
*In the United States Court of
Appeals for the Seventh Circuit*

GRIPUM, LLC, 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 STAY PENDING REVIEW**

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DISCLOSURE STATEMENT

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

Dated: October 26, 2021

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Amici medical, public health, and community organizations submit this brief urging the Court to deny Petitioner Gripum LLC's ("Gripum") 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. Petitioner and Respondent each consent to the filing of this brief.

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 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 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 children² 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—all of which are flavored and include flavors such as Lemon Sugar Drop and Watermelon Lollipop—to remain

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 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 *Id.* at 535-539.

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

on the market for even one more day poses a significant risk to 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 two 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 one in five (19.6%) U.S. high schoolers

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

reported 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

Despite Petitioner’s claim that “youth use ENDS for the nicotine, not the flavors...,” Motion at 13, the data shows that flavors play a major role in youth initiation and use of e-cigarettes.¹⁴ A 2020 Surgeon General Report concluded that “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.”¹⁵ Data from the 2021 NYTS show that 84.7% of

⁹ A102; 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 *See, e.g.*, A100; 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 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>.

middle and high school e-cigarette users had used a flavored product in the past month.¹⁶ Petitioner cites to no authority suggesting that youth are attracted to e-cigarettes by the nicotine—and its highly addictive properties—rather than by flavors that make the products more appealing. *See* Motion at 13. Nicotine operates to move young people from experimentation to addiction; flavors draw them to e-cigarettes in the first place.

Petitioner dismisses the role of flavors by attributing the rise in youth e-cigarette use between 2017 and 2018 —the peak of the youth vaping epidemic—to the “introduction of high-concentration nicotine closed system products sold in general retail channels” rather than flavors. Motion at 22-23. However, the data show that as youth e-cigarette usage rose during this period, so did the percentage of youth e-cigarette users who reported using flavored products, rising from 58.7% in 2017 to 65.2% in 2018¹⁷—clearly demonstrating that flavors were and continue to be a key driver of the youth vaping epidemic.

Petitioner also attributes the subsequent decrease in youth e-cigarette use to the 2019 raising of the federal minimum age for sale of tobacco products to 21.

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

¹⁷ Karen E. Cullen et al., *Flavored Tobacco Product Use Among Middle and High School Students – United States, 2018*, 68 MORBIDITY & MORTALITY WKLY. REP. 839, 840 (2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6839a2-H.pdf>; Hongying Dai, *Changes in Flavored Tobacco Product Use Among Current Youth Tobacco Users in the United States, 2014-2017*, JAMA PEDIATRICS E1, E1 tbl. (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6396867/>.

Motion at 23. However, as the 2020 NYTS report noted, the decrease from 2019 to 2020 was likely due to “multiple factors” including “prioritize[d] enforcement against certain flavored e-cigarette products that appeal to youths” and recent measures imposed by “[s]everal states and communities” to “restrict[] the sale of flavored tobacco products, including e-cigarettes” in addition to the rise in federal sales age.¹⁸ That efforts to restrict flavored products likely contributed to the decline in youth usage from 2019 to 2020 simply confirms the importance of flavors in fueling the youth e-cigarette epidemic. And, as noted, *supra* at 3 & n.8, the CDC explicitly warned that the 2021 NYTS data is not comparable to prior years due to methodology changes.

Contrary to Petitioner’s misdirections, the U.S. Food and Drug Administration (“FDA”) accurately summarized the data when it concluded that “the flavoring in tobacco products (including ENDS) make them more palatable for novice youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use.”¹⁹

¹⁸ Andrea S. Gentzke et al, *Tobacco Product Use Among Middle and High School Students – United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1881, 1883-84 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6950a1.htm>.

¹⁹ A103.

E-liquids, like Petitioner’s products, typically contain nicotine,²⁰ a highly addictive drug that can have lasting damaging effects on adolescent brain development.²¹ 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.”²² Nicotine also impacts the cardiovascular system.²³ The Surgeon General has warned that, “[t]he use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”²⁴

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.²⁵ 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.”²⁶ A nationally

²⁰ The vast majority of Petitioner’s products that were denied marketing authorization contain nicotine. *See* A3-A6.

²¹ A104.

²² OSG Advisory, *supra* note 6, at 1.

²³ A105.

²⁴ 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.

²⁵ A104-A105.

²⁶ NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 10 (2018), <https://www.nap.edu/catalog/24952/public-health-consequences-of-e-cigarettes>; *see also* A104.

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.²⁷

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

Petitioner is a manufacturer of flavored e-liquids, *see* Motion at 3, and all 281 of its products subject to the challenged Marketing Denial Order (“MDO”) are the flavored, kid-friendly products that are fueling the youth vaping epidemic.²⁸

Petitioner’s products come in flavors such as Grape Bubblegum, Key Lime Doughnut, Lemon Sugar Drop, Strawberry Pineapple Kiwi, Sugar Cookie, Sugary Watermelon, and Watermelon Lollipop.²⁹

Gripum, however, contends that its products do not attract youth because (1) its “products are designed for use in open-system ENDS devices” and that (2) “Gripum only manufacturers [sic] products for the industry segment which operates specialty [age-restricted] retail stores” (i.e., “vape shops”). Motion at 21-22; *see also id.* at 5, 11. For the reasons below, these measures are insufficient to protect young people from Gripum’s flavored products.

²⁷ 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>.

²⁸ *See* A3-A6.

²⁹ *Id.*

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.³⁰

Second, vape shops are a significant source of e-cigarettes for children. According to the 2020 NYTS, 17.5% of high school e-cigarette users report obtaining e-cigarettes from a vape shop in the past month, compared to 22.2% from a gas station or convenience store.³¹ 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.³²

Petitioner cites to its own analysis of FDA’s enforcement data to argue that “substantially all youth sales [94.7%] occurred in non-age-restricted retailers....” Motion at 23-24. Petitioner’s analysis and presentation of this data is deeply flawed. First, since FDA’s compliance database does not classify retailers by store type, Petitioner was left to guess each retailer’s store type based on its name alone—an exercise full of uncertainty.³³ Second, whether a vape shop is age-restricted

³⁰ See Park-Lee et al., *supra* note 1, at 1388 tbl.

³¹ Teresa W. Wang et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4 JAMA NETWORK OPEN 1, 6 tbl. 2 (2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780705>.

³² 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>.

³³ See A185 n.3; A186-A372.

at all depends on how it is licensed at the state and local level. Finally, the data is meaningless without information on FDA’s sampling strategy. If FDA selected fewer vape shops for compliance checks compared to other retailers—which is likely because far more tobacco products are sold at gas stations and convenience stores than at vape shops³⁴—then vape shops would inherently make up a smaller number of violations. The reality of youth access to products sold in vape shops—as documented in high quality analyses³⁵—underscores the health harms from allowing Petitioner’s flavored products to remain on the market while litigation is pending.

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

³⁴ Shelley D. Golden et al., *Trends in the Number and Type of Tobacco Product Retailers, United States, 2000-2017*, NICOTINE & TOBACCO RES. (2021), <https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntab150/6327606?redirectedFrom=fulltext>.

³⁵ See *supra* notes 31 & 32.

evidence,”³⁶ demonstrating that, compared to unflavored (i.e., tobacco-flavored) products, flavored products like Petitioner’s benefit smokers by helping them to stop smoking cigarettes and to issue an MDO for failure to furnish such evidence.

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 is insufficient evidence to recommend any e-cigarettes for smoking cessation.³⁷ According to a 2020 Surgeon General Report, “there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”³⁸

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

³⁶ A99.

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* (last reviewed Jan. 23, 2020), https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html; NASEM, *supra* note 26.

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

for various e-cigarette attributes found “inconclusive evidence” as to whether flavored e-cigarettes assisted quitting smoking.³⁹ 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.⁴⁰

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 cigarettes, a stay of the Gripum 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 26, 2021

³⁹ 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/>.

⁴⁰ Petitioner speculates that “[o]pen-system products like Gripum’s have been remarkably effective in prompting adult smokers to quit....” Motion at 26. Petitioner cites no support for this assertion.

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**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT,
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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 2,592 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 CONFERENCE

I hereby certify under Fed. R. App. P. 29(a)(2) that on October 22, 2021 I contacted the Petitioner and the Respondent by electronic mail and that the Respondent and the Petitioner each consented to the filing of the Brief of *Amici Curiae*.

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CERTIFICATE OF SERVICE

I hereby certify that on October 26, 2021, I filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

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