

No. 21-3902

IN THE UNITED STATES COURT OF
APPEALS FOR THE SIXTH CIRCUIT

BREEZE SMOKE, LLC,

Petitioner, v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

ON PETITION FOR REVIEW OF A FINAL MARKETING DENIAL ORDER
BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION
FDA Submission No. PM0000983

**MOTION FOR LEAVE TO FILE BRIEF OF *AMICI CURIAE* AMERICAN
ACADEMY OF PEDIATRICS, AMERICAN CANCER SOCIETY CANCER
ACTION NETWORK, AMERICAN HEART ASSOCIATION, AMERICAN
LUNG ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS,
PARENTS AGAINST VAPING E-CIGARETTES AND TRUTH
INITIATIVE IN SUPPORT OF RESPONDENT'S OPPOSITION TO
PETITIONER'S MOTION FOR A STAY PENDING REVIEW**

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DISCLOSURE STATEMENT

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.

Dated: October 26, 2021

/s/ Jacquelyn A. Klima
Jacquelyn A. Klima (P69403)
Lead counsel for *Amici Curiae*

MOTION FOR LEAVE TO FILE BRIEF OF AMICI CURIAE

Pursuant to Rule 29 of the Federal Rules of Appellate Procedure, the proposed *amici* hereby move the Court for leave to file the attached brief *amicus curiae* in support of Respondent’s Opposition to Petitioner’s Motion for a Stay Pending Review of the Marketing Denial Order (“MDO”) that is the subject of this Petition. Respondent has consented to the filing of this brief. Petitioner declined to consent to the filing of this brief.

Prospective *amici* respectfully submit that their brief will assist the Court because *amici* have substantial expertise in the role that flavored e-cigarettes, such as Petitioner’s products, play in enticing youth to use tobacco products and the health harms that result from youth usage of these products—matters relevant to the disposition of this case. *Amici* have filed this motion and the accompanying brief one day after Respondent’s brief was filed to give *amici* an opportunity to review Respondent’s brief to ensure against unnecessary duplication. Petitioner suffers no prejudice from *amici*’s filing, which leaves Petitioner sufficient opportunity to respond.

Amici here include the following national medical, public health, and community organizations: American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Parents Against Vaping e-cigarettes

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. From pediatricians who counsel their young patients and their parents about the hazards of tobacco use, to organizations with formal programs to urge users to quit, to groups representing parents and families struggling to free young people from nicotine addiction, each of these organizations has a direct and immediate interest in curbing the sale of flavored e-cigarette products. A stay of the MDO would allow the continued sale of Petitioner’s flavored e-cigarettes, which constitute a substantial threat of addiction and other health harms to young people.

Amici also have an interest in this litigation because six of the *amici* were the plaintiffs in *Am. Academy of Pediatrics, et al. v. FDA*, 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) (“AAP”), which resulted in a federal court order setting a timeline for submission of premarket tobacco applications by Petitioner and other tobacco companies and disposition of those applications by the U.S. Food and Drug Administration (“FDA”). Thus, *amici* have a strong interest in ensuring that FDA’s premarket review process functions to protect the public, and particularly young people, from the health harms of new tobacco products like those marketed by Petitioner, as contemplated by the rulings in the AAP case.

Participation as an *amicus* is within the sound discretion of the court. *United States v. Michigan*, 940 F.2d 143, 165 (6th Cir. 1991). This *amicus* brief is desirable because the proposed *amici* have substantial expertise in the role that flavored e-cigarette products—like Petitioner’s—play in enticing young people to use tobacco, which was a key factor in FDA’s decision to deny a marketing order to Petitioner. They also have expertise in the health harms to young people from use of products like Petitioner’s. These matters are relevant to the disposition of Petitioner’s motion because, if the motion is granted, Petitioner’s products will remain on the market for an indefinite period while this litigation is pending. During such time, young people drawn to Petitioner’s products by flavors like Strawberry Cream and Blueberry Lemon, *see* A5, would be at risk of suffering serious health harms.

For these reasons, the proposed *amici* urge the Court to grant this motion for leave to file the attached brief *amicus curiae*.

Dated: October 26, 2021

Respectfully submitted,

/s/ Jacquelyn A. Klima

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

1. The foregoing motion complies with the word limits of Fed. R. App. P. 32(g)(1) and Fed. R. App. P. 27(d)(2)(A) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f) and Fed. R. App. P. 27(d)(2), the word count feature in Microsoft Word reports that this document contains 635 words.

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

/s/ Jacquelyn A. Klima

Jacquelyn A. Klima (P69403)
Attorney for *Amici Curiae*

CERTIFICATE OF CONFERENCE

I hereby certify under Fed. R. App. P. 29(a)(2) that on October 21, 2021 I contacted the Petitioner and the Respondent by electronic mail and that the Respondent consented to the filing of the Brief of *Amici Curiae*, but the Petitioner did not consent to the filing of the Brief of *Amici Curiae*.

/s/ Daniel J. Ferris

Daniel J. Ferris (P38154)

Attorney for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on October 26, 2021, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

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Dated: October 26, 2021

/s/ Jacquelyn A. Klima
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Amici medical, public health, and community organizations submit this brief urging the Court to deny the Motion of Petitioner Breeze Smoke, LLC (“Breeze Smoke”) for a Stay Pending Review (“Motion”) because a stay would be contrary to the public interest, given the (1) substantial risk of youth usage of Petitioner’s 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.

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the following national medical, public health, and community organizations: American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Parents Against Vaping e-cigarettes 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 Petitioner’s ENDS products that would result from the requested stay pending review.

Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* represent that no party’s counsel authored the brief in whole or in part, neither the parties nor their counsel

contributed money intended to fund preparing or submitting the brief, and no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the 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 as children² and that flavored products are essential to successfully market their products to young people.³ In 2021, over 80% of youth e-cigarette users used a flavored product.⁴

In contrast to the well-documented risk of youth initiation and use posed by flavors, there is little evidence that flavors have any role in helping cigarette smokers quit. Petitioner’s products are all flavored—with flavors like Strawberry Cream and Blueberry Lemon—and disposable. Motion at 6; A23. The use of

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://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf>.

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://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf.

³ *Id.* at 535-539.

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

these disposable, flavored e-cigarettes by young people has surged in recent years.⁵ In 2021, disposables are the most commonly used e-cigarette device type among current youth e-cigarette users.⁶ Allowing Petitioner’s products that are the subject of this litigation to remain on the market for even one more day poses a significant risk to our children with no countervailing public health benefit. Therefore, the stay sought by Petitioner 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 Petitioner’s Products.

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

E-cigarettes have been the most commonly used tobacco product among youth since 2014.⁷ In December 2018, the U.S. Surgeon General declared the growing problem an “epidemic.”⁸ 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.⁹

⁵ See Teresa W. Wang et al., *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1310, 1310 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>

⁶ Park-Lee et al., *supra* note 1, at 1387.

⁷ *Id.*

⁸ OSG, HHS, SURGEON GENERAL’S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 1 (2018), <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf> (“OSG Advisory”).

⁹ Park-Lee et al., *supra* note 1, at 1387.

While the Centers for Disease Control and Prevention (“CDC”) warns these data are not comparable to previous survey years due to methodology changes,¹⁰ just prior to the pandemic in 2020, nearly one in five (19.6%) U.S. high schoolers reported current e-cigarette use,¹¹ about the same level as in 2018 when the Surgeon General first declared youth e-cigarette use an “epidemic.”¹²

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 frequent use, defined as 20 or more days per month.¹³ Even more alarming, 27.6% of high school e-cigarette users reported *daily* use, a strong indication of deep nicotine addiction.¹⁴ Half a million middle and high school students are vaping every single day.¹⁵

Flavored products are especially appealing to youth and are largely driving the alarming rates of youth e-cigarette use.¹⁶ As the Food and Drug

¹⁰ 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 the rates may have been much higher had the survey been conducted entirely in schools.

¹¹ A12; Wang et al., *supra* note 5, at 1310.

¹² OSG Advisory, *supra* note 8, at 1.

¹³ Park-Lee et al., *supra* note 1, at 1387.

¹⁴ *Id.*

¹⁵ *Id.* at 1388.

¹⁶ A10; *see also* Li-Ling Huang, *Impact of non-menthol flavours in tobacco products on perceptions and use among youth, young adults and adults: a systematic review*, 26 TOBACCO CONTROL 709 (2017), <https://tobaccocontrol.bmj.com/content/tobaccocontrol/26/6/709.full.pdf>.

Administration (“FDA”) recognized in evaluating Petitioner’s products, “[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.”¹⁷ Data from the 2021 NYTS show that 84.7% of middle and high school e-cigarette users had used a flavored product in the past month.¹⁸ 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.”¹⁹

E-cigarette liquids, such as Petitioner’s products, typically contain nicotine, a highly addictive drug that can have lasting damaging effects on adolescent brain development.²⁰ 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.”²¹ Nicotine also impacts the cardiovascular system.²² Moreover, as the country is in the midst of a mental health crisis, the

¹⁷ A12.

¹⁸ Park-Lee et al., *supra* note 1, at 1388.

¹⁹ OSG, HHS, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 611 (2020), <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

²⁰ A14.

²¹ OSG Advisory, *supra* note 8, at 1.

²² A15-A16; *see also* OSG, HHS, *Cardiovascular System, in* HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE: A REPORT OF THE SURGEON GENERAL 407 (2010), https://www.ncbi.nlm.nih.gov/books/NBK53017/pdf/Bookshelf_NBK53017.pdf.

data show that nicotine can amplify symptoms of anxiety and depression.²³ The Surgeon General has warned that, “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”²⁴

Petitioner’s products that are the subject of this litigation have nicotine salt concentrations of 5%,²⁵ making them highly addictive. According to a 2018 Surgeon General advisory on e-cigarette use among youth, nicotine salts allow users to inhale high levels of nicotine more easily and with less irritation than e-cigarettes that use free-base nicotine. As a result, it could be easier for young people to initiate the use of nicotine with these products.²⁶ Analysis of youth trend data from the 2017-2019 International Tobacco Control surveys found that “[t]he use of high-nicotine salt-based products is associated with greater symptoms of dependence, including JUUL and other higher-nicotine brands. Greater use of

²³ William V. Lechner et al., *Bi-directional associations of electronic and combustible cigarette use onset patterns with depressive symptoms in adolescents*, 96 PREVENTIVE MED. 73 (2017), <https://pubmed.ncbi.nlm.nih.gov/28024859/>; Munir Gunes Kutlu & Thomas J. Gould, *Nicotine modulation of fear memories and anxiety: Implications for learning and anxiety disorders*, 97 BIOCHEMISTRY PHARMACOLOGY 498 (2015), <https://pubmed.ncbi.nlm.nih.gov/26231942/>.

²⁴ 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.

²⁵ A5.

²⁶ OSG Advisory, *supra* note 8, at 2.

high-nicotine salt-based products may account for recent increases in the frequency of vaping among youth in Canada and the USA.”²⁷

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.²⁸ 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.”²⁹ 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, compared with youth who had never used a tobacco product.³⁰

That fact that Petitioner’s products are not only flavored, but disposable, makes them especially appealing to young people. Even a quick glance at

²⁷ David Hammond et al., *Trends in e-cigarette brands, devices and the nicotine profile of products used by youth in England, Canada and the USA: 2017-2019*, TOBACCO CONTROL (2021), <https://pubmed.ncbi.nlm.nih.gov/34099572/>.

²⁸ A15.

²⁹ NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), <https://www.nap.edu/catalog/24952/public-health-consequences-of-e-cigarettes>; see also A15.

³⁰ 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>.

Petitioner's website shows these products to be light, portable and easy to conceal, as any young person can see on the website by simply claiming to be over 21. *See* <https://www.breezesmoke.com/>. The use of disposables by youth has surged in recent years—by 1000%—from 2.4% to 26.5% between 2019 and 2020.³¹ In 2021, 55.8% of high school e-cigarette users reported using disposable products.³²

B. There is a significant risk of youth usage of Petitioner's products.

Petitioner describes itself as “a manufacturer of disposable, flavored, pod-based ENDS products,” Motion at 6, exactly the kinds of products that are fueling the youth vaping epidemic. Its assurance that it has “undertaken a number of measures to prevent youth use . . .”, Motion at 6-7, is hardly sufficient to ameliorate the threat its products pose to young people. The measures listed by Petitioner largely consist of informing retailers of the requirements of the law.³³ Moreover, stating on the packaging that “this product is only for people above the age of 21,”³⁴ accomplishes little when the product itself has all the features that make it attractive to youth. Finally, given that the youth e-cigarette epidemic has occurred despite existing legal restrictions on youth access to tobacco products, it

³¹ Wang et al., *supra* note 5, at 1311.

³² Park-Lee et al., *supra* note 1, at 1388 tbl.

³³ *See* Haddad Decl., at A352-53 ¶ 5. Petitioner claims that it has “chang[ed] its product names to avoid unintentionally attracting youth interest,” Motion at 7, but the paragraph cited from its Haddad Declaration says nothing of the kind. *See* Haddad Decl., at A352-53 ¶ 5.

³⁴ A46.

cannot be doubted that such restrictions, even if strongly enforced, are insufficient to address products with such intense appeal to youth, particularly the flavored, disposable products that young people prefer. Given the shocking level of continued youth usage of e-cigarettes, FDA can hardly be criticized for observing that “we are not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS.”³⁵

Every day that Petitioner’s 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 Petitioner’s Products for 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,”³⁶ demonstrating that, compared to unflavored (i.e., tobacco-flavored) products, flavored products like Petitioner’s benefit smokers by helping them to stop smoking cigarettes and to issue an MDO for failure to furnish such evidence.

The publicly-available evidence does not convincingly show that e-cigarettes facilitate smoking cessation—and the evidence is even weaker that

³⁵ A17 n.xix.

³⁶ A9.

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.³⁷

According to a 2020 Surgeon General Report, “there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”³⁸

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 quit. A systematic review that examined consumer preference for various e-cigarette attributes found “inconclusive evidence” as to whether flavored e-cigarettes assisted quitting smoking.³⁹ The FDA correctly concluded that “the literature does not establish that flavors differentially promote switching amongst ENDS users in general.”⁴⁰ Thus, it is entirely reasonable for the FDA to

³⁷ OSG Smoking Cessation, *supra* note 19; USPSTF, *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* (last reviewed Jan. 23, 2020), https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html; NASEM, *supra* note 29.

³⁸ OSG Smoking Cessation, *supra* note 19, at 7.

³⁹ 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/>.

⁴⁰ A18.

require Petitioner to demonstrate the effectiveness of its flavored products in helping smokers stop smoking through randomized clinical trials, longitudinal cohort studies or similarly rigorous studies.

Instead of doing rigorous scientific studies, Petitioner conducted its own customer survey showing that 92% of those surveyed “stated that flavored e-liquids were important to them in choosing to vape instead of smoke cigarettes.” A72; *see also* Motion at 7. Such surveys measure only users’ beliefs about their experience with flavored products; they prove nothing about whether the use of flavors actually affects smoking behavior when compared to tobacco-flavored products. Petitioner presented no studies showing that users of their flavored products were more likely to quit smoking cigarettes than users of tobacco-flavored products. Only the kinds of rigorous studies required by FDA—measuring the extent to which smokers actually quit smoking cigarettes using flavored products vs. using tobacco flavored products—can establish the link between flavors and smoking behavior. Given the overwhelming evidence that flavored e-cigarettes have addicted millions of young people to nicotine, FDA is more than justified in requiring scientifically valid studies to demonstrate that flavors help smokers quit smoking cigarettes, instead of relying on customer surveys.

Therefore, given the overwhelming evidence of the risk flavored e-cigarette products, like Petitioner's, pose to young people, and the absence of sufficient evidence showing that those products help smokers quit smoking cigarettes, a stay of the Breeze Smoke MDO would not serve the public interest.

CONCLUSION

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

Dated: October 26, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 26, 2021, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

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