

**UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT**

Diamond Vapor, L.L.C.,)
)
) *Petitioner,*)
)
) v.)
)
) U.S. Food and Drug Administration)
)
) *Respondent.*)

No. 21-13387

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

Johnny Copper L.L.C.,)
)
) *Petitioner,*)
)
) v.)
)
) U.S. Food and Drug Administration)
)
) *Respondent.*)

No. 21-13438

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

Vapor Unlimited L.L.C.,)
)
) *Petitioner,*)
)
) v.)
)
) U.S. Food and Drug Administration)
)
) *Respondent.*)

No. 21-13454

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

**UNOPPOSED BRIEF OF *AMICI CURIAE* MEDICAL AND PUBLIC
HEALTH GROUPS IN SUPPORT OF RESPONDENT’S OPPOSITION
TO PETITIONERS’ MOTION FOR A STAY PENDING REVIEW**

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to 11th Cir. R. 26.1-1 through 26.1-3, the undersigned counsel certifies that, in addition to those listed on the Certificates of Interested Persons and Corporate Disclosure Statements filed by Petitioners and Respondent, to the best of my knowledge, the following persons and entities have an interest in the outcome of this case:

American Academy of Family Physicians, *amicus curiae*

American Academy of Pediatrics, *amicus curiae*

American Cancer Society Cancer Action Network, *amicus curiae*

American Heart Association, *amicus curiae*

American Lung Association, *amicus curiae*

American Medical Association, *amicus curiae*

Campaign for Tobacco-Free Kids, *amicus curiae*

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Parents Against Vaping e-cigarettes, *amicus curiae*

Truth Initiative, *amicus curiae*

Zuckerman Spaeder LLP, counsel for *amici curiae*

Pursuant to Fed. R. App. P. 26.1(a) and 11th Cir. R. 26.1-3, the undersigned counsel certifies that *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.

Dated: December 29, 2021

/s/ Sara A. Lawson _____
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Amici medical, public health, and community organizations submit this brief urging the Court to deny the Opposed Motion for a Stay Pending Review (“Motion”) jointly filed by Petitioners Diamond Vapor, L.L.C., Johnny Copper L.L.C., and Vapor Unlimited L.L.C. because a stay would be contrary to the public interest, given the (1) substantial risk of youth usage of Petitioners’ products and (2) insufficient evidence of any potential benefit of those products in helping smokers to stop smoking that would outweigh the demonstrated risk to youth. This brief is filed with the consent of the parties.

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the following 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 (PAVe) and Truth Initiative. Each of these groups 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 are particularly well suited to inform the Court of the substantial public health harm from the continued availability of Petitioners’ ENDS products that would result from the requested stay.

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 this brief.

INTRODUCTION

E-cigarettes are the most popular tobacco product among youth, with more than two million young people reporting current e-cigarette use in 2021.¹ The tobacco industry has long understood that almost all new tobacco users begin their addiction before the age of 18² and that flavored products are essential to successfully market their products to young people.³ In 2021, almost 85% of youth e-cigarette users used a flavored product.⁴

The risk of youth initiation and use posed by flavors is well documented, but there is little evidence that flavors have any role in helping cigarette smokers quit.

¹ 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, 1387 (2021), <https://bit.ly/3BBMXLT>.

² OFFICE OF THE SURGEON GENERAL (“OSG”), U.S. DEP’T OF HEALTH & HUMAN SERVICES (“HHS”), PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS 508 (2012), <https://bit.ly/3oigB4H>.

³ *Id.* at 535-539.

⁴ Park-Lee et al., *supra* note 1, at 1387.

Accordingly, allowing Petitioners' flavored products—available in flavors such as “Apple Pie,” “Blueberry Crunch Glazed Donut,” “Fruity Cereal,” and “Rainbow Nerds,” A1408; A1427; A1437—to remain on the market for even one more day poses a significant risk to youth with no countervailing public health benefit. Therefore, the stay sought by Petitioners is entirely contrary to the public interest.

ARGUMENT

I. A Stay Is Contrary to the Public Interest Because There Is a Substantial Risk of Youth Usage of Petitioners' Products.

A. Youth use of e-cigarettes, particularly flavored products, is an ongoing public health crisis.

E-cigarettes have been the most commonly used tobacco product among youth since 2014.⁵ In December 2018, the U.S. Surgeon General declared the growing problem an “epidemic.”⁶ According to the National Youth Tobacco Survey (“NYTS”), in 2021, during the midst of the COVID-19 pandemic, over two million youth, including 11.3% of high schoolers, reported current e-cigarette use.⁷ While the Centers for Disease Control and Prevention (“CDC”) warns these data are not

⁵ *Id.*

⁶ OSG, HHS, SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 1 (2018), <https://bit.ly/3EIN531> (“OSG Advisory”).

⁷ Park-Lee et al., *supra* note 1, at 1387.

comparable to previous survey years due to methodology changes,⁸ just prior to the pandemic in 2020, nearly one in five (19.6%) U.S. high schoolers reported current e-cigarette use, *see* A1189, about the same level as in 2018 when the Surgeon General first declared youth e-cigarette use an “epidemic.”⁹

Young people are not just experimenting with e-cigarettes, but are using them frequently. In 2021, 43.6% of high school e-cigarette users reported using them on at least 20 of the preceding 30 days.¹⁰ Even more alarming, 27.6% of high school e-cigarette users reported *daily* use, a strong indication of deep nicotine addiction.¹¹ Half a million middle and high school students are vaping every single day.¹²

Flavored products are especially appealing to youth and are largely driving the alarming rates of youth e-cigarette use. According to FDA, “[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.” A1189. Data from the 2021 NYTS show that 84.7% of middle and high school e-cigarette users had used a flavored product

⁸ Whereas previous years’ surveys were conducted entirely in-school, the 2021 survey included both in-school and at-home responses; students who completed surveys in school reported higher e-cigarette use, suggesting that rates may have been much higher had the survey been conducted entirely in schools.

⁹ OSG Advisory, *supra* note 6, at 1.

¹⁰ Park-Lee et al., *supra* note 1, at 1387.

¹¹ *Id.*

¹² *Id.* at 1388 tbl.

in the past month.¹³ According to a 2020 Surgeon General Report, “the role of flavors in promoting initiation of tobacco product use among youth is well established . . . and appealing flavor is cited by youth as one of the main reasons for using e-cigarettes.”¹⁴ In denying a stay of a marketing denial order (“MDO”) in a similar case, the U.S. Court of Appeals for the Sixth Circuit found the special appeal of flavored e-cigarettes to youth to be “a matter of scientific consensus.” *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 508 (6th Cir. 2021).¹⁵

Petitioners’ e-liquids contain nicotine, Motion at 5, a highly addictive substance that can have lasting damaging effects on adolescent brain development. A1191. According to the Surgeon General, “[n]icotine exposure during adolescence can impact learning, memory, and attention,” and “can also increase risk for future addiction to other drugs.”¹⁶ Nicotine also impacts the cardiovascular system. A320. The Surgeon General has warned that, “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”¹⁷

¹³ *Id.*

¹⁴ OSG, HHS, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 611 (2020), <https://bit.ly/3lq1qED> (“OSG Smoking Cessation”).

¹⁵ The Supreme Court denied a stay of the MDO on Dec. 10, 2021. *Breeze Smoke, LLC v. FDA*, – S. Ct. –, No. 21A176, 2021 WL 5860294 (Dec. 10, 2021).

¹⁶ OSG Advisory, *supra* note 6, at 1.

¹⁷ OSG, HHS, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS, A REPORT OF THE SURGEON GENERAL 5 (2016), <https://bit.ly/3EjjjB>.

Use of e-cigarettes may also function as a gateway to the use of conventional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A1191-92. A 2018 report by the National Academies of Sciences, Engineering, and Medicine (“NASEM”) found “substantial evidence that e-cigarette use increases [the] risk of ever using combustible tobacco cigarettes among youth and young adults.” A241; *see also* A1191-92. Additionally, 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.¹⁸

B. There is a significant risk of youth usage of Petitioners’ products.

Petitioners manufacture “nicotine-containing e-liquids,” and their products come in such youth-appealing flavors as “Apple Pie,” “Blueberry Crunch Glazed Donut,” “Fruity Cereal,” and “Rainbow Nerds.” Motion at 5; A1408; A1427; A1437.

Despite selling these kid-friendly products, Petitioners contend that “their flavored products will not induce youth initiation.” Motion at 19. Specifically, Petitioners note that (1) “their ENDS products are bottled e-liquids for use in open-system devices, not the closed-system cartridges popular with youth,” (2) their

¹⁸ 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://bit.ly/3GfhrW1>.

“marketing plans called for products to be only sold in age-gated specialty tobacco shops and through age-gated online sales,” and (3) “Petitioners’ specific practices, which do not make them [flavored e-cigarettes] attractive to youth.” *Id.* For the reasons below, these assurances are insufficient to protect young people from Petitioners’ products.

First, open-system products (which use e-liquids like those sold by Petitioners) remain popular among children. Smok and Suorin, for example, are open-system devices and among the most popular e-cigarette devices among youth.¹⁹ Moreover, e-cigarette use by young people was a serious problem before closed-system products came to dominate the youth market beginning in 2017; indeed, youth e-cigarette prevalence reached 16% in 2015.²⁰

Second, specialty tobacco shops, such as vape shops, are a significant source of e-cigarettes for children. According to the 2018 NYTS, 16.5% of middle and high school e-cigarette users under 18 years of age report obtaining e-cigarettes from a vape shop in the past month, compared to 9.8% from a gas station or convenience

¹⁹ See Park-Lee et al., *supra* note 1, at 1388 tbl.

²⁰ See FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)**, at 11 (Apr. 2020), <https://bit.ly/3e7e0ED> (“2020 Guidance”).

store.²¹ 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.²² Further, as FDA noted in its 2020 Final Guidance,²³ most 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.²⁴ The reality of youth access to products sold in specialty tobacco shops underscores the health harms that would result if Petitioners’ flavored products are allowed to stay on the market while litigation is pending.

Finally, the “specific practices” Petitioners claim make their products unattractive to youth, Motion at 19, apparently refer to the companies’ “limited social media presence targeted at adult ENDS users.” Motion at 8 (citing A182; A1096-97; A1132). Specifically, Petitioners each assert that their social media pages are either inactive and/or restricted to users who are 21 years of age or older.

²¹ Sherry T. Liu et al., *Youth Access to Tobacco Products in the United States, 2016-2018*, 5 TOBACCO REG. SCI. 491, 495 (2019), <https://bit.ly/32kUZfa>.

²² April Roeseler et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, 173 JAMA PEDIATRICS 795, 796 (2019), <https://bit.ly/3e8PfYD>.

²³ 2020 Guidance, *supra* note 20, at 28-29.

²⁴ Teresa W. Wang et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4 JAMA NETWORK OPEN 1, 5 (published online June 7, 2021), <https://bit.ly/3pfgh6U> (57.1% of high school e-cigarette users reported getting e-cigarettes from a friend).

See A182 (“our brand’s now inactive Instagram and Facebook pages . . .”); “our [social media] pages were restricted to profiles of those over 21....”); A1097 (“our age-gated social media pages”); A1132 (“Facebook business page that restricts users who are not 21 years of age or older”). However, those claims appear to be groundless, as Petitioners’ social media pages are both active and not age-gated. Someone who is not even logged into a Facebook account, and therefore has not been asked to verify their age—let alone prove it—is able to view Petitioners’ Facebook pages, which include posts promoting Petitioners’ flavored e-liquids as well as store addresses and telephone numbers.²⁵ Regardless, even if Petitioners had effectively restricted their social media sites, this marginal measure would accomplish little given that Petitioners’ products have the feature—flavors—that make them powerfully attractive to youth, Petitioners sell through retail outlets through which young people obtain their products, and social sources are readily available for youth access.

²⁵ See, e.g., Diamond Vapor (@diamond.vapor5), FACEBOOK, <https://www.facebook.com/diamond.vapor.5/> (last visited Dec. 17, 2021); Johnny Copper Vapor Co. (9735 Old St. Augustine Rd. Suite #12, Jacksonville, FL), FACEBOOK, <https://www.facebook.com/pages/category/Lounge/Johnny-Copper-Vapor-Co-1938296819736713/> (last visited DEC. 17, 2021); Vapor Unlimited Smoke & Vape Shop (@vaporunlimitedbv), https://www.facebook.com/pg/vaporunlimitedbv/posts/?ref=page_internal (last visited Dec. 17, 2021).

Every day that Petitioners' flavored products remain on the market, they contribute to the risk of nicotine addiction and other health harms to young people. A stay is decidedly not in the public interest.

II. A Stay is Contrary to the Public Interest Because Any Potential Benefit of Petitioners' Products in Helping Smokers to Stop Smoking Is Outweighed by the Demonstrated Risk of Flavored E-Cigarette Products to Youth.

Given the overwhelming evidence that flavored products are attractive to young people, it is entirely reasonable for FDA to require “the strongest types of evidence” demonstrating that, in comparison to unflavored (i.e., tobacco-flavored) products, flavored products like Petitioners' benefit smokers by helping them to stop smoking cigarettes and to issue an MDO for failure to furnish such evidence. A1186.

The publicly-available evidence does not convincingly show that e-cigarettes facilitate smoking cessation—and the evidence is even weaker that flavors are necessary to help smokers stop smoking. The leading public health authorities in the U.S., including the Surgeon General, the U.S. Preventive Services Task Force (“USPSTF”), the CDC, and the NASEM, have all concluded that there is insufficient evidence to recommend any e-cigarettes for smoking cessation.²⁶ In the words of a

²⁶ OSG Smoking Cessation, *supra* note 14; USPSTF, *Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: USPSTF Recommendation Statement*, 325 J. AM. MED. ASS'N 265 (2021), <https://bit.ly/3Ig889N>; CDC, *Adult Smoking Cessation – The Use of E-Cigarettes*, <https://bit.ly/3Dfx97> (last updated Jan. 23, 2020); NASEM, PUBLIC HEALTH

2020 Surgeon General Report, “there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”²⁷

There is even less evidence that *flavored* e-cigarettes, with their intense appeal to youth, are more effective than tobacco-flavored e-cigarettes at helping cigarette smokers stop smoking. As the FDA observed, “the literature does not establish that flavors differentially promote switching [from cigarettes to e-cigarettes] amongst ENDS users in general.” A1194. A systematic review that examined consumer preference for various e-cigarette attributes also found “inconclusive evidence” as to whether flavored e-cigarettes assisted smokers to quit.²⁸ Thus, it was entirely reasonable for the FDA to require Petitioners to demonstrate the effectiveness of their flavored products in helping smokers to stop smoking through randomized clinical trials, longitudinal cohort studies, or other similarly rigorous studies.

Given the overwhelming evidence of the risks to youth posed by flavored e-cigarette products like Petitioners’, and the absence of sufficient evidence showing that those products help smokers quit smoking cigarettes, a stay of the MDO would not serve the public interest.

CONSEQUENCES OF E-CIGARETTES (2018), <https://bit.ly/32WnfoT> (included in Petitioners’ Addendum at A208).

²⁷ OSG Smoking Cessation, *supra* note 14, at 7.

²⁸ 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://bit.ly/3y1PHkR>.

CONCLUSION

For these reasons, and those presented by the government, *amici* urge the Court to deny Petitioners' Motion.

Dated: December 29, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. The foregoing brief complies with the word limits set forth in Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(g)(1) 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 2,472 words.

2. The foregoing brief 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.

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CERTIFICATE OF CONFERENCE

I hereby certify under Fed. R. App. P. 29(a)(2) that on December 22, 2021, I contacted counsel for the Petitioners and Respondent by electronic mail and that Petitioners and Respondent each consented to the filing of the brief of *amici curiae*.

/s/ Sara A. Lawson
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CERTIFICATE OF SERVICE

I hereby certify that on December 29, 2021, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Sara A. Lawson
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