

No. 23-60037

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

R.J. REYNOLDS VAPOR COMPANY, ET AL.,

Petitioners,

v.

U.S. FOOD & DRUG ADMINISTRATION, ET AL.,

Respondents.

On Review from Order of the Food and Drug Administration Denying Premarket Tobacco Product Applications PM0000637 (Vuse Vibe) and PM0000713 (Vuse Ciro)

**MOTION FOR LEAVE TO FILE BRIEF OF *AMICI CURIAE* MEDICAL,
PUBLIC HEALTH, CIVIL RIGHTS, AND COMMUNITY GROUPS IN
SUPPORT OF RESPONDENTS' OPPOSITION TO PETITIONERS'
MOTION FOR A STAY PENDING REVIEW**

Scott P. Lewis
Christina S. Marshall
Austin P. Anderson
ANDERSON & KREIGER LLP
50 Milk Street, 21st Floor
Boston, MA 02109
Tel: (617) 621-6500
Fax: (617) 621-6660
lewis@andersonkreiger.com
cmarshall@andersonkreiger.com
aanderson@andersonkreiger.com

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

Attorneys for Amici Curiae

SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rules 27.4 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, in addition to those listed in the parties' briefs, 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. Action on Smoking and Health
2. African American Tobacco Control Leadership Council
3. American Academy of Family Physicians
4. American Academy of Pediatrics
5. American Cancer Society Cancer Action Network
6. American Heart Association
7. American Lung Association
8. American Medical Association
9. Campaign for Tobacco-Free Kids
10. Louisiana State Medical Society
11. Parents Against Vaping e-cigarettes
12. 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.

/s/ Scott P. Lewis
Scott P. Lewis
Attorney of record for *Amici Curiae*

Pursuant to Rule 29 of the Federal Rules of Appellate Procedure and Fifth Circuit Rule 29, proposed *amici* Action on Smoking and Health, African American Tobacco Control Leadership Council, 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, Louisiana State Medical Society, Parents Against Vaping e-cigarettes (PAVe), and Truth Initiative (the “medical, public health, civil rights, and community groups”) move for leave to file the attached brief urging the Court to deny Petitioners’ Motion for a Stay Pending Review of the marketing denial order issued to R.J. Reynolds Vapor Company (“Reynolds”) for its menthol Vuse Vibe e-cigarette cartridge. All parties consent to the filing of the *amicus* brief.

Each of the medical, public health, civil rights, and community groups works daily to reduce the devastating health harms of tobacco products, including menthol and other electronic nicotine delivery system (“ENDS” or “e-cigarette”) products. Consistent with those efforts, they have an acute interest in whether Reynolds is allowed to continue to sell its menthol Vuse Vibe e-cigarette cartridge while its appeal of the marketing denial order proceeds.

In addition, the medical, public health, civil rights, and community groups are particularly well suited to inform the Court of the substantial public health harm

from the continued availability of Petitioner's menthol e-cigarettes that would result from the requested stay. Many of these groups have participated, in a similar capacity, as *amici* in several Courts of Appeals, including this Circuit, in proceedings by other e-cigarette manufacturers challenging FDA marketing denial orders. *E.g.*, 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, *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130 (5th Cir. 2021) (No. 21-60766), Doc. No. 00516055972.

Accordingly, the medical, public health, civil rights, and community groups respectfully ask the Court to grant the instant motion and allow them to participate as *amici* through the attached brief.

Date: February 16, 2023

Respectfully submitted,

/s/ Scott P. Lewis

Scott P. Lewis

Christina S. Marshall

Austin P. Anderson

ANDERSON & KREIGER LLP

50 Milk Street, 21st Floor

Boston, MA 02109

Tel: (617) 621-6500

Fax: (617) 621-6660

Email: lewis@andersonkreiger.com

Email: cmarshall@andersonkreiger.com

Email: aanderson@andersonkreiger.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 360 words.

2. The foregoing motion 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 has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14 font.

/s/ Scott P. Lewis
Scott P. Lewis
Attorney for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2023, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Austin P. Anderson
Austin P. Anderson
Attorney for *Amici Curiae*

No. 23-60037

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

R.J. REYNOLDS VAPOR COMPANY, ET AL.,

Petitioners,

v.

U.S. FOOD & DRUG ADMINISTRATION, ET AL.,

Respondents.

On Review from Order of the Food and Drug Administration Denying Premarket Tobacco Product Applications PM0000637 (Vuse Vibe) and PM0000713 (Vuse Ciro)

**BRIEF OF *AMICI CURIAE* MEDICAL, PUBLIC HEALTH, CIVIL
RIGHTS, AND COMMUNITY GROUPS IN SUPPORT OF
RESPONDENTS' OPPOSITION TO PETITIONERS'
MOTION FOR A STAY PENDING REVIEW**

Scott P. Lewis
Christina S. Marshall
Austin P. Anderson
ANDERSON & KREIGER LLP
50 Milk Street, 21st Floor
Boston, MA 02109
Tel: (617) 621-6500
Fax: (617) 621-6600
lewis@andersonkreiger.com
cmarshall@andersonkreiger.com
aanderson@andersonkreiger.com

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

Attorneys 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, in addition to those listed in the parties' briefs, 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. Action on Smoking and Health
2. African American Tobacco Control Leadership Council
3. American Academy of Family Physicians
4. American Academy of Pediatrics
5. American Cancer Society Cancer Action Network
6. American Heart Association
7. American Lung Association
8. American Medical Association
9. Campaign for Tobacco-Free Kids
10. Louisiana State Medical Society
11. Parents Against Vaping e-cigarettes
12. 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.

/s/ Scott P. Lewis
Scott P. Lewis
Attorney of record for *Amici Curiae*

TABLE OF CONTENTS

STATEMENT OF INTEREST OF <i>AMICI CURIAE</i>	1
INTRODUCTION	2
ARGUMENT	4
I. A Stay Is Contrary to the Public Interest Because There Is a Substantial Risk of Youth Use of Menthol Vuse Vibe.....	4
A. Youth use of e-cigarettes, particularly flavored products including menthol, is an on-going public health crisis.	4
B. There is a significant risk of youth use of menthol Vuse Vibe.....	7
II. A Stay is Contrary to the Public Interest Because Any Potential Benefit of Menthol Vuse Vibe in Helping Smokers to Stop Smoking Is Outweighed by the Known Risk of Menthol E-Cigarettes to Youth.....	10
CONCLUSION	12
CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS.....	14
CERTIFICATE OF SERVICE	15

TABLE OF AUTHORITIES

Cases

Am. Acad. of Pediatrics 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)10

Nken v. Holder,
 556 U.S. 418, 426 (2009)3

Prohibition Juice Co. v. FDA,
 45 F.4th 8 (D.C. Cir. 2022)6

Rules

Tobacco Product Standard for Menthol in Cigarettes,
 87 Fed. Reg. 26,454 (proposed May 4, 2022)6

Other Authorities

CDC,
Adult Smoking Cessation – The Use of E-Cigarettes (Jan. 23, 2020).....11

FDA,
*Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and
 Other Deemed Products on the Market Without Premarket Authorization
 (Revised)* (Apr. 2020) 3, 7, 8, 9

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)7

Karen A. Cullen et al.,
e-Cigarette Use Among Youth in the United States, 2019, 322 J. AM. MED. ASS’N
 2095 (2019).....9

Lin Li et al.,
*How Does the Use of Flavored Nicotine Vaping Products Relate to Progression
 Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV, 23
 NICOTINE & TOBACCO RESEARCH* 1490 (2021)11

Maria Cooper et al.,
Notes from the Field: E-Cigarette Use Among Middle and High School Students –United States, 2022, 71 MORBIDITY & MORTALITY WKLY. REP. 1283 (2022)
 passim

NATIONAL ACADEMY OF SCIENCES, ENGINEERING, AND MEDICINE,
 PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (2018).....7, 11

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,
 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,
 SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL (2020)5, 11

OFFICE OF THE SURGEON GENERAL, U.S. DEP’T OF HEALTH & HUMAN SERVICES,
 SURGEON GENERAL’S ADVISORY ON E-CIGARETTE USE AMONG YOUTH (2018)..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)11

Teresa W. Wang et al.,
Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020, 4 JAMA NETWORK OPEN 18

U.S. Preventive Services Task Force,
Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: USPSTF Recommendation Statement, 325 J. AM. MED. ASS’N 265 (2021).....11

Amici, medical, public health, civil rights, and community organizations, submit this brief urging the Court to deny Petitioners’ Motion for a Stay Pending Review of the marketing denial order (“MDO”) issued to R.J. Reynolds Vapor Company (“Reynolds”) for its menthol Vuse Vibe e-cigarette cartridge because a stay would be contrary to the public interest, given the (1) substantial risk of youth use of menthol Vuse Vibe and (2) insufficient evidence of any potential benefit of this product in helping smokers to stop smoking that would outweigh the demonstrated risk to youth.

STATEMENT OF INTEREST OF *AMICI CURIAE*¹

Amici are the following national and state medical, public health, civil rights, and community organizations: Action on Smoking and Health, African American Tobacco Control Leadership Council, 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, Louisiana State Medical Society, Parents Against Vaping e-cigarettes (PAVe), and Truth Initiative. Each group works daily to reduce the devastating health harms of tobacco products,

¹ 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.

including menthol and other electronic nicotine delivery system (“ENDS” or “e-cigarette”) products, and thus are particularly well suited to inform the Court of the substantial public health harm from the continued availability of Reynolds’ menthol e-cigarette that would result from the requested stay.

INTRODUCTION

E-cigarettes are the most popular tobacco products among youth, with more than 2.5 million young people reporting current e-cigarette use in 2022.² The tobacco industry has long understood that almost all new tobacco users begin their addiction before the age of 18³ and that flavored products, including menthol products, are essential to successfully market their products to young people.⁴ The product at issue here, menthol Vuse Vibe, is a menthol-flavored e-cigarette cartridge. Pet. for Review, Doc. No. 1-1, Ex. A (“Order”) at 5 (Jan. 24, 2023).⁵ In

² Maria Cooper et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students –United States, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1283, 1283-84 (2022), <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf>.

³ 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.

⁴ *Id.* at 535-539.

⁵ The Petition (Doc. 1-1, Jan. 24, 2023) also seeks to overturn the denial of Reynolds’ menthol Vuse Ciro product, but that product is not subject to Petitioners’ present Motion for a Stay Pending Review. See Mot. for Stay Pending Review, Doc. 62, at 1 & n.1 (Feb. 8, 2023).

2022, almost 85% of youth e-cigarette users used a flavored product, and among that subset, 26.6% used a menthol product.⁶ Among youth users of flavored e-cigarette cartridges, such as menthol Vuse Vibe, over half (53.9%) reported using a menthol e-cigarette in 2022.⁷ Flavored cartridges were the products that ignited an epidemic of youth vaping,⁸ and remain popular with young people today.⁹

The risk of youth initiation and use posed by menthol e-cigarettes, particularly cartridges, is well documented, but there is little evidence that these products have any role in helping cigarette smokers to stop smoking. Accordingly, allowing Reynolds' menthol cartridge to remain on the market while the Court considers the Petition poses a significant risk to youth with no countervailing public health benefit. The stay sought by Reynolds is entirely contrary to the public interest, a key factor in the Court's consideration of a stay motion. *See Nken v. Holder*, 556 U.S. 418, 426 (2009).

⁶ Cooper, *supra* note 2, at 1283.

⁷ *Id.*

⁸ FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (Apr. 2020), <https://www.fda.gov/media/133880/download> (“FDA Enforcement Priorities”).

⁹ Cooper, *supra* note 2, at 1284 tbl. (cartridges were the second most common e-cigarette device type used by youth in 2022).

ARGUMENT

I. A Stay Is Contrary to the Public Interest Because There Is a Substantial Risk of Youth Use of Menthol Vuse Vibe.

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

E-cigarettes have been the most commonly used tobacco product among youth since 2014.¹⁰ According to the National Youth Tobacco Survey (“NYTS”), in 2022, over 2.5 million youth, including 14.1% of high schoolers, reported current e-cigarette use.¹¹ Young people are not just experimenting with e-cigarettes—they are using them frequently. In 2022, 46% of high school e-cigarette users reported using them on at least 20 of the preceding 30 days.¹² Even more alarming, 30.1% of high school e-cigarette users reported *daily* use, a strong indication of nicotine addiction.¹³ Roughly 700,000 middle and high school students are vaping on a daily basis.¹⁴

Flavored products, including menthol, are especially appealing to youth and largely driving the alarming rates of youth e-cigarette use. 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

¹⁰ Cooper, *supra* note 2, at 1283.

¹¹ *Id.* at 1283, 1285.

¹² *Id.* at 1284 tbl.

¹³ *Id.*

¹⁴ *Id.*

youth as one of the main reasons for using e-cigarettes.”¹⁵ Data from the 2022 NYTS show that 84.9% of middle and high school e-cigarette users had used a flavored product in the past month.¹⁶

Menthol Vuse Vibe contains nicotine, Order at 5, a highly addictive substance that can have lasting damaging effects on adolescent brain development.¹⁷ According to the Surgeon General, “Nicotine exposure during adolescence can impact learning, memory and attention,” and “can also increase risk for future addiction to other drugs.”¹⁸ The Surgeon General has warned that “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”¹⁹ In upholding an MDO for flavored e-cigarettes, the U.S. Court of Appeals for the D.C. Circuit summarized the evidence on flavors, nicotine, and youth: “A vast body of scientific evidence shows that flavors

¹⁵ 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> (“OSG Smoking Cessation”).

¹⁶ Cooper, *supra* note 2, at 1283.

¹⁷ 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”).

¹⁸ *Id.*

¹⁹ 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.

encourage youth to try e-cigarettes, and together with the nicotine, keep them coming back.” *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 11 (D.C. Cir. 2022).

Reynolds’ e-cigarette cartridge also contains menthol, Order at 4, which FDA has found can enhance the addictive effects of nicotine in the brain, including in young people.²⁰ In its proposed rule to prohibit menthol as a characterizing flavor in cigarettes, FDA concluded that the combination of menthol and nicotine increases youth initiation, increases youth progression to regular cigarette smoking, and increases the intensity of addiction among both youth and adults, making it harder to stop.²¹ Although the evidence FDA discussed in the proposed rule was largely drawn from experience with cigarette smokers, there is no scientific basis to suggest that menthol does not similarly enhance the addictiveness of the nicotine in e-cigarettes.

Finally, use of e-cigarettes may function as a gateway to the use of conventional cigarettes, thereby undermining decades of progress in curbing youth smoking. 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

²⁰ Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,464 (proposed May 4, 2022).

²¹ *Id.*

adults.”²² 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.²³

B. There is a significant risk of youth use of menthol Vuse Vibe.

Menthol Vuse Vibe has two features that make it particularly appealing to youth. First, it is mentholated. Second, it is a cartridge, the type of e-cigarette most responsible for igniting the youth vaping epidemic.

There is overwhelming evidence that menthol e-cigarettes are highly appealing to youth, and that youth will gravitate to these products if they are left on the market. *See* Order at 2 (“There is substantial evidence that the use of menthol flavors in tobacco products, like the menthol flavors in the new products, has significant appeal to youth and is associated with youth initiation of such products.”). When FDA restricted the sale of cartridge-based e-cigarettes in flavors other than menthol and tobacco in February 2020,²⁴ youth shifted to using

²² NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), <https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes>.

²³ 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>.

²⁴ FDA Enforcement Priorities, *supra* note 8, at 18.

menthol e-cigarettes.²⁵ In 2020, over one million middle and high school youth used menthol e-cigarettes.²⁶ High levels of youth menthol e-cigarette use persist today. In 2022, 26.6% of all youth flavored e-cigarette users reported using a menthol product.²⁷ The rates are even higher among youth users of flavored cartridge-based products, the product type at issue, with 53.9% reporting use of a menthol product.²⁸ In total, over half a million middle and high schoolers reported current use of a menthol e-cigarette in 2022.²⁹

Reynolds' product is not only mentholated, it is a cartridge-based product, the type of e-cigarette that drove youth e-cigarette use rates to historically high levels and led FDA, in 2020, to revise its enforcement priorities to attach the highest priority to enforcement against cartridge-based e-cigarettes in flavors other than tobacco or menthol.³⁰ In 2019, before FDA's revised enforcement policy took effect, 27.5% of high school students reported current e-cigarette use, with most

²⁵ See Teresa W. Wang et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4 JAMA NETWORK OPEN 1, 9 (published online June 7, 2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780705>.

²⁶ *Id.* at 7 tbl.3.

²⁷ Cooper, *supra* note 2, at 1283.

²⁸ *Id.*

²⁹ *Id.* at 1284 tbl.

³⁰ FDA Enforcement Priorities, *supra* note 8.

youth e-cigarette users reporting a cartridge-based product as their usual brand.³¹ FDA found that the “design features” of cartridge-based e-cigarettes contribute to their youth appeal.³² Reynolds’ device, with which the menthol Vuse Vibe cartridge is designed to be used, is roughly the size of a USB drive,³³ which “allows for easy concealability” and “may allow youth to use the product in circumstances where use of tobacco products is prohibited, such as a school.”³⁴

The risk that youth will use Reynolds’ product is not just theoretical. In 2022, Vuse was the second most popular brand among youth e-cigarette users, with 580,000 middle and high schoolers (or 23.9% of all current youth e-cigarette users) reporting use of a Vuse product in the last 30 days.³⁵ Reynolds repeatedly notes that Vuse Vibe has been on the market for a number of years, *see, e.g.*, Mot. for Stay Pending Review at 1, 23, as if that confers a right to stay on the market regardless of the public health harm a product is causing. The fact is that the long-term presence on the market of e-cigarettes like Vuse Vibe has been without the

³¹ Karen A. Cullen et al., *e-Cigarette Use Among Youth in the United States, 2019*, 322 J. AM. MED. ASS’N 2095, 2097-2098 (2019), <https://jamanetwork.com/journals/jama/fullarticle/2755265>.

³² FDA Enforcement Priorities, *supra* note 8, at 16.

³³ Reynolds’ Vuse Vibe devices measure 13 mm in diameter and 82.5 mm in length (0.51 x 3.25 inches). *See* FDA, Marketing Granted Orders for certain R.J. Reynolds Vapor Company products at 5, 6 (May 12, 2022), <https://www.fda.gov/media/158752/download>.

³⁴ FDA Enforcement Priorities, *supra* note 8, at 16.

³⁵ Cooper, *supra* note 2, at 1284 tbl.

legally required marketing authorization—an exercise of enforcement discretion by FDA that a federal court found to be an illegal “holiday from meeting the obligations of the law” that allowed manufacturers to “continue to advertise and sell products that are addictive and that target a youth market” *Am. Acad. of Pediatrics v. FDA*, 379 F.Supp.3d 461, 492-93 (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). Every additional day that menthol Vuse Vibe remains on the market, it contributes to the risk of nicotine addiction and other health harms to young people. Allowing this product to remain on the market while the Court considers the Petition is decidedly not in the public interest.

II. A Stay is Contrary to the Public Interest Because Any Potential Benefit of Menthol Vuse Vibe in Helping Smokers to Stop Smoking Is Outweighed by the Known Risk of Menthol E-Cigarettes to Youth.

Given the overwhelming evidence that menthol e-cigarette cartridges attract young people, it is entirely reasonable for FDA to require “robust and reliable evidence” demonstrating that, in comparison to an unflavored (i.e., tobacco-flavored) product, menthol Vuse Vibe benefits smokers by helping them to stop smoking cigarettes and to issue an MDO for failure to furnish such evidence. Order at 2.

The publicly available evidence does not convincingly show that e-cigarettes help smokers stop smoking—and the evidence is just as unclear as to whether

flavors, including menthol, play a beneficial role for people who currently smoke. Studies of adult smokers have found that while many adult e-cigarette users use flavored e-cigarettes, there is little evidence to suggest that flavored e-cigarette use is associated with successfully stopping cigarettes.³⁶ The leading public health authorities in the U.S., including the Surgeon General, the U.S. Preventive Services Task Force (“USPSTF”), the CDC, and NASEM, have all concluded that there is insufficient evidence to recommend any e-cigarettes for smoking cessation.³⁷ In the words of the Surgeon General: “[T]here is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”³⁸

Indeed, the evidence that *menthol* e-cigarettes are more effective than tobacco-flavored e-cigarettes at helping people who smoke cigarettes to stop smoking is similarly unpersuasive. As FDA observed, “the published literature on

³⁶ E.g., Lin Li et al., *How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV*, 23 NICOTINE & TOBACCO RESEARCH 1490 (2021), <https://pubmed.ncbi.nlm.nih.gov/33631007/>; 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/>.

³⁷ 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://jamanetwork.com/journals/jama/fullarticle/2775287>; CDC, *Adult Smoking Cessation – The Use of E-Cigarettes*, https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/factsheets/adult-smoking-cessation-e-cigarettes-use/index.html (Jan. 23, 2020); NASEM, *supra* note 22, at 10.

³⁸ OSG Smoking Cessation, *supra* note 15, at 7.

the role of menthol-flavored ENDS and smoking cessation or reduction is limited and does not demonstrate that menthol-flavored ENDS are more effective in promoting complete switching or significant cigarette reduction relative to tobacco-flavored ENDS.” Order at 3. Thus, it was entirely reasonable for FDA to require Reynolds to provide evidence that menthol Vuse Vibe is “more likely to promote complete switching or significant cigarette reduction compared to tobacco-flavored products,” and to deny authorization for failure to provide such evidence. *Id.*

CONCLUSION

For these reasons, and those presented by the government, *amici* urge the Court to deny the Motion for a Stay Pending Review.

Date: February 16, 2023

Respectfully submitted,

/s/ Scott P. Lewis

Scott P. Lewis

Christina S. Marshall

Austin P. Anderson

ANDERSON & KREIGER LLP

50 Milk Street, 21st Floor

Boston, MA 02109

Tel: (617) 621-6500

Fax: (617) 621-6600

Email: lewis@andersonkreiger.com

Email: cmarshall@andersonkreiger.com

Email: aanderson@andersonkreiger.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 set forth in Fed. R. App. P. 29(a)(5) (permitting amicus briefs that are “no more than one-half the maximum length authorized by these rules for a party’s principal brief”) and Fed. R. App. P. 27(d)(2)(A) (permitting motions and responses to motion of up to 5,200 words) 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 2,588 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 has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14 font.

/s/ Scott P. Lewis
Scott P. Lewis
Attorney for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2023, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Austin P. Anderson

Austin P. Anderson

Attorney for *Amici Curiae*