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

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

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

*Appellants,*

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

*Intervenors-Appellants.*

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AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

*Plaintiffs-Appellees,*

v.

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

*Defendants-Appellees.*

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**THE STATE OF MARYLAND'S *AMICUS CURIAE* BRIEF  
SUPPORTING PLAINTIFFS-APPELLEES**

BRIAN E. FROSH  
Attorney General of Maryland

/s/ Sarah W. Rice

STEVEN M. SULLIVAN  
Solicitor General

SARAH W. RICE  
Assistant Attorney General

200 Saint Paul Place  
Baltimore, Maryland 21202  
(410) 576-7847 (tel.); (410) 576-6955 (fax)  
srice@oag.state.md.us

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## TABLE OF CONTENTS

	Page
INTEREST OF <i>AMICUS CURIAE</i> .....	2
ARGUMENT .....	3
I. DELAY IN THE FDA’S PREMARKET REVIEW HAS HARMED MARYLAND BY PERMITTING YOUTH-TARGETED PRODUCTS TO REMAIN ON THE MARKET AND ADDICT A NEW GENERATION. ....	3
II. MARYLAND CONTINUES TO INCUR COSTS AND EXPEND SIGNIFICANT POLICY-MAKING EFFORT TO PREVENT HARMS FROM TOBACCO AND NOVEL TOBACCO PRODUCTS. ....	11
CONCLUSION .....	14
CERTIFICATE OF COMPLIANCE WITH RULE 32(A) .....	15
CERTIFICATE OF SERVICE .....	15

## TABLE OF AUTHORITIES

Page

### Federal Cases

<i>American Acad. of Pediatrics v. Food and Drug Admin.</i> , 379 F. Supp. 3d 461 (D. Md. May 15, 2019) .....	3
<i>Food and Drug Admin. v. Brown &amp; Williamson Tobacco Corp.</i> , 529 U.S. 120 (2000) ...	11
<i>Maryland v. Philip Morris Inc.</i> , 179 Md. App. 140 (Md. App. 2008) .....	11
<i>United States v. Philip Morris USA, Inc.</i> , 449 F. Supp. 2d 1 (D.D.C. 2006) <i>aff'd in part and vacated in part</i> , 566 F.3d 1095 (D.C. Cir. 2009), <i>cert. denied</i> , 561 U.S. 1025 (2010) .....	6

### Statutes

21 U.S.C. § 387b(6) .....	2
21 U.S.C. § 387j(a) .....	2, 7
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AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

*Plaintiffs-Appellees,*

v.

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

*Defendants-Appellees.*

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**THE STATE OF MARYLAND'S *AMICUS CURIAE* BRIEF  
SUPPORTING PLAINTIFFS-APPELLEES**

The State of Maryland submits this *amicus curiae* brief in support of the plaintiffs-appellees. The issuance by the Food and Drug Administration (“FDA”) of the January 2020 guidance document (App. 187-240), which announces a

schedule for enforcement of premarket review requirements that has already begun, supersedes the August 2017 guidance, which would have delayed enforcement of premarket review requirements until 2022. (App. 139-153.) Consequently, this appeal, which concerns only the validity of the FDA's August 2017 guidance, is now moot. The Intervenor-Appellants' request for a remand to the FDA of the August 2017 guidance document seeks a remedy that is no longer available, since the January 2020 guidance has already been issued. Indeed, Maryland has already taken action in conjunction with the January 2020 guidance by announcing enforcement against the sale of all cartridge-based and disposable electronic smoking device (e-cigarette) products containing flavors other than tobacco or menthol.

#### ***INTEREST OF AMICUS CURIAE***

Maryland is home to thousands of children who have used e-cigarettes and cigars that, by law, should have been subjected to 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, which increases their risk of becoming lifelong cigarette and cigar 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 novel lung diseases e-cigarettes inflict, but also the many diseases associated with traditional combustible cigarettes and cigars. As these young Marylanders age and sicken, the State will incur medical expenses for treating

them through Medicaid. Thus, Maryland has an interest in ensuring that e-cigarette and cigar companies submit their new products to the FDA for premarket review in a definite and reasonable time frame, as Congress intended for novel tobacco products to be regulated when it enacted the Family Smoking Prevention and Tobacco Control Act (“TCA”) in 2009. 123 Pub. L. No. 111-31, 123 Stat. 1776. Because the FDA has now appropriately set compliance deadlines that it sought to avoid in the August 2017 guidance, this interest can be furthered by recognizing that the case is moot and dismissing this appeal.

## ARGUMENT

### **I. DELAY IN THE FDA’S PREMARKET REVIEW HAS HARMED MARYLAND BY PERMITTING YOUTH-TARGETED 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 February 25, 2020). The following table summarizes the Department of Health’s findings about Maryland’s high-school population’s use of



“electronic vapor product (including 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])”:

Question	2016	2018	Percent Increase
Percent who have ever used	35.3	39.7	12.5
Percent used in last 30 days	13.3	23.0	75.2

Maryland Department of Health, Youth Risk Behavior Survey/Youth Tobacco Survey (YRBS/YTS) 2018-2019: Trend Analysis 7, 8 (2018), [https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2018%20YRBS%20YTS%20Reports/Maryland/2018\\_HS\\_YRBS\\_YTS%20Trend%20Analysis.pdf](https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2018%20YRBS%20YTS%20Reports/Maryland/2018_HS_YRBS_YTS%20Trend%20Analysis.pdf) (“2018 Trend Analysis Report”).

Youth usage increased between 2016 and 2018 and the Department of Health labeled both trends as a significant change. *Id.* That increase reversed a downward trend that had been observed between 2014 and 2016 in both measures. Maryland Department of Health, 2016 Maryland Youth Risk Behavior Survey and Youth Tobacco Survey 35 (2016), [https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2016%20YRBS%20YTS%20Reports/MDH%20YRBS\\_Report\\_2016\\_final.pdf](https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2016%20YRBS%20YTS%20Reports/MDH%20YRBS_Report_2016_final.pdf). (“2016 YRBS Report”). During the period while FDA was operating under its August 2017 Guidance, which extended the deadline for compliance to 2022, Maryland’s youth were increasingly drawn to and addicted to the Intervenor-Appellants’ products.

Maryland’s experience is similar to what the national data show. The findings of the National Youth Tobacco Survey among middle- and high-school students is summarized in the following table:

Question	2017	2018	Percent Increase
Current <sup>1</sup> high-school use	11.7	20.8	78
Proportion of current high-school users who used on 20 or more of past 30 days	20.0	27.7	38.5
Current middle-school use	3.3	4.9	48

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>.

These rising percentages of e-cigarette use make it all too certain that the lives of young Maryland residents will be adversely affected by any further delay of FDA review. According to the Maryland Department of Education, 259,898 students were enrolled in public high schools in 2018. Maryland State Department of

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<sup>1</sup> 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>.

Education 2018 Maryland School Report Card; <https://reportcard.msde.maryland.gov/Graphs/#/Demographics/Enrollment/3/H/6/99/XXXX> (select “Grade: high” and “Gender: all students” in dropdown menus and click “Show Table”) (last visited February 25, 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,<sup>2</sup> 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 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).

Youth also disproportionately use cigars and cigarillos when compared to adults. Maryland Department of Health, *Monitoring Changing Tobacco Use Behaviors: Maryland 2000-2016* 33 (May 2018), <https://phpa.health.maryland.gov/ohpetup/Documents/2000%20-%202016%20Legislative%20Report%20Monitoring%20Changing%20Tobacco%20Use%20Behaviors.pdf> (“Monitoring Changing Tobacco Use Behaviors”). In Maryland, there was a shift

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<sup>2</sup> 13.3 percent of 259,898 is 34,566, and 23.0 percent of 259,898 is 59,777.

in youth usage from cigarettes to cigars and cigarillos in 2008 through 2010, and, while cigar use has been declining in more recent years, it decreased at a slower rate than youth cigarette use between 2013 and 2016. *Id.* In 2018, a higher percentage of youth continued to report cigar use within the last 30 days as opposed to cigarette use in the last 30 days. *Compare* 2018 Trend Analysis Report at 13 *with* 2018 Trend Analysis Report at 5.

Because of the FDA's original decision to delay enforcement of products subject to premarket review under the 2016 deeming rule, tobacco companies have been able to exploit large gaps in the regulatory structure to addict a new generation of nicotine users. In 2009, Congress banned specific characterizing flavors in cigarettes in § 907(a)(1)(A) of the TCA, the same law that authorized the FDA to use its deeming authority to regulate novel tobacco products. But e-cigarettes and cigars were not included in that ban, and instead Congress delegated authority to the FDA to conduct a premarket review on novel tobacco products. 21 U.S.C. § 387j(a)(1)-(2). The FDA delayed in exercising this authority, and then, as challenged by the plaintiff-appellees below, impermissibly extended compliance deadlines with the result that new market entrants, including e-cigarettes and many smaller cigars, were permitted to circumvent protections aimed at curbing youth usage.

With their “sleek, easily concealable designs,” “little ‘smoke’ clouds,” low odor, and “huge variety of fruit and candy flavors,” e-cigarettes are packaged to be attractive to youth. 2016 YRBS Report at 34. So too are cigars and cigarillos, which are also often packaged in single-use or small packages that are more affordable for youth. Maryland Department of Health and Mental Hygiene, *How are Cigarillos and Little Cigars Sold?* (2011), [https://health.maryland.gov/THECIGARTRAP/pdf/How\\_are\\_Cigarillos\\_and\\_Little\\_Cigars\\_Sold.pdf](https://health.maryland.gov/THECIGARTRAP/pdf/How_are_Cigarillos_and_Little_Cigars_Sold.pdf). A focus group of Maryland parents reported that little cigar packaging is “like picking up a pack of gum. It’s going to catch your eye,” and further commented that “[y]ou can actually buy them with lunch money.” *Id.* Research corroborates that flavored tobacco products are perceived as more appealing and less harmful than non-flavored products, and that this effect is stronger among youth users. L. Huang et al., *Impact of non-menthol flavours in tobacco products on perceptions and use among youth, young adults, and adults: a systematic review.* *Tobacco Control* (2016), <https://tobaccocontrol.bmj.com/content/26/6/709.full>. This research corresponds to Maryland’s experience with youth usage of electronic delivery system products. In 2016, only 4 percent of youth who reported using such products in the past 30 days reported using tobacco-flavored vapor while 62 percent reported using fruit-flavored vapor. 2016 YRBS Report at 35. There is evidence that the vast majority of youth

users would stop using e-cigarette products if they were not flavored. MB Harrell, et al., *Flavored Tobacco Product Use Among Youth and Young Adults: What if Flavors Didn't Exist*, Tobacco Regulatory Science (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5536860/>.

Maryland youth who have started using e-cigarettes during the pendency of the long-awaited FDA review are subject to significant health risks. According to the Centers for Disease Control and Prevention (“CDC”), the nicotine in e-cigarettes is highly addictive and can harm adolescent brain development by affecting parts of the brain that control attention, mood, learning, and impulse control. CDC, *Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults* (2020), [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html#one](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html#one) (last visited February 25, 2020). E-cigarettes not only pose health risks associated with youth nicotine addiction, but the CDC also warns that e-cigarette aerosol can be “harmful to the lungs in the long-term.” *Id.* Specifically, this aerosol may contain harmful substances such as heavy metals, cancer-causing chemicals, flavoring chemicals linked to serious lung disease, and other substances that should not be inhaled deeply into the lungs. *Id.*

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), <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* 532 (Washington, DC: The National Academies Press 2018), <https://www.nap.edu/read/24952/chapter/22#531> (emphasis in original). 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 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), <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.” *Monitoring Changing Tobacco Use Behaviors* at 48.

## II. MARYLAND CONTINUES TO INCUR COSTS AND EXPEND SIGNIFICANT POLICY-MAKING EFFORT TO PREVENT HARMS FROM TOBACCO AND NOVEL TOBACCO PRODUCTS.

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* 98 (2014), [https://www.cdc.gov/tobacco/stateandcommunity/best\\_practices/pdfs/2014/comprehensive.pdf](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). And Maryland expends significant effort on tobacco use prevention. Following a marked upward trend in youth cigar use in 2010, Maryland launched in



2011 “The Cigar Trap” campaign, which sought to increase public awareness of the dangers of flavored cigar smoking for youth. Maryland Department of Health and Mental Hygiene, *Press Release: Cigar Use Among Maryland Youth Threatens Gains in Tobacco Control* (Nov. 17, 2011), [https://health.maryland.gov/THECIGARTRAP/pdf/DHMH\\_Press\\_Release.pdf](https://health.maryland.gov/THECIGARTRAP/pdf/DHMH_Press_Release.pdf).

The campaign involved radio, print, outdoor, and digital advertising. In 2016, Maryland was again forced to counter industry marketing toward youth by launching “The Vape Experiment” campaign, which includes a digital advertising campaign, to gather all of the currently-known information about the dangers of e-cigarette use. 2016 YRBS Report at 59. The information the Maryland Health Department has been able to disseminate through this campaign is incomplete, because the FDA has not completed the premarket review that could lead to a definitive disclosure of dangers, including what new health risks are posed by aerosolized flavor additives.

Most recently, Maryland has acted decisively to capitalize on the FDA’s 2020 guidance. The Comptroller of Maryland’s Field Enforcement Division announced on February 10, 2020 that the Division will be prioritizing “enforcement actions against those unauthorized products most widely used by children – specifically, cartridge-based and disposable” e-cigarette products “with flavors other than tobacco or menthol.” Jeffrey A. Kelly, Director, Field Enforcement Division, Comptroller of Maryland, *Bulletin TT-77* (Feb. 10, 2020),

[https://content.govdelivery.com/attachments/MDCOMP/2020/02/10/file\\_attachments/1376534/Tobacco%20Bulletin%2077%20-%2002.10.2020%20-%20Flavored%20ESDs%20Unlawful.pdf](https://content.govdelivery.com/attachments/MDCOMP/2020/02/10/file_attachments/1376534/Tobacco%20Bulletin%2077%20-%2002.10.2020%20-%20Flavored%20ESDs%20Unlawful.pdf). This announcement expanded upon the FDA's January 2, 2020 announcement of enforcement actions. *Id.* The Division based its decision to expand the scope of the announced FDA enforcement action on FDA's declaration that all electronic smoking device (or e-cigarette) "products currently on the market are considered illegally marketed" under federal law because premarket review has not yet been completed. *Id.* The Maryland General Assembly is also currently considering a bill that would ban the sale of *all* flavored tobacco products, including cigars, cigarillos, and menthol-flavored products. Reg. Session 2020, House Bill 3, <http://mgaleg.maryland.gov/mgaweb/Legislation/Details/hb0003> (tracking page).

The intervenors-appellants and their member companies have had ample notice for years that their products would be subject to premarket review, yet they have marketed their products in Maryland and created a new public-health disaster for which Maryland will have to pay the bill. The FDA and Maryland have each moved forward to address the immediate public health needs caused by the past years of unchecked entry into the market. The additional delay that would result from further proceedings in this case would expose Maryland's youth and the State to

unjustifiable risk of further harm. Therefore, Maryland urges this Court to dismiss the appeal as moot, or, in the alternative, to affirm the district court's orders.

### CONCLUSION

The appeals should be dismissed as moot, or, in the alternative, the district court's orders should be affirmed.

Respectfully submitted,

BRIAN E. FROSH  
Attorney General of Maryland

/s/ Sarah W. Rice  
STEVEN M. SULLIVAN  
Solicitor General  
SARAH W. RICE  
Assistant Attorney General  
200 Saint Paul Place  
Baltimore, Maryland 21202  
(410) 576-7847 (tel.); (410) 576-6955 (fax)  
srice@oag.state.md.us

**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 2582 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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/ Sarah W. Rice*

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SARAH W. RICE

**CERTIFICATE OF SERVICE**

I certify that, on this 27th day of February 2020, the state of Maryland's *amicus curiae* brief supporting plaintiffs-appellees was filed electronically and served on counsel of record through the CM/ECF system.

*/s/ Sarah W. Rice*

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SARAH W. RICE