

No. 21-71327

**IN THE UNITED STATES COURT OF  
APPEALS FOR THE NINTH CIRCUIT**

MH GLOBAL LLC, doing business as	)	On Petition for Review
STREAMLINE VAPE CO. LLC,	)	of a Final Marketing
	)	Denial Order by the
Petitioner,	)	United States Food and
	)	Drug Administration
v.	)	
	)	
UNITED STATES FOOD AND DRUG	)	
ADMINISTRATION,	)	
	)	
Respondent.	)	
	)	

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**UNOPPOSED BRIEF OF *AMICI CURIAE* MEDICAL AND PUBLIC  
HEALTH GROUPS 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: December 14, 2021

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*Amici* medical, public health, and community organizations submit this brief urging the Court to deny the Motion for a Stay Pending Review (“Motion”) filed by Petitioner MH Global LLC 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. This brief is filed with the consent of the parties.

**STATEMENT OF INTEREST OF *AMICI CURIAE***

*Amici* are the following state and 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, California 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 Petitioner’s 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 the brief.

## INTRODUCTION

E-cigarettes are the most popular tobacco products among youth, with more than two million young people reporting current e-cigarette use in 2021.<sup>1</sup> The tobacco industry has long understood that almost all new tobacco users begin their addiction before the age of 18<sup>2</sup> and that flavored products are essential to successfully market their products to young people.<sup>3</sup> In 2021, almost 85% of youth e-cigarette users used a flavored product.<sup>4</sup> All of Petitioner’s products subject to the challenged marketing denial order (“MDO”) are flavored.

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.

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<sup>1</sup> 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>.

<sup>2</sup> 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>.

<sup>3</sup> *Id.* at 535-539.

<sup>4</sup> Park-Lee et al., *supra* note 1, at 1387.

Accordingly, allowing Petitioner’s flavored products—with names like Bam’s Cannoli Birthday, Juice Head Blueberry Lemon Freeze, and Juice Head Strawberry Kiwi Freze, Opp. A1—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 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 ongoing public health crisis.**

E-cigarettes have been the most commonly used tobacco products among youth since 2014.<sup>5</sup> In December 2018, the U.S. Surgeon General declared the growing problem an “epidemic.”<sup>6</sup> 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.<sup>7</sup> While the Centers for Disease Control and Prevention (“CDC”) warns these data are not comparable to previous survey years due to methodology changes,<sup>8</sup> just prior to the

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<sup>5</sup> *Id.*

<sup>6</sup> OSG, HHS, SURGEON GENERAL’S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 1 (2018), <https://bit.ly/3E1N531> (“OSG Advisory”).

<sup>7</sup> Park-Lee et al., *supra* note 1, at 1387.

<sup>8</sup> Whereas previous years’ surveys were conducted entirely in-school, the 2021 survey included both in-school and at-home responses; students who completed

pandemic in 2020, nearly one in five (19.6%) U.S. high schoolers reported current e-cigarette use, *see* A39, about the same level as in 2018 when the Surgeon General first declared youth e-cigarette use an “epidemic.”<sup>9</sup>

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 20 of the preceding 30 days.<sup>10</sup> Even more alarming, 27.6% of high school e-cigarette users reported *daily* use, a strong indication of deep nicotine addiction.<sup>11</sup> Half a million middle and high school students are vaping every single day.<sup>12</sup>

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.” A39. 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.<sup>13</sup> 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

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surveys in school reported higher e-cigarette use, suggesting that rates may have been much higher had the survey been conducted entirely in schools.

<sup>9</sup> OSG Advisory, *supra* note 6, at 1.

<sup>10</sup> Park-Lee et al., *supra* note 1, at 1387.

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

<sup>12</sup> *Id.* at 1388.

<sup>13</sup> *Id.*

using e-cigarettes.”<sup>14</sup> In denying a stay of an 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*, \_\_F.4th \_\_, No. 21-3902, 2021 WL 5276303, at \*5 (6th Cir. Nov. 12, 2021).<sup>15</sup>

Petitioner’s e-liquids contain nicotine, Motion at 6, a highly addictive substance that can have lasting damaging effects on adolescent brain development. A41. 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.”<sup>16</sup> Nicotine also impacts the cardiovascular system. A42; A110. 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>17</sup>

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. A41-42. 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

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

<sup>15</sup> The Supreme Court denied a stay of the MDO on Dec. 10, 2021. *Breeze Smoke, LLC v. FDA*, No. 21A176 (U.S. Dec. 10, 2021).

<sup>16</sup> OSG Advisory, *supra* note 6, at 1.

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

cigarettes among youth and young adults.”<sup>18</sup> 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.<sup>19</sup>

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

Petitioner is a “manufacturer of bottled nicotine-containing e-liquids” and all of its products at issue in this litigation are the flavored, kid-friendly products that are fueling the youth vaping epidemic. Motion at 1, 7. Petitioner’s products come in flavors such as Cake Batter Cannoli, Caramel Cream, and Strawberry Kiwi. Opp. A1.

Nevertheless, Petitioner contends that it submitted information to FDA that demonstrates “that its flavored products will not induce youth initiation and will assist with adult cessation.” Motion at 16. Specifically, Petitioner points to (1) its “[r]isk mitigation strategies, such as age verification,” (2) “[a]ge-appropriate marketing and labeling of the products,” and (3) the fact that its “flavored ENDS products are bottled e-liquids for use in an open system device, and not the types of ENDS products...that are used more heavily by youth.” Motion at 16. For the

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<sup>18</sup> NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), <https://bit.ly/32WnfoT>; see also A41-42.

<sup>19</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://bit.ly/3GfhrW1>.

reasons below, these assurances are insufficient to protect young people from Petitioner's products.

First, Petitioner's "[r]isk mitigation strategies" appear to consist of nothing more than reminding the retail sellers of its products to verify that a customer is legally old enough to purchase tobacco products—something they are already legally required to do. *See* A19 ("Age verification is done to avoid its use by youth under age 21 as per applicable laws."). Petitioner says nothing about how it enforces age verification by its retailers. *See id.* In any event, youth usage of flavored e-cigarettes rose to epidemic levels despite existing legal age restrictions and verification requirements; they are clearly insufficient to prevent young people from obtaining and using such highly appealing and addictive products.

Second, as evidence of its "[a]ge-appropriate marketing and labeling," Petitioner cites to its own assurances that it (a) does not make false claims about its products, (b) provides health warnings and nicotine content statements, (c) does not provide free samples at promotional events, (d) does not include youth-appealing pictures on its products, and (e) does not promote its products using social media influencers. A19; *see also* Motion at 16. The first three measures are already required under federal law. *See* 21 U.S.C. § 387c(a)(7)(A) (prohibiting false or misleading advertisements); 15 U.S.C. § 45(a) (prohibiting unfair or deceptive marketing); 21 C.F.R. § 1143.3 ("Minimum Required Warning Statements"); 21

C.F.R. § 1140.16(d)(1) (free sample prohibition). Given the intense appeal of flavors as the driver of youth usage, Petitioner’s purported commitment to not use youth-appealing pictures on its products is the bare minimum that should be done, but it can be expected to have minimal impact. Similarly, Petitioner’s final commitment to not promote its products using social media influencers is also unlikely to deter youth usage, given that Petitioner has not vowed to cease all of its social media activity, the ubiquitous use of social media by young people, the intense appeal of flavors, and the addictiveness of Petitioner’s products. These marginal measures—many of which simply recite existing obligations under federal law—are hardly sufficient to keep its youth-appealing flavored products out of the hands of kids.

Finally, Petitioner’s claim that open system products (which use e-liquids like those sold by Petitioner) do not appeal to youth also misses the mark. Smok and Suorin, for example, are open system devices and are among the most popular e-cigarette devices used by youth.<sup>20</sup>

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.

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<sup>20</sup> See Park-Lee et al., *supra* note 1, at 1388 tbl.

**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” demonstrating that, in comparison 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. A99.

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.<sup>21</sup> According to a 2020 Surgeon General Report, “there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”<sup>22</sup>

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<sup>21</sup> 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, *supra* note 18.

<sup>22</sup> OSG Smoking Cessation, *supra* note 14, at 7.

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.” A44. A systematic review that examined consumer preference for various e-cigarette attributes also found “inconclusive evidence” as to whether flavored e-cigarettes assisted quitting smoking.<sup>23</sup> Thus, it was entirely reasonable for the FDA to require Petitioner to demonstrate the effectiveness of its 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 Petitioner’s, 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.

## CONCLUSION

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

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<sup>23</sup> 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>.

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I hereby certify that on this 14th day of December, 2021, a true and correct copy of the foregoing was filed with the Clerk of the United States Court of Appeals for the Ninth Circuit via the the Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

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