No. 23-2403

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

SWT GLOBAL SUPPLY, INC.,

Petitioner,

v.

U.S. FOOD & DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Final Marketing Denial Order by the U.S. Food and Drug Administration

BRIEF OF *AMICI CURIAE* MEDICAL, PUBLIC HEALTH, CIVIL RIGHTS, AND COMMUNITY GROUPS IN SUPPORT OF RESPONDENT

William B. Schultz
Andrew N. Goldfarb
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036-5807
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
agoldfarb@zuckerman.com

Attorneys for Amici Curiae

Of Counsel:
Dennis A. Henigan
Connor Fuchs
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 Eye Street NW, Suite 1200
Washington, DC 20005
Tel: (202) 296-5469
Fax: (202) 296-5427
dhenigan@tobaccofreekids.org
cfuchs@tobaccofreekids.org

CORPORATE DISCLOSURE STATEMENT AND STATEMENT OF FINANCIAL INTEREST

Pursuant to Fed. R. App. P. 26.1(a), *amici curiae* Action on Smoking and Health, African American Tobacco Control Leadership Council, American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Medical Association, Campaign for Tobacco-Free Kids, Missouri State Medical Association, National Medical Association, Parents Against Vaping e-cigarettes (PAVe), and Truth Initiative are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

Dated: October 20, 2023

/s/ William B. Schultz
William B. Schultz
Attorney for *Amici Curiae*

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Amici medical, public health, civil rights, and community organizations submit this brief in support of Respondent United States Food and Drug Administration ("FDA") and urge the Court to uphold the Marketing Denial Order ("MDO") issued to Petitioner SWT Global Supply, Inc. By denying authorization to Petitioner's menthol-flavored e-liquids, FDA has acted to protect public health by removing from the market menthol-flavored products that have helped fuel an epidemic of youth use of highly addictive and harmful e-cigarettes, with no demonstrated countervailing benefit in helping adult smokers to stop smoking cigarettes. All parties have consented to the filing of this brief.

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are the following national and state medical, public health, civil rights, and community organizations: Action on Smoking and Health, African American Tobacco Control Leadership Council, American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Medical Association, Campaign for Tobacco-Free Kids, Missouri State Medical Association, National Medical Association, Parents Against Vaping e-cigarettes

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* affirm that no party's counsel authored this brief in whole or in part, neither the parties nor their counsel contributed money that was intended to fund preparing or submitting this brief, and no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

(PAVe), and Truth Initiative. *Amici* include physicians who counsel young patients and their parents about the hazards of tobacco use, organizations with formal programs to urge users to quit, and groups representing parents and families struggling to free young people from nicotine addiction. Each of these organizations works on a daily basis to reduce the devastating health harms of tobacco products, including electronic nicotine delivery system ("ENDS" or "e-cigarette") products and the e-liquids used in those products.[2] Accordingly, *amici* have a direct and immediate interest in ensuring that Petitioner's highly addictive and youth-appealing menthol e-liquids not be permitted on the market. Upholding the MDO will serve that interest.

Amici also have a special interest in this case because many of the *amici* were plaintiffs in *American Academy of Pediatrics v. FDA*, in which they obtained a federal court order: (1) establishing new deadlines for the required submission of premarket tobacco product applications for e-cigarette products, and (2) limiting the time period that e-cigarettes may remain on the market without the required premarket orders. 379 F. Supp. 3d 461 (D. Md. 2019); 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020). *Amici* therefore have a strong interest in ensuring that the premarket review process functions to protect the public health by removing from the market

[2] This brief uses the terms "e-cigarette" and "ENDS" interchangeably.

flavored e-cigarette products, like Petitioner's menthol-flavored e-liquids, that threaten the health and well-being of young people without sufficient countervailing evidence of any benefit to adult cigarette smokers.

INTRODUCTION

Petitioner manufactures menthol-flavored, "nicotine-containing e-liquids," Petr' Br. 9-10, highly addictive and harmful products that have consistently been shown to appeal to youth. FDA denied the applications from Petitioner to market its menthol e-liquids because the applications lacked sufficient evidence that the products are more effective than unflavored (i.e., tobacco-flavored) products in helping adult smokers stop smoking cigarettes, so as to outweigh the known risks to youth posed by these products. A.R. 808-09.[3]

In light of the overwhelming evidence of youth attraction to menthol-flavored e-cigarettes, and the addictiveness and health harms to young people from those products—including products, like Petitioner's e-liquids, used in open-system e-cigarettes—it was entirely reasonable for FDA to require Petitioner to submit robust and reliable product-specific evidence of the benefit of its products, compared to tobacco-flavored products, in aiding smokers to stop smoking. It was not arbitrary

[3] At the time of filing, *amici* do not have access to the parties' joint appendix. Therefore, this brief cites only to the administrative record, without parallel citations to the appendix. The portions of the administrative record that this brief pin cites to were included in Petitioner's Addendum (Aug. 31, 2023).

and capricious for FDA to issue a denial order based on Petitioner's failure to provide such evidence.

It also was not arbitrary and capricious for FDA to conclude that Petitioner's youth access and marketing restrictions would be insufficient to reduce the risk of youth initiation of Petitioner's products. Given flavored products' overwhelming appeal to young people, FDA's experience, along with other real-world data, clearly demonstrate that, when it comes to flavored e-cigarettes, these types of restrictions are inadequate to reduce youth access.

Moreover, after selling its product on the market for years without the order required by statute, Petitioner now seeks an order that would require FDA to allow its products to remain on the market while Petitioner conducts studies in an effort to demonstrate that its menthol-flavored products provide a public health benefit. Petitioner's request is contrary to law and if accepted would be detrimental to public health. The requested relief is flatly barred by the Tobacco Control Act, under which a product such as menthol e-liquids may be marketed only *after* it has been shown to be appropriate for the protection of the public health. Moreover, allowing Petitioner's highly addictive menthol e-liquids to remain on the market for would add to the significant risk these products pose to children.

Just yesterday (October 19, 2023), the U.S. Court of Appeals for the Third Court upheld an MDO for menthol flavored e-cigarettes, holding that FDA's

approach to evaluating menthol-flavored e-cigarette applications was consistent with the Tobacco Control Act, and that its MDO was not arbitrary and capricious, and based on valid scientific judgments that are within the scope of FDA's expertise. *Logic Tech. Dev. LLC v. FDA*, No. 22-3030, slip op. (3d Cir. Oct. 19, 2023) (ECF No. 115).

ARGUMENT

I. Given the Overwhelming Evidence of Youth Attraction to Menthol-Flavored E-Cigarettes, Including Open-System Products, It Was Not Arbitrary and Capricious for FDA to Deny Petitioner's Application for Failure to Provide Robust and Reliable Evidence That Its Menthol E-Liquids Help Smokers Stop Smoking More Effectively Than Unflavored Products.

In determining whether the marketing of an e-cigarette meets the statutory "appropriate for the protection of the public health" standard, FDA must weigh two factors: (1) the likelihood that the product will help existing tobacco users stop using tobacco products; and (2) the likelihood that the product will lead non-tobacco users, including youth, to begin using such products. 21 U.S.C. § 387j(c)(4). Applying this framework to e-cigarettes, FDA found overwhelming evidence that menthol and other flavors—across all types of e-cigarette products—appeal to youth more than tobacco-flavored products. A.R. 808, 1672-77. Given this unequivocal evidence, it was reasonable, and certainly not arbitrary and capricious, for FDA to require Petitioner to submit "robust and reliable evidence" demonstrating that its menthol e-liquids, as compared to tobacco-flavored products, benefit smokers by helping them

to stop smoking cigarettes. A.R. 808. Because Petitioner failed to furnish such evidence, FDA correctly issued an MDO. A.R. 808.

The impact of a product on youth initiation is particularly critical because, as FDA noted in its Technical Project Lead Review of Petitioner's products ("TPL Review"), "[u]se of tobacco products, no matter what type, is almost always started and established during adolescence when the developing brain is most vulnerable to nicotine addiction." A.R. 1674. Whereas "almost 90 percent of adult daily smokers started smoking by the age of 18 . . . youth and young adults who reach the age of 26 without ever starting to use cigarettes will most likely never become daily smokers." A.R. 1674. FDA concluded: "Because of the lifelong implications of nicotine dependence that can be established in youth, preventing tobacco use initiation in young people is a central priority for protecting population health." A.R. 1674-75.

A. FDA correctly concluded that there is "robust and consistent" evidence demonstrating that Petitioner's menthol-flavored e-liquids are particularly attractive to youth.

E-cigarettes are the most commonly used tobacco product among youth. A.R. 1675. According to the National Youth Tobacco Survey ("NYTS"), in 2022, over 2.5 million youth, including 14.1% of high schoolers, reported current e-cigarette use. A.R. 1675, 1679-80.

Flavors, including menthol, drive these high rates of youth e-cigarette usage. A.R. 1675. As FDA found in its TPL Review, "the flavoring in tobacco products (including ENDS) make them more palatable for novice users, including youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use." A.R. 1676. In 2022, 85.5% of high school e-cigarette users and 81.5% of middle school users reported using a flavored product. A.R. 1675. Moreover, according to data from the federal government, over 93% of youth users reported that their first e-cigarette product was flavored, and 71% of current youth e-cigarette users reported using e-cigarettes because of flavors. A.R. 1676. As the U.S. Court of Appeals for the D.C. Circuit found in upholding several denial orders for flavored e-liquids, "[f]lavored tobacco products lie at the heart of the problem." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 11 (D.C. Cir. 2022); *see also Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 505 (6th Cir. 2021) ("Flavored ENDS products especially appeal to children.").

As to menthol, the flavor at issue here, FDA correctly found that menthol-flavored products (like other flavored products) "have significant appeal to youth and are associated with youth initiation and use." A.R. 808. In 2022, 26.6% of current youth flavored e-cigarette users reported use of a menthol product, similar to the rates for mint (29.4%) and candy/desserts/sweets (38.3%). A.R. 1672 n.ix,

1675. In short, as FDA concluded, there is "clear evidence of substantial use of menthol-flavored ENDS among youth." A.R. 1672 n.ix.

Petitioner contends that FDA failed to "account for the markedly reduced actual youth appeal of e-liquids for open-tank systems . . . compared to cartridge or disposable products . . . ." Petr's Br. 39. This argument is without merit for two reasons. First, the record shows that FDA considered the youth appeal of various device types and reasonably concluded that flavors—regardless of device type—drive youth usage. A.R. 1677. Second, the evidence shows that open-system products are in fact popular among youth.

FDA found that, "across . . . different device types, the role of flavor is consistent." A.R. 1677. The published literature demonstrating "the substantial appeal to youth of flavored ENDS . . . is robust and consistent" and this youth preference for flavored products "is consistently demonstrated across large, national surveys and longitudinal cohort studies." A.R. 1677. In contrast, FDA found that youth preference for particular device types and brands is "likely fluid and affected by the marketplace—that is, the options, especially flavors, that are available for consumers to choose from." A.R. 1677. Courts have consistently rejected the argument that FDA ignored a material distinction between open and closed systems. *See Prohibition Juice*, 45 F.4th at 26; *Avail Vapor, LLC v. FDA*, 55 F.4th 409, 427

(4th Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553, 560 (7th Cir. 2022); *Liquid Labs LLC v. FDA*, 52 F.4th 533, 545 (3d Cir. 2022).

The role of flavors in driving youth e-cigarette use—regardless of device type—is perhaps most vividly demonstrated by what occurred after FDA, in 2020, changed its enforcement priorities to prioritize enforcement against flavored cartridge-based e-cigarettes (other than menthol), which at the time were the most popular products among youth. *See* FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* at 3 (Apr. 2020) ("2020 Guidance"),[4] A.R. 5764-5815. Following this prioritization of enforcement against cartridge-based e-cigarettes, the rates of high school use of disposable e-cigarettes (i.e., products that are not reusable or re-fillable), which were available in any flavor but were not prioritized for enforcement purposes, increased ten-fold. A.R. 1677. As FDA concluded, this youth migration to alternative device types for which flavors were available "underscor[es] the fundamental role of flavor in driving appeal." A.R. 1677.[5]

[4] https://www.fda.gov/media/133880/download.

[5] Notably, after FDA prioritized enforcement against cartridges in flavors other than tobacco or menthol, youth also shifted to using menthol e-cigarettes, further underscoring the point that youth migrate to e-cigarette products that are available in non-tobacco flavors. *See* Teresa W. Wang et al., *Characteristics of e-Cigarette*

In an attempt to distinguish open-system products from other device types, Petitioner points to a 2019 quote from then-FDA Commissioner Gottlieb to portray open-system devices as large and unwieldy—and therefore, having little youth-appeal. Petr's Br. 38. However, open-system products have evolved dramatically, and many current iterations bear little resemblance to the products Commissioner Gottlieb called "big open-tank contraptions." *Id.* For example, the sleek, easy-to-conceal Smok and Suorin devices pictured below can be used to consume Petitioner's e-liquids. For reference, the Smok devices below weigh less than 1.6 ounces and measure roughly 3.7 inches tall, 1.2 inches wide, and 0.75 inches deep.[6]

Suorin Drop Rainbow Chrome open-system e-cigarette device.[7]

Smok Nord open-system e-cigarette devices.[8]

Use Behaviors Among US Youth, 2020, 4 JAMA NETWORK OPEN 1, 9 (2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780705.

[6] *Nord Kit*, SMOK, https://www.smoktech.com/product/pod_mod/nord-kit (last visited Oct. 12, 2023).

[7] *Suorin Drop Rainbow Chrome – Pod System Device with Cartridge Kit*, SUORIN USA, https://www.suorinusa.com/collections/suorin-drop/products/suorin-drop-rainbow-chrome (last visited Oct. 12, 2023).

[8] *Nord Kit*, *supra* note 6.

Petitioner also ignores the fact that e-cigarette use by young people was a serious problem before cartridge-based products began to dominate the youth market in 2017 (and certainly before the rise in popularity of disposables among youth). In 2015, youth e-cigarette prevalence reached 16%. *See* 2020 Guidance 11. In short: ***flavor***, and not the delivery system, is the dominant factor driving youth use.

In any event, open-system products in fact remain popular among youth, as FDA recognized. *See* A.R. 1677 ("[I]n the intervening years since [FDA's] enforcement policy was announced, youth have been purchasing and using open systems."). Smok and Suorin, for example, are open-system devices and are currently among the most popular e-cigarette devices used by youth.[9] In 2022, one in seven (14.3%) high school e-cigarette users reported using a Smok brand in the past month.[10]

Finally, in asserting that youth use of open-system products has dropped in recent years, Petitioner falsely claims that, according to the 2021 National Youth Tobacco Survey, "only 7.5% of [high school e-cigarette users] reported using an open system device—and thus bottled e-liquids." Petr's Br. 39. Petitioner fails to mention that an additional 28.9% of high school e-cigarette users (480,000 students)

---

[9] *See* Maria Cooper et al., *Notes from the Field: E-cigarette Use Among Middle and High School Students, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1283, 1284 tbl. (2022), https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf.

[10] *Id.*

reported using "Prefilled or refillable pods or cartridges." That category includes popular refillable open-system products like Smok and Suorin, which are compatible with Petitioner's e-liquids.[11] Thus, the true percentage of youth e-cigarette users who report using open-system products is much higher than 7.5%—and even that understated 7.5% figure translates to ***120,000*** high school students.[12]

It is undisputed that Petitioner's products have the central feature—a non-tobacco flavor—that makes e-cigarettes attractive to youth. It was therefore reasonable, and certainly not arbitrary, for FDA to conclude that Petitioner's menthol-flavored e-liquids have substantial appeal to youth, necessitating robust and reliable evidence of a benefit to smokers sufficient to outweigh the risk to young people.

B. FDA correctly concluded that Petitioner's menthol e-liquids pose a direct threat of addiction and other health harms to young people.

Petitioner's menthol e-liquids contain nicotine, Petr's Br. 9-10, which is "among the most addictive substances used by humans." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). In its TPL Review, FDA explained that it is "during adolescence when the developing brain is most vulnerable to nicotine

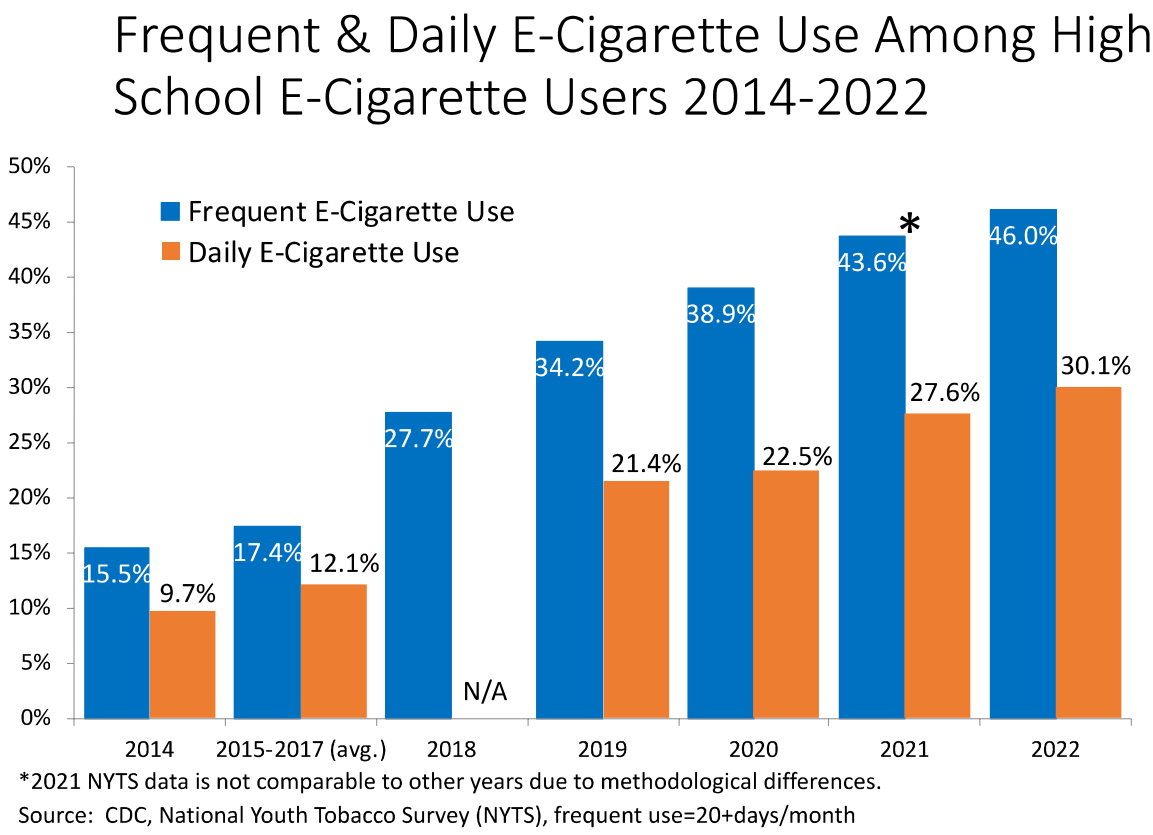
---

[11] Eunice Park-Lee et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 70 MORBIDITY & MORTALITY WKLY. REP. 1387, 1388 tbl. (2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf.

[12] *Id.*

addiction." A.R. 1674. And nicotine's grip over young people is borne out by the numbers. In 2022, 46% of high school e-cigarette users reported using e-cigarettes on at least 20 of the preceding 30 days. A.R. 1678. Even more alarming, 30.1% of high school e-cigarette users reported *daily* use, a strong indication of nicotine addiction. A.R. 1678. Roughly 700,000 middle and high school students are vaping on a daily basis.[13] And as FDA observed (A.R. 1678), the data suggest that nicotine dependence among young people is increasing. *See* Chart 1.

Chart 1



[13] Cooper et al., *supra* note 9, at 1284 tbl.

In its TPL Review, FDA also noted that the scientific literature indicates that flavors in e-cigarettes, including menthol, "not only facilitate initiation but also promote established regular ENDS use." A.R. 1676. Flavors make e-cigarettes and other tobacco products "more palatable for novice youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use." A.R. 1676. "Research also shows that flavors can increase nicotine exposure by potentially influencing the rate of nicotine absorption through pH effects and by promoting the reward of ENDS use." A.R. 1676. FDA concluded that, "[t]ogether, this evidence suggests flavored ENDS may pose greater addiction risk relative to tobacco flavored ENDS, which increases concerns of addiction in youth . . . ." A.R. 1676. As the D.C. Circuit found in *Prohibition Juice*, "[a] vast body of scientific evidence shows that flavors encourage youth to try e-cigarettes and, together with the nicotine, keep them coming back." 45 F.4th at 11.

In addition to the risk of addiction, FDA found that youth exposure to nicotine "can induce short and long-term deficits in attention, learning, and memory." A.R. 1678. FDA cited other health harms from e-cigarettes as well, including "associations between ENDS use and self-reported history of asthma, chronic bronchitis, emphysema, or chronic obstructive pulmonary disease with increased ENDS use (i.e., daily use) relating to increased odds of disease." A.R. 1679.

FDA also noted the data documenting a risk of progression from e-cigarettes to other tobacco products. *See* A.R. 1678-79. In its TPL Review, FDA cited a "systematic review and meta-analysis that summarized nine prospective cohort studies" finding "significantly higher odds of smoking initiation . . . and past 30-day combusted cigarette use . . . among youth who had used ENDs as compared to youth who had not used ENDS." A.R. 1679. A 2018 report by the National Academies of Sciences, Engineering, and Medicine, cited in the TPL Review, found "substantial evidence that ENDS use increases [the] risk of ever using combusted tobacco cigarettes among youth and young adults." A.R. 1679. Thus, the threat of menthol-flavored e-cigarettes is not just a short-term health threat; it also is a threat to a young person's future health by increasing the risk that they will progress to a lifetime of addiction to even more hazardous tobacco products.

C. FDA acted reasonably in requiring Petitioner to present robust and reliable evidence that its menthol e-liquids help smokers stop smoking more effectively than tobacco-flavored products.

Precisely because the evidence that flavored tobacco products appeal to youth is so "robust and consistent," A.R. 1677, it was reasonable for FDA to require similarly "robust and reliable" evidence showing that Petitioner's menthol e-liquids help smokers stop smoking more effectively than tobacco-flavored products, and that such a benefit be "substantial enough to overcome the significant risk of youth

uptake and use posed by the flavored ENDS product." A.R. 1681. Petitioner's evidence fell short.

FDA found that, "in contrast to the evidence related to youth initiation—which shows clear and consistent patterns of real-world use that supports strong conclusions—the evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive." A.R. 1682. For example, a systematic review that examined consumer preference for various e-cigarette attributes found "inconclusive evidence" as to whether flavored e-cigarettes, including menthol, assisted smokers to stop smoking.[14] In its TPL Review, FDA noted that although the "[t]he scientific literature suggest that menthol smokers show a preference for menthol-flavored ENDS . . . the existing literature does not demonstrate that menthol-flavored ENDS differentially promote switching or cigarette reduction," which "is the behavioral outcome measurable with available methods that most directly and most robustly determines the potential benefit to users." A.R. 1673. Thus, it was reasonable for FDA to require Petitioner to demonstrate the effectiveness of its menthol-flavored products in helping smokers stop smoking

[14] Samane Zare et al., *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type*, 13 PLoS ONE 1, 12 (2018), https://pubmed.ncbi.nlm.nih.gov/29543907/.

through randomized controlled trials, longitudinal cohort studies, or other similarly rigorous studies.[15]

Instead of submitting any such studies, Petitioner offered cross-sectional surveys on "use and perceptions" and "likelihood of use." Petr's Br. 30; *see also* A.R. 1650. These surveys are insufficient to demonstrate that Petitioner's menthol e-liquids better enable cigarette smokers to stop smoking than tobacco-flavored products. As FDA noted, such studies measure only users' beliefs about their experience with menthol and other flavored products; they prove nothing about whether the use of menthol actually affects smoking behavior when compared to unflavored products. *See* A.R. 1684 ("Consumer perception studies (surveys or experiments) typically assess outcomes believed to be precursors to behavior, such as preferences or intentions related to new products, but are not designed to directly assess actual product use behavior."). In its TPL Review, FDA explained in detail why it is necessary to perform studies that "enable direct assessment of behavioral

[15] Petitioner's claim that this study requirement created an unfair surprise, and thus violated Petitioner's reliance interest, is an argument that has been consistently rejected by courts of appeals. Most recently, the Third Circuit rejected this argument in a decision upholding an MDO for menthol-flavored e-cigarettes. *See Logic*, No. 22-3030, slip op. at 30 ("FDA's evidentiary requirements did not constitute a 'surprise switcheroo.'") (quoting *Liquid Labs*, 52 F.4th at 540); *see also Avail Vapor*, 55 F.4th at 422 ("FDA neither changed the standard nor the types of evidence required."); *Prohibition Juice*, 45 F.4th at 21 (rejecting argument that "FDA without warning altered the types of evidence it would accept") *Liquid Labs*, 52 F.4th at 541; *Gripum*, 47 F.4th at 559-60; *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657, 672 (9th Cir. 2023).

outcomes associated with actual product use over time," A.R. 1684, which the studies offered by Petitioner did not do. The agency's approach was entirely reasonable and certainly not arbitrary.

FDA was also correct to issue the MDO because Petitioner failed to include any studies comparing the effectiveness of its menthol e-liquids with tobacco-flavored e-cigarettes in assisting smokers to stop smoking. *See* A.R. 1650; Petr's Br. 30. The Tobacco Control Act "expressly asks for evidence concerning whether an applicant's 'tobacco product presents less risk than other tobacco products . . . .'" *Prohibition Juice*, 45 F.4th at 23 (quoting 21 U.S.C. § 387j(b)(1)(A)). Given that "[t]obacco-flavored ENDS may offer the same type of public health benefit as flavored ENDS, i.e., increased switching and/or significant reduction in smoking, but do not pose the same degree of risk of youth uptake," A.R. 1677, such a comparison is reasonable and precisely the "judgment . . . the [Tobacco Control Act] envisioned the FDA could make." *Avail Vapor*, 55 F.4th at 421; *see also Liquid Labs*, 52 F.4th at 542 ("We also join our sister circuits in concluding that the FDA permissibly required a comparison of a manufacturer's flavored products with tobacco-flavored ENDS' products in their ability to assist adult smokers to quit or switch.") (cleaned up).[16]

[16] Petitioner also argues that this comparative analysis requirement created an unfair surprise. Petr's Br. 25-29, 26-27 n.3. Courts of appeals have consistently rejected this argument. *See Logic*, No. 22-3030, slip op. at 33 (in upholding MDO for

D. FDA's requirement for product-specific evidence showing the comparative benefit of flavored versus tobacco-flavored products in helping smokers to stop smoking was reasonable.

Contrary to Petitioner's claim (Petr's Br. 37-39), FDA did not act arbitrarily and capriciously by relying on general evidence regarding the impact of flavors on youth e-cigarette use, while requiring product-specific evidence to assess any benefits to smokers from use of Petitioner's products. *See, e.g.*, *Prohibition Juice*, 45 F.4th at 22 (rejecting argument that "FDA imposed an evidentiary 'double standard' by using literature reviews to as evidence for flavored products' risks but eschewing literature reviews as evidence of their benefits."); *Avail Vapor*, 55 F.4th at 421 ("FDA did not use an 'evidentiary double standard' when reviewing petitioners' applications."); *Breeze Smoke*, 18 F.4th at 508 (concluding that FDA

---

menthol-flavored e-cigarettes, finding that "FDA had made clear already both the appropriate comparators, including tobacco, and types of data that would show their relative efficacy"); *Prohibition Juice*, 45 F.4th at 23 ("This argument is far off base."); *Lotus Vaping*, 73 F.4th at 671 (same). Both the Tobacco Control Act (21 U.S.C. § 387j(b)(1)(A)), and FDA's 2019 Premarket Tobacco Product Applications for Electronic Nicotine Delivery System Guidance (A.R. 7106-7160), which recommended that applicants compare their products to products in the same category or subcategory, "are clear about comparative analysis." *Liquid Labs*, 52 F.4th at 542-53. "Because the 2019 Guidance gave fair notice of the analysis the agency would perform and the purpose of those comparisons, we hold the agency did not create unfair surprise by focusing on comparisons between otherwise similar flavored and nonflavored products." *Prohibition Juice*, 45 F.4th at 24. The Third Circuit similarly held that "FDA did not apply unannounced or changed standards . . . ." *Liquid Labs*, 52 F.4th at 542-53 (citing *Prohibition Juice*). Thus, Petitioner is wrong in claiming that the *Liquid Labs* decision did not address the same "unfair surprise" argument it advances here. *See* Petr's Br. 26-27 n.3.

acted reasonably in "requiring [Petitioner] present more than literature reviews to justify its products' public health benefits").

FDA reasonably relied on general scientific literature to show the special appeal of flavored e-cigarettes to youth because, in the Sixth Circuit's words, "those risks are understood as a matter of scientific consensus." *Id.* And, as discussed, FDA found that the "role of flavor" in attracting youth is consistently demonstrated "across . . . different device types." A.R. 1677.

In contrast, FDA found that there is no scientific consensus on whether flavors, including menthol, help cigarette smokers stop smoking to a greater degree than tobacco-flavored e-cigarettes. *See* A.R. 1673, 1682. FDA observed that "[t]he heterogeneity of the literature is likely due to the fact that the effectiveness of a product in promoting switching among smokers arises from a combination of its product features—including labeled characteristics like flavor and nicotine concentration—as well as the sensory and subjective experience of use (taste, throat hit, nicotine delivery), and can also be influenced by how the device itself looks and feels to the use[r]." A.R. 1684. As the D.C. Circuit held, FDA "reasonably drew differing conclusions from evidence of differing strength." *Prohibition Juice*, 45 F.4th at 22.

II. FDA's Determination That Access and Marketing Restrictions Are Insufficient to Reduce Youth Initiation of Flavored Products Was Reasonable.

Petitioner argues that FDA "summarily discounted Petitioner's marketing restrictions aimed at preventing youth use *in light of the reduced youth appeal of open tank e-liquids* compared to disposables and cartridge-based products." Petr's Br. 34 (emphasis in original). As the TPL Review shows, FDA gave due consideration to the role of Petitioner's proposed access and marketing restrictions. And based on the agency's experience with those restrictions, FDA reasonably concluded that they are insufficient to prevent youth usage of flavored and highly addictive products—including menthol-flavored e-liquids designed for use in open-system e-cigarettes. *See, e.g.*, A.R. 1659, 1686-87, 1689.

Petitioner relies heavily on the Eleventh Circuit's *Bidi Vapor LLC v. FDA* decision. *See* Petr's Br. 34-35. That reliance is misplaced. In *Bidi*, the court held that FDA erred in not reviewing the applicants' proposed marketing and access restrictions, and that its failure to review "measures not specifically mentioned in the 2020 Guidance" was not harmless. 47 F.4th 1191, 1205 (11th Cir. 2022). Here, the TPL Review makes clear that, "given the concerns expressed by certain federal courts," FDA *did* review "all applicant-proposed marketing restrictions and mitigation measures to ensure that there are no other types of novel and materially different proposals, such as device access restrictions, that have the potential to

mitigate the substantial risk to youth from flavored ENDS sufficiently to decrease the magnitude of adult benefit required" to secure authorization. A.R. 1688. Petitioner points specifically to the "Trace/Verify" program that it, and one of the applicants in *Bidi*, proposed as a measure that the Eleventh Circuit had found FDA had not yet evaluated. Petr's Br. 35.

The Eleventh Circuit's finding on this point was more limited than Petitioner represents. The Court simply found that the Trace/Verify program was not specifically mentioned in the 2020 Guidance. *Bidi*, 47 F.4th at 1205. Here, in contrast, the TPL Review confirms that FDA has experience with the Trace/Verify program—as well as all of Petitioner's other proposed restrictions—and considered them within the context of Petitioner's application. *See, e.g.*, A.R. 1659, 1687, 1689. After doing so, FDA concluded that they are not "materially different . . . from those [measures] that FDA has previously considered and found insufficient." A.R. 1651. "FDA has found that to date these restrictions do not by themselves mitigate the high risk to youth posed by flavored ENDS" enough to lower Petitioner's evidentiary burden. A.R. 1687. Other courts have upheld marketing denial orders where the applicants have not proposed "materially different [measures] from those the FDA had previously found insufficient to stem the surge in youth e-cigarette use." *Prohibition Juice*, 45 F.4th at 17; *see also Liquid Labs*, 52 F.4th at 544 (Applicant "has not explained how the approaches in its plan differ from ones previously found

insufficient . . ."); *Avail Vapor*, 55 F.4th at 418 (Applicant's "marketing plan included only garden variety restrictions that the FDA had previously found wholly inadequate in preventing youth use").

While access and marketing restrictions are important and indeed *necessary* to support a premarket tobacco product application, as FDA has emphasized time and again, *see* Petr's Br. 36-37, FDA's experience, and other real-world data, confirm that measures like those proposed by Petitioner are not *sufficient* when it comes to flavored e-cigarettes. The core problem with flavored e-cigarettes is the product itself—in particular, its appeal to youth and its addictiveness—not simply youth access or the marketing of these products.

In March 2019, in response to the youth vaping epidemic, FDA issued a Draft Guidance ("2019 Draft Guidance"),[17] which "proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold . . . ." 2020 Guidance 21 (describing 2019 Draft Guidance). For example, FDA stated that it would prioritize enforcement against products "sold in locations that minors are able to enter at any time," "sold online without independent, third-party age- and identity-

[17] FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products; Guidance for Industry; Draft Guidance* (Mar. 2019), https://tobacco.ucsf.edu/sites/g/files/tkssra4661/f/wysiwyg/Draft%20guidance%20-%20modifications%20to%20compliance%20policy%20-%20March%202019.pdf.

verification services," and whose "[l]abeling and/or advertising . . . has included . . . cartoons" and other youth-appealing imagery. 2019 Draft Guidance 13-15.

In 2020, FDA announced in its Final Guidance that these access and marketing restrictions had been insufficient to protect youth from flavored e-cigarettes. "The reality," FDA found, "is that youth have continued access to these [e-cigarette] products in the face of legal prohibitions and even after voluntary actions by some manufacturers." 2020 Guidance 21. "[A]fter considering . . . comments, the public health threats, and the new evidence . . . FDA determined that focusing on how the product was sold would not appropriately address youth use of the products that are most popular among youth . . . ." *Id.*

FDA's conclusion regarding the inadequacy of Petitioner's proposed measures is also supported by other data indicating that youth obtain e-cigarettes with relative ease. According to the 2022 Monitoring the Future Survey, over half of 10th grade students reported that it would be easy to get vaping devices (51.9%) and nicotine-containing e-liquids (50.8%).[18] As the agency explained in its TPL Review (A.R. 1687) and its 2020 Guidance (at 28-29), the majority of youth e-cigarette users obtain e-cigarettes through social sources, such as older friends or

[18] *Table 16: Trends in Availability of Drugs as Perceived by 10th Graders*, MONITORING THE FUTURE (2022), https://monitoringthefuture.org/wp-content/uploads/2022/12/mtf2022table16.pdf.

relatives—avenues of access unlikely to be significantly affected by youth access restrictions.

Given FDA's consideration of and experience with Petitioner's proposed restrictions, the ease with which youth report obtaining e-cigarettes, and the alarming level of continued youth usage of flavored e-cigarettes, FDA reasonably concluded that Petitioner's access and marketing restrictions are insufficient to adequately reduce the risk of youth initiation of Petitioner's menthol-flavored e-liquids.

III. Petitioner's Requested Relief Would Be Contrary to the Tobacco Control Act and Harm Public Health.

In addition to requesting that the Court vacate the MDO, Petitioner further urges the Court to enjoin FDA from "taking any further adverse action on Petitioners' [sic] PMTAs until they have had a reasonable opportunity to execute a comparative efficacy study . . . ." Petr's Br. 40. Petitioner's request to remain on the market pending an additional study essentially asks the Court to turn the Tobacco Control Act's regulatory regime on its head. Such relief would violate the statute and harm public health.

Under the Tobacco Control Act, manufacturers may only market their tobacco products if they have first demonstrated that their products are appropriate for the protection of the public health; they have no right to market their products without having met that standard. *See* 21 U.S.C. § 387j(c)(2)(A). Indeed, because they have

no marketing order, Petitioner's products have been on the market only through the enforcement forbearance of FDA. *See generally*, *Am. Acad. of Pediatrics*, 379 F. Supp. 3d at 468, 493 (D. Md. 2019) (noting that e-cigarette manufacturers lacking a marketing order have enjoyed "a holiday from meeting the obligations of the law").

Should the Court grant Petitioner's request to vacate the MDO, any further relief to Petitioner allowing it to keep its products on the market would be directly contrary to the Tobacco Control Act's pre-market authorization requirement. Further relief would also effectively place the burden of Petitioner's continuing failure to meet the public health standard on the young people who have already suffered so seriously at the hands of flavored e-cigarette manufacturers, rather than on the companies that have enjoyed the benefit of a years-long regulatory "holiday." If granted, Petitioner's requested relief would have profoundly negative public health consequences. Petitioner's request for relief should be denied.

CONCLUSION

For these reasons, and those presented by Respondent, *amici* urge the Court to uphold the MDO.

Dated: October 20, 2023

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz
Andrew N. Goldfarb
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036-5807
Tel: (202) 778-1800
Fax: (202) 822-8106
Email: wschultz@zuckerman.com
Email: agoldfarb@zuckerman.com

Dennis A. Henigan (Of Counsel)
Connor Fuchs (Of Counsel)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 Eye Street NW, Suite 1200
Washington, DC 20005
Tel: (202) 481-9366
Fax: (202) 296-5427
Email: dhenigan@tobaccofreekids.org
Email: cfuchs@tobaccofreekids.org

Attorneys for *Amici Curiae*

CERTIFICATE OF COMPLIANCE

1. This document complies with the word limits set forth in Fed. R. App. P. 29(a)(5) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), the word count feature in Microsoft Word reports that this document contains 5,785 words.

2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14 font.

/s/ William B. Schultz
William B. Schultz
Attorney for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on October 20, 2023, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ William B. Schultz
William B. Schultz
Attorney for *Amici Curiae*