No. 21-13340

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BIDI VAPOR LLC,

Petitioner,

v.

U.S. FOOD AND DRUG ADMINISTRATION; JANET WOODCOCK, M.D., in her official capacity as Acting Commissioner of the FDA; and the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Respondents.

On Petition for Review of a Final Marketing Denial Order Issued by the U.S. Food and Drug Administration Under the Federal Tobacco Control Act

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

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to 11th Cir. R. 26.1-1 through 26.1-3, the undersigned counsel certifies that, in addition to those listed on the Certificates of Interested Persons and Corporate Disclosure Statements filed by Petitioner and Respondents, as well as the Certificates included in the prior filings by *Amici Curiae* 37 National and State Electronic Delivery System Product Advocacy Associations and *Amici Curiae* Dr. David B. Abrams, Clive D. Bates, and David T. Sweanor, J.D., to the best of my knowledge, the following persons and entities have an interest in the outcome of this case:

American Academy of Family Physicians, *amicus curiae*

American Academy of Pediatrics, *amicus curiae*

American Cancer Society Cancer Action Network, *amicus curiae*

American Heart Association, *amicus curiae*

American Lung Association, *amicus curiae*

American Medical Association, *amicus curiae*

Campaign for Tobacco-Free Kids, *amicus curiae*

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Medical Association of Georgia, *amicus curiae*

Parents Against Vaping e-cigarettes, *amicus curiae*

Truth Initiative, *amicus curiae*

Zuckerman Spaeder LLP, counsel for *amici curiae*

Pursuant to Fed. R. App. P. 26.1(a) and 11th Cir. R. 26.1-3, the undersigned counsel certifies that *amici curiae* are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

Dated: January 12, 2022

/s/ Sara A. Lawson
Sara A. Lawson
Attorney for *Amici Curiae*

Proposed *amici* hereby move the Court for leave to file the attached Brief of *Amici Curiae* Medical and Public Health Groups in Support of Respondents' Opposition to Petitioner's Renewed Motion for a Stay Pending Review of the Marketing Denial Order ("MDO") that is the subject of this litigation. Respondents consented to the filing of the brief. Petitioner did not.

Amici here 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, Campaign for Tobacco-Free Kids, Medical Association of Georgia, 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 the *amici* works on a daily basis to reduce the devastating health harms of tobacco products, including electronic nicotine delivery system ("ENDS" or "e-cigarette") products. Accordingly, *amici* have a direct and immediate interest in curbing the sale of flavored disposable e-cigarette products, including those sold by Petitioner, which have proven to be especially attractive to youth. 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 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), 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 *AAP* rulings.

This *amicus* brief is desirable because the proposed *amici* have substantial expertise in the role flavored e-cigarette products, like those sold by Petitioner, 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 respond to Petitioner's claim that a stay would serve the public interest, a central argument in Petitioner's motion, *see* Petitioner's Renewed Motion for a Stay Pending Review (Dec. 29, 2021) at 23-

24, and a key factor in the Court's consideration of Petitioner's motion for a stay. *See Nken v. Holder,* 556 U.S. 418, 426 (2009).

Unlike *amici's* brief on the merits, which did not address whether Petitioner has satisfied the requirements for a stay pending judicial review of the MDO, *see* Unopposed Brief of *Amici Curiae* Medical and Public Health Groups in Support of Respondents (Dec. 22, 2021), this proposed brief focuses exclusively on the public interest factor as it bears on whether a stay should be granted. Specifically, it argues that a stay would be contrary to the public interest because: (1) there is a substantial risk of current youth usage of Petitioner's products, and (2) any potential benefit of Petitioner's products for helping smokers to stop smoking during the pendency of the litigation 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 indeterminate period while this litigation is pending. During such time, young people drawn to Petitioner's flavored and disposable e-cigarettes—available in flavors such as Dragonfruit Strawberry ("Bidi Stick – Regal") and Mango Apple Orange ("Bidi Stick – Tropic"), Petr's Addendum A039—would be at risk of suffering health harms.

The U.S. Court of Appeals for the Fifth Circuit recently granted a motion for leave to file an *amicus* brief—filed by a substantially similar group of *amici*[1]—in support of respondent FDA, opposing a similar motion for a stay pending review of an MDO for e-cigarette products. *Wages and White Lion Investments, L.L.C. v. FDA*, No. 21-60766, Order Granting Motion for Leave to File Brief as *Amici Curiae* (5th Cir. Oct. 14, 2021) (attached as addendum).

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

Dated: January 12, 2022

Respectfully submitted,

/s/ Sara A. Lawson

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[1] The following organizations were *amici* on that brief: 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 (PAVe) and Truth Initiative.

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CERTIFICATE OF COMPLIANCE

1. The foregoing motion complies with the word limits set forth in Fed. 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 810 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/ Sara A. Lawson
Sara A. Lawson
Attorney for *Amici Curiae*

CERTIFICATE OF CONFERENCE

I hereby certify under Fed. R. App. P. 29(a)(2) that on January 5, 2022, I contacted counsel for Respondents and Petitioner by electronic mail and that Respondents consented to the filing of the brief of *amici curiae* but Petitioner did not consent.

/s/ Sara A. Lawson
Sara A. Lawson
Attorney for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2022, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Sara A. Lawson
Sara A. Lawson
Attorney for *Amici Curiae*

ADDENDUM

United States Court of Appeals for the Fifth Circuit

No. 21-60766

WAGES AND WHITE LION INVESTMENTS, L.L.C., DOING BUSINESS AS TRITON DISTRIBUTION,

Petitioner,

versus

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

Petition for Review of an Order of the
Food and Drug Administration

Before ELROD, OLDHAM, and WILSON, *Circuit Judges*.

PER CURIAM:

IT IS ORDERED that petitioner's motions to expedite the appeal and to expedite a ruling on the request for emergency relief are GRANTED.

IT IS FURTHER ORDERED that the Food and Drug Administration's marketing denial order is ADMINISTRATIVELY STAYED pending further order of this motions panel.

IT IS FURTHER ORDERED that the motion for leave to file a brief as *amici curiae* by the American Academy of Pediatrics *et al.* is GRANTED.

No. 21-13340

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BIDI VAPOR LLC,

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Pursuant to Fed. R. App. P. 26.1(a) and 11th Cir. R. 26.1-3, the undersigned counsel certifies that *amici curiae* are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

Dated: January 12, 2022

/s/ Sara A. Lawson
Sara A. Lawson
Attorney for *Amici Curiae*

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Amici medical, public health, and community organizations submit this brief urging the Court to deny Petitioner Bidi Vapor LLC's Renewed 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 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, Campaign for Tobacco-Free Kids, Medical Association of Georgia, 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 this brief.

INTRODUCTION

E-cigarettes are the most popular tobacco product among youth, with more than two million young people reporting current e-cigarette use in 2021.[1] The tobacco industry has long understood that almost all new tobacco users begin their addiction before the age of 18[2] and that flavored products are essential to successfully market their products to young people.[3] In 2021, almost 85% of youth e-cigarette users used a flavored product.[4] The risk of youth initiation and use posed by flavors is well documented, but there is little evidence that flavors have any role in helping cigarette smokers quit.

Petitioner's products are both flavored and disposable, Motion at 8, making them the type of e-cigarette product now most popular among youth.[5] Allowing

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[1] Eunice Park-Lee et al., Notes from the Field: *E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 70 MORBIDITY & MORTALITY WKLY. REP. 1387, 1387 (2021), https://bit.ly/3BBMXLT.

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

[3] *Id.* at 535-539.

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

[5] *Id.*

Petitioner's products—available in flavors such as Dragonfruit Strawberry ("Bidi Stick – Regal") and Mango Apple Orange ("Bidi Stick – Tropic"), Petr's Addendum ("A") A039—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 product among youth since 2014.[6] In December 2018, the U.S. Surgeon General declared the growing problem an "epidemic."[7] 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.[8] While the Centers for Disease Control and Prevention ("CDC") warns these data are not

[6] *Id.*

[7] OSG, HHS, SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 1 (2018), https://bit.ly/3ElN53l ("OSG Advisory").

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

comparable to previous survey years due to methodology changes,[9] just prior to the 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") OA5-6.

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

Flavored products are especially appealing to youth and are largely driving the alarming rates of youth e-cigarette use. According to FDA, "[t]he evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of ENDS among youth." OA6. Data from the 2021 NYTS show that 84.7% of middle and high school e-cigarette users had used a flavored product

[9] Whereas previous years' surveys were conducted entirely in-school, the 2021 survey included both in-school and at-home responses; students who completed surveys in school reported higher e-cigarette use, suggesting that rates may have been much higher had the survey been conducted entirely in schools. *See* Park-Lee et al., *supra* note 1, at 1387-1389.

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

[11] *Id.*

[12] *Id.* at 1388 tbl.

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

Petitioner's e-cigarettes contain nicotine, *see* A039, a highly addictive substance that can have lasting damaging effects on adolescent brain development. OA8. Indeed, Petitioner's products all have nicotine concentrations of 60 mg/ml (or 6%), *see* A039, A147, exceeding the nicotine concentration of products like Juul which have dominated the market in recent years.[16] 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."[17]

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[13] *Id.*

[14] OSG, HHS, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 611 (2020), https://bit.ly/3lq1qED ("OSG Smoking Cessation").

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

[16] *See What is the Size of a JUULpod?*, JUUL (June 15, 2020), https://www.juul.com/resources/what-is-the-size-of-a-juulpod (products available in 3% and 5% nicotine concentrations).

[17] OSG Advisory, *supra* note 7, at 1.

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. *See* A047. 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."[18] A nationally representative analysis also 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 to youth with no prior tobacco use.[19]

The fact that Petitioner's products are not only flavored, but disposable, makes them especially appealing to youth. Youth use of disposables has surged in recent years, increasing more than 1000%—from 2.4% to 26.5%—among high school e-cigarette users between 2019 and 2020. OA8. In 2021, 55.8% of high school e-cigarette users reported using disposable products.[20] Petitioner is the

[18] NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), https://bit.ly/32WnfoT; *see also* OA8.

[19] 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.

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

market leader in disposable e-cigarette sales.[21]

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

Despite selling the kinds of e-cigarettes that are now most popular with youth, Petitioner denies that its products pose a risk to young people. Motion at 24. Petitioner points to "survey data and behavioral studies showing BIDI® Sticks are not used by minors, but rather older adult smokers," *id.* at 16, as well as the "extensive youth prevention measures" it claims to have implemented. *Id.* at 8-9. For the reasons below, Petitioner's arguments are unpersuasive.

Petitioner appears to refer to two studies it claims show its products "are not used by minors, but rather older adult smokers." *Id.* at 16. The studies show nothing of the kind. First, Petitioner's sales data, *see* A107, reveals only who is legally purchasing its products, not who is actually using them. According to the 2020 NYTS, 57.1% of high school e-cigarette users reported getting e-cigarettes from a friend, the most commonly reported source for accessing e-cigarettes.[22] These youth e-cigarette users would not be captured in Petitioner's sales data. Second, Petitioner's Consumer Insight Survey, which concluded that "[t]he Bidi brand appeals primarily to adult-only converts and dual users," A110, did not even survey

[21] Goldman Sachs, *Americas Tobacco: Nielsen Data thru 12/4: Total nicotine volume pressure continues as pricing holds strong* 14 ex.30 (Dec. 14, 2021).

[22] Teresa W. Wang et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4 JAMA NETWORK OPEN 1, 5 (2021), https://bit.ly/3pfgh6U.

individuals under 21 years of age. Therefore, Petitioner's data tell us nothing about youth usage of its products.

Petitioner's youth prevention measures are similarly unavailing. For all of the measures Petitioner claims to have implemented, *see* Motion at 8-9, one thing it is unwilling to do is avoid selling the products that are most appealing to young people. Much of Petitioner's "youth prevention measures" consist of little more than encouraging its downstream sellers to comply with the law. *See* A073 (noting that wholesalers and direct retailers are required to sign agreements "which, among other things, requires parties to comply with all applicable regulations and abide by our comprehensive age verification procedures."). Petitioner offers no evidence that it has ever terminated, or disciplined in any way, a wholesaler or direct retailer who has failed to comply with its agreements. Similarly, while Petitioner claims to "not employ online influencers or brand ambassadors," Motion at 8, nothing suggests that it requires its downstream sellers to do the same—a significant omission given that Petitioner does not itself market or sell directly to consumers. *See* A070, A072-73. Moreover, Petitioner continues to maintain its social media accounts. *See* A070.

Finally, Petitioner's other "youth prevention measures," such as "not sponsor[ing] sporting or music events," "not market[ing] using kid-friendly imagery or messaging [such as cartoons], and includ[ing] extensive age-related warnings on its products," Motion 8-9, are the bare minimum that should be done, but can be

expected to have little impact given that Petitioner's flavored and disposable products have the central features that make e-cigarettes intensely appealing to youth. Given the overwhelming youth appeal of Petitioner's e-cigarettes, Petitioner's measures are patently insufficient to prevent youth usage of its products.[23]

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 in Helping Smokers to Stop Smoking Is Outweighed by the Demonstrated Risk of Flavored E-Cigarette Products to Youth.

Given the overwhelming evidence that flavored e-cigarette 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

[23] It also is revealing that, as of the date of this filing, Petitioner's website contains a banner on each webpage falsely stating that "all 11 flavors of the BIDI® Stick are legal to be marketed and distributed" because "FDA has granted Bidi Vapor a stay order." *See, e.g.*, https://bidivapor.com/. Given that more than three weeks have passed since FDA lifted the administrative stay (on December 17, 2021), *see* OA56, this statement represents Petitioner's continued efforts to sell its youth-appealing flavors by misleading its downstream sellers and the public about the legal status of those products.

them to stop smoking cigarettes and to issue an MDO for failure to furnish such evidence. A046.

Although Petitioner asserts that a stay would be in the public interest because its "products are . . . singularly successful at helping[] adult smokers switch from traditional, combustible cigarettes," Motion at 24, it cites no data to support this claim. The publicly-available evidence does not convincingly show that e-cigarettes help smokers stop smoking—and the evidence is even weaker that flavors are necessary to help cigarette smokers quit.

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.[24] In the words of a 2020 Surgeon General Report, "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation."[25]

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

[24] 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/3Dfxf97 (last updated Jan. 23, 2020); NASEM, *supra note* 18.

[25] OSG Smoking Cessation, *supra* note 14, at 7.

smokers stop smoking. In fact, Petitioner's own literature review found that "there is not enough evidence from well-designed studies to determine whether e-cigarette flavors aid in smoking cessation." OA38. FDA arrived at the same conclusion, observing that "the literature does not establish that flavors differentially promote switching [from cigarettes to e-cigarettes] amongst ENDS users in general." A050. A systematic review that examined consumer preference for various e-cigarette attributes also found "inconclusive evidence" as to whether flavored e-cigarettes assisted smokers to quit.[26] 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. *See* A046.

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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[26] 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: January 12, 2022

Respectfully submitted,

/s/ Sara A. Lawson

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CERTIFICATE OF COMPLIANCE

1. The foregoing brief complies with the word limits set forth in Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(g)(1) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), the word count feature in Microsoft Word reports that this document contains 2,510 words.

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

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CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2022, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Sara A. Lawson
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