

No. 23-1038

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IN THE  
**Supreme Court of the United States**

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FOOD AND DRUG ADMINISTRATION,  
*Petitioner,*  
v.  
WAGES AND WHITE LION INVESTMENTS, L.L.C.,  
DBA TRITON DISTRIBUTION, ET AL.,  
*Respondents.*

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**On Petition for a Writ of Certiorari to the  
United States Court of Appeals  
for the Fifth Circuit**

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

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## **Rules**

*Deeming Tobacco Products To Be Subject to the  
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*Amici*, a group of medical, public health, and community organizations, submit this brief in support of Petitioner Food and Drug Administration (“FDA”) and urge the Court to grant the petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case. That judgment, if allowed to stand, would significantly undermine FDA’s efforts to protect the health of children from the 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 Main 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 these 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” or “TCA”).<sup>1</sup>

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<sup>1</sup> Counsel of record for all parties received notice of *amici*’s intention to file this brief at least 10 days prior to April 18, 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.

**INTERESTS OF *AMICI CURIAE***

*Amici* are nine national 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, Parents Against Vaping E-cigarettes, and Truth Initiative. The *amici* include organizations with formal programs urging users to quit 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 every day 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. *Amici* therefore have a strong and continuing interest in ensuring that the premarket review process in the TCA functions to protect the 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 evidence of any 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 that would allow Respondents’ youth-appealing, flavored e-liquids to remain on the market, with no demonstration that they meet the statutory



standard of being “appropriate for the protection of the public health.”

### SUMMARY OF ARGUMENT

The petition for a writ of certiorari should be granted both because, as the petition persuasively argues, the Fifth Circuit’s decision is misguided and in direct conflict with the decisions of seven other federal courts of appeals, and because, if left to stand, the Fifth Circuit ruling would have significant adverse consequences for the health of children.

In *FDA v. Brown & Williamson Tobacco Corp.*, this Court recognized that “the thousands of premature deaths that occur each year because of tobacco use” constitute “one of the most troubling public health problems facing our Nation . . . .” 529 U.S. 120, 125 (2000). Indeed, use of tobacco products remains the leading cause of preventable death in the United States, resulting in 480,000 deaths per year.<sup>2</sup> Moreover, the tobacco industry has long understood that almost all new tobacco users begin their addiction in their youth: 90% of adult smokers begin smoking in their teens.<sup>3</sup> This pattern applies to e-cigarettes as the

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<sup>2</sup> OFFICE OF THE SURGEON GENERAL (“OSG”), U.S. DEPT’ OF HEALTH & HUMAN SERVS. (“HHS”), THE HEALTH CONSEQUENCES OF SMOKING - 50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL, *Executive Summary* 2 (2014), <https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf>.

<sup>3</sup> OSG, HHS, THE HEALTH CONSEQUENCES OF SMOKING - 50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 708 (2014), [https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf\\_NBK179276.pdf](https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf).

D.C. Circuit noted in a recent e-cigarette case, where it declared that “[b]usinesses seeking to make a profit selling tobacco products . . . face powerful economic incentives to reach younger customers.” *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 12 (D.C. Cir. 2022).

The tobacco industry has long known that to successfully market its products to young people, flavors are essential. 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.”<sup>4</sup>

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. FDA has recognized that flavors have driven youth usage of these products, with young people gravitating to whatever e-cigarette device affords them the flavors they seek. Nearly 90% of middle and high school users of e-cigarettes use flavored (*i.e.*, non-tobacco-flavored) products.<sup>5</sup> As FDA has begun denying applications for marketing authorization of flavored e-cigarettes in recent years, youth e-cigarette use has declined, but remains unacceptably high today, with

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<sup>4</sup> *Regulation of Flavors in Tobacco Products*, Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 12,294, 12,295 (Mar. 21, 2018).

<sup>5</sup> 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, 1173 (2023), <https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7244a1-H.pdf>.

2.1 million high school and middle school students currently using these products.<sup>6</sup>

E-cigarettes are harmful to young people. The nicotine in e-cigarettes makes them highly addictive, particularly for adolescents whose brains are still developing and who are especially vulnerable to nicotine addiction. 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.”<sup>7</sup> E-cigarettes also create a substantial risk of progression to cigarette smoking, and thereby threaten decades of progress against youth smoking. The Surgeon General has warned that “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”<sup>8</sup>

If left to stand, the Fifth Circuit ruling will undermine FDA’s exercise of its authority to protect the public, and particularly young people, from the health harms of flavored e-cigarettes. It will immediately harm young people in the three states of that Circuit, which already have rates of youth e-cigarette use that exceed the national average. But, as explained by Petitioner, this impact will not be limited

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<sup>6</sup> *Id.*

<sup>7</sup> OSG, 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](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html)

<sup>8</sup> OSG, HHS, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 5 (2016), [https://e-cigarettes.surgeongeneral.gov/documents/2016\\_SGR\\_Full\\_Report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf).

to the Fifth Circuit because that court’s rulings have effectively nullified the limits on venue imposed by the Tobacco Control Act. E-cigarette companies have exploited the rulings on venue to flock to the Fifth Circuit to challenge FDA marketing denial orders (“MDOs”), avoiding the seven circuits where MDOs for flavored products have been upheld.

## ARGUMENT

### I. Flavored E-Cigarettes Harm the Health of Young People.

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”).<sup>9</sup> Young people are not just experimenting with e-cigarettes—they are using them frequently. In 2023, 39.7% of high school e-cigarette users reported using them on at least 20 of the preceding 30 days.<sup>10</sup> Even more alarming, 29.9% of high school e-cigarette users reported *daily* use, a strong indication of nicotine addiction.<sup>11</sup> Roughly 530,000 middle and high school students are vaping on a daily basis.<sup>12</sup>

Flavored products “lie at the heart of the problem” and are largely driving these high rates of

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<sup>9</sup> Birdsey et al., *supra* note 5, at 1173, 1177.

<sup>10</sup> *Id.* at 1180 tbl.3.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

youth e-cigarette use. *Prohibition Juice*, 45 F.4th at 11. 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.” *Id.* at 190a. In 2023, 89.4% of current middle and high school e-cigarette users had used a flavored product in the past month.<sup>13</sup> And according to data from FDA and National Institutes of Health’s Population Assessment of Tobacco and Health Study, 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.” Pet. App. 189a.

Moreover, Respondents and other companies often promote their flavored e-liquids in youth-appelling ways. Some examples appear below. The products featured in Respondents’ social media posts below—Pink Lemonade, Blackberry Lemonade, and Milk of the Poppy—are subject to the challenged denial orders. *See* C.A. App. A109-A123.

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<sup>13</sup> Birdsey et al., *supra* note 5, at 1173.

**WARNING: This product contains nicotine. Nicotine is an addictive chemical.**

vapetasia • Follow

vapetasia Only way to start the day off with a fresh bottle of Milk of the Poppy! A complex mixture of Strawberries, Dragon Fruit, and a splash of cream!

Tag a friend that loves Milk of the Poppy!

Not for Sale to Minors

#vapetasia #vapehooligans #vapers #vapefam #vapenation #ejuice #eliquid #improof #vapelikeaboss #vape4you #vapefeed #notblowingsmoke #vapejuice #vapelikeaboss #vapesafe

136 likes  
August 4, 2020

Add a comment...

14

**WARNING: This product contains nicotine. Nicotine is an addictive chemical.**

vapetasia • Follow

vapetasia Vape Lemonade quenching your thirst since 2014!

Tell us about your experience with Vape Lemonade!

Not for Sale to Minors

#vapetasia #vapehooligans #vapers #vapefam #vapenation #ejuice #eliquid #improof #vapelikeaboss #vape4you #vapefeed #notblowingsmoke #vapejuice #vapelikeaboss #vapesafe #vapestyle #vapepom #vapeyle #vapefeed #vape4you #vape #vapingsaveslives

89 likes  
August 3, 2020

Add a comment...

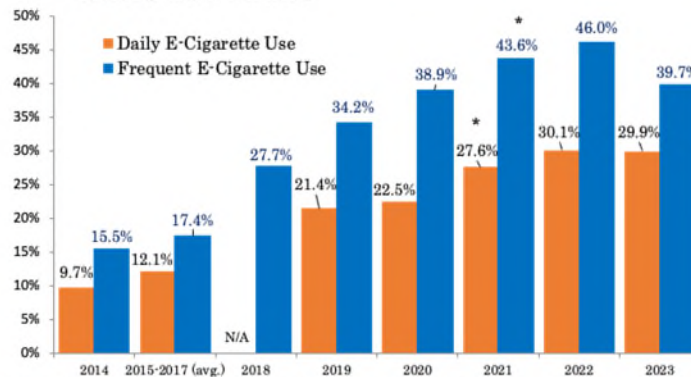
15

14 Vapetasia (@vapetasia), INSTAGRAM, <https://www.instagram.com/p/CDcJ7GKFIWo/> (Aug. 3, 2020).

15 Vapetasia (@vapetasia), INSTAGRAM, <https://www.instagram.com/p/CDcStFqlP3P/> (Aug. 4, 2020).

Respondents' 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 the chart below, frequent and daily use among high school e-cigarette users has remained at high levels over the years, even as overall high school e-cigarette use prevalence has declined. *See infra* Section III. Thus, while fewer high schoolers use e-cigarettes now than in prior years, the ones that do, use them more frequently, indicating that the level of addiction among these students has been rising.

**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.

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.” Pet. App. 194a. 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.” *Id.* at 194a-195a.<sup>16</sup>

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<sup>16</sup> Flavored ENDS do not have countervailing health benefits. The leading U.S. public health authorities, including the Surgeon General, the U.S. Preventive Services Task Force, the Centers for Disease Control and Prevention (“CDC”), and the National Academies of Science, Engineering and Medicine have all determined there is insufficient evidence to recommend any e-cigarettes for smoking cessation. OSG, HHS, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 7 (2020), <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf> ; U.S. Preventive Servs. Task Force, *Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: USPSTF Recommendation Statement*, 325 J. AM. MED. ASS’N 265 (2021), <https://jamanetwork.com/journals/jama/fullarticle/2775287>; CDC, *Adult Smoking Cessation – The Use of E-Cigarettes*, [https://www.cdc.gov/tobacco/data\\_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html](https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html) (Oct. 25, 2023); NAT’L ACADS. OF SCI., ENG’G & MED. PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018),



Use of e-cigarettes may also function as a gateway to the use of traditional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A 2018 report by the National Academies of Science, 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 e-cigarette use was associated with more than four times the odds of trying combustible cigarettes and nearly three times the odds of current combustible cigarette use.<sup>17</sup>

If left to stand, the Fifth Circuit’s decision will ensure that Respondents’ flavored e-cigarettes 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).

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<https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes>.

<sup>17</sup> Kaitlin M. Berry et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2 JAMA NETWORK OPEN 1, 7 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425>.

## **II. The Decision Below Will Harm Young People in the Fifth Circuit and Across the Country.**

If allowed to stand, the Fifth Circuit’s decision can be expected to have an immediate negative impact on young people living in states located in that Circuit. Those states already have above-average rates of youth e-cigarette use; in 2021 (the latest year with comparable state-level data), 25.5%, 20.9%, and 18.7% of high schoolers in Louisiana, Mississippi, and Texas, respectively, used e-cigarettes, compared to a national rate of 18%.<sup>18</sup> The decision below will allow sellers in these states to continue selling flavored e-cigarettes that FDA has determined are not “appropriate for the protection of the public health” due largely to their high level of youth appeal. The availability of these products will further exacerbate youth tobacco use disparities that exist in the Fifth Circuit.

Worse still, the public health harms of the decision below, if allowed to stand, will expand beyond the Fifth Circuit and be felt nationwide, given that Circuit’s decisions to nullify the TCA’s venue restrictions. The TCA allows an adversely affected person to seek judicial review of a denial order in the D.C. Circuit, the circuit where it resides, or the circuit where its principal place of business is located. *See* 21 U.S.C. § 387l(a)(1). The Fifth Circuit, however, has allowed manufacturers located outside of that circuit to obtain review of a denial order within the Fifth Circuit

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<sup>18</sup> CDC, *1991-2021 High School Youth Risk Behavior Survey Data*, <https://nccd.cdc.gov/Youthonline/App/Default.aspx> (last visited Apr. 3, 2024).

so long as it joins a seller of the manufacturer's product (*e.g.*, a gas station or distributor) that is located within the circuit. *See R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 188 & n.5 (5th Cir. 2023). Unsurprisingly, manufacturers of the leading e-cigarettes, including those most popular with youth, are now steering their lawsuits to the Fifth Circuit, rather than in their home circuits, many of which have already upheld similar MDOs for flavored e-cigarette products.

For example, after its home Fourth Circuit rejected a challenge to an MDO for flavored e-cigarettes, *see Avail Vapor v. FDA*, 55 F.4th 409 (4th Cir. 2022), North Carolina-based R.J. Reynolds Vapor Company filed subsequent challenges to FDA decisions on its flavored Vuse e-cigarette products in the Fifth Circuit. *See R.J. Reynolds Vapor Co.*, 65 F.4th at 191; Pet. for Review, *R.J. Reynolds Vapor Co. v. FDA*, No. 23-60545 (5th Cir. Oct. 12, 2023), ECF 1-1; Pet. for Review, *R.J. Reynolds Vapor Co. v. FDA*, No. 23-60128 (5th Cir. Mar. 17, 2023), ECF 1-1. In 2023, Vuse was the third-most popular e-cigarette brand among youth, used by 20.7% of all middle and high school e-cigarette users.<sup>19</sup> The Fifth Circuit's decisions to nullify the statutory venue restrictions and to stay the MDOs ensure that Reynolds can continue selling its flavored Vuse products across the nation. *See R.J. Reynolds Vapor Co.*, 65 F.4th at 191; Order, *R.J. Reynolds Vapor Co.*, Nos. 23-60037, 23-60128, 23-60545 (5th Cir. Feb. 2, 2024), ECF 133-2.

Similarly, Fontem U.S. L.L.C., the North Carolina-based maker of blu e-cigarettes, which are

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<sup>19</sup> Birdsey et al., *supra* note 5, at 1175.

also popular with youth,<sup>20</sup> filed a petition in the Fifth Circuit challenging an FDA marketing denial order for several of its flavored e-cigarettes. Pet. for Review, *Corr-Williams Co. v. FDA*, No. 24-60068 (5th Cir. Feb. 8, 2024), ECF 1-1; Letter (Feb. 12, 2024), ECF 28 (referring to FDA press release noting that products subject to MDO are flavored).<sup>21</sup> Fontem went forum-shopping after it previously lost its challenge to a similar MDO for some of its other flavored blu products in the D.C. Circuit. *Fontem US, LLC v. FDA*, 82 F.4th 1207 (D.C. Cir. 2023).

Finally, the Chinese-based manufacturers of SMOK and Suorin, the sixth and fourteenth most popular e-cigarette brands among youth respectively,<sup>22</sup> have similarly taken advantage of the Fifth Circuit's venue decisions. These companies added either a retailer or distributor that is located within the Fifth Circuit and then filed suit in that court, rather than in the D.C. Circuit, the TCA's default venue, which has repeatedly upheld similar MDOs. See *Prohibition Juice*, 45 F.4th 8; *Fontem*, 82 F.4th 1207; Pet. for Review, *Shenzhen Youme Info. Tech. Co. v. FDA*, No. 24-60060 (5th Cir. Feb. 5, 2024), ECF 1-1; Pet. for Review, *Shenzhen IVPS Tech. Co., Ltd. v. FDA*, No. 24-60032 (5th Cir. Jan. 19, 2024), ECF 1-1.

Absent review and reversal of the Fifth Circuit's decision, manufacturers of the leading e-cigarette

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<sup>20</sup> *Id.* at 1180 tbl.3.

<sup>21</sup> The Fifth Circuit subsequently issued a temporary administrative stay of the denial order, which remains in effect today. Order (Feb. 14, 2024), ECF 32-1.

<sup>22</sup> Birdsey et al., *supra* note 5, at 1180 tbl.3.

products, including those most popular with youth, will continue to steer their cases to the Fifth Circuit. This practice has already allowed makers of some of the most youth-appealing e-cigarettes to keep their flavored products on the market and to continue to addict kids, and is likely to grow as FDA issues additional decisions on e-cigarette marketing applications. Reversal of the Fifth Circuit's decision is necessary to avoid significant and long-term negative public health consequences.

### **III. 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,<sup>23</sup> these products were allowed to remain on the market with no risk of regulatory enforcement, even though they lacked the required FDA premarket authorization. *See generally Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020) (vacating FDA guidance that suspended premarket review requirement for e-cigarette products for four or more years and deferred enforcement during that

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<sup>23</sup> *See Deeming Tobacco Products To Be Subject to the Federal, Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974 (May 10, 2016).

period). Unsurprisingly, during this regulatory “holiday,” youth use of e-cigarettes reached “epidemic” levels. *Am. Acad. of Pediatrics*, 379 F. Supp. 3d at 492-93. High school use rates increased by 143% between 2016 and 2019 (11.3% to 27.5%).<sup>24</sup>

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%.<sup>25</sup> The decline began with FDA’s January 2020 guidance prioritizing enforcement against certain flavored cartridge-based products, C.A. App. A183,<sup>26</sup> 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

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<sup>24</sup> 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>.

<sup>25</sup> Birdsey et al., *supra* note 5, at 1178; Andrea S. Gentzke, *Tobacco Product Use Among Middle and High School Students – United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1181, 1181 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950a1-H.pdf>.

<sup>26</sup> The 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.

products, has contributed to the recent decline in youth vaping.<sup>27</sup>

Allowing the Fifth Circuit decision to stand unreviewed by this Court will 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 grant the petition and reaffirm FDA's authority to protect the public, and especially the nation's youth, from flavored e-cigarettes.

### CONCLUSION

For these reasons and those presented in the petition, *amici* urge the Court to grant the petition for a writ of certiorari.

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<sup>27</sup> The 2023 National Youth Tobacco Survey Report found that increased federal action was among several factors likely contributing to declining youth usage of e-cigarettes: the “decline since 2022 in high school student e-cigarette use is likely attributable to multiple factors, such as ongoing efforts at the national, state, and local levels to implement tobacco control strategies, including Food and Drug Administration regulatory actions.” Birdsey et al., *supra* note 5, at 1178.

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