IN THE UNITED STATES COURT OF
APPEALS FOR THE FIFTH CIRCUIT
No. 21-60766

WAGES AND WHITE LION INVESTMENTS, LLC d/b/a TRITON DISTRIBUTION, 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

---

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 EMERGENCY MOTION FOR A STAY PENDING REVIEW

Leane K. Capps
POLSINELLI, PC
2950 N. Harwood Street,
Suite 2100
Dallas, TX 75201
Tel: (214) 661-5537
Fax: (214) 397-0033
Email: lcapps@polsinelli.com

Dennis A. Henigan (Of Counsel)
Connor Fuchs (Of Counsel)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I Street, NW, Suite 1200
Washington, DC 20005
Tel: (202) 296-5469
Fax: (202) 296-5427
Email: dhenigan@tobaccofreekids.org
Email: cfuchs@tobaccofreekids.org

Counsel for Amici Curiae

SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rules 29.2 and 28.2.1, the undersigned counsel of record for *amici curiae* certifies that the following persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. American Academy of Pediatrics
2. American Cancer Society Cancer Action Network
3. American Heart Association
4. American Lung Association
5. Campaign for Tobacco-Free Kids
6. Parents Against Vaping e-cigarettes
7. Truth Initiative Foundation d/b/a Truth Initiative

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 13, 2021

/s/ Leane K. Capps
Leane K. Capps
Lead counsel for *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 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-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 *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), a*ppeal 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.

"Courts enjoy broad discretion to grant or deny leave to *amici* under Rule 29." *Lefebure v. D'Aquilla*, No. 19-30702, 2021 WL 4552965, at *3 (5th Cir. Oct. 5, 2021). 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 flavored e-liquids like "Jimmy the Juice Man Strawberry Astronaut" would be at risk of suffering 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 13, 2021

Respectfully submitted,

/s/ Leane K. Capps

Leane K. Capps
POLSINELLI, PC
2950 N. Harwood Street, Suite 2100
Dallas, TX 75201
Tel: (214) 661-5576
Fax: (214) 397-0033
Email: lcapps@polsinelli.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 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 581 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/ Leane K. Capps
Leane K. Capps
Attorney for *Amici Curiae*

CERTIFICATE OF CONFERENCE

I hereby certify under 5th Cir. R. 27.4 and Fed. R. App. P. 29(a)(2) that on October 12, 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 the *Amici Curiae*.

/s/ Leane K. Capps
Leane K. Capps
Attorney for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on October 13, 2021, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Leane K. Capps

Leane K. Capps
POLSINELLI, PC
2950 N. Harwood Street, Suite 2100
Dallas, TX 75201
Tel: (214) 661-5537
Fax: (214) 397-0033
Email: lcapps@polsinelli.com

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT
No. 21-60766

WAGES AND WHITE LION INVESTMENTS, LLC d/b/a TRITON DISTRIBUTION, 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

---

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 EMERGENCY MOTION FOR A STAY PENDING REVIEW

Leane K. Capps
POLSINELLI, PC
2950 N. Harwood Street,
Suite 2100
Dallas, TX 75201
Tel: (214) 661-5537
Fax: (214) 397-0033
Email: lcapps@polsinelli.com

Dennis A. Henigan (Of Counsel)
Connor Fuchs (Of Counsel)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I Street NW, Suite 1200
Washington, DC 20005
Tel: (202) 296-5469
Fax: (202) 296-5427
Email: dhenigan@tobaccofreekids.org
Email: cfuchs@tobaccofreekids.org

Counsel for Amici Curiae

SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rules 29.2 and 28.2.1, the undersigned counsel of record for *amici curiae* certifies that the following persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. American Academy of Pediatrics
2. American Cancer Society Cancer Action Network
3. American Heart Association
4. American Lung Association
5. Campaign for Tobacco-Free Kids
6. Parents Against Vaping e-cigarettes
7. Truth Initiative Foundation d/b/a Truth Initiative

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 13, 2021

/s/ Leane K. Capps
Leane K. Capps
Lead counsel for *Amici Curiae*

TABLE OF CONTENTS

STATEMENT OF INTEREST OF *AMICI CURIAE* 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 for Helping Smokers to Stop Smoking Is Outweighed by the Demonstrated Risk of Flavored E-Cigarette Products to Youth. 9

CONCLUSION 12

TABLE OF AUTHORITIES

Statutes

21 U.S.C. § 387g(a)(3) 12

21 U.S.C. § 387j(a)(1)(A) 12

21 U.S.C. §387j(c)(4) 11

Other Authorities

April Roeseler et al.,
Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops, 173 JAMA PEDIATRICS 795 (2019) 8

Brian A. King,
Awareness and ever-use of electronic cigarettes among U.S. adults, 2010-2011, 15 NICOTINE & TOBACCO RES. 1623 (2013) 10

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 (2021) 2, 3, 4, 5

Kaitlin M. Berry et al.,
Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths, 2 JAMA NETWORK OPEN 1 (2019) 6

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) 4

OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVICES,
Cardiovascular System, *in* HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE: A REPORT OF THE SURGEON GENERAL (2010) 5

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 508 (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, 4, 5

Samane Zare et al., *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type*, 13 PLoS ONE 1 (2018) 10

Sherry T. Liu et al., *Youth Access to Tobacco Products in the United States, 2016-2018*, 5 TOBACCO REG. SCI. 491 (2019) 8

USPSTF, *Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: USPSTF Recommendation Statement*, 325 J. AM. MED. ASS'N 265 (2021).....10

Amici medical, public health, and community organizations submit this brief urging the Court to deny Petitioner Wages and White Lion Investments, LLC d/b/a Triton Distribution's ("Triton") Emergency Motion 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 work 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, 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 children[2] 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. Allowing Petitioner's products—which include Jimmy the Juice Man Strawberry Astronaut and Chew Clouds Sour Grape—to remain on the market for even one more day poses a significant risk to

[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] A163 (citing 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] OSG, *supra* note 2, at 535-539.

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

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.[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 2 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 comparable to previous survey years due to methodology changes,[8] just prior to the pandemic in 2020, nearly 1 in 5 (19.6%) U.S. high schoolers reported

[5] *Id.*

[6] 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").

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

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

current e-cigarette use,[9] about the same level as in 2018 when the Surgeon General first declared youth e-cigarette use an "epidemic."[10]

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.[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.[14] As the 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."[15] Data from the 2021 NYTS show that 84.7% of middle and high school

---

[9] A40 (citing 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).

[10] OSG Advisory, *supra* note 6, at 1.

[11] Park-Lee et al., *supra* note 1, at 1387.

[12] *Id.*

[13] *Id.* at 1388.

[14] A38; *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.

[15] A40.

e-cigarette users had used a flavored product in the past month.[16] 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."[17]

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.[18] 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."[19] Nicotine also impacts the cardiovascular system.[20] The Surgeon General has warned that, "[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe."[21]

Use of e-cigarettes may also function as a gateway to the use of

---

[16] Park-Lee et al., *supra* note 1, at 1388.

[17] 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.

[18] A42.

[19] OSG Advisory, *supra* note 6, at 1.

[20] A43; *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.

[21] 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.

conventional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking.[22] 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."[23] 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.[24]

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

Petitioner is a leading manufacturer of nicotine-containing e-liquids, *see* Motion at 5, and all of its products subject to the challenged Marketing Denial Order ("MDO") are the flavored, kid-friendly products that are fueling the youth vaping epidemic.[25] Petitioner's products have names like Jimmy the Juice Man

[22] A43.

[23] NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), https://www.nap.edu/catalog/24952/public-health-consequences-of-e-cigarettes; *see also* A43.

[24] 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.

[25] *See* A5-A8.

Strawberry Astronaut, Suicide Bunny Mother's Milk and Cookies, Chew Clouds Sour Grape, Telos [sic] Crunch, and Teleos Remixed Pound Cake.[26]

Despite the overwhelming evidence that flavored e-cigarettes appeal to youth, Triton contends that "its flavored products will not induce youth initiation," because they (1) are "for use in open-system devices, not the closed-system cartridges that are popular among youth," (2) will be sold only in "age-gated vape and specialty tobacco shops and through age-gated online sales," and (3) "are only marketed to existing users of cigarettes and vaping products, and not marketed in a manner that would make them attractive to youth." Motion at 16. There are at least four reasons to believe that these assurances are insufficient to protect young people from Triton's flavored products.

First, open system products remain popular among children. Smok and Suorin, for example, are open system devices and among the most popular e-cigarette devices among youth.[27]

Second, 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

[26] *Id.*

[27] *See* Park-Lee et al., *supra* note 1, at 1388 tbl.

month, compared to 9.8% from a gas station or convenience store.[28] 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.[29] The reality of youth access to products sold in vape shops underscores the health harms that would result if Petitioner's flavored products are allowed on the market while litigation is pending.

Third, nothing in Petitioner's premarket application remotely suggests that it is marketing its flavored products only to existing users of tobacco products, as opposed to the general public.[30] With products like "Jimmy the Juice Man Strawberry Astronaut," it is difficult to accept Petitioner's claim that it does not make its products appealing to youth.[31]

Finally, given that the youth e-cigarette epidemic has occurred despite existing legal restrictions on youth access to tobacco products, it cannot be doubted

---

[28] Sherry T. Liu et al., *Youth Access to Tobacco Products in the United States, 2016-2018*, 5 TOBACCO REG. SCI. 491, 495 (2019), https://pubmed.ncbi.nlm.nih.gov/31745494/.

[29] April Roeseler et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, 173 JAMA PEDIATRICS 795, 796 (2019), https://jamanetwork.com/journals/jamapediatrics/fullarticle/2735684.

[30] *See* A308-A311.

[31] Petitioner cites to its own survey showing that the majority of its consumers were between 25 and 44 years old. Motion at 7. Not only does this finding leave open the possibility that a substantial percentage of its consumers are below the legal age of 21, but it is not even clear that young people were part of the survey.

that such restrictions, even if strongly enforced, are insufficient to address products with such intense appeal to youth, like flavored e-liquids.

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,"[32] demonstrating that, compared to unflavored (i.e., tobacco-flavored) products, flavored products like Petitioner's benefit smokers by helping them to stop smoking 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 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

[32] A37.

is insufficient evidence to recommend any e-cigarettes for smoking cessation.[33] According to a 2020 Surgeon General Report, "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation."[34]

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.[35] Thus, it is entirely reasonable for the FDA to 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.

Petitioner misreads the statutory public health standard when it asserts that the FDA is violating the statutory scheme by requiring robust evidence showing that their flavored products benefit smokers by more effectively helping them quit

---

[33] OSG Smoking Cessation, *supra* note 17; 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; Brian A. King, *Awareness and ever-use of electronic cigarettes among U.S. adults*, 2010-2011, 15 NICOTINE & TOBACCO RES. 1623, 1624 (2013); NASEM, *supra* note 23.

[34] OSG Smoking Cessation, *supra* note 17, at 7.

[35] 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/.

smoking as compared to tobacco-flavored products. *See* Motion at 18. Under Section 910 of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act ("TCA"), whether the marketing of a new tobacco product is "appropriate for the protection of the public health" requires a determination of whether non-users of tobacco products "will start using such products" (initiation) and whether "existing users of tobacco products will stop using such products" (cessation).[36] In arguing that FDA cannot consider the effectiveness of Petitioner's flavored products versus tobacco-flavored products in helping smokers stop smoking, Petitioner simply ignores the relevant statutory language.

Petitioner again misinterprets the statute when it contends that the FDA cannot require rigorous studies comparing the effectiveness of Petitioner's flavored products vs. tobacco-flavored products in helping smokers to stop smoking without going through the notice and comment rulemaking required for tobacco product standards under Section 907 of the TCA. *See* Motion at 20. Petitioner here confuses quite distinct parts of the statute. The FDA's requirement of rigorous studies showing that specific products help smokers quit smoking for purposes of new product review under Section 910 has nothing to do with product standard

[36] 21 U.S.C. §387j(c)(4).

rulemaking, which would set conditions for the marketing of any tobacco product, whether they are "new" products (introduced after February 15, 2007)[37] or not. The fact that a product standard must also be "appropriate for the protection of the public health," involving an assessment of the impact of the standard on both tobacco initiation and cessation,[38] does not mean that application of that same standard for purposes of new product review under Section 910 is somehow a disguised product standard requiring notice and comment rulemaking.

Therefore, given the overwhelming evidence of the risk of flavored e-cigarette products like Petitioner's to young people, and the absence of sufficient evidence showing that those products help smokers quit smoking, a stay of the Triton 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 13, 2021

[37] 21 U.S.C. § 387j(a)(1)(A).

[38] 21 U.S.C. § 387g(a)(3).

Respectfully submitted,

/s/ Leane K. Capps

Leane K. Capps
POLSINELLI, PC
2950 N. Harwood Street, Suite 2100
Dallas, TX 75201
Tel: (214) 661-5537
Fax: (214) 397-0033
Email: lcapps@polsinelli.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 WITH TYPE-VOLUME LIMIT, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

1. The foregoing brief 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 2,534 words.

2. The foregoing brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and 5th Cir. R. 32.1, and the typestyle requirements of Fed. R. App. P. 32(a)(6) because this document, except the footnotes, has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14 font. Pursuant to 5th Cir. R. 32.1, the footnotes have been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 12 font.

/s/ Leane K. Capps
Leane K. Capps
Attorney for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on October 13, 2021, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Leane K. Capps

Leane K. Capps
POLSINELLI PC
2950 N. Harwood Street, Suite 2100
Dallas, TX 75201
Tel: (214) 661-5537
Fax: (214) 397-0033
Email: lcapps@polsinelli.com