marketers and Convenience Stores Association—"has its 'principal place of business here'" in the Fifth Circuit, while "at least one" *other* petitioner, Reynolds, "has standing." *R.J. Reynolds Vapor Company v. FDA*, 65 F.4th 182, 188 (5th Cir. 2023) (emphasis added). In its pending motion to dismiss or transfer, the FDA contends this "mix-and-match approach" is impermissible because it violates the requirements set forth in 21 U.S.C. § 387l(a) and is at odds with the structure and purpose of the Tobacco Control Act (TCA).

While Petitioners are correct that the FDA has unsuccessfully raised these arguments regarding venue in prior related matters, the FDA is equally correct in underscoring that neither of the two prior motions panels addressed the government's arguments on the merits. And although today's panel does engage, it fails to address the principal defect with Petitioners' argument: its position would render the venue limitations in 21

U.S.C. § 387l(a)(1) surplusage. This expansive reading of venue cannot seem to be reconciled with the other provisions of the TCA—including retailers' inability to sue when marketing authorization is withdrawn, *see* 21 U.S.C. § 387j(d)(2), which naturally would more directly impair their interests; and the confidentiality requirements regarding the information contained in retailers' marketing applications, *see, e.g.*, 21 U.S.C. § 387f(c). Nor, ultimately, can Reynolds' position be harmonized with the purpose of the TCA, which the panel majority characterizes as "continu[ing] to permit the sale of tobacco products to adults," truncating the remainder of the text in that clause—"in conjunction with measures to ensure that they are not sold or accessible to underage purchasers"—as well as skipping over the nine other stated purposes, including "to ensure that the [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco" and "to authorize the [FDA] to set national standards controlling the manufacture of tobacco products." Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776, 1781-82.

A fair reading of the text and the purpose of the TCA compels me to dissent. I would transfer this case to either the D.C. Circuit or the Fourth Circuit. Those two courts have already ruled on questions central to these cases in a manner that is adverse to Reynolds' position. *See Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022); *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022), *cert. denied*, No. 22-1112, 2023 WL 6558399 (Oct. 10, 2023). By contrast, our court had as well, but vacated and effectively reversed that decision *en banc*, in conflict with the majority of circuits to have addressed

the same issue. *See Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 392 (5th Cir. 2024) (Haynes, J., dissenting).