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Nos. 19-2130(L), 19-2132, 19-2198, 19-2242 (Consolidated)

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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.*,

*Defendant-Appellees.*

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**On Appeal from the United States District Court  
for the District of Maryland**

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**MARYLAND ASSOCIATION OF COUNTY HEALTH OFFICERS’  
MOTION FOR LEAVE TO FILE AN *AMICUS CURIAE* BRIEF IN  
SUPPORT OF PLAINTIFFS-APPELLEES’ BRIEF**

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**MARYLAND ASSOCIATION OF COUNTY HEALTH OFFICERS'  
MOTION FOR LEAVE TO FILE AN *AMICUS* BRIEF SUPPORTING  
PLAINTIFFS-APPELLEES' BRIEF SEEKING DISMISSAL OF APPEALS,  
OR IN THE ALTERNATIVE, AFFIRMANCE**

1. The Maryland Association of County Health Officers (MACHO) requests that the Court grant leave to file a concise *amicus* brief in support of Plaintiffs-Appellees' Brief. No. 19-2130 (L) seeking dismissal of appeals, or in the alternative, affirmance of the district court's ruling. A copy of the proposed *amicus* brief is submitted with this motion as Exhibit 1.

2. MACHO has an interest in dismissal of this appeal and in preventing reversal of the district court's judgment and the remedy it provides. MACHO is a private, non-profit organization whose primary purpose is to promote the health and well-being of Maryland citizens. In so doing, MACHO actively cooperates and works with the Maryland Department of Health, the Maryland Comptroller, the Maryland Attorney General, the Maryland General Assembly, Maryland's local legislative bodies, the Food and Drug Administration's Center for Tobacco Products (CTP), the Centers for Disease Control and Prevention (CDC), and other health-related or complementary agencies, organizations, individuals, and community groups. MACHO is comprised of the health officers for Maryland's 23 counties and the Health Commissioner for Baltimore City. Local health department activities include educating the community on health risks and prevention; providing health care services to the community; developing, implementing,

enforcing, and evaluating public health policy; collecting and analyzing data related to public health; and much more. Local health departments are the first line of enforcement of many tobacco laws and policies, the source for cessation services, and the primary point of contact on tobacco issues for the community, including schools, parents, health professionals, tobacco businesses, and law enforcement.

Because of these responsibilities, local health departments are spending a significant amount of their limited resource responding to and seeking to prevent and ameliorate the public health effects associated with the massive increase in e-cigarette use/vaping, particularly among youth. Yet local health departments cannot control the marketplace of electronic smoking devices or vaping products; CTP is primarily responsible for that. This case demonstrates CTP's failure to do so effectively by failing to perform its duties under the Family Smoking Prevention and Tobacco Control Act, allowing the vaping epidemic to bud and blossom and placing significant burden on local health departments. Dismissing these appeals or affirming and leaving in place the district court's orders imposing certain deadlines is a step toward CTP fulfilling its obligation to serve in the best interests of public health. With an established deadline for the filing of premarket tobacco product applications (PMTAs), the local health officers comprising MACHO will be better able to promote and protect the public health in Maryland. MACHO has been

interest in the FDA requiring premarket review of vape products in a timely manner. The deadline will result in some products being considered unlawful immediately, potentially reducing the market size. And ultimately, the FDA will only allow the marketing of products whose existence in the marketplace will support public health; the Agency may also impose marketing and sales restrictions that support the public health mission. MACHO shares that mission and is depending on CTP to do its part. The first step, however, is enforcing the PMTA process in a rational and reasonable manner as the district court has ordered.

3. An *amicus* brief from MACHO is desirable, as it will explain the impact of the vaping epidemic on local health officials, how a set deadline for PMTAs will reduce uncertainty and narrow the market, and why reversing the district court order would impose unwarranted additional delay, increase uncertainty, harm Maryland residents, and have an acute impact on Maryland's local governments.
4. Appellants consent to the filing of the *amicus curiae* brief attached to this motion.

## CONCLUSION

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

Respectfully submitted,

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Dated: February 26, 2020

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**MARYLAND ASSOCIATION OF COUNTY HEALTH OFFICERS’  
AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFFS-  
APPELLEES’ BRIEF**

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The Maryland Association of County Health Officers (MACHO) submits this *amicus curiae* brief in support of the brief (No. 19-2130 (L)) filed by Plaintiffs-Appellees seeking dismissal of the appeals filed by Appellants and by Intervenors-Appellants, or in the alternative, seeking affirmance of the district court's orders.<sup>1</sup>

#### INTEREST OF *AMICUS CURIAE*

Thousands of Maryland consumers have purchased and used e-cigarettes, also known as vape or vaping products, that have remained on the market in violation of the spirit and letter of the Family Smoking Prevention and Tobacco Control Act and related regulations. *See* 123 Pub. L. No. 111-31, 123 Stat. 1776, codified in 21 U.S.C. §§ 387b(6), 387j(a); *see* 81 Fed. Reg. 28973 (May 10, 2016). Through unbridled exercise of enforcement discretion, the Food and Drug Administration (FDA) has allowed the entire category of electronic nicotine delivery systems, referred to as vaping products, to remain on the market despite

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<sup>1</sup> This brief was prepared in whole by counsel for the Maryland Association of County Health Officers (MACHO)(Kathleen Hoke as Counsel of Record); counsel did not contribute money toward preparation or submission of the brief; and no other entity contributed money towards the preparation or submission of the brief. This brief is submitted on behalf of MACHO and not on behalf of the University of Maryland Carey School of Law; the University of Maryland, Baltimore; or the University of Maryland System, and does not reflect the official position of the School of Law. Third-year law student, Megan Parkhurst, contributed to the preparation of this brief.

Congress' express intent that products not on the market as of February 15, 2007, be subject to the premarket tobacco product application (PMTA) process prior to being allowed in the marketplace. As a result, vaping products are widely available in Maryland and youth and young adults have been successfully enticed into purchasing the products. Many of these consumers, particularly youth, are now addicted to nicotine, which presents serious health risks to the developing brain and body and may lead to smoking cigarettes. Similarly, youth and adults are ingesting into their lungs and pulmonary systems chemicals that have not been evaluated for safety—and there is reason to be deeply concerned about the health impact of such exposure for youth, for non-smoking adults, and for adults who are or have been smokers.

Local health departments, led by the members of MACHO, are the first line of enforcement of many tobacco laws and policies, particularly those related to youth tobacco access and use; the source for cessation services for the community; and the primary point of contact on tobacco issues for schools, health professionals, parents, tobacco businesses, law enforcement, and others. Because of these responsibilities, local health departments spend a significant amount of their limited resources responding to and seeking to prevent and ameliorate the public health effects associated with the massive increase in e-cigarette use/vaping, particularly among youth. The FDA's decision to allow the virtually unfettered

sale of vaping products in contradiction to Congress' intent and in derogation of public health is directly responsible for the current dynamic of vaping in Maryland and nationally.

MACHO's members have an interest in the dismissal of this appeal or the prompt and efficient enforcement of the district court's order; either will result in requiring e-cigarette manufacturers to submit their PMTAs by May 11, 2020. Enforcement of this deadline—set by the district court and then by the FDA directly—will result in fewer products lawfully on the market and quicker resolution of what products should be permitted to remain. This first and important step in effective federal regulation of vaping products will serve as an interrupter in the, until now, rapid proliferation of vaping products being marketed in Maryland and being used by our youth and young adults.

#### ARGUMENT

**DENYING THE REQUEST TO DISMISS THIS APPEAL, OR REVERSING THE DISTRICT COURT'S ORDERS, WILL ALLOW FOR CONTINUED UNFETTERED MARKETING OF VIRTUALLY ALL VAPING PRODUCTS AND WILL CONTRIBUTE TO THE CONTINUATION OF THE VAPING EPIDEMIC IN MARYLAND AND NATIONALLY**

These appeals should be dismissed because the FDA issued a new guidance document in January 2020 (2020 Guidance) setting May 11, 2020, as the date on which PMTAs must be filed for all vaping products seeking authority to remain on the market. Plaintiffs-Appellees ably explain why the 2020 Guidance renders these appeals moot. MACHO echoes that explanation. For MACHO, the establishment

of a May 11, 2020, deadline for PMTAs for vaping manufacturers achieves the goal underlying this *amicus* brief—securing market certainty, narrowing the market, and moving toward FDA restricting the market to those products that have been found to support the public’s health. If the appeals are not dismissed, this Court should affirm the district court’s orders for the reasons explained fully in the brief for the Plaintiffs-Appellees. Such an outcome provides the same result for MACHO as dismissal of the appeals—narrowing of the market and hope for further narrowing and regulation consistent with the public health standard the FDA must apply to PMTAs.

We understand that the state of Maryland will also be filing an *amicus curiae* brief in support of the Plaintiffs-Appellees. MACHO knows well the impact the vaping epidemic has had on the State. This brief enhances the discussion by explaining the impact on local health departments, with a particular look at disproportionate impact in rural communities, the effect of the epidemic in Maryland schools and the demand that creates for local public health services, and the need for increased enforcement efforts by local health departments.

The youth vaping epidemic impacts the state of Maryland as a whole; that impact is felt at the local level, disproportionately in certain counties. According to the Maryland Department of Health’s 2018 Youth Risk Behavior Survey, 23% of

Maryland high school students reported “current”<sup>2</sup> use of vape products in 2018. *See* Maryland Department of Health, 2018 Maryland Youth Risk Behavior Survey & Youth Tobacco Survey-Trend Analysis Report, <https://phpa.health.maryland.gov/ccdpc/Reports/Pages/YRBS2018.aspx>. The survey also reveals that 39.7% of Maryland high school students and 18.9% of middle school students reported “ever” using “an electronic vapor product” in 2018. *Id.* These numbers are alarming and reveal why narrowing the vape product market and imposing restrictions consistent with the public health standard are imperative. Yet data also show that in certain counties, including Allegany, Caroline, Cecil, Garrett, Kent, and Queen Anne’s, youth e-cigarette use was nearly *double* the statewide number. At least 40% of high school students in these counties reported current use of vape products in 2018, revealing the significance of the problem and the great need for public health resources to combat it. *Id.* Yet these are our more rural communities, those that struggle most acutely with insufficient funding to address myriad public health issues and they are experiencing heightened public health burdens due to the vaping epidemic. For our State and for our challenged communities, FDA’s narrowing of the market and restricting vape products to those that meet the public health standard will buttress

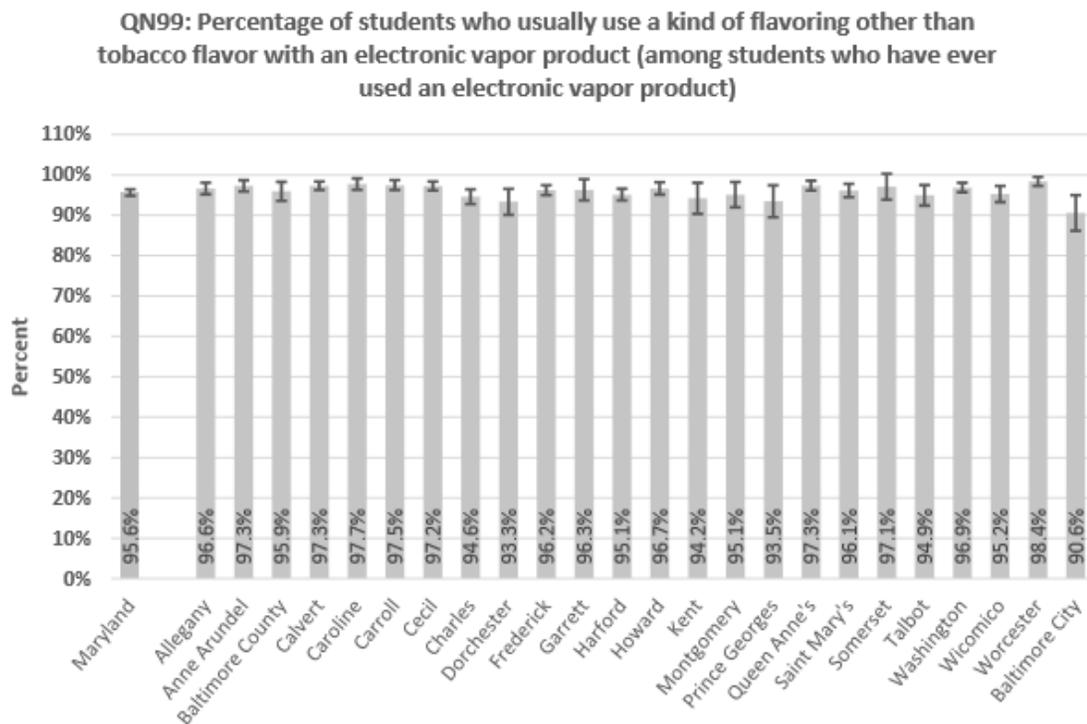
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<sup>2</sup> The survey asked students whether they had used an electronic vapor product on at least 1 day in the past 30 days before the survey.

the hard work of local health departments to restrict youth access and increase youth cessation.

One example of the impact of dismissing the appeals and allowing the 2020 Guidance to remain in effect relates to flavored vape products that are widely used by Maryland youth. Of the Maryland students who have ever used an e-cigarette, 95.6% of them used a flavor other than tobacco. This is consistent across every county in the state. See Maryland Department of Health, 2018 Maryland Youth Risk Behavior Survey and Youth Tobacco Survey High School Summary Tables by County,

[https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2018%20YRBS%20YTS%20Reports/Maryland/2018\\_HS\\_YRBS\\_YTS%20Figures.pdf](https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2018%20YRBS%20YTS%20Reports/Maryland/2018_HS_YRBS_YTS%20Figures.pdf).



MACHO members are confident that restrictions on flavored vape products will complement local public health efforts to reduce youth and young adult use of vaping products. Specifically, flavor restrictions reducing youth attraction to and use of vape products will alleviate some of the demand for local health departments to assist our local school systems as they try to manage the youth vaping epidemic.

The impact of the vaping epidemic is being keenly felt by our school systems and, therefore, increasing the burden on local health departments. As a result of the swift and intense increase in youth vaping, the ease with which students can hide vaping while at school, and the interruption in education for those students suffering nicotine addiction as a result of vaping, our schools are increasingly in need of services for their students. Indeed, Montgomery County, Maryland, has sued one of the leading vape product manufacturers, JUUL, because of the massive costs associated with managing the vaping epidemic in Montgomery County Public Schools. *See Montgomery County, Maryland v. Juul Labs, Inc. et al.*, Case. 3:19-cv-07037 (transferred and consolidated) (N.D. Ca. Oct. 25, 2019). Anecdotally, students in Maryland have shared that school bathrooms are referred to as vaping lounges and teachers report the inability to stop students from vaping in class. MACHO's local health departments are desperately working with school administrators to develop and implement effective policies and

practices to mitigate the problem but stretched resources and the newness of the dynamic of vaping create hurdles to success. Yet time is of the essence.

Local health departments have always been a reliable source for public health communication and support for schools in Maryland. In fact, the Maryland Guidelines for a State Code of Discipline recommend that schools refer students to the local health departments for assistance with vaping education, prevention, and cessation; services that MACHO members provide for students who have been caught smoking. Maryland State Department of Education, *Maryland Guidelines for a State Code of Discipline* (2014) at 21, <http://marylandpublicschools.org/about/Documents/DSFSS/SSSP/MDGuidelinesforStateCodeDiscipline08072014.pdf>. But not all of our 24 local health departments offer vaping cessation for adults, let alone for young people. We are still working to determine best practices for vaping cessation programs and for vaping cessation targeting youth; the problem spread so quickly that our policies and programs are unable to keep pace. Because we cannot provide comprehensive services to all schools or all students in need, some schools resort to suspending students caught vaping. This creates an additional public health concern because removing students from school contributes to lower grades, lack of access to school lunch programs, inability to participate in extracurricular activities, and myriad other negative outcomes. *See Council on School Health. Policy statement: out-of-school*

*suspension and expulsion*. Pediatrics. 2013; 131(3): e1000; doi:10.1542/peds.2012-3932, <http://pediatrics.aappublications.org/content/131/3/e1000#ref-2>. Efforts by the FDA to regulate the vaping market under the public health standard, albeit late, will support local health department and school system efforts to support Maryland students lured into vaping.

The FDA's efforts to reduce the supply of vape products to just those that can survive the public health standard applicable in the PMTA process complements the work local health departments in Maryland do with respect to enforcement of youth sales prohibitions. Pursuant to Maryland Health-General Article §24-305, local health departments in Maryland have the authority to issue civil citations to retailers that sell vape products to minors. Some county health departments also enforce local laws regulating the sale of vape products to minors. *See, e.g.*, Baltimore County Code §13-12-103; Howard County Code §12.1301. With more than 8,000 tobacco product retailers in the State that may sell vape products, it is impossible for local health departments to check every establishment with frequency given resource constraints. Moreover, many youth access their vape products through "social sourcing," including older friends or siblings or adults who gladly buy for youth. Liu, *et al.*, *Youth Access to Tobacco Products in the United States, 2016-2018*, Tobacco Regulatory Science, 5(6): 491-501, 2019. Local health department enforcement efforts are critical to sending the message to

retailers that they may not sell to minors, but FDA action narrowing the market, restricting flavors, and imposing other sales and marketing restrictions consistent with the public health standard will address the supply side of the transaction. Both are needed to drive down youth vaping. Dismissing the appeals or affirming the district court's orders will allow us to realize the benefits of the PMTA process and the 2020 Guidance.

#### **ARGUMENT BY ADOPTION OF BRIEFS**

MACHO hereby adopts the arguments, submitted in the Brief of Plaintiffs-Appellees, American Academy of Pediatrics, *et al.*, seeking dismissal of the appeals, or in the alternative, affirmance of the district court's orders.

#### **CONCLUSION**

For the foregoing reasons and the reasons stated in the brief of the Plaintiffs-Appellees, MACHO respectfully requests that the appeals be dismissed, or in the alternative, that the district court's orders be affirmed.

Respectfully submitted,

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Dated: February 26, 2020