

No. 21-71319

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

7 Daze LLC,

Petitioner,

v.

U.S. FOOD & DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Final Marketing Denial Order
by the United States Food and Drug Administration

**MOTION FOR LEAVE TO FILE BRIEF OF *AMICI CURIAE*
MEDICAL AND PUBLIC HEALTH GROUPS IN SUPPORT
OF RESPONDENT'S OPPOSITION TO PETITIONER'S
EMERGENCY MOTION FOR A STAY PENDING APPEAL**

Jordan Raphael
BYRON RAPHAEL LLP
1055 West 7th St., Suite 3300
Los Angeles, CA 90067
Tel: (213) 291-9800
Fax: (213) 377-5771
jraphael@byronraphael.com

Attorneys for *Amici Curiae*

Of Counsel:
Dennis A. Henigan
Connor Fuchs
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 Eye Street, NW, Suite 1200
Washington, DC. 2005
Tel: (202) 296-5469
Fax: (202) 296-5427
dhenigan@tobaccofreekids.org
cfuchs@tobaccofreekids.org

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: April 14, 2022

/s/ Jordan Raphael
Jordan Raphael
Attorney for *Amici Curiae*

MOTION FOR LEAVE

Proposed *amici* hereby move the Court for leave to file the attached Proposed Brief of *Amici Curiae* Medical and Public Health Groups in Support of Respondent’s Opposition to Petitioner’s Emergency Motion for a Stay Pending Appeal. Respondent has consented to the filing of the *amicus* brief, but Petitioner has not.

Amici here are the following national and state 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.

From physicians who counsel their young patients and their parents about the hazards of tobacco use, to organizations with formal programs to help users quit, to groups representing parents and families struggling to free young people from nicotine addiction, each of these organizations 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 the e-liquids used in those products. Accordingly, *amici* have a direct and immediate interest in curbing the sale of flavored e-cigarette products, such as Petitioner’s e-liquids. A stay of the marketing denial order (“MDO”) would allow the continued sale of Petitioner’s flavored e-

liquids, 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 groups 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 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.

This *amicus* brief is desirable because proposed *amici* have substantial expertise in the role 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.

Based on this expertise, *amici* are well suited to inform the Court of the harm to the public interest that would result from a stay, a key factor in the Court’s consideration of Petitioner’s motion. *See Nken v. Holder*, 556 U.S. 418, 426 (2009).

The proposed *amicus* brief argues that a stay would be contrary to the public interest because: (1) there is a substantial risk of youth usage of Petitioner's products, and (2) any potential benefit of Petitioner's products in helping smokers to stop smoking is outweighed by the demonstrated risk of flavored e-cigarette products to youth. 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 flavored e-liquids, such as "Reds Apple Fruit Mix" and "Reds Apple Mango," Petr's App'x. 11, would be at risk of suffering health harms.

Finally, given the briefing schedule set by the Court, the proposed *amicus* brief has been filed in a timely fashion, affording Petitioner ample opportunity to respond in its reply brief, which is due on April 18, 2022.

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

Dated: April 14, 2022

Respectfully submitted,

/s/ Jordan Raphael

Jordan Raphael
BYRON RAPHAEL LLP
1055 West 7th St., Suite 3300
Los Angeles, CA 90067
Tel: (213) 291-9800
Fax: (213) 377-5771
Email: jraphael@byronraphael.com

Dennis A. Henigan (Of Counsel)
Connor Fuchs (Of Counsel)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I St. NW, Suite 1200
Washington, DC 20005
Tel: (202) 481-9366
Fax: (202) 296-5427
Email: dhenigan@tobaccofreekids.org
Email: cfuchs@tobaccofreekids.org

Attorneys for Proposed *Amici Curiae*

CERTIFICATE OF COMPLIANCE

1. The foregoing motion complies with the type-volume limitation set forth in Fed. R. App. P. 27(d)(2)(A) and 9th Cir. R. 27-1(1)(d) because, excluding the parts of the document exempted by Fed. R. App. 32(f), the motion is four pages and contains 630 words, as reported by the word count feature in Microsoft Word.

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/ Jordan Raphael

Jordan Raphael

BYRON RAPHAEL LLP

1055 West 7th St., Suite 3300

Los Angeles, CA 90067

Tel: (213) 291-9800

Fax: (213) 377-5771

Email: jraphael@byronraphael.com

Attorney for Proposed *Amici Curiae*

CERTIFICATE OF CONFERENCE

I hereby certify that, pursuant to 9th Cir. R. 29-3, on April 8, 2022, I contacted counsel for both the Petitioner and the Respondent by electronic mail seeking consent to file the subject Brief of *Amici Curiae* and that counsel for Respondent provided consent on April 8, 2022 and counsel for Petitioner represented that Petitioner did not consent on April 10, 2022.

/s/ Jordan Raphael

Jordan Raphael

BYRON RAPHAEL LLP

1055 West 7th St., Suite 3300

Los Angeles, CA 90067

Tel: (213) 291-9800

Fax: (213) 377-5771

Email: jraphael@byronraphael.com

Attorney for Proposed *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of April, 2022, 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 Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

/s/ Jordan Raphael

Jordan Raphael

BYRON RAPHAEL LLP

1055 West 7th St., Suite 3300

Los Angeles, CA 90067

Tel: (213) 291-9800

Fax: (213) 377-5771

Email: jraphael@byronraphael.com

Attorney for Proposed *Amici Curiae*

No. 21-71319

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

7 Daze LLC,

Petitioner,

v.

U.S. FOOD & DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Final Marketing Denial Order
by the United States Food and Drug Administration

**PROPOSED BRIEF OF *AMICI CURIAE* MEDICAL
AND PUBLIC HEALTH GROUPS IN SUPPORT OF
RESPONDENT'S OPPOSITION TO PETITIONER'S
EMERGENCY MOTION FOR A STAY PENDING APPEAL**

Jordan Raphael
BYRON RAPHAEL LLP
1055 West 7th St., Suite 3300
Los Angeles, CA 90067
Tel: (213) 291-9800
Fax: (213) 377-5771
jraphael@byronraphael.com

Attorneys for *Amici Curiae*

Of Counsel:
Dennis A. Henigan
Connor Fuchs
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 Eye Street, NW, Suite 1200
Washington, DC. 2005
Tel: (202) 296-5469
Fax: (202) 296-5427
dhenigan@tobaccofreekids.org
cfuchs@tobaccofreekids.org

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: April 14, 2022

/s/ Jordan Raphael
Jordan Raphael
Attorney for *Amici Curiae*

TABLE OF CONTENTS

STATEMENT OF INTEREST OF <i>AMICI CURIAE</i>	1
INTRODUCTION.....	2
ARGUMENT	3
I. A Stay Is Contrary to the Public Interest Because There Is a Substantial Risk of Youth Usage of Petitioner’s Products.....	3
A. Youth use of e-cigarettes, particularly flavored products, is an on-going public health crisis.	3
B. There is a significant risk of youth usage of Petitioner’s products.....	6
II. A Stay is Contrary to the Public Interest Because Any Potential Benefit of Petitioner’s Products in Helping Smokers Stop Smoking Is Outweighed by the Known Risk of Flavored E-Cigarettes to Youth.	10
CONCLUSION	11

TABLE OF AUTHORITIES

Cases

<i>Breeze Smoke, LLC v. FDA</i> , 142 S. Ct. 638 (2021).....	1
<i>Breeze Smoke, LLC v. FDA</i> , 18 F.4th 499 (6th Cir. 2021)	5
<i>My Vape Order, Inc. v. FDA</i> , No. 21-71302, ECF No. 18 (9th Cir. Oct. 28, 2021).....	1

Other Authorities

Andrea S. Gentzke et al., <i>Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021</i> , 71 MORBIDITY & MORTALITY WKLY. REP. 1 (2022).....	7, 8
April Roeseler et al., <i>Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops</i> , 173 JAMA PEDIATRICS 795 (2019)	7
Centers for Disease Control and Prevention, <i>Adult Smoking Cessation – The Use of E-Cigarettes</i> (2020).....	10
Eunice Park-Lee et al., Notes from the Field: <i>E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021</i> , 70 MORBIDITY & MORTALITY WKLY. REP. 1387 (2021).....	2, 3, 4, 8
Kaitlin M. Berry et al., <i>Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths</i> , 2 JAMA NETWORK OPEN 1 (2019).....	6
NATIONAL ACADEMY OF SCIENCES, ENGINEERING, AND MEDICINE, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (2018).....	10
OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS, A REPORT OF THE SURGEON GENERAL (2016)	5

OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS (2012).....	2
OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL (2020).....	5, 10
OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH (2018)...	3, 5
Samane Zare et al., <i>A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type</i> , 13 PLoS ONE 1 (2018)	11
U.S. Preventive Services Task Force, <i>Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: USPSTF Recommendation Statement</i> , 325 J. AM. MED. ASS'N 265 (2021).....	10

Amici medical, public health, and community organizations submit this brief urging the Court to deny the motion for a stay pending appeal filed by Petitioner 7 Daze 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.¹ Both the U.S. Supreme Court and this Court have previously denied emergency stays of similar marketing denial orders (“MDOs”). *Breeze Smoke, LLC v. FDA*, 142 S. Ct. 638 (2021); *My Vape Order, Inc. v. FDA*, No. 21-71302, ECF No. 18 (9th Cir. Oct. 28, 2021).

STATEMENT OF INTEREST OF *AMICI CURIAE*²

Amici are the following national and state 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

¹ The Court denied Petitioner’s emergency request for an administrative stay. ECF No. 21 (Apr. 7, 2022).

² 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.

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 the e-liquids used in those products, and thus are particularly well suited to inform the Court of the substantial public health harm from the continued availability of Petitioner’s e-liquids that would result from the requested stay.

INTRODUCTION

E-cigarettes are the most popular tobacco products among youth, with more than two million young people reporting current e-cigarette use in 2021.³ The tobacco industry has long understood that almost all new tobacco users begin their addiction before the age of 18⁴ and that flavored products are essential to successfully market their products to young people.⁵ In 2021, almost 85% of youth e-cigarette users used a flavored product.⁶ All of Petitioner’s products subject to the challenged 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 stop

³ 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>.

⁴ 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>.

⁵ *Id.* at 535-539.

⁶ Park-Lee et al., *supra* note 3, at 1387.

smoking. Accordingly, allowing Petitioner’s flavored products—such as Reds Apple Fruit Mix and Reds Apple Mango, Petr’s App’x (“App.”) 11—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 on-going public health crisis.

E-cigarettes have been the most commonly used tobacco products 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 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

⁷ *Id.*

⁸ OSG, HHS, SURGEON GENERAL’S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 1 (2018), <https://bit.ly/3EIN53I> (“OSG Advisory”).

⁹ Park-Lee et al., *supra* note 3, at 1387.

¹⁰ 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, about the same level as in 2018 when the Surgeon General first declared youth e-cigarette use an “epidemic.” Opp’n Addendum (“OA”) 5-6.

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.¹¹ Even more alarming, 27.6% of high school e-cigarette users reported *daily* use, a strong indication of deep nicotine addiction.¹² Half a million middle and high school students are vaping every single day.¹³

Flavored products are especially appealing to youth and are largely driving the alarming rates of youth e-cigarette use. *See* OA6 (“The evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of ENDS among youth.”). 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, and that fruit is the most popular flavor among youth e-cigarette users.¹⁴ 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

surveys in school reported higher e-cigarette use, suggesting that rates may have been much higher had the survey been conducted entirely in schools. *Id.* at 1387-89.

¹¹ Park-Lee et al., *supra* note 3, at 1387.

¹² *Id.*

¹³ *Id.* at 1388.

¹⁴ *Id.*

flavor is cited by youth as one of the main reasons for using e-cigarettes.”¹⁵ In denying a stay of an MDO in a similar case, the U.S. Court of Appeals for the Sixth Circuit found that “[f]lavored ENDS products especially appeal to children” and that this appeal is “understood as a matter of scientific consensus.” *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 505, 508 (6th Cir. 2021).

The vast majority of Petitioner’s e-liquids contain nicotine, App.11, a highly addictive substance that can have lasting damaging effects on adolescent brain development. OA8. 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 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

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. OA9. A 2018 report by the National Academies of Sciences, Engineering, and Medicine (“NASEM”), cited in FDA’s review of Petitioner’s products, found “substantial evidence that ENDS use increases [the] risk

¹⁵ OSG, HHS, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 611 (2020), <https://bit.ly/3lq1qED> (“OSG Smoking Cessation”).

¹⁶ OSG Advisory, *supra* note 8, at 1.

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

of ever using combusted tobacco cigarettes among youth and young adults.” *Id.* 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 Petitioner’s products.

All of Petitioner’s e-liquids at issue in this litigation are the fruit-flavored, kid-friendly products fueling the youth vaping epidemic. App.11. Petitioner’s products come in flavors like Apple Berries, Apple Mango, and Apple Peach. *Id.*

Nevertheless, Petitioner contends that it submitted “evidence that its ‘flavored’ e-liquid products...do not appeal to youth.” Mot. 11. Specifically, Petitioner points to (1) its marketing plan, Mot. 19-20, and (2) the fact that its “e-liquids [are] designed for use in open-pod or refillable-tank systems.” Mot. 21. For the reasons below, these assurances are insufficient to protect young people from Petitioner’s products.

1. Petitioner’s marketing plan consists of a combination of unsupported assertions and measures known to be insufficient to prevent youth access to flavored e-cigarettes. Petitioner claims to “market[] exclusively to current adult smokers,”

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>.

Mot. 19, yet provides no details to support this claim. *See* App.39-40. Petitioner similarly asserts that “it requires its midstream customers to ensure petitioner’s products are sold only to adults,” Mot. 19, but again offers nothing to indicate how it enforces this asserted requirement. *See* App.39-40.

Moreover, Petitioner’s claim that “it prohibits the sale of its products in outlets permitting under-age entry (like gas stations)” is unlikely to limit youth access to its products. Mot. 19; *see also* App.40 (“Products are sold solely in adult-only (21+)...retailers (e.g., vape shops.)”). According to the 2021 NYTS, more youth report buying e-cigarettes from vape or tobacco shops (22.2%) than from gas stations or convenience stores (17.7%).¹⁹ A 2019 study 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.²⁰ Petitioner’s remaining measure—“conduct[ing] online sales on an age-gated website,” Mot. 19—can be easily circumvented. Youth can access Petitioner’s website by simply entering a false birthday.²¹ Moreover, the overwhelming majority of youth e-cigarette users do not purchase e-cigarettes themselves, but instead acquire these

¹⁹ 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://bit.ly/3JoJdQP>.

²⁰ April Roeseler et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, 173 JAMA PEDIATRICS 795, 796 (2019), <https://bit.ly/3JIYdyX>.

²¹ DAZE, <https://7dazemfg.com/> (last accessed Apr. 11, 2022).

products through social sources, such as older friends and relatives,²² an avenue of access unlikely to be significantly affected by any access restrictions. Given that the youth e-cigarette epidemic has occurred despite existing legal restrictions on youth access to tobacco products, and the fact that Petitioner's products have the central feature—flavors—that make e-cigarettes attractive to youth, Petitioner's restrictions, even if strongly enforced, would be insufficient to prevent youth access.

2. 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.²³ Smok is the preferred brand of nearly one in ten (9.6%) high school e-cigarette users and has surpassed JUUL in popularity.²⁴

Petitioner points to a 2019 quote from then-FDA Commissioner Gottlieb to portray open-system devices as large and unwieldy—and therefore, having little youth-appeal. Mot. 21-22. However, these products have evolved dramatically since Commissioner Gottlieb's statement. For example, the sleek, easy-to-conceal Smok and Suorin devices pictured below can be used to consume Petitioner's e-

²² Gentzke et al., *supra* note 19, at 23 tbl.7 (31.1% of youth e-cigarette users reported buying the products themselves).

²³ See Park-Lee et al., *supra* note 3, at 1388 tbl.

²⁴ *Id.*

liquids. For reference, the Smok devices below weigh less than 0.2 pounds and measure roughly 3.7 inches tall, 1.2 inches wide, and 0.75 inches deep.²⁵



Figure 1: Suorin Drop Rainbow Chrome open-system e-cigarette device.²⁶



Figure 2: Smok Nord open-system e-cigarette devices.²⁷

Given the overwhelming appeal to youth of flavored e-liquids, such as Petitioner's products, Petitioner's argument that immediate enforcement against its products "accomplishes *nothing*," Mot. 26, is divorced from the reality of youth e-cigarette use and addiction. 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. Allowing these products to remain on the market is decidedly not in the public interest.

²⁵ *Nord Kit*, SMOK, https://www.smoktech.com/product/pod_mod/nord-kit (last accessed Apr. 11, 2022).

²⁶ *Suorin Drop Rainbow Chrome – Pod System Device with Cartridge Kit*, SUORIN USA, <https://www.suorinusa.com/collections/suorin-drop/products/suorin-drop-rainbow-chrome> (last accessed Apr. 11, 2022).

²⁷ *Nord Kit*, *supra* note 25.

II. A Stay is Contrary to the Public Interest Because Any Potential Benefit of Petitioner’s Products in Helping Smokers Stop Smoking Is Outweighed by the Known Risk of Flavored E-Cigarettes 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. OA3.

The publicly-available evidence does not convincingly show that e-cigarettes help smokers stop smoking—and the evidence is even weaker that flavors play a beneficial role for current smokers. 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.²⁸ According to a 2020 Surgeon General Report, “there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”²⁹

²⁸ OSG Smoking Cessation, *supra* note 15; 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 CONSEQUENCES OF E-CIGARETTES 10 (2018), <https://bit.ly/32WnfoT>.

²⁹ OSG Smoking Cessation, *supra* note 15, 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.” OA12. 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.³⁰ Thus, it was entirely reasonable for 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 e-liquids, and the absence of sufficient evidence showing that those products help smokers stop 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.

³⁰ 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>.

Dated: April 14, 2022

Respectfully submitted,

/s/ Jordan Raphael

Jordan Raphael
BYRON RAPHAEL LLP
1055 West 7th St., Suite 3300
Los Angeles, CA 90067
Tel: (213) 291-9800
Fax: (213) 377-5771
Email: jraphael@byronraphael.com

Dennis A. Henigan (Of Counsel)
Connor Fuchs (Of Counsel)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I St. NW, Suite 1200
Washington, DC 20005
Tel: (202) 481-9366
Fax: (202) 296-5427
Email: dhenigan@tobaccofreekids.org
Email: cfuchs@tobaccofreekids.org

Attorneys for *Amici Curiae*

CERTIFICATE OF COMPLIANCE

1. The foregoing proposed brief complies with the type-volume limitations set forth in Fed. R. App. P. 29(a)(5) (permitting amicus briefs that are “no more than the one-half the maximum length authorized by these rules for a party’s principal brief”), 9th Cir. R. 27-1(1)(d) (permitting motions and responses to motions of up to 20 pages), and 9th Cir. R. 32-3 (deeming compliant a “brief or other document in which the word count divided by 280 does not exceed the designated page limit”) because, excluding the parts of the document exempted by Fed. R. App. 32(f), the word count feature in Microsoft Word reports that the proposed brief contains 2,473 words.

2. The foregoing proposed 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.

/s/ Jordan Raphael

Jordan Raphael

BYRON RAPHAEL LLP

1055 West 7th St., Suite 3300

Los Angeles, CA 90067

Tel: (213) 291-9800

Fax: (213) 377-5771

Email: jraphael@byronraphael.com

Attorney for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of April, 2022, 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 Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

/s/ Jordan Raphael

Jordan Raphael

BYRON RAPHAEL LLP

1055 West 7th St., Suite 3300

Los Angeles, CA 90067

Tel: (213) 291-9800

Fax: (213) 377-5771

Email: jraphael@byronraphael.com

Attorney for *Amici Curiae*