No. 21-60766 consolidated with 21-60800

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

WAGES AND WHITE LION INVESTMENTS, L.L.C., doing business as TRITON DISTRIBUTION,

Petitioners,

v.

U.S. FOOD AND DRUG ADMINISTRATION

Respondent.

On Petition for Review of a Final Marketing Denial Order
by the United States Food and Drug Administration

BRIEF OF *AMICI CURIAE* MEDICAL, PUBLIC HEALTH, AND COMMUNITY GROUPS IN SUPPORT OF RESPONDENT ON REHEARING *EN BANC*

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SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rules 29.2 and 28.2.1, the undersigned counsel of record for *amici curiae* certifies that the following persons and entities as described in the fourth sentence of Rule 28.2.1, in addition to those listed in the parties' briefs, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. American Academy of Family Physicians
2. American Medical Association
3. Louisiana State Medical Society

Pursuant to Fed. R. App. P. 26.1(a), *amici curiae* 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.

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Amici medical, public health, and community organizations submit this brief in support of Respondent United States Food and Drug Administration ("FDA") and urge the *en banc* Court to uphold the Marketing Denial Orders ("MDO") issued to Petitioners Wages and White Lion Investments, LLC d/b/a Triton and Vapetasia LLC. By issuing MDOs for Petitioners' flavored e-liquids—including Chewy Clouds Sour Grape (A10), Jimmy the Juice Main Crème Brulee (A23), Vapetasia Pink Lemonade (A119), and Vapetasia Rainbow Road (A120)—FDA has acted to protect public health by removing from the market flavored products that have fueled an epidemic of youth usage of highly addictive and harmful e-cigarettes, with no demonstrated countervailing benefit in helping adult smokers to stop smoking cigarettes. The parties consent to the filing of this brief.[1] Fed. R. App. P. 29(a)(2).

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the following 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, American Lung Association, American Medical Association, Campaign for Tobacco-Free Kids, Louisiana State Medical Society,

[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.

Parents Against Vaping e-cigarettes, and Truth Initiative. *Amici* include physicians who counsel their 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 Petitioners' highly addictive and youth-appealing flavored e-liquids not be permitted on the market, which can only be assured by upholding the MDO.

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 ("PMTAs" or "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

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

from the market flavored e-cigarette products, like Petitioners' e-liquids, that threaten the health and well-being of young people without sufficient countervailing evidence of any benefit to adults who smoke cigarettes.

INTRODUCTION AND SUMMARY OF ARGUMENT

Petitioners manufacture and/or sell nicotine-containing flavored e-liquids, Petrs' Br. 14-15, a highly addictive and harmful product that has consistently been shown to appeal to youth. FDA denied Petitioners' applications to market their flavored e-liquids because the applications lacked sufficient evidence that the flavored 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 flavored products. A57; A66; A124.

In light of the mountain of evidence of youth attraction to flavored e-cigarettes, and the addictiveness and health harms to young people from those products—including products, like Petitioners' e-liquids, used in open-system e-cigarettes—it was entirely reasonable for FDA to require Petitioners to submit robust evidence of the benefit of its products compared to tobacco-flavored products in aiding smokers to stop smoking. It was not arbitrary and capricious for FDA to issue MDOs based on Petitioners' failure to provide such evidence.

It also was not arbitrary and capricious for FDA to conclude that Petitioners' youth access and marketing restrictions would be insufficient to reduce the risk of

youth initiation of Petitioners' flavored e-liquids. 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 given flavored products' overwhelming appeal to youth.

ARGUMENT

I. The MDOs Were Not Arbitrary and Capricious.

A. Given the overwhelming evidence of youth attraction to flavored e-cigarettes, including open-system products, it was reasonable for FDA to deny Petitioners' applications for failure to provide robust evidence that its flavored e-liquids help smokers stop smoking more effectively than unflavored products.

In determining if the marketing of an e-cigarette is "appropriate for the protection of the public health"—the standard for a marketing order under the TCA—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 the evidence overwhelming that flavors—across all device types—appeal to youth more than tobacco-flavored products. A89-90; A141-42. Given this unequivocal evidence, it was entirely reasonable, and certainly not arbitrary and capricious, for FDA to require Petitioners to submit "the strongest types of evidence" demonstrating that their flavored products, as compared to tobacco-flavored products, benefit

smokers by helping them to stop smoking cigarettes. A85; A137. And when Petitioners failed to furnish such evidence, FDA correctly issued MDOs.

The impact of a product on youth initiation is particularly critical because, as FDA noted in its Technical Project Lead Reviews ("TPL Review") of Petitioners' products, "use 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." A87; A139. 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 a daily smoker." A87-88; A139-40. As FDA reasonably concluded, "[b]ecause 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." A88; A140.

1. FDA correctly concluded that there is "robust and consistent" evidence demonstrating that Petitioners' flavored e-cigarettes are particularly attractive to youth.

As FDA explained in its TPL Reviews, e-cigarettes are the most popular tobacco product among youth, with more than 3.6 million young people reporting current use in 2020, according to the National Youth Tobacco Survey ("NYTS"). A88; A140. Nearly one in five (19.6%) U.S. high school students were current e-

cigarette users in 2020—about the same level as in 2018 when the U.S. Surgeon General first declared youth e-cigarette use an "epidemic." A87-88; A139-40.[3]

Flavors are driving these high rates of youth e-cigarette use. *See* A88; A140 ("The evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of ENDS among youth."). "[T]he flavoring in tobacco products (including ENDS) make them more palatable for novice youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use." A89; A141. In 2020, 84.7% of high school e-cigarette users reported using a flavored product. A88; A140. And 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 they come in flavors I like." A88-89; A140-41. As the U.S. Court of Appeals for the D.C. Circuit found in upholding several MDOs for flavored e-liquids, "[f]lavored tobacco products lie at the heart of the problem. A

[3] Since FDA issued the challenged MDO, the 2021 and 2022 NYTS data have become available. *See* 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 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf; Maria Cooper et al., *Notes from the Field: E-cigarette Use Among Middle and High School Students, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1283 (2022), https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf. Youth e-cigarette use remains unacceptably high, with over 2.5 million youth, including 14.1% of high schoolers, reporting current e-cigarette use in 2022. *Id.* at 1284 tbl.

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. 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.").

Nevertheless, Petitioners contend that "FDA overlooked evidence that youth do not use Petitioners' bottled e-liquids." Petrs' Br. 44. Tellingly, Petitioners do not point to any evidence regarding their products that FDA failed to consider.[4] Instead, they claim that FDA acted arbitrarily and capriciously by failing to treat open-system e-cigarettes, which use Petitioners' flavored e-liquids, differently from other device types in terms of their youth appeal. Petrs' Br. 44-48. This argument is without merit.

As FDA found, "across . . . different device types, the role of flavor is consistent." A89; A141. The "published literature" showing "the substantial appeal

[4] In a separate section of the brief describing their PMTA submission, Petitioners claim to have submitted as part of their marketing plan "consumer surveys" that "found that over two-thirds of users of the subject bottled e-liquids were over the age of 35." Petrs' Br. 18 (citing A395; A447). However, no information on the survey methodology or sample size is included in either Petitioners' brief or the Joint Appendix. *See* A395; A447. Thus, this survey appears to suffer from the same or similar "methodological flaws" as a separate survey (or at least what appears to be a separate survey) that the merits panel considered: (1) small sample size; "(2) the survey respondents are all [Petitioners'] customers; and (3) it's not clear how these individuals were selected to take the survey." *Wages & White Lions Inves., L.L.C. v. FDA*, 41 F.4th 427, 436 (5th Cir. 2022), *vacated* 58 F.4th 233 (5th Cir. 2023).

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." A89; A141. 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." A90; A142. As the merits panel concluded, "FDA *did* consider Petitioners' device type, and it concluded (reasonably) that what truly impacts youth smokers is flavor preference, not device preference. *Wages*, 41 F.4th at 438 (emphasis in original); *see also Prohibition Juice*, 45 F.4th at 26 (rejecting argument that "FDA ignored a material distinction between open and closed systems."); *Avail Vapor, LLC v. FDA*, 55 F.4th 409, 427 (4th Cir. 2022) (same); *Gripum, LLC v. FDA*, 47 F.4th 553, 560 (7th Cir. 2022) (same).

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* A194. Following this prioritization against cartridge-based e-cigarettes, the rates of high school use of disposables, which were available in flavors, increased ten-fold. A90; A142. Petitioners attempt to explain this away by asserting that cartridge-based and disposable devices share "many

characteristics," not shared by open-system devices, that make them attractive to youth, specifically their "small size, concealability, high nicotine content, and ease of use for the uninitiated." Petrs' Br. 45 (citing 2020 Enforcement Guidance, A198-202). However, many open-system products today possess these same youth-appealing characteristics. For example, the sleek, easy-to-conceal Smok and Suorin devices pictured below can be used to consume Petitioners' e-liquids. For reference, the Smok devices below weigh less than 0.2 pounds and measure roughly 3.7 inches tall, 1.2 inches wide, and 0.75 inches deep.[5]

Figure 1: Suorin Drop Rainbow Chrome open-system ENDS device.[6]

Figure 2: Smok Nord open-system ENDS devices.[7]

[5] *Nord Kit*, SMOK, https://www.smoktech.com/product/pod_mod/nord-kit (last visited Mar. 21, 2023).

[6] *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 Mar. 21, 2023).

[7] *Nord Kit*, *supra* note 5.

Petitioners also ignore 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* A194. Flavor, and not the delivery system, is the consistent factor in use by youth.

Moreover, the fact is that open-system products remain popular among youth. Smok and Suorin, for example, are open-system devices and are currently among the most popular e-cigarette devices used by youth.[8] In 2022, one in seven (14.3%) high school e-cigarette users reported using a Smok brand in the past month.[9]

Finally, in asserting that youth use of open-system products has dropped in recent years, Petitioners falsely claim that according to the 2021 NYTS, "only 7.5% of [high school e-cigarette users] reported using an open system device." Petrs' Br. 46. However, Petitioners fail to mention that an additional 28.9% of high school e-cigarette users (480,000 students) reported using "Prefilled or refillable pods or cartridges," which include popular refillable open-system products like Smok and Suorin which are compatible with Petitioners' e-liquids.[10] Thus, the true percentage of youth e-cigarette users who report using open-system products is necessarily far

[8] *See* Cooper et al., *supra* note 3, at 1284 tbl.

[9] *Id.*

[10] Park-Lee et al., *supra* note 3, at 1388 tbl.

greater than the 7.5% figure Petitioners cite, which itself still translates to 120,000 high school students.[11]

It is undeniable that Petitioners' products have the central feature—flavors—that makes e-cigarettes attractive to youth. It was therefore entirely reasonable for FDA to conclude that Petitioners' flavored e-liquids appeal to youth.

2. As FDA found, Petitioners' flavored e-liquids pose a direct threat of addiction and other health harms to young people.

Petitioners' e-liquids contain nicotine, Petrs' Br. 14, 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 Reviews, FDA noted the factors making "[y]outh and young adult brains . . . more vulnerable to nicotine's effect than the adult brain due to ongoing neural development." A90; A142. FDA found that the high prevalence of youth e-cigarette use was increasing nicotine dependence among young people. A90; A142. In 2019, as FDA noted, an estimated 30.4% of middle and high school e-cigarette users reported frequent use (i.e., use on 20 or more of the previous 30 days), and even more alarming, 2l.4% of high school users and 8.8% of middle school users reported *daily* use. A90; A142. Frequent and daily use prevalence among high school students has continued to rise. In 2022, 46% of high

[11] *Id.*

school e-cigarette users (980,00 students) reported frequent use and 30.1% (640,000 students) reported daily use, a strong sign of nicotine addiction.[12]

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." A90; A142. 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." A91; A143.

FDA also noted the data documenting a risk of progression from e-cigarettes to other tobacco products. A90-91; A142-43. In its TPL Reviews, 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 . . . . " A90-91; A142-43. A 2018 report by the National Academies of Sciences, Engineering, and Medicine, cited in the TPL Reviews, found "substantial evidence that ENDS use increases [the] risk of ever using combusted tobacco cigarettes among youth and young adults." A91; A143. Thus, the threat of flavored e-cigarettes is not just a short-term health threat; it also is a threat to a young

[12] Cooper et al., *supra* note 3, at 1284 tbl.

person's future health by increasing the risk of progression to a lifetime of addiction to even more hazardous tobacco products.

3. FDA acted reasonably in requiring robust evidence showing that Petitioners' flavored 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," A89; A141, it was entirely reasonable for FDA to require similarly "robust and reliable" evidence showing that Petitioners' flavored e-cigarettes 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." A92; A141. The available evidence falls far short of making such a showing.

FDA found that "in contrast to the evidence related to youth initiation—which shows clear and consistent patterns of real-world use that support strong conclusions—the evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive." A93; A145. For example, a systematic review that examined consumer preference for various e-cigarette attributes found "inconclusive evidence" as to whether flavored e-cigarettes assisted smokers to stop smoking.[13] As FDA concluded, "the literature does not establish

[13] 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/.

that flavors differentially promote switching amongst ENDS users in general." A93-94; A145-46. Thus, it was entirely reasonable for FDA to require Petitioners to demonstrate the effectiveness of their flavored products in helping smokers to stop smoking through randomized controlled trials, longitudinal cohort studies, or other similarly rigorous studies, which Petitioners do not claim to have submitted.

B. FDA's determination that access and marketing restrictions are insufficient to reduce youth initiation of flavored products was reasonable.

Petitioners argue that FDA failed to consider their marketing and sales-access restriction plans. Petrs' Br. 48-53. As is apparent from the TPL Reviews, FDA gave due consideration to the role of access and marketing restrictions, like those proposed by Petitioners. *See* A93 n.xix; A145 n.xix. 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 that are so intensely appealing to young consumers. *Id.*

While access and marketing restrictions are important and indeed necessary to support a PMTA, as FDA has emphasized time and again, *see* Petrs' Br. 48-49, restrictions like the ones proposed by Petitioners are not sufficient when it comes to flavored e-cigarettes. For example, Petitioners claim that youth access is limited because their "bottled e-liquids are only sold in age-restricted vape and tobacco specialty shops." *Id.* at 16. However, according to the latest NYTS data, more youth

report buying e-cigarettes from vape or tobacco shops (22.2%) than from gas stations or convenience stores (17.7%).[14] A 2019 study also found that in California, e-cigarette sales to minors violations are significantly higher in tobacco and vape shops than in any other type of retailer, with 44.7% selling to underage buyers.[15]

Petitioners' other measures, such as age verification, quantity limits, and contractual penalties for downstream retailers, *see* Petrs' Br. 16-17, mirror those that FDA previously found were insufficient to curb youth usage of flavored e-cigarettes. *See* 2020 Guidance 6-8, 21 (A189-91, A204). In March 2019, in response to the youth vaping epidemic, FDA issued Draft Guidance ("2019 Draft Guidance"),[16] which "proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold . . . ." A204 (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 with no limit on the

[14] Andrea S. Gentzke et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 1, 23 tbl.7 (2022), https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.

[15] April Roeseler et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, 173 JAMA PEDIATRICS 795, 796 (2019), https://jamanetwork.com/journals/jamapediatrics/fullarticle/2735684.

[16] 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.

quantity that a customer may purchase," and "sold online without independent, third-party age- and identity-verification services," 2019 Draft Guidance 13. FDA also noted that some manufacturers had implemented age-verification measures and quantity limits. *Id.* 5; *see also* 2020 Guidance 7 (A190). These are all measures that Petitioners propose here. *See* Petrs' Br. 16-17.

In 2020, FDA announced in its Final Guidance that these access 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." *Id.* "[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.* Petitioners here fail to explain why access and marketing restrictions that FDA previously found insufficient to curb youth access to flavored e-cigarettes would be effective as to its youth-appealing flavored e-liquids. Other courts have upheld MDOs against similar company arguments. *See, e.g.*, *Prohibition Juice*, 45 F.4th at 17 ("The measures [applicants] highlight in their marketing plans are not materially different from those the FDA had previously found insufficient to stem the surge in youth e-cigarette use."); *Liquid Labs v. FDA*, 52 F.4th 533, 544 (3d Cir. 2022) (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.”).

FDA’s conclusion regarding the inadequacy of Petitioners’ 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%).[17] As FDA explained in its 2020 Guidance (at 28-29, A211-12), the majority of youth e-cigarette users obtain e-cigarettes through social sources, such as older friends or relatives—an avenue of access unlikely to be significantly affected by youth access restrictions.

Given FDA’s experience with restrictions like the ones Petitioners proposed, 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 Petitioners’ access and marketing restrictions are insufficient to adequately reduce the risk of youth initiation of Petitioners’ flavored products that are so appealing to the young.

[17] *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.

CONCLUSION

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

Date: March 31, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

1. The foregoing brief complies with the type-volume limit of 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 3,955 words.

2. The foregoing brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and 5th Cir. R. 32.1, 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/ Scott P. Lewis
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CERTIFICATE OF SERVICE

I hereby certify that on March 31, 2023, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Scott P. Lewis
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