
No. 19-2130 (L)
Consolidated with Nos. 19-2132, 19-2198, 19-2242
(8:18-cv-00883-PWG)

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

In re: CIGAR ASSOCIATION OF AMERICA, *et al.*,

Appellants,

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION,
et al.,

Intervenors-Appellants.

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants-Appellees.

**THE STATE OF MARYLAND'S MOTION FOR LEAVE TO FILE AN
AMICUS BRIEF SUPPORTING PLAINTIFFS-APPELLEES' AND
UNITED STATES' OPPOSITIONS TO INTERVENORS-APPELLANTS'
AND NON-PARTY-APPELLANTS' MOTIONS TO STAY**

1. The State of Maryland requests that the Court grant it leave to file a concise *amicus* brief in support of the oppositions (No. 19-2130 (L) Documents 46, 47, 48) filed by the plaintiffs-appellees and the United States objecting to the e-

cigarette trade association intervenors-appellants' and cigar trade association appellants' motions for stay of judgment (No. 19-2130 (L) Documents 36 and 37). A copy of the proposed *amicus* brief is submitted with this motion as Exhibit 1.

2. The State of Maryland has an interest in this appeal and in preventing a stay of the district court's judgment and the remedy it provides. Maryland is home to thousands of children who have become addicted to the products the trade associations' members have been selling without submitting them to the Food and Drug Administration ("FDA") for the premarket review mandated by Congress when it enacted the Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009). Maryland has an interest in securing that FDA review as soon as possible in order to prevent the marketing of products that are not "appropriate for the protection of the public health," 21 U.S.C. § 387j(c)(2)(A), and thereby protect additional children from the ravages of nicotine addiction and spare taxpayers the costs that the State's Medicaid program will bear for the long-term health consequences to children currently using appellants' products.

3. An *amicus* brief from the State of Maryland is desirable, as it will explain why granting the trade associations' stay motions will impose unwarranted additional delay and harm the State and its residents.

4. The State of Maryland previously filed an *amicus* brief in support of the plaintiffs in the District Court of Maryland. The district court cited Maryland's

brief in the Memorandum and Order from which the trade associations have appealed. *Am. Acad. of Pediatrics v. Food and Drug Admin.*, 399 F. Supp. 3d 479, 481, 482 (D. Md. July 12, 2019).

5. The United States and the plaintiffs-appellees consent to this motion for leave to file an *amicus* brief. The intervenors-appellants have authorized Maryland to make the following statement: “Intervenors-Appellants/Appellants do not consent to this motion. While they are willing to consent to a single *amicus* brief filed in this appeal in support of any principal briefs, it is their position that this motion comes too late in the briefing for the motion to stay and will not have an opportunity to adequately respond before filing their reply on January 7.” The non-party appellants have authorized Maryland to state as follows: “The Cigar Association Appellants are prepared to consent to a single *amicus* brief on the merits, but believe that *amicus* briefing on the stay motion would be inappropriate, and do not consent thereto.”

CONCLUSION

For the reasons set forth above, the State of Maryland respectfully requests that this Court grant leave to file the proposed *amicus* brief.

Respectfully submitted,

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Date: January 7, 2020

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SUPPORTING PLAINTIFFS-APPELLEES' AND UNITED STATES'
OPPOSITIONS TO INTERVENORS-APPELLANTS'
AND NON-PARTY APPELLANTS' MOTIONS TO STAY**

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January 7, 2020

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The State of Maryland submits this *amicus curiae* brief in support of the oppositions (No. 19-2130 (L) Documents 46, 47, 48) filed by the plaintiffs-appellees

and the United States objecting to the motions for stay pending appeal (No. 19-2130 (L) Documents 36 and 37) filed by the e-cigarette trade association intervenors-appellants and the non-party cigar trade association appellants.

INTEREST OF *AMICUS CURIAE*

Maryland is home to thousands of children who have used e-cigarettes that, by law, should have been subjected to Food and Drug Administration (“FDA”) premarket review years ago, but were not. *See* 21 U.S.C. §§ 387b(6), 387j(a). As a result, many young Marylanders have developed an addiction to nicotine that increases their risk of becoming lifelong cigarette smokers while a new health crisis, caused by e-cigarettes, becomes ever more severe. Maryland children are now at risk of developing not only the lung diseases e-cigarettes inflict, but also the many diseases associated with traditional combustible cigarettes. As these young Marylanders age and sicken, the State will incur medical expenses for treating them through Medicaid. Thus, Maryland has an interest in prompt and efficient enforcement of the district court’s order requiring e-cigarette companies to submit their new products to the FDA for premarket review, as Congress intended when it enacted the Family Smoking Prevention and Tobacco Control Act (“TCA”) in 2009. 123 Pub. L. No. 111-31, 123 Stat. 1776.

ARGUMENT

FURTHER DELAY IN THE FDA’S PREMARKET REVIEW WILL HARM MARYLAND BY PERMITTING ELECTRONIC VAPING PRODUCTS TO REMAIN ON THE MARKET AND ADDICT A NEW GENERATION.

“The surge in e-cigarette use by teenagers” noted by the court below, *American Acad. of Pediatrics v. Food and Drug Admin.*, 379 F. Supp. 3d 461, 467 (D. Md. May 15, 2019), is consistent with Maryland’s experience. The Maryland Department of Health tracks youth use of tobacco products through the Maryland Youth Risk Behavior Survey and the Youth Tobacco Survey. *See* Maryland Department of Health, *The Maryland Youth Risk Behavior Survey & Youth Tobacco Survey – YRBS/YTS*, <https://phpa.health.maryland.gov/ohpetup/Pages/YTRBS.aspx> (last visited January 6, 2020). The Department of Health found that in 2016, the most recent year for which it has published data, 35.3 percent of Maryland’s high-school population had used an electronic vaping product,¹ and 13.3 percent had done so at least once during the 30 days before the survey.² The numbers

¹ The survey described electronic vapor products as “e-cigarettes, e-cigars, e-pipes, vape pipes, vaping pens, e-hookahs, and hookah pens [such as blu, NJOY, Vuse, MarkTen, Logic, Vapin Plus, eGo, and Halo].” Maryland Department of Health, *2016 Youth Risk Behavior Survey Results, Maryland High School Survey: Trend Analysis Report at 5, available at* <https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2016%20YRBS%20YTS%20Reports/2016MDH%20Trend%20Report.pdf>.

² *Id.* at 5-6. Data for 2014 showed higher high school e-cigarette use within the last 30 days, at nearly 20 percent; the wording in the survey question may have led to a decline in responses from 2014 to 2016. *See* Maryland Department of

have gone up since publication of this data. Recent unpublished data from the Maryland Department of Health shows that high-school use of electronic smoking devices within the previous 30 days increased from 13.3 percent in 2016 to 23.0 percent in 2018. Maryland Department of Health, Local Health Department Tobacco Control Program Coordinator Meeting, November 21, 2019 at slide 4.³

Maryland's experience is similar to what the national data show. The National Youth Tobacco Survey found that current e-cigarette use nationwide among high school students increased 78 percent between 2017 and 2018, from 11.7 percent to 20.8 percent.⁴ Karen A. Cullen, et al., *Use of Electronic Cigarettes and Any Tobacco Product among Middle and High School Students — United States, 2011–2018*, 67 *Morbidity and Mortality Weekly Rep.* 1276 (2018), *available at* <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6745a5-H.pdf>. Of high school students who reported current e-cigarette use, 27.7 percent reported using e-

Health, 2016 Maryland Youth Risk Behavior Survey and Youth Tobacco Survey at 34-35, *available at* https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2016%20YRBS%20YTS%20Reports/MDH%20YRBS_Report_2016_final.pdf.

³ The powerpoint presentation used as the source for this data is attached to this brief in .pdf format as an appendix.

⁴ The survey defined “current” tobacco product use as “a response greater than ‘0 days’ to the question, ‘During the past 30 days, on how many days did you use e-cigarettes?’” Karen A. Cullen, et al., *Use of Electronic Cigarettes and Any Tobacco Product among Middle and High School Students — United States, 2011–2018*, 67 *Morbidity and Mortality Weekly Rep.* 1276 (2018), *available at* <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6745a5-H.pdf>.

cigarettes on 20 or more of the past 30 days, up from 20 percent in 2017. *Id.* The same survey shows that current e-cigarette use among middle school students nationwide increased 48 percent between 2017 and 2018, from 3.3 percent to 4.9 percent. *Id.*

These rising percentages of e-cigarette use make it all too certain that the lives of young Maryland residents will be adversely affected by the further delay of FDA review, which would result if the Court were to grant the pending stay motions. According to the Maryland Department of Education, 259,898 students were enrolled in public high schools in 2018. Maryland State Department of Education 2018 Maryland School Report Card; <https://reportcard.msde.maryland.gov/Graphs/#/Demographics/Enrollment/3/H/6/9/XXXX> (select “Grade: high” and “Gender: all students” in dropdown menus and click “Show Table”) (last visited January 7, 2020). Applying this number to the Maryland Department of Health data shows that teen use of e-cigarettes jumped from 34,566 teenagers in 2016 to more than 59,777 in 2018,⁵ during the time Maryland was waiting for e-cigarette companies to submit their addictive products to the FDA for premarket review. While Maryland waited, these teenagers developed what for many will be a lifelong addiction to the nicotine marketed to them by the intervenors-appellants and their member companies. *See, e.g., United States v. Philip Morris*

⁵ 13.3 percent of 259,898 is 34,566, and 23.0 percent of 259,898 is 59,777.

USA, Inc., 449 F. Supp. 2d 1, 208-18 (D.D.C. 2006) (discussing addictive properties of nicotine), *aff'd in part and vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 561 U.S. 1025 (2010).

As the recent epidemic of lung injuries associated with e-cigarettes has gained national attention, an increasingly robust body of data shows that Maryland youth who have become addicts during the long-delayed FDA review will become lifelong smokers of combustible cigarettes. A study by the RAND Corporation found that youth who use e-cigarettes are more likely to start smoking cigarettes. Michael S. Dunbar, et al., *Disentangling Within- and Between-Person Effects of Shared Risk Factors on E-cigarette and Cigarette Use Trajectories From Late Adolescence to Young Adulthood*, *Nicotine & Tobacco Research* (Oct. 2, 2018), *available at* <https://www.ncbi.nlm.nih.gov/pubmed/30277535>. Similarly, the Consensus Study Report of the National Academy of Sciences found that “[t]here is *substantial evidence* that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.” National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes*. (Washington, DC: The National Academies Press 2018) at 532 (emphasis in original), *available at* <https://www.nap.edu/read/24952/chapter/22#531>. One recent study quantified that increased risk, with its finding that youth who use e-cigarettes are four times more likely to take up cigarette use than youth who do not. *See*

Abstract: Results, Kaitlyn M. Berry, et al., *Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths*, JAMA Network Open (Feb. 1, 2019), available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425>. And in Maryland, data show that “over half of youth [e-cigarette] users (52.3%) also use traditional tobacco products.” Maryland Department of Health, *Monitoring Changing Tobacco Use Behaviors: Maryland 2000-2016* (May 2018) at 48, available at <https://pha.health.maryland.gov/ohpetup/Documents/2000%20-%202016%20Legislative%20Report%20Monitoring%20Changing%20Tobacco%20Use%20Behaviors.pdf>.

For decades, the severe adverse health effects caused by cigarettes have been beyond dispute. *See, e.g., Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 188 (2000) (Breyer, J., dissenting) (noting the “firm” and “wide consensus” about the adverse health effects of cigarettes). The health-care costs associated with smoking cigarettes are similarly well documented. In Maryland, those costs amounted to \$2.71 billion in 2014, the last year for which data is available. Centers for Disease Control and Prevention, *Best Practices for Comprehensive Tobacco Control Programs – 2014* (2014) at 98, available at https://www.cdc.gov/tobacco/stateandcommunity/best_practices/pdfs/2014/comprehensive.pdf. Maryland has a strong interest in preventing its youth from using e-cigarettes as a gateway to chronic use of combustible tobacco cigarettes. Maryland

is a signatory to the 1998 Master Settlement Agreement, a landmark public-health agreement that imposes permanent injunctive relief and settlement payment obligations on numerous cigarette manufacturers, including some parties involved in this case. *See Maryland v. Philip Morris Inc.*, 179 Md. App. 140, 143 (Md. App. 2008). The intervenors-appellants and their member companies have had ample notice for years that their products would be subject to premarket review, yet have marketed their products in Maryland and created a new public-health disaster for which Maryland will have to pay the bill. The additional delay sought in the pending stay motions would expose Maryland's youth and the State to unjustifiable risk of further harm. Therefore, Maryland urges this Court to deny the requests for a stay.

CONCLUSION

The Court should deny the motions for stay pending appeal.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

1. This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B), because this brief contains 1496 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in Fourteen point, Times New Roman.

/s/ Steven M. Sullivan

STEVEN M. SULLIVAN

CERTIFICATE OF SERVICE

I certify that, on this 7th day of January 2020, the state of Maryland's *amicus curiae* brief supporting plaintiffs-appellees' and United States oppositions to intervenors-appellants' and non-party appellants' motions to stay filed electronically and served on counsel of record through the CM/ECF system.

/s/ Steven M. Sullivan

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