No. 23-1038

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, PETITIONER

v.

WAGES AND WHITE LION INVESTMENTS, L.L.C., DBA TRITON DISTRIBUTION, 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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INTERESTS OF *AMICI CURIAE*

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. That judgment, if allowed to stand, would significantly undermine FDA's efforts to protect youth from the health harms of flavored e-cigarette products. Respondents Wages and White Lion Investments, LLC d/b/a Triton and Vapetasia LLC sell flavored e-liquids with names like Chewy Clouds Sour Grape, Jimmy the Juice Man Crème Brulee, Vapetasia Pink Lemonade, and Vapetasia Rainbow Road. C.A. App. A10, A23, A119, A120. Respondents' e-liquids and other flavored e-cigarette products have fueled persistently high rates of youth usage of highly addictive and harmful products. In denying marketing authorization for Respondents' products and thus requiring that they be removed from the market, FDA acted to protect public health, as required by the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 ("Tobacco Control Act").[1]

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[1] Counsel of record for all parties received notice of amici's intention to file this brief at least 10 days prior to September 3, 2024, the deadline for filing this brief. 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.

Amici are eleven national medical, public health, and community organizations, most of whom participated as *amici* in the court below: American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, 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. *Amici* include organizations with formal 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 e-cigarettes. Each works to reduce the devastating health impact of tobacco products, including electronic nicotine delivery system ("ENDS" or "e-cigarette") products and the e-liquids used in those products. *Amici* therefore have a strong and continuing interest in ensuring that the premarket review process in the Tobacco Control Act functions to protect public health by removing from the market flavored e-cigarette products, like Respondents' e-liquids, that threaten the health and well-being of young people without sufficient countervailing benefit to adults who smoke cigarettes.

Accordingly, *amici* have a direct and immediate interest in this Court's review and reversal of the Fifth Circuit decision, which would allow Respondents' youth-appealing, flavored e-liquids to remain on the

market, with no demonstration that they meet the requirements of the Tobacco Control Act.

INTRODUCTION AND SUMMARY OF ARGUMENT

In 2023, over 2.1 million youth, including 10% of high schoolers, reported e-cigarette use.[2] E-cigarettes pose unique health risks for youth, as adolescent brains are more susceptible to nicotine's effects due to ongoing neural development.[3] Adolescents are thus especially vulnerable to nicotine addiction, which can lead to permanent effects on the developing brain.[4] 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."[5] E-cigarettes also create a substantial risk of progression to cigarette smoking,

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[2] Jane Birdsey et al., *Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023*, 72 MORBIDITY & MORTALITY WKLY. REP. 1173, 1177–82 (2023), http://dx.doi.org/10.15585/mmwr.mm7244a1.

[3] Pet. App. 193a, FDA, TRITON TECHNICAL PROJECT LEAD REVIEW OF PMTAS (Sept. 9, 2020) [hereinafter FDA REVIEW OF TRITON PMTA].

[4] Pet. App. 187a, FDA REVIEW OF TRITON PMTA (citing Apelberg BJ et al., *Symptoms of Tobacco Dependence Among Middle and High School Tobacco Users: Results from the 2012 National Youth Tobacco Survey*, 47 AM. J. PREVENTATIVE MED. S4-14 (Suppl. 2014)).

[5] OFFICE OF THE SURGEON GENERAL ("OSG"), U.S. DEP'T OF HEALTH & HUMAN SERVS. ("HHS"), SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 2 (2018), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html.

and thereby threaten decades of progress against youth smoking.[6] The Surgeon General has warned that "[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe."[7]

The tobacco industry has long known that flavors are important to its ability to 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."[8] And as demonstrated by Figures 1 and 2, e-cigarettes that can be used to consume Respondents' e-liquids frequently come in sleek, colorful designs that appeal to youth.

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[6] Pet. App. 194a (citing NATIONAL ACADEMIES OF SCIENCES ENGINEERING MEDICINE, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (2018)).

[7] 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.

[8] FDA, Advance Notice of Proposed Rulemaking on Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12294, 12295 (Mar. 21, 2018).

Figure 1: Suorin Drop Rainbow Chrome Open-System E-cigarette Device.[9]

Figure 2: Smok Nord Open-System E-Cigarette Device[10]

[9] SuorinUSA, https://www.suorinusa.com/collections/suorin-drop/products/suorin-drop-rainbow-chrome.

[10] Smok, https://www.smoktech.com/product/pod_mod/nord-kit.

E-cigarettes have been the most popular tobacco product among youth since 2014, with youth usage rising to epidemic proportions during the 2018-2020 period. Nearly 90% of middle and high school users of e-cigarettes use flavored (*i.e.*, non-tobacco-flavored) products.[11] 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 2.1 million high school and middle school students currently using these products.[12]

Amici are submitting this brief to make three points. First, flavored e-cigarettes are responsible for a persistent public health crisis. Second, FDA's marketing denial orders ("MDOs") for Respondents' products were not arbitrary and capricious. Third, preserving FDA authority is critical to protecting public health. If left to stand, the Fifth Circuit ruling will undermine FDA's ability to protect young people from the health harms of flavored e-cigarettes, an objective entirely consistent with the Tobacco Control Act. *Amici* therefore urge the Court to reverse the judgment of the Fifth Circuit.

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[11] Birdsey, *supra* note 2, at 1173.

[12] *Id.*

ARGUMENT

A. Flavored E-Cigarettes Are Harmful to Youth.

The use of tobacco products is a "pediatric disease of considerable proportions."[13] This is because "[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) (upholding FDA's MDO of a flavored e-cigarette application) Today, tobacco use by youth is primarily driven by e-cigarettes,[14] which like traditional cigarettes pose a serious risk of addiction.

1. Youth Use of E-Cigarettes Is a Public Health Crisis.

FDA issued MDOs for Respondents' products during a significant, and continuing, crisis of youth e-cigarette use. E-cigarettes have been the leading tobacco product among youth since 2014[15] and youth use reached epidemic proportions around 2018.[16] This ongoing crisis poses significant health risks for 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, E-CIGARETTE USE AMONG YOUTH (May 15, 2024), https://www.cdc.gov/tobacco/e-cigarettes/youth.html#:~:text=E%2Dcigarettes%20are%20the%20most,e%2Dcigarette%20use%20among%20youth.

[15] Birdsey, *supra* note 2, at 1177.

[16] Elizabeth Hair et al., *Patterns of Daily Cigarette and E-cigarette Use Among United States Youth and Young Adults: Insights from the Truth Longitudinal Cohort Between 2018 and*

1. Health Risks

In its decision issuing Respondents' MDOs, FDA found that youth exposure to nicotine "can induce short and long-term deficits in attention, learning, and memory." Pet. App. 194a. The Agency 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." *Id.* at 194a-195a.

Use of e-cigarettes may also function as a gateway to the use of deadly 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, cited in FDA's reviews of Respondents' applications, found "substantial evidence that e-cigarette use increases [the] risk of ever using combusted tobacco cigarettes among youth and young adults." Pet. App. 194a. 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.[17]

2019, 36 PREV. MED. REP. 1-6 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10518703/.

[17] Kaitlin M. Berry et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2 JAMA NETWORK OPEN 1-13 (2019),

2. Addiction

Respondents' flavored e-liquids also pose a serious threat of addiction. These e-liquids contain nicotine, 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 reviews of Respondents' applications, 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." Pet. App. 193a-194a. FDA found that the high prevalence of youth e-cigarette use has increased nicotine dependence among young people. *Id.* As shown in Figure 3 below, frequent and daily use among high school e-cigarette users has remained at high levels over the years. Most alarming, in 2023, 29.9% of high school e-cigarette users reported *daily* use, an unacceptably high percentage. Thus, 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 rising.

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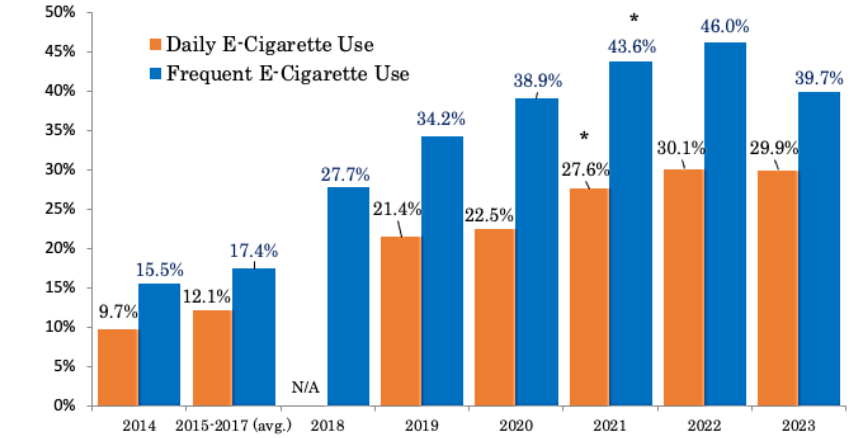
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425.

Figure 3: Frequent (20+ Days/Month) & Daily E-Cigarette Use Among High School E-Cigarette Users 2014-2023



*2021 NYTS data is not comparable to other years due to methodological differences.
Source: CDC, National Youth Tobacco Survey (NYTS), frequent use=20+days/month

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.

3. Prevalence

Over 2.1 million youth, including 10% of high schoolers, reported current e-cigarette use in 2023, making it the most popular tobacco product among youth for the ninth year in a row, according to the National Youth Tobacco Survey ("NYTS").[18] As shown above in Figure 3, young people are not just experimenting with e-cigarettes—they are using them

[18] Birdsey, *supra* note 2.

frequently. Roughly 530,000 middle and high school students are vaping on a daily basis.[19]

If left to stand, the Fifth Circuit's decision will ensure that Respondents' flavored e-liquids remain on the market and create an environment in which countless youth "perceive e-cigarettes as another Baby Ruth or Milky Way, only to find themselves in the grip of a surreptitious nicotine addiction." *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 428 (4th Cir. 2022) (opinion by Judge J. Harvey Wilkinson).

2. Flavored E-Cigarette Products Attract Youth.

Persistent youth usage of e-cigarettes is fueled by flavored products like Respondents' flavored e-liquids. Flavored products "lie at the heart of the problem" and drive these high rates of youth e-cigarette use. *Prohibition Juice*, 45 F.4th at 11. As Figure 4 demonstrates, flavored products are used by almost 90% of youth e-cigarette users,[20] and prevalence of youth usage of flavored products has been steadily rising over the last decade.

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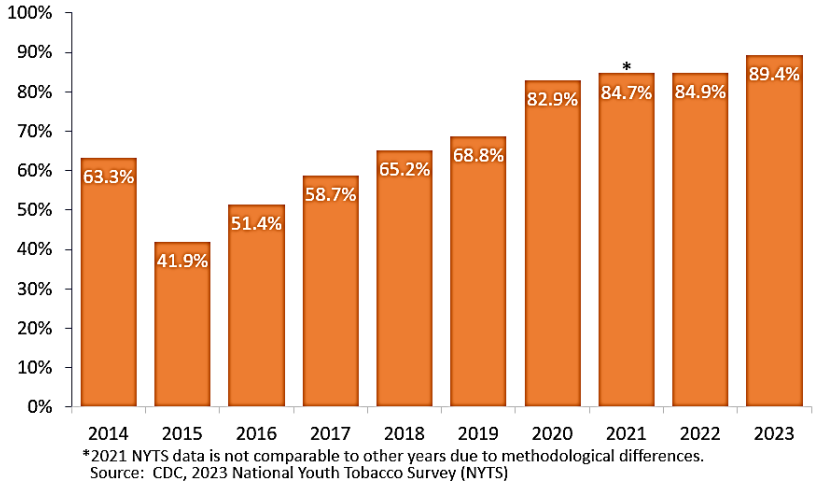
[19] *Id.*

[20] FDA, MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED PRODUCTS: GUIDANCE FOR INDUSTRY, DRAFT GUIDANCE 9 (Mar. 14, 2019), https://www.regulations.gov/document/FDA-2019-D-0661-0003.

Figure 4: Proportion of Middle and High School E-Cigarette Users Who Use Flavored Products, 2014 - 2023.



Youth gravitate to e-cigarette devices that feature flavors. That is why FDA, in 2020, announced enforcement priorities that specifically targeted "[a]ny flavored, cartridge-based ENDS product."[21] As FDA noted in its review of Respondents' applications, "[t]he evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of ENDS among youth." Pet. App. 187a. "[T]he flavoring in tobacco products (including ENDS) makes them more palatable for novice youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use."

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[21] FDA, GUIDANCE, ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION 3 (Apr. 2020), https://www.fda.gov/media/133880/download [hereinafter 2020 Guidance].

Id. at 190a. Seventy-one percent of current youth e-cigarette users reported using e-cigarettes "because they come in flavors I like." Pet. App. 189a. "Open-system" e-cigarettes, which use flavored e-liquids like Respondents' products, are popular among youth.[22] For example, Smok and Suorin, which are pictured above in Figures 1 and 2, are open-system devices and currently are among the most popular e-cigarette brands used by youth.[23] In 2023, more than one in nine (11%) youth e-cigarette users reported using a Smok brand.[24] And as demonstrated above in Figures 1 and 2, these open-system e-cigarettes frequently come in sleek, colorful designs that appeal to youth.

Moreover, Respondents and other companies often promote their flavored e-liquids in youth-appealing ways. Figures 5 and 6 are depictions of flavored products featured in Respondents' social media posts below—Pink Lemonade, Blackberry Lemonade, and Milk of the Poppy—which are subject to the challenged MDOs. *See* C.A. App. A109-A123. These marketing campaigns attract youth with colorful and innocuous images.

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[22] Robert McMillen et al., *Adolescent Use of Different E-cigarette Products*, 142 PEDIATRICS 4 (2018).

[23] Birdsey, *supra* note 2, at 1180 tbl.3.

[24] *Id.*

Figure 5: Marketing Example by Vapetesia[25]

Figure 6: Marketing Example by Vapetasia[26]

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[25] Vapetasia (@vapetasia), INSTAGRAM (Aug. 4, 2020), https://www.instagram.com/p/CDeStFqlP3P/.

[26] Vapetasia (@vapetasia), INSTAGRAM (Aug. 3, 2020), https://www.instagram.com/p/CDcJ7GKFlWo/.

B. FDA's Marketing Denial Orders for Respondents' E-Liquids Were Not Arbitrary and Capricious.

The FDA's decision to issue MDOs for Respondents' products was based on (1) overwhelming evidence of harm to youth from flavored e-cigarette products, including Respondents' flavored e-liquids, and (2) a lack of demonstrated benefit from those flavored products to adults who smoke. FDA's decision was not arbitrary and capricious.

1. Respondents Failed to Provide Sufficient Evidence of Any Health Benefits of Flavored E-Cigarettes or That They Could Adequately Restrict Youth Use of Their Products.

Under the Tobacco Control Act, the public health standard for marketing new tobacco products requires the weighing of two factors. FDA must consider the "likelihood that existing users of tobacco products will stop using such products" and the "likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. 387j(c)(4)(A), (B).

Respondents could have demonstrated a benefit to existing users of tobacco products either through existing scientific literature or their own studies. As FDA found, the existing scientific literature does not establish that flavored products, such as Respondents' e-liquids, aid individuals who smoke to cease smoking. Pet. App. 166a-167a (Triton MDO); Pet. App. 279a-281a (Vapetasia MDO). In fact, as the dissent below noted, Respondents themselves "admitted their own

literature reviews found 'not enough evidence from well-designed studies to determine whether e-cigarette flavors aid in smoking cessation.'" Pet. App. 78a, 87a n.12. FDA also correctly concluded that Respondents' own studies were insufficient to demonstrate benefit since they did not even evaluate the key metric – "product switching or cigarette reduction resulting from use of [Respondents'] products over time." Pet. App. 280a (Vapetasia MDO); *see also* Pet. App. 227a-228a (Triton MDO).

As to the likelihood that the availability of flavored e-cigarettes will lead to greater tobacco use, in addition to the data that youth strongly prefer flavored e-cigarettes,[27] FDA cited a growing body of evidence that youth initiate their tobacco product use with flavored e-cigarettes. Pet. App. 186a, 189a-191a. For instance, a National Institutes of Health study found that between 2013-2014, over 80% of youth aged 12-17 and 75% of young adults aged 18-24 reported that the first e-cigarette that they used was flavored. *Id.* In addition, youth consistently select flavors as a top reason for why they use e-cigarettes. *Id.*

Given the overwhelming evidence of youth usage of harmful flavored products, the evidence that use of flavored e-cigarettes leads to cigarette use, and the absence of support in the literature on the benefits of flavored products to individuals who smoke, FDA reasonably interpreted the Tobacco Control Act to require FDA to deny Respondents' marketing applications unless they contained robust evidence of a

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[27] *See supra* Section I.B.

public health benefit sufficient to outweigh those harms—*i.e.*, evidence that their flavored products help individuals who smoke stop smoking. FDA reasonably explained why Respondents failed to make a showing of any public health benefit,[28] and as such, the MDO was not arbitrary and capricious.

2. FDA Correctly Determined That Respondents' Access and Marketing Restrictions Were Insufficient.

Respondents argued in the court below that FDA failed to consider their marketing and sales-access restriction plans, C.A. App. A48-53, but Respondents' argument ignores the agency's previous findings on this issue and FDA's conclusion that Respondents' marketing restrictions were not "novel or materially different" from existing traditional approaches. In its 2020 Guidance, FDA announced that access restrictions had been insufficient to protect youth from flavored e-cigarettes.[29] "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.* Respondents fail to explain why access and marketing restrictions that FDA previously found insufficient to curb youth access to flavored e-

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[28] Pet. App. D, F (Triton Marketing Denial Orders).

[29] FDA, *supra* note 21.

cigarettes would be effective as to youth-appealing flavored e-liquids.

In fact, FDA's conclusion regarding the inadequacy of Respondents' marketing and access restrictions is supported by data collected since the 2020 Guidance. 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%).[30] And although Respondents have claimed that youth access to open-system e-cigarettes is limited because they are generally sold in age-restricted vape shops, more youth report buying e-cigarettes from vape shops (22.2%) than from gas stations or convenience stores (17.7%).[31] Further, as FDA explained in its 2020 Guidance, 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. 2020 Guidance at 28-29.

Given the ease with which youth report obtaining e-cigarettes and the alarming level of continued youth usage of flavored e-cigarettes, FDA

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[30] *Trends in Availability of Drugs as Perceived by 10th Graders,* MONITORING THE FUTURE, tbl. 10 (2022), https://monitoringthefuture.org/wpcontent/uploads/2022/12/mtf2022table16.pdf.

[31] 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.

reasonably concluded that Petitioners' access and marketing restrictions are insufficient to adequately reduce the risk of youth initiation of Petitioners' flavored products.

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

FDA regulatory action against flavored e-cigarettes yields 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,[32] 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 Fed. 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-

[32] *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. 28974 (May 10, 2016).

93. High school use rates increased from 11.3% to 27.5% between 2016 and 2019.[33]

Yet also unsurprisingly, when FDA's regulatory oversight and action increased, youth use began to subside. Between 2020 and 2023, high school e-cigarette use prevalence declined from 19.6% to 10%.[34] The decline began with FDA's January 2020 guidance prioritizing enforcement against certain flavored cartridge-based products, C.A. App. A183,[35] and continued as the agency issued MDOs for flavored e-cigarettes beginning in August 2021. In short, FDA regulatory action against flavored e-cigarettes, including through the issuance of MDOs for such products, has contributed to the recent decline in youth vaping.[36]

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[33] 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.

[34] Birdsey, *supra* note 2, at 1178; Gentzke, *supra* note 31, at 1181.

[35] The 2020 Guidance 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* C.A. App. A214.

[36] 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

Allowing the Fifth Circuit decision to stand would leave more young people in the grip of nicotine addiction and exposed to the health harms of e-cigarettes. It is imperative to public health that this Court reverse the decision below to protect the public, and especially the nation's youth, from flavored e-cigarettes.

CONCLUSION

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

Respectfully submitted,

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national, state, and local levels to implement tobacco control strategies, including Food and Drug Administration regulatory actions." Birdsey, *supra* note 2, at 1178.

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