

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

Case No. 23-60037

R.J. Reynolds Vapor Company; RJR Vapor
Company, L.L.C.; Avail Vapor Texas,
L.L.C.; Mississippi Petroleum Marketers
and Convenience Stores Association,
Petitioners

v.

Food & Drug Administration; Robert Califf,
in his official capacity as Commissioner of
the United States Food & Drug
Administration; United States Department of
Health and Human Services; Xavier Becerra,
in his official capacity as Secretary of the
United States Department of Health and
Human Services,

Respondents

consolidated with

Case No. 23-60128

R.J. Reynolds Vapor Company; RJR Vapor
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L.L.C.; Mississippi Petroleum Marketers
and Convenience Stores Association,
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in his official capacity as Secretary of the
United States Department of Health and
Human Services,

Respondents

**BRIEF OF AMICI CURIAE
MEDICAL, PUBLIC
HEALTH, CIVIL RIGHTS,
AND COMMUNITY GROUPS
IN SUPPORT OF
RESPONDENTS'
OPPOSITION TO
PETITIONERS'
MOTION FOR A STAY IN
CASE NO. 23-60545**

consolidated with

Case No. 23-60545

R.J. Reynolds Vapor Company; RJR Vapor Company, L.L.C.; Mississippi Petroleum Marketers and Convenience Stores Association; Avail Vapor Texas, L.L.C.,

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Food & Drug Administration; Robert Califf, in his official capacity as Commissioner of the United States Food & Drug Administration; United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services,

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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 filings of the parties and *Amici Curiae* 24 Vaping Product Advocacy Associations, 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. Parents Against Vaping e-cigarettes
11. 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

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 NICOTINE & TOBACCO RESEARCH* 1490 (2021)12

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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 Alto e-cigarette cartridges because a stay would be contrary to the public interest, given the (1) substantial risk of youth use of menthol Vuse Alto and (2) insufficient evidence of any potential benefit of these products helping smokers to stop smoking that would outweigh the demonstrated risk to youth. In accordance with Fed. R. App. P. 29(a)(2), all parties consent to the filing of this brief.

STATEMENT OF INTEREST OF *AMICI CURIAE*¹

Amici are the following 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, Parents Against Vaping e-cigarettes (PAVe), and Truth Initiative. Each group works daily to reduce the devastating health harms of

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.

tobacco products, 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 products at issue here, menthol Vuse Alto, are menthol-flavored e-cigarette cartridges, Pet. for Review, Doc. No. 1-1, Ex. A (“Order”) 5-6 (Oct. 12, 2023), with demonstrated youth appeal. Vuse is the second most popular e-cigarette brand among youth,³ and menthol-flavored Alto products are far and away the most popular Vuse products. Admin. Stay Mot. 5 (Oct. 13, 2023) (“menthol-flavored Vuse Alto products account for the majority” of Reynolds’ 2022 revenue). In 2022, roughly 580,000 middle and high schoolers reported using a Vuse e-cigarette in the past month.⁴

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, 1283-85 (2022), <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf>.

³ *Id.*

⁴ *Id.* at 1284 tbl.

Menthol Vuse Alto's flavoring and cartridge design make these products especially attractive to youth. In 2022, almost 85% of youth e-cigarette users used a flavored product, and among that subset, 26.6% used a menthol product.⁵ Among youth users of flavored e-cigarette cartridges, such as menthol Vuse Alto, over half (53.9%) reported using a menthol e-cigarette in 2022.⁶ Flavored cartridges were the products that ignited an epidemic of youth vaping,⁷ and remain popular with young people today.⁸

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 cartridges 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

⁵ *Id.* at 1283.

⁶ *Id.*

⁷ 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").

⁸ Cooper, *supra* note 2, at 1284 tbl. (cartridges were the second most common e-cigarette device type used by youth in 2022).

in the Court’s consideration of a stay motion. *See Nken v. Holder*, 556 U.S. 418, 426 (2009).

ARGUMENT

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

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 2014.⁹ 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.¹⁰ 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.¹¹ Even more alarming, 30.1% of high school e-cigarette users reported *daily* use, a strong indication of nicotine addiction.¹² Roughly 700,000 middle and high school students are vaping on a daily basis.¹³

⁹ *Id.* at 1283.

¹⁰ *Id.* at 1283, 1285.

¹¹ *Id.* at 1284 tbl.

¹² *Id.*

¹³ *Id.*

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, “[T]he 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 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.¹⁵

Menthol Vuse Alto cartridges contain nicotine, Order 5-6, a highly addictive substance that can have lasting damaging effects on adolescent brain development.¹⁶ 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.”¹⁷ The Surgeon General has warned that “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is

¹⁴ OFFICE OF THE SURGEON GENERAL (“OSG”), U.S. DEP’T OF HEALTH & HUMAN SERVICES (“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”).

¹⁵ Cooper, *supra* note 2, at 1283.

¹⁶ 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>.

¹⁷ *Id.*

unsafe.”¹⁸ 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 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).

The e-cigarette cartridges at issue also contain menthol, Order 5-6, which FDA has found can enhance the addictive effects of nicotine in the brain, including in young people.¹⁹ 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.²⁰ 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

¹⁸ 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.

¹⁹ Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,464 (proposed May 4, 2022).

²⁰ *Id.*

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 adults.”²¹ 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.²²

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

Menthol Vuse Alto cartridges have two features that make them particularly appealing to youth. First, they are mentholated. Second, they are cartridges, 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 2 (“There is substantial evidence that flavored ENDS (including menthol) . . . have significant appeal to youth and are associated with

²¹ NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), <https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes>.

²² 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>.

youth initiation of such products.”). When FDA restricted the sale of cartridge-based e-cigarettes in flavors other than menthol and tobacco in February 2020,²³ youth shifted to using menthol e-cigarettes.²⁴ In 2020, over one million middle and high school youth used menthol e-cigarettes.²⁵ 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.²⁶ The rates are even higher among youth users of flavored cartridge-based products, with 53.9% reporting use of a menthol product.²⁷ In total, over half a million middle and high schoolers reported current use of a menthol e-cigarette in 2022.²⁸

The products here are not only mentholated, they are cartridge-based, 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

²³ FDA Enforcement Priorities, *supra* note 7, at 18.

²⁴ 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>.

²⁵ *Id.* at 7 tbl.3.

²⁶ Cooper, *supra* note 2, at 1283.

²⁷ *Id.*

²⁸ *Id.* at 1284 tbl.

menthol.²⁹ In 2019, before FDA’s revised enforcement policy took effect, 27.5% of high school students reported current e-cigarette use, with most youth e-cigarette users reporting a cartridge-based product as their usual brand.³⁰ FDA found that the “design features” of cartridge-based e-cigarettes contribute to their youth appeal.³¹ Reynolds’ device, with which the menthol Vuse Alto cartridge is designed to be used, is roughly the size of a USB drive,³² 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.”³³

The risk that youth will use menthol Vuse Alto cartridges 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.³⁴ And Vuse Alto is “by far the most popular line of Vuse e-cigarettes, accounting for over

²⁹ FDA Enforcement Priorities, *supra* note 7.

³⁰ 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>.

³¹ FDA Enforcement Priorities, *supra* note 7, at 16.

³² *See Vuse Alto Power Unit Kit*, BREAZY, <https://breazy.com/products/vuse-alto-power-unit-kit#:~:text=Dimensions%3A%204in%20x%200.75in,Battery%20Capacity%3A%20350mAh> (last visited Oct. 23, 2023) (“Dimensions: 4in x 0.75in x 0.25in”).

³³ FDA Enforcement Priorities, *supra* note 7, at 16.

³⁴ Cooper, *supra* note 2, at 1284 tbl.

ninety percent of RJRV’s U.S. revenue in 2022” with the “menthol-flavored Vuse Alto products account[ing] for the majority of that revenue.” Admin. Stay Mot. 5, 20.

Reynolds notes that its Vuse Alto products have been on the market for a number of years, *see, e.g.*, Admin. Stay Mot. 5, 19-20, 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 Alto has been without the 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 Alto cartridges remain on the market, they contribute to the risk of nicotine addiction and other health harms to young people. Allowing these products to remain on the market 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 Alto 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, including Vuse Alto, 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 Alto benefits smokers by helping them to stop smoking cigarettes and to issue an MDO for failure to furnish such evidence. Order 1-2.

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. 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.³⁵ In the words of the Surgeon General: “[T]here is presently

³⁵ 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://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 21, at 10.

inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”³⁶ Moreover, studies of adult smokers have found that while some 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.³⁷

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 the role of flavored ENDS,” including menthol, “and smoking cessation or reduction did not demonstrate that flavored ENDS are more effective in promoting complete switching or significant cigarette reduction relative to tobacco-flavored ENDS.” Order 2-3. Thus, it was entirely reasonable for FDA to require Reynolds to provide evidence that menthol Vuse Alto products are “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.* at 2.

³⁶ OSG Smoking Cessation, *supra* note 14, at 7.

³⁷ 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/>.

CONCLUSION

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

Date: October 31, 2023

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**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 2,581 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 tpestyle 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
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CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2023, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ Scott P. Lewis
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