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 PUBLIC HEALTH, MEDICAL, AND COMMUNITY GROUPS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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Amici, a group of medical, public health, and community organizations, submit this brief in support of Petitioner Food and Drug Administration ("FDA") and urge the Court to reverse the judgment of the United States Court of Appeals for the Fifth Circuit. If allowed to stand, that judgment, which effectively nullifies the venue restrictions in the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (2009), codified at 21 U.S.C. § 387 *et seq.*, ("Tobacco Control Act"), will inflict great harm to public health by undermining FDA's efforts to protect youth from the health harms of flavored e-cigarette products. The Fifth Circuit's judgment has allowed Respondent R.J. Reynolds Vapor Co. ("Reynolds") and other e-cigarette manufacturers to improperly steer their lawsuits challenging FDA denial orders for flavored e-cigarettes to the Fifth Circuit, to obtain stays of FDA's denial orders and thereby continue marketing their unauthorized, addictive, and harmful flavored e-cigarettes, fueling persistently high rates of youth usage.[1]

INTERESTS OF *AMICI CURIAE*

Amici are eleven national and state medical, public health, and community organizations: American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association,

[1] No counsel for any party authored this brief in whole or in part; neither the parties nor their counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no person—other than *amici* or their counsel—contributed money that was intended to fund the preparation or submission of this brief.

American Lung Association, American Medical Association, American Thoracic Society, Campaign for Tobacco-Free Kids, Louisiana State Medical Society, Parents Against Vaping E-cigarettes, and Truth Initiative. The *amici* include organizations with programs that urge users to quit use of tobacco products, as well as groups representing physicians who counsel young patients and their parents about the hazards of tobacco use and families struggling to free young people from nicotine addiction. These organizations have substantial expertise in the health harms of tobacco products, including electronic nicotine delivery systems ("ENDS" or "e-cigarettes"), and work on a daily basis to reduce those harms. Some of the a*mici* have filed more than 20 *amicus* briefs supporting FDA premarket review decisions on flavored e-cigarette products in the Courts of Appeals, as well as in this Court.[2] *Amici* therefore have a strong and continuing interest in ensuring that the venue provisions in the Tobacco Control Act are enforced, to protect against the forum shopping by Reynolds and other e-cigarette manufacturers. Accordingly, *amici* have a direct and immediate interest in this Court's reversal of the Fifth Circuit decision.

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[2] *See, e.g.*, Br. of Public Health, Medical, and Community Groups as *Amici Curiae* Supp. Pet'r, *FDA* v. *Wages & White Lions Invs., L.L.C.*, No. 23-1038 (Aug. 30, 2024); Br. of Public Health, Medical, and Community Groups as *Amici Curiae* Supp. Pet'r, *Wages*, No. 23-1038 (Apr. 18, 2024) (in support of petition for cert.); *see also* Br. of *Amici Curiae* Medical, Public Health, Civil Rights, and Community Groups Supp. Resp't's Opp'n to Pet'rs' Mot. for a Stay, No. 23-60545, *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182 (5th Cir. 2023), C.A. Doc. 93-1 (filed Oct. 31, 2023).

INTRODUCTION AND SUMMARY OF ARGUMENT

In *FDA* v. *Brown & Williamson Tobacco Corp.*, this Court recognized that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." 529 U.S. 120, 161 (2000). Indeed, use of tobacco products remains the leading cause of preventable death in the United States, resulting in 480,000 deaths per year.[3]

It has long been understood that almost all new tobacco users begin their addiction in their youth: 90% percent of adult smokers begin smoking in their teens.[4] This pattern applies to e-cigarettes, as the D.C. Circuit noted in a recent e-cigarette case where it declared that "[b]usinesses seeking to make a profit selling tobacco products . . . face powerful economic incentives to reach younger customers." *Prohibition Juice Co.* v. *FDA*, 45 F.4th 8, 12 (D.C. Cir. 2022).

It has also been long understood that flavors are essential to the tobacco companies' ability to

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[3] OFFICE OF THE SURGEON GENERAL ("OSG"), U.S. DEP'T OF HEALTH & HUMAN SERVS. ("HHS"), THE HEALTH CONSEQUENCES OF SMOKING - 50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL, *Executive Summary* 2 (2014), https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf.

[4] OSG, HHS, THE HEALTH CONSEQUENCES OF SMOKING - 50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 779-80 (2014), https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.

successfully market its products to young people. As FDA has found, "the availability of tobacco products with flavors at these developmental stages attracts youth to initiate use of tobacco products and may result in lifelong use."[5]

E-cigarettes have been the most popular tobacco product among youth since 2014, with youth usage rising to epidemic levels between 2018 and 2020. *See infra* 15-16 & n.3. Today, nearly 90% of middle and high school users of e-cigarettes use flavored (*i.e.*, non-tobacco-flavored) products.[6] As FDA has denied applications for marketing authorization of flavored e-cigarettes in recent years, youth e-cigarette use has declined, but remains unacceptably high today, with over 1.6 million middle and high school students currently using these products.[7]

E-cigarettes pose unique health risks to youth, as adolescent brains are particularly susceptible to nicotine's effects due to ongoing neural development.[8]

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[5] *Regulation of Flavors in Tobacco Products*, Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 12,294, 12,295 (Mar. 21, 2018) (to be codified at 21 C.F.R., pts. 1100, 1140, and 1143).

[6] Eunice Park-Lee et al. Notes from the Field: *E-Cigarette and Nicotine Pouch Use Among Middle and High School Students – United States, 2024*, 73 MORBIDITY & MORTALITY WKLY. REP. 774, 774 (2024), https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf.

[7] *Id*.

[8] FDA, TECHNICAL PROJECT LEAD (TPL) REVIEW OF PMTAS 8 (Sept. 17, 2021), https://www.fda.gov/media/152504/download [hereinafter FDA TECHNICAL REVIEW].

Adolescents are thus especially vulnerable to nicotine addiction, which can lead to permanent effects on the developing brain.[9] According to the U.S. Surgeon General, "[n]icotine exposure during adolescence can impact learning, memory and attention" and "can also increase risk for future addiction to other drugs."[10] E-cigarettes also create a substantial risk of progression to cigarette smoking, and thereby threaten decades of progress against youth smoking.[11] The Surgeon General has warned that "[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe."[12]

By effectively nullifying the Tobacco Control Act's venue provision, the decision below cripples FDA's ability to protect children from e-cigarettes. The Act allows an "adversely affected" person to obtain judicial review in the D.C. Circuit or the circuit in which the "person resides or has their principal place of business." 21 U.S.C. § 387l(a)(1)(B). Nevertheless, the Fifth Circuit held that a manufacturer located

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[9] *Id.* at 9.

[10] OSG, HHS, SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 2 (2018), https://web.archive.org/web/20181220114136/https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf.

[11] FDA TECHNICAL REVIEW 8-9 (citing NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, MEDICINE, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (2018)).

[12] OSG, HHS, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 5 (2016), https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf.

outside the circuit may obtain review there, as long as its petition is joined by a retail seller of the manufacturer's product that is located within the circuit. Seeking to avoid the seven circuits that have upheld MDOs for flavored e-cigarettes, e-cigarette companies have exploited this ruling by flocking to the Fifth Circuit to obtain stays of FDA's decisions and then to challenge FDA's adverse marketing denial orders ("MDOs"). Such results undermine FDA's e-cigarette regulatory authority, which experience shows has been critical to reducing youth use of these addictive and harmful products.

ARGUMENT

I. Flavored E-Cigarettes, Like Reynolds' Vuse Products, Are Harmful to Youth.

The use of tobacco products causes "pediatric disease of considerable proportions."[13] Today, youth tobacco use is primarily driven by flavored e-cigarettes,[14] which "especially appeal to children[,]" *Breeze Smoke, L.L.C.* v. *FDA*, 18 F.4th 499, 505 (6th Cir. 2021), and pose a serious risk of addiction and other health harms.

A. Flavored E-Cigarettes Attract Youth.

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[13] Tobacco Control Act Section 2(1), 21 U.S.C. § 387(1) (2009).

[14] CENTERS FOR DISEASE CONTROL & PREVENTION: SMOKING & TOBACCO USE, E-CIGARETTE USE AMONG YOUTH (Oct. 17, 2024), https://www.cdc.gov/tobacco/e-cigarettes/youth.html.

E-cigarettes have been the most commonly used tobacco product among youth since 2014.[15] In 2024, over 1.6 million youth, including 7.8% of high schoolers, reported current e-cigarette use.[16] Vuse, the brand at issue here, is the fourth most popular e-cigarette brand among youth.[17] In 2024, roughly 210,000 middle and high schoolers (13.7% of all youth e-cigarette users) reported use of a Vuse product in the past month.[18]

Flavored e-cigarette products, including Reynolds' Vuse products, are fueling these high rates of youth usage. According to a 2020 Surgeon General Report, "the role of flavors in promoting initiation of tobacco product use among youth is well established . . . and appealing flavor is cited by youth as one of the main reasons for using e-cigarettes."[19] In 2024, 87.6% of middle and high school e-cigarette users reported using a flavored product.[20] Over 93% of youth users reported that their first e-cigarette was flavored and

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[15] Ahmed Jamal et al., *Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2024*, 73 MORBIDITY & MORTALITY WKLY. REP. 917, 920 (2024), https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7341a2-H.pdf.

[16] Park-Lee et al., *supra* note 6, at 774.

[17] *Id.* at 775 tbl.

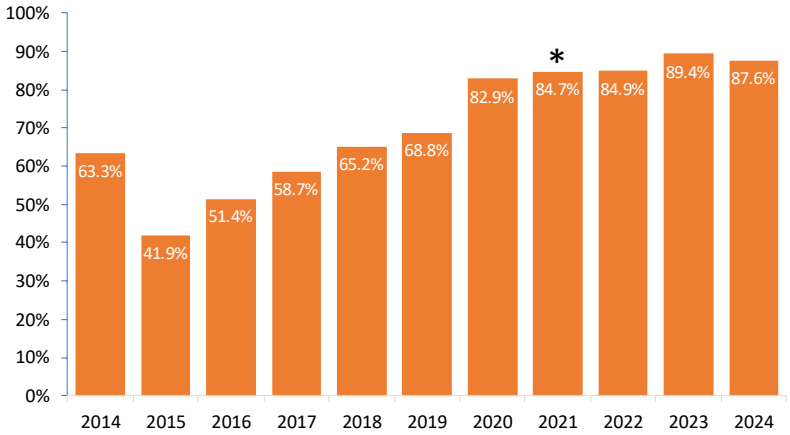
[18] *Id.*

[19] OSG, HHS, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 611 (2020), https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.

[20] Park-Lee et al., *supra* note 6, at 774.

71% of current youth e-cigarette users reported using e-cigarettes "because they come in flavors I like."[21] As the D.C. Circuit observed in upholding several MDOs for flavored e-cigarettes, "[f]lavored tobacco products lie at the heart of the problem" of youth e-cigarette use. *Prohibition Juice Co.*, 45 F.4th at 11. Moreover, as Figure 1 demonstrates, the prevalence of youth usage of flavored products has steadily risen over the last decade.

Figure 1: Proportion of Middle and High School E-Cigarette Users Who Use Flavored Products, 2014-2024



*2021 NYTS data is not comparable to other years due to methodological differences.

Source: CDC, National Youth Tobacco Survey (NYTS)

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[21] FDA TECHNICAL REVIEW 6 (citing Brian L. Rostron et al., *Prevalence and Reasons for Use of Flavored Cigars and ENDS among US Youth and Adults: Estimates from Wave 4 of the PATH Study, 2016-2017*, 44 AM. J. HEALTH BEHAV. 76 (2020)).

B. Flavored E-Cigarettes Are Highly Addictive, Particularly to Youth.

Reynolds' flavored Vuse products and other e-cigarettes pose a serious threat of addiction, especially to youth. These products contain nicotine, which is "among the most addictive substances used by humans." *Nicopure Labs, L.L.C.* v. *FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). FDA has noted the factors that make "[y]outh and young adults brains . . . more vulnerable to nicotine's effects than the adult brain due to ongoing neural development."[22] FDA has found that the high prevalence of youth e-cigarette use has increased nicotine dependence among young people.[23] As shown in Figure 2 below, frequent and daily use among high school students has remained at high levels over the last several years. In 2024, 42.1% of high school e-cigarette users reported using e-cigarettes on at least 20 of the past 30 days, and 29.7% reported *daily* use.[24] The data show that high schoolers who are using e-cigarettes use them more frequently, indicating that the level of addiction among these students has been increasing.

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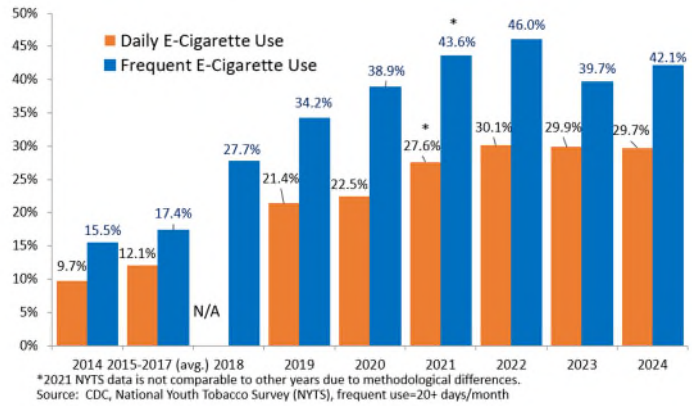
[22] FDA TECHNICAL REVIEW 8.

[23] *Id.*

[24] Park-Lee et al., *supra* note 6, at 775 tbl.

Figure 2: Daily & Frequent (20+ days/month) E-Cigarette Use Among High School E-Cigarette Users 2014-2024



In upholding an MDO for flavored e-cigarettes, the D.C. Circuit summarized the evidence on flavors, nicotine, and youth: "A vast body of scientific evidence shows that flavors encourage youth to try e-cigarettes, and together with the nicotine, keep them coming back." *Prohibition Juice Co.*, 45 F.4th at 11.

C. E-Cigarettes Harm the Health of Youth.

In decisions denying marketing authorization for flavored e-cigarettes, FDA has found that youth exposure to nicotine "can induce short and long-term deficits in attention, learning, and memory."[25] The Agency has also cited other health harms from e-cigarettes, including "associations between ENDS use and self-reported history of asthma, chronic

[25] FDA TECHNICAL REVIEW 8.

bronchitis, emphysema, or chronic obstructive pulmonary disease with increased ENDS use (i.e., daily use) relating to increased odds of disease."[26]

Use of e-cigarettes may also function as a gateway to the use of traditional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A 2018 report by the National Academies of Sciences, Engineering, and Medicine found "substantial evidence that e-cigarette use increases [the] risk of ever using combustible tobacco cigarettes among youth and young adults."[27] A nationally representative analysis found that from 2013 to 2016, youth using e-cigarettes were more than four times more likely to try combustible cigarettes and nearly three times more likely to be current users of combustible cigarettes.[28]

By enabling out-of-circuit e-cigarette manufacturers to improperly steer their MDO challenges to the Fifth Circuit, which has repeatedly stayed the challenged MDOs, s*ee infra* 12, the venue decision below allows Reynolds' Vuse products and

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[26] *Id.* at 9.

[27] NATIONAL ACADEMIES OF SCIENCES, ENGINEERING & MEDICINE, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

[28] Kaitlyn M. Berry et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2 JAMA NETWORK OPEN 1, 7 (Feb. 1, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425.

other youth-appealing, addictive, and harmful flavored e-cigarettes to remain on the market despite a finding by FDA that such products do not meet the statutory public health standard for marketing authorization. Such a result does grievous harm to public health, particularly to the health of young people.

II. The Fifth Circuit's Nullification of the Venue Restrictions in the Tobacco Control Act Creates a Loophole Allowing Companies to Sell Harmful, Unauthorized Flavored E-Cigarettes.

The Fifth Circuit is an outlier in terms of how it has decided challenges against materially similar FDA denial orders for flavored e-cigarettes. Of the nine courts of appeals to decide such cases, seven have upheld the MDOs. *Magellan Tech., Inc.* v. *FDA*, 70 F.4th 622 (2d Cir. 2023), petition for cert. pending, No. 23-799 (filed Jan. 22, 2024); *Liquid Labs L.L.C.* v. *FDA*, 52 F.4th 533 (3d Cir. 2022); *Avail Vapor, L.L.C.* v. *FDA*, 55 F.4th 409 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023); *Gripum, L.L.C.* v. *FDA*, 47 F.4th 553 (7th Cir. 2022), cert. denied, 143 S. Ct. 2458 (2023); *Lotus Vaping Techs., L.L.C.* v. *FDA*, 73 F.4th 657 (9th Cir. 2023), petition for cert. pending, No. 23-871 (filed Feb. 9, 2024); *Electric Clouds, Inc.* v. *FDA*, 94 F.4th 950 (10th Cir. 2024); *Prohibition Juice Co.*, 45 F.4th 8 (D.C. Cir. 2022). One court, the Eleventh Circuit, vacated a marketing denial order on what it described as "procedural" grounds. *Bidi Vapor L.L.C.* v. *FDA*, 47 F.4th 1191, 1206 (11th Cir. 2022). In contrast, the *en banc* Fifth Circuit has vacated at least seven companies' MDOs, on grounds identical to those

rejected by these other circuit courts. *See, e.g., Wages & White Lion Invs., L.L.C.* v. *FDA*, 90 F.4th 357 (2024) (vacating MDOs issued to two companies); *SWT Global Supply, Inc.* v. *FDA*, No. 21-60762, 2024 WL 3595387 (5th Cir. July 31, 2024), petition for cert. pending, No. 24-474 (filed Oct. 29, 2024) (vacating MDOs issued to five companies). Not surprisingly, e-cigarette companies have concluded that the Fifth Circuit is a uniquely receptive forum in which to challenge MDOs for flavored e-cigarettes.

Seeking to take advantage of the Fifth Circuit's permissive venue ruling, Reynolds steered its lawsuits challenging the Vuse MDOs to that court, rather than the two circuits in which the statute allows Reynolds to properly sue—the D.C. Circuit and Reynolds' "home" Fourth Circuit, both of which had already rejected similar challenges. *See Prohibition Juice Co.*, 45 F.4th 8 (D.C. Cir. 2022); *Avail Vapor,* 55 F.4th 409 (4th Cir. 2022). Reynolds attempted to satisfy the statutory venue requirement by joining sellers based in the Fifth Circuit (a Texas convenience store and Mississippi trade association). Over the government's objection, the Fifth Circuit allowed this practice. *See* Pet. App. 1a-8a.

As it has done with other flavored e-cigarette denial orders, the Fifth Circuit also stayed the Vuse MDOs. *See R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182, 195 (5th Cir. 2023) (Vuse Vibe MDO); *Reynolds*, No. 23-60128, C.A. Doc. 221-2, at 1-3 (Feb. 2, 2024) (Vuse Solo MDO); *Reynolds*, No. 23-60037, C.A. Doc. 305-2, at 1-3 (Feb. 2, 2024) (Vuse Alto MDO). Reynolds, like other similarly situated companies, has

relied on these stays to continue selling the products subject to the MDOs.

Unsurprisingly, other out-of-circuit manufacturers of the leading e-cigarettes, including those most appealing to youth, have followed Reynolds' strategy of satisfying the Fifth Circuit's unique venue ruling by adding a seller located in the Fifth Circuit. For example, Fontem U.S. L.L.C., another North Carolina-based manufacturer, filed its petition challenging denial orders for several of its flavored blu e-cigarettes, which is among the leading brands used by youth,[29] in the Fifth Circuit rather than in the D.C. or Fourth Circuits. Pet. for Review, *Corr-Williams Co.* v. *FDA*, No. 24-60068 (5th Cir. Feb. 8, 2024), C.A. Doc. 1-1; Letter (Feb. 12, 2024), C.A. Doc. 28 (referring to FDA press release noting that products subject to MDO are flavored).[30] Fontem went forum-shopping after it lost its challenge, in the D.C Circuit, to a separate but similar MDO that the FDA issued for some of its other flavored blu products. *Fontem US, L.L.C.* v. *FDA*, 82 F.4th 1207, 1216-17 (D.C. Cir. 2023).

Similarly, Michigan-based Breeze Smoke, L.L.C., manufacturer of the second most popular e-cigarette brand among youth,[31] added a Texas-based wholesaler and filed a petition in the Fifth Circuit, rather than in its home circuit or the D.C. Circuit,

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[29] Park-Lee et al., *supra* note 6, at 775 tbl.

[30] The Fifth Circuit subsequently issued a temporary administrative stay of the denial order, which remains in effect today. Order (Feb. 14, 2024), C.A. Doc. 32-1.

[31] Park-Lee et al., *supra* note 6, at 775 tbl.

challenging a MDO for some of its flavored e-cigarettes, including the Strawberry Kiwi and Peach Soda flavored products. Pet. for Review at 1-2 & Ex. A at 4-6, *Breeze Smoke, L.L.C.* v. *FDA*, No. 24-60304 (5th Cir. June 14, 2024). Like Fontem, Breeze Smoke went forum-shopping only after it received an adverse decision from another circuit in an earlier MDO challenge. In 2021—before the Fifth Circuit had considered the present venue issue—Breeze Smoke filed a petition in its home Sixth Circuit challenging an earlier MDO applicable to its other flavored e-cigarettes. *Breeze Smoke, L.L.C.* v. *FDA*, 18 F.4th 499 (6th Cir. 2021), stay denied, 142 S. Ct. 638 (2021). Breeze Smoke later dropped its challenge in the Sixth Circuit after the Sixth Circuit and this Court declined to stay the MDO. *Id.*; Order, No. 21-3902, C.A. Doc. 40 (6th Cir. Feb. 11, 2022).

The Chinese-based manufacturer of SMOK, the eighth most popular e-cigarette brand among youth,[32] has also taken advantage of the Fifth Circuit's nullification of the statutory venue restrictions. It added a distributor located in the Fifth Circuit and filed suit in that court, rather than in the D.C. Circuit, the TCA's default venue, which has repeatedly upheld similar MDOs. *See* Pet. for Review, *Shenzhen IVPS Tech. Co.* v. *FDA*, No. 24-60032 (5th Cir. Jan. 19, 2024), C.A. Doc. 1-1; *Fontem*, 82 F.4th at 1216-17 (D.C Cir. 2023); *Prohibition Juice Co.*, 45 F.4th 8 (D.C. Cir. 2022); *see also* Pet. for Review, *Shenzhen Youme Info. Tech. Co.* v. *FDA*, No. 24-60060 (5th Cir. Feb. 5, 2024), C.A. Doc. 1-1 (Chinese-based manufacturer of SMOK

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[32] *Id.*

e-cigarette brand added local retailer and sued in Fifth Circuit).

If the Court affirms the Fifth Circuit's decision, manufacturers of the most harmful, youth-appealing flavored e-cigarettes—no matter where the companies are located—will continue to direct their denial order challenges to the Fifth Circuit. Meanwhile, these products will continue to addict and harm young people.

The decision below has allowed the venue provision in the Tobacco Control Act to undermine the purpose of the Act's premarket review provision: to prevent the introduction of new tobacco products unless they are shown to be appropriate for protection of the public health. *See Nicopure*, 944 F.3d at 271 ("Congress . . . took the then-current tobacco product market as a baseline from which to ratchet down tobacco products' harms to public health."). To prevent the continued marketing of unauthorized e-cigarettes that FDA has found pose an unacceptable risk to youth, this Court must give effect to the Tobacco Control Act's restrictive venue provision.

III. Experience Shows that Preserving FDA Authority to Regulate Flavored E-Cigarettes Is Critical for Public Health.

FDA regulatory actions against flavored e-cigarettes have yielded important public health benefits, particularly in reducing e-cigarette use among young people. For years after 2016, when FDA first asserted its regulatory jurisdiction over e-

cigarettes,[33] these products were allowed to remain on the market with no risk of regulatory enforcement, even though they lacked the required FDA premarket authorization. *See generally Am. Acad. of Pediatrics* v. *FDA*, 379 F. Supp. 3d 461 (D. Md. 2019), appeal dismissed sub nom. *In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020) (vacating FDA guidance that suspended premarket review requirement for e-cigarette products for four or more years and deferred enforcement during that period). Unsurprisingly, during this regulatory "holiday," youth use of e-cigarettes reached "epidemic" levels. *Am. Acad. of Pediatrics*, 379 F. Supp. 3d at 492-93. High school use rates increased by 143% between 2016 and 2019 (from 11.3% to 27.5%).[34]

Yet also unsurprisingly, when FDA's regulatory oversight increased, youth use began to subside. Between 2020 and 2023, high school e-cigarette use prevalence declined from 19.6% to 10%.[35] The decline

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[33] *See Deeming Tobacco Products To Be Subject to the Federal, Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R., pts. 1100, 1140, and 1143).

[34] Teresa W. Wang et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students – United States, 2019*, 68 MORBIDITY & MORTALITY WKLY. REP. 1, 5 (2019), https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf; Ahmed Jamal et al., *Tobacco Use Among Middle and High School Students – United States, 2011-2016,* 66 MORBIDITY & MORTALITY WKLY. REP. 597, 597 (2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6623a1.pdf.

[35] Jamal et al., *supra* note 15, at 920; Andrea S. Gentzke, *Tobacco Product Use Among Middle and High School Students – United*

began with FDA's January 2020 guidance prioritizing enforcement against certain flavored cartridge-based products,[36] and continued as the agency issued MDOs for flavored e-cigarettes beginning in August 2021.[37] In short, FDA regulatory action against flavored e-cigarettes, including through the issuance and enforcement of MDOs for such products, has contributed to the recent decline in youth vaping.[38] The decision below allows companies to evade the effect of FDA's denial orders by steering their cases to

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States, 2020, 69 MORBIDITY & MORTALITY WKLY. REP. 1881, 1881 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950a1-H.pdf.

[36] FDA, GUIDANCE, ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION (2020), https://www.fda.gov/media/133880/download. The guidance, which was originally issued in January 2020, was revised and updated in April 2020 to reflect an extension of the submission deadline for e-cigarette marketing applications from May 2020 to September 9, 2020. *See id.* at 31-32.

[37] FDA News Release, *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://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence (noting that these were the first MDOs issued for e-cigarette products).

[38] The 2023 National Youth Tobacco Survey Report found that increased federal action was among several factors likely contributing to declining youth usage of e-cigarettes: the "decline since 2022 in high school student e-cigarette use is likely attributable to multiple factors, such as ongoing efforts at the national, state, and local levels to implement tobacco control strategies, including Food and Drug Administration regulatory actions." Ahmed et al., *supra* note 15, at 920.

the Fifth Circuit. Such a result undermines FDA's regulatory authority, which has been crucial in stemming the youth e-cigarette epidemic.

CONCLUSION

For these reasons and those presented in Petitioner's brief, the Court should reverse the judgment of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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