UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LEXINGTON DIVISION

VAPOR TECHNOLOGY ASSOCIATION, et al. Plaintiffs v. U.S. FOOD AND DRUG ADMINISTRATION, et al Defendants.	)	Case No. 5:19-cv-0330-KKC

MOTION OF AMICI CURIAE FOR LEAVE TO FILE A BRIEF IN SUPPORT OF THE DEFENDANTS' COMBINED MOTION TO DISMISS AND OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND, IN THE ALTERNATIVE, MOTION TO TRANSFER TO THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

Amici Curiae American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative move this Court for leave to file the accompanying amici curiae brief in the above entitled case. In support of the motion, Amici Curiae provide the attached memorandum.

Respectfully submitted,

CRAIG HENRY PLC

/s/ Michele Henry
Michele Henry
401 W. Main Street
Suite 1900
Louisville, KY 40202
(502) 614-5962
mhenry@craighenrylaw.com

Of Counsel:
Dennis Henigan
Mark Greenwold
Campaign for Tobacco-Free Kids
1400 Eye Street NW
Washington, D.C. 20005

CERTIFICATE OF SERVICE

I certify that I filed the foregoing Motion for Leave to File an Amici Curiae Brief on October 18, 2019 using the Court's CM/ECF system, which will electronically serve all counsel of record.

/s/ Michele Henry
Counsel for Amici Curiae

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LEXINGTON DIVISION

VAPOR TECHNOLOGY ASSOCIATION, et al. Plaintiffs v. U.S. FOOD AND DRUG ADMINISTRATION, et al Defendants.	)	Case No. 5:19-cv-0330-KKC *Electronically filed*

MEMORANDUM OF AMICI CURIAE IN SUPPORT OF THEIR MOTION FOR LEAVE TO FILE A BRIEF IN SUPPORT OF THE DEFENDANTS' COMBINED MOTION TO DISMISS AND OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND, IN THE ALTERNATIVE, MOTION TO TRANSFER TO THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

Amici Curiae American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative move this Court for leave to file the accompanying amici curiae brief in the above entitled case. This motion should be granted for the following reasons:

1. Amicus Curiae American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of the AAP has grown from the original group of 60 physicians specializing in children's health to 67,000 pediatricians. Over the past 89 years, the AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to

protect the well-being of America's children. The AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to secondhand tobacco smoke.

2. Amicus Curiae American Cancer Society Cancer Action Network (ACS CAN) is making cancer a top priority for public officials and candidates at the federal, state and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

3. Amicus Curiae American Heart Association is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. The association invests in research, professional and public education, community-based programs, and advocacy so people across America can live longer, healthier lives. Preventing and reducing tobacco use is a top priority for the association.

4. Amicus Curiae American Lung Association is the nation's oldest voluntary health organization. The American Lung Association has long been active in research, education and public policy advocacy regarding the adverse health effects caused by tobacco use, including supporting eliminating the sale of all flavored tobacco products.

5. Amicus Curiae Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent

kids from smoking, help smokers quit and protect everyone from secondhand smoke.

6. Amicus Curiae Truth Initiative is a 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports programs in the United States to reduce youth tobacco use and to prevent diseases associated with tobacco use. Its nationally recognized truth® campaign has educated hundreds of millions of young people about the health effects and social costs of tobacco.

7. Reducing the death and disease caused by tobacco products is central to the mission of each of the amicus organizations. Amici are the organizational plaintiffs who on March 27, 2018, filed suit against the Food and Drug Administration in *Am. Acad. of Peds. v. FDA,* (No. 18-cv-883, D. Md. 2019) (hereinafter "the Maryland lawsuit) challenging FDA's wholesale suspension of statutorily-required public health review of new e-cigarette products.

8. The Maryland lawsuit has resulted in court orders vacating the FDA Guidance that had suspended the required public health review of these products, 379 F. Supp. 3d 461 (D. Md. 2019), and establishing a new timeline for the conduct of public health review. No. 18-cv-883, 2019 WL 3067492, Jul. 12, 2010. Because plaintiffs in the instant case seek relief that would nullify the orders entered in the Maryland lawsuit and because nullification of those orders would have adverse public health consequences, the amici have a strong interest in ensuring that the orders entered

in the Maryland lawsuit are protected against unjustified and legally defective collateral attack. Amici's expertise in issues surrounding the current crisis in youth e-cigarette use and the FDA's authority to address that crisis will be of material assistance to the court.

For these reasons, amici respectfully request that this Court grant this motion and accept their amicus curiae brief for filing.

Respectfully submitted,

CRAIG HENRY PLC

/s/ Michele Henry
Michele Henry
401 W. Main Street
Suite 1900
Louisville, KY 40202
(502) 614-5962
mhenry@craighenrylaw.com

Of Counsel:
Dennis Henigan
Mark Greenwold
Campaign for Tobacco-Free Kids
1400 Eye Street NW
Washington, D.C. 20005

CERTIFICATE OF SERVICE

I certify that I filed the foregoing Memorandum in Support of Amicus Curiae's Motion for Leave to File an Amicus Curiae Brief on October 18, 2019 using the Court's CM/ECF system, which will electronically serve all counsel of record.

/s/ Michele Henry
Counsel for Amicus Curiae

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LEXINGTON DIVISION

VAPOR TECHNOLOGY ASSOCIATION, et al. Plaintiffs v. U.S. FOOD AND DRUG ADMINISTRATION, et al Defendants.	)	Case No. 5:19-cv-0330-KKC

ORDER

Pending before the Court is the Motion of Amici Curiae American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative to file an amici brief in support of the Defendants' combined motion to dismiss and opposition to Plaintiff's motion for a preliminary injunction and, in the alternative, motion to transfer this case to the U.S. District Court for the District of Maryland.

The Court, having reviewed the arguments of counsel and being fully informed, hereby **GRANTS** the motion and **ORDERS** the Clerk to file the Amici Brief attached to Amici Curiae's motion as Exhibit A.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LEXINGTON DIVISION

VAPOR TECHNOLOGY ASSOCIATION, et al.	)	
	)	
Plaintiffs	)	
	)	Case No. 5:19-cv-0330-KKC
v.	)	
	)	
	)	
U.S. FOOD AND DRUG ADMINISTRATION, et al	)	
	)	
Defendants.	)	

BRIEF OF AMICI CURIAE PUBLIC HEALTH AND MEDICAL ORGANIZATIONS IN SUPPORT OF THE DEFENDANT'S COMBINED MOTION TO DISMISS AND OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND, IN THE ALTERNATIVE, MOTION TO TRANSFER TO THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

INTRODUCTION AND STATEMENT OF INTEREST OF THE AMICI CURIAE[1]

Amici curiae public health and medical organizations file this brief in support of the Motion to Dismiss and Opposition to Plaintiff's Motion for Preliminary Judgment filed by the Defendant, U.S. Food and Drug Administration ("FDA").

Amici are Plaintiffs in *Am. Acad. of Peds. v. FDA*, 379 F.Supp.3d 461 (D. Md. 2019): American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative. Descriptions of the amici organizations are provided in the Appendix to this brief.

Reducing the death and disease caused by tobacco products is central to the mission of each of the amicus organizations. Since March 2018, amici have prosecuted the *American Academy of Pediatrics* lawsuit (hereinafter "the Maryland lawsuit"), challenging FDA's wholesale suspension of statutorily-required public health review of new e-cigarette products. The Maryland lawsuit has resulted in court orders vacating the FDA Guidance that had suspended the required public health review of these products and establishing a new timeline for the conduct of public health review. Because Plaintiffs in the instant case seek relief that would nullify the orders entered in the Maryland lawsuit, and because nullification of those orders would have adverse public health consequences, the amici have a strong interest in ensuring that those court orders are protected against unjustified and legally defective collateral attack. Amici's expertise in issues surrounding the current crisis in youth e-cigarette use, and the FDA's authority to address that crisis, will be of material assistance to the court.

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[1] The Defendants consent to the filing of this Brief. The Plaintiffs have indicated their intent to object to its filing.

SUMMARY OF ARGUMENT

As demonstrated in FDA's brief in support of its Combined Motion to Dismiss and Opposition to the Plaintiffs' Motion for a Preliminary Injunction, the relief Plaintiffs seek in this case is improper for numerous reasons. First, it would nullify the order issued by United States in the Maryland lawsuit and therefore constitutes an impermissible collateral attack on that judgment. Second, Plaintiffs have no protectable interest in continuing the marketing of e-cigarettes, an activity for which there is currently no legal basis, in the absence of a valid marketing order issued by the FDA upon a finding that marketing the product is appropriate for the protection of the public health. Most important, however, the relief Plaintiffs seek would prevent FDA, the principal public health regulatory arm of the federal government, from taking actions it has recognized are necessary to address an unprecedented epidemic of youth e-cigarette usage and addiction. The relief Plaintiffs seeks is thus profoundly contrary to the public interest.

Although a federal statute unambiguously prohibits the sale of e-cigarettes in the absence of a marketing order issued by FDA finding that the product is "appropriate for the protection of the public health," not a single e-cigarette sold since August 2016 has been marketed legally. Rather, these products have been marketed because FDA illegally adopted a policy of deferring enforcement of the law. The gravity of this public health crisis, which continues to grow, has persuaded FDA that the non-enforcement policy it had adopted in August 2017 was no longer adequate to protect the public health and needed to be changed. The emergence of this crisis was also a principal factor motivating the United States District Court for the District of Maryland to enter the order that Plaintiffs now seek to nullify.

Since 2017, youth e-cigarette usage in the United States has skyrocketed to what the U.S. Surgeon General and the FDA have called "epidemic" levels. Youth e-cigarette usage is a public health crisis and it is unmistakably getting worse. Newly released data from the 2019 National Youth Tobacco Survey (NYTS) compiled by the Centers for Disease Control and Prevention (CDC), the most authoritative governmental statistical survey, shows that e-cigarette usage among high school students more than doubled between 2017 and 2019, increasing from 11.7 percent in 2017 to 20.8 percent in 2018, to 27.5 percent in 2019, or more than one in every four high schoolers.[2] Altogether, 5 million middle and high school students used e-cigarettes in 2019, an increase of nearly 3 million users since 2017.[3] E-cigarettes are addicting a new generation of kids and threaten to reverse decades of progress in reducing youth tobacco use.

E-cigarettes have become by far the most commonly used tobacco products among U.S. youth. Adolescents are not just experimenting with e-cigarettes but are using them frequently. More than a quarter of high school e-cigarette users are frequent users, using e-cigarettes on at least 20 of the preceding 30 days.[4] Alarmingly, a separate national survey, the 2019 Monitoring the Future Survey, found that one out of nine high school seniors (11.7 percent) report that they vaped nicotine nearly daily, a strong indication of addiction.[5] According to this 2019 Survey,

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[2] FDA, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*, September 11, 2019, https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

[3] Edney, A., et al., *Vaping Furor Intensifies as Trump Vows Tough U.S. Scrutiny*, Bloomberg, September 11, 2019, https://www.bloomberg.com/news/articles/2019-09-11/trump-to-hold-meeting-on-vaping-after-reports-of-u-s-illness.

[4] CDC, *Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018*, MMWR, 67(45): 1276-1277. https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w.

[5] Miech, R, et al., *Trends in Adolescent Vaping, 2017-2019*, N. Engl. J. of Med., 2019, 381:1490-1, published online September 18, 2019, https://www.nejm.org/doi/full/10.1056/NEJMc1910739.

25.4% of twelfth-graders reported vaping nicotine in the past 30 days, compared to 20.9 percent in 2018 and 11 percent in 2017.[6] E-cigarette use also increased among eighth and tenth graders between 2018 and 2019. Nine percent of eighth graders and 20.2 percent of tenth graders reported vaping nicotine in 2019, up from 6.1 percent and 16.1 percent, respectively, in 2018.[7] Nearly half (46 percent) of high school seniors who vape nicotine do so nearly every day.[8] One-third of tenth graders who vape nicotine vape nearly every day.[9] These numbers demonstrate that a new generation of American youth are becoming addicted to nicotine.

Moreover, studies have found that young people who use e-cigarettes are more likely than non-users to become cigarette smokers, and many of them are low-risk youth who would not otherwise have smoked cigarettes. A January 2018 report by the National Academies of Sciences, Engineering and Medicine (NASEM) concluded, "there is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults."[10] One recent study found that youth who used e-cigarettes were four times more likely to subsequently smoke cigarettes.[11]

When Congress enacted the Tobacco Control Act it gave broad regulatory authority to FDA to regulate tobacco products. Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21

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6 *Id.*

7 *Id.*

8 *Id.*

9 *Id.*

10 National Academies of Sciences, Engineering, and Medicine (NASEM), *Public health consequences of e-cigarettes*, Washington, DC: The National Academies Press, 2018, http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx, at S-7.

11 Berry, KM, et al., *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths*, JAMA Network Open, 2(2), published online February 1, 2019.

U.S.C. §§387-387u)(TCA). There is no legitimate basis for preventing FDA from enforcing the Tobacco Control Act in the face of so severe a public health crisis.

ARGUMENT

I. Plaintiffs have no legally protected interest in marketing e-cigarettes without having received a marketing order from the FDA.

A. The Tobacco Control Act prohibits the marketing of any new tobacco product without a marketing order from the FDA.

The Tobacco Control Act, enacted on June 22, 2009, granted FDA immediate jurisdiction to regulate cigarettes, smokeless tobacco and roll-your-own tobacco, and gave FDA discretion to extend its jurisdiction to other "tobacco products" (defined to include "any product derived from tobacco") by issuing a rule. *See* 21 U.S.C. § 387a. At the time the Tobacco Control Act was enacted, e-cigarettes had only recently been introduced. When FDA sought to regulate e-cigarettes as "drugs," e-cigarette manufacturers successfully argued, in a lawsuit brought against FDA, that, in the absence of therapeutic claims, e-cigarettes could not be regulated as drugs and instead had to be regulated as "tobacco products." *See Sottera, Inc. v. FDA*, 627 F. 3d 891 (D.C. Cir. 2010). Following the court's ruling, in April 2011, FDA announced its intention to issue a rule that would apply the provisions of the Tobacco Control Act to e-cigarettes. 79 Fed. Reg. 23,142, 23,149-50 (April 25, 2014).

One of the principal provisions of the Tobacco Control Act is the requirement for premarket review of "new tobacco products." 21 U.S.C. § 387j. The term "new tobacco products" is defined as tobacco products not commercially marketed as of February 15, 2007, a

date specified in the statute.[12] *Id.* Since virtually no e-cigarettes had been marketed as of that date, virtually all e-cigarette products are "new tobacco products" and would automatically be subjected to the requirement of premarket review if and when FDA promulgated a rule subjecting them to the Tobacco Control Act.

The statute directed FDA to issue an order authorizing the marketing of a "new tobacco product" only if the manufacturer had demonstrated that the marketing of the product is "appropriate for the protection of the public health" taking account of the impact of the new product on the population as a whole, including both current users of tobacco products and non-users. 21 U.S.C § 387j(c)(2)(A). It also specified the categories of information a manufacturer would have to provide in an application for a PMTA authorization. 21 U.S.C. § 387(j)(b). Thus, as of March 2011, e-cigarette manufacturers were on notice that FDA intended to subject their products to the Tobacco Control Act, which would then require them to apply for and obtain PMTA authorization in order for them to be marketed. Subsequent to FDA's announcement, numerous e-cigarette products were marketed by manufacturers who were well aware that these requirements would become applicable once FDA had issued the rule asserting jurisdiction over them.

In April 2014, FDA issued a proposed rule asserting jurisdiction over all tobacco products not already covered by the original grant of jurisdiction. 79 Fed. Reg. 23141 (April 25, 2014). Pursuant to the proposed rule, e-cigarette manufacturers with products on the market on the effective date of the rule were informed that, as an exercise of enforcement jurisdiction FDA would not take enforcement action against products that had not yet received PMTAs provided

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[12] In *Nicopure Labs LLC v. FDA*, 266 F. Supp. 3d 360 (D.D.C. 2017) the U.S. District Court for the District of Columbia held that FDA had no discretion under the statute to alter that date.

the manufacturers filed their applications within 24 months after the effective date of the final rule. 79 Fed. Reg. at 23,172-23,176. The proposed rule contained an extensive discussion of the public health necessity of imposing these requirements. 79 Fed. Reg. at 23,148-23,149.

On May 10, 2016, after consideration of thousands of public comments, FDA promulgated the final Deeming Rule and made it effective on August 8, 2016. 81 Fed. Reg. 28974 (May 10, 2016). The rule prohibited the introduction of any new e-cigarette product after that date in the absence of the issuance of a PMTA. *Id.* FDA also provided that, as a matter of enforcement discretion, FDA would not take enforcement action to prohibit the marketing of a product for which the manufacturer had filed a PMTA within two years of the effective date of the rule, i.e., August 8, 2018, and that FDA would not take enforcement action against products as to which an application had been filed for one year following the application date. Simultaneous with the Deeming Rule FDA published a detailed draft guidance informing manufacturers of the information they would have to provide in a PMTA application[13] and a second draft guidance designed to simplify the application process for manufacturers who purchased nicotine liquids from other manufacturers.[14] 81 Fed. Reg. 28,781 (May 10, 2016); 81 Fed. Reg. 28,778 (May 10, 2016).

Thus, as of May 2016, e-cigarette manufacturers were aware that in order to keep their products on the market during the application process they would have to file their applications no more than 27 months later (i.e., by August 2018) and they were made aware of the required contents of their applications. Moreover, the Deeming Rule made clear that there was no

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[13] FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Draft Guidance, May 10, 2016, https://www.regulations.gov/document?D=FDA-2015-D-2496-0002.

[14] FDA, Tobacco Product Master Files; Guidance for Industry, May 10, 2016, https://www.regulations.gov/document?D=FDA-2015-D-2325-0002.

statutory basis for the marketing of new e-cigarette products in the absence of a PMTA and that the only basis for the continued marketing of such products was FDA's discretionary decision not to exercise its enforcement authority.

B. FDA's extension of the compliance period in August 2017 did not and could not provide statutory authority for the marketing of new e-cigarette products and FDA has repudiated it.

Shortly after the new FDA Commissioner took office in 2017 FDA first extended the compliance period by three months and then, on July 28, announced that as matter of enforcement discretion, FDA would not take action to require the removal from the market of e-cigarette products provided the manufacturer filed a PMTA application by August 8, 2022—in effect a four-year extension of the compliance period.[15] It was clear from the outset that the extension of the compliance period was an exercise of what FDA regarded as its enforcement discretion.

Any manufacturer with a serious intent to comply with the statutory requirement would have made substantial progress toward submission of an application by August 2017. At the time this extension was announced, it had been more than six years since FDA had declared its intention to subject e-cigarettes to the premarket review provisions of the Tobacco Control Act,

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[15] FDA, FDA's Plan for Tobacco and Nicotine Regulation, Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, Guidance for Industry (May 2017), https://web.archive.org/web/20170723001238/https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf; FDA, Press Release, FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death (Jul. 28, 2017), https://web.archive.org/web/20180125072233/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm;; FDA, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, Revised Guidance for Industry (August 2017), https://web.archive.org/web/20170811164449/https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf.

more than three years since the issuance of the Proposed Deeming Rule and more than one year since the promulgation of the Final Rule and the draft guidances accompanying it.

Moreover, the text of the guidance FDA issued in August 2017 stressed its limitations, stating that "this guidance represents the current thinking of the Food and Drug Administration on this topic. It does not establish any rights for any person and is not binding on FDA or the public." 82 Fed. Reg. 37,459, 37460 (Aug. 10, 2017).

Within a year of the announcement of the extension, FDA was confronted with data from the National Youth Tobacco Survey showing an explosion of youth usage addiction to e-cigarettes. Speaking in September 2018, Commissioner Gottlieb admitted that "we didn't predict what I now believe is an epidemic of e-cigarette use among teenagers. Today we can see that this epidemic of addiction was emerging when we first announced our plan [in August 2017]. Hindsight, and that data now available to us, reveal these trends. . .In view of the accelerating use among youth we're actively considering whether we will enforce the premarket review provision earlier."[16]

C. The United States District Court for the District of Maryland has vacated the August 2017 FDA guidance and ordered FDA to establish a shorter deadline for enforcement of the premarket review requirement.

On March 27, 2018 amici in this case brought suit in the United States District Court for the District of Maryland, the judicial district in which FDA's headquarters are located, alleging that FDA had acted beyond its statutory authority in extending the compliance period and that its action had no legal basis. Complaint, *Am. Acad. of Peds. v. FDA*, 379 F. Supp. 3d. 461 (D. Md. 2019) (No. 18-cv-883). Although FDA asserted that issuance of the August 2017 Guidance had

[16] FDA, Statement of Commissioner Scott Gottlieb, September 11, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use.

been a valid exercise of its enforcement discretion, by the summer of 2018 it become clear to FDA that there had been a sharp increase in youth usage of e-cigarettes and that "data from the 2018 National Youth Tobacco Survey…documented a significant increase in youth use of ENDS products…and prompted FDA to review its compliance policies with respect to the continued marketing of deemed tobacco products that have not obtained premarket authorization…."[17] 84 Fed. Reg. 9345 (Mar. 14, 2019). In March 2019 FDA formally announced its intention to abandon the August 2017 compliance period for flavored ENDS products (other than tobacco-flavored, mint-flavored and menthol-flavored products). *Id.* Its Draft Guidance proposed to shorten the compliance period by one year for flavored products and to require those products to be sold only in adult-only facilities in order to stay on the market.[18] *Id.*

Despite the fact that FDA had announced its intention to abandon the August 2017 compliance period and the continued pendency of the Maryland lawsuit in which the public health groups contended that the August 2017 guidance was unlawful and should be invalidated, Plaintiffs in this case made no effort to intervene in the Maryland lawsuit. On May 15, 2019, the court ruled that FDA's August 2017 guidance was an abdication of the agency's obligation to enforce the premarket review requirements of the Tobacco Control Act and was issued in violation of the notice-and-comment requirements of the Administrative Procedure Act. *See Am. Acad. of Peds.* 379 F.Supp.3d at 494. The court invalidated the guidance in its entirety and ordered the parties to file briefs on remedies. *Id.*

Contrary to Plaintiffs' allegations, in its brief on remedies FDA did not request the court to order the agency to establish a 10-month compliance period, but rather to remand the matter to

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17 FDA, Modifications to Compliance Policy for Certain Deemed Tobacco Products, Draft Guidance for Industry (March 2019), https://www.fda.gov/media/121384/download, at 6.

18 *Id.* at 13-15.

FDA without vacating the August 2017 Guidance. FDA also opposed the public health groups' proposal to limit the compliance period to 120 days. FDA suggested that, in the event the court established a limit on the compliance period, a 10-month compliance period would permit the filing of quality applications by the companies. On July 12, 2019, the court, citing the "extraordinary circumstances of this case in which prompt action is necessary to combat the epidemic-level rise in youth e-cigarette use," ordered FDA to require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule, applications for marketing orders must be filed within 10 months of the date [of the order] (i.e., by May 12, 2020); that new products for which applications have not been filed within this period shall be subject to FDA enforcement actions; and that FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis." *See Am. Acad. of Peds. v. FDA*, No. PWG-18-883, 2019 WL 3067492, at *7 (D. Md. July 12, 2019).

II. The relief Plaintiffs seek is a collateral attack on a valid order of the United States District Court for the District of Maryland and would improperly require FDA to disobey that order.

This Court should dismiss the complaint or grant summary judgment to FDA because the relief Plaintiffs seek constitutes an impermissible collateral attack on a valid order of another federal court. As noted above, the United States District Court for the District of Maryland issued an order holding that FDA's August 2017 guidance was inconsistent with the Tobacco Control Act, violated the APA, and was therefore vacated. *Am. Acad. of Peds*, 379 F. at 461 (D. Md. 2019). On July 12, 2019, after receiving briefs on remedies, including an amicus brief filed by numerous organizations representing the e-cigarette industry, the court ordered FDA to require that new tobacco products on the market as of August 8, 2016 become subject to FDA enforcement actions, in FDA's discretion, unless the manufacturer had filed an application for a

marketing order within ten months of the Court's Opinion. *See Am. Acad. of Peds.*, No. PWG-18-883, 2019 WL 3067492, at *7 (D. Md. 2019). Pursuant to the court's order, new products for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for up to one year from the date of application. *Id.* Furthermore, the order gives FDA the ability to exempt new products from the filing requirements for good cause on a case-by-case basis. *Id.*

The relief sought by Plaintiffs is directly contradictory to that Order and, if granted, would require FDA to disobey that Order. Furthermore, it would require FDA to reinstate a guidance that had been vacated by a federal court because it was contrary to a federal statute and to reinstate a vacated order that the agency itself had repudiated as inconsistent with its statutory responsibilities. Under these circumstances, it would be improper for this court to grant the relief Plaintiffs seek. The authorities cited in FDA's brief make it clear that the relief Plaintiffs seek has no legal basis.

The proper course for parties who oppose the Maryland District Court decision is to participate in the appeal of that decision to the Fourth Circuit. On October 2, Judge Grimm granted motions of numerous e-cigarette associations, including several with close ties to Plaintiffs, to intervene for the express purpose of appealing his decision to the Fourth Circuit. Court Order, *Am. Acad. of Peds. v. FDA*, No. 18-cv-883, Oct. 2, 2019, ECF No. 154. The intervenor appellants include some members of the Vapor Technology Association[19] and

[19] VTA members who are intervenor appellants include Arizona Smoke Free Business Alliance, Iowans for Alternative to Smoking and Tobacco, Kentucky Smoke Free Association, Maryland Vapor Alliance, Ohio Vapor Trade Association, Tennessee Smoke Free Association, Texas Vapor Coalition. https://vaportechnology.org/vta-members/.

appellants can, in a proper forum, seek to make any and the substantive arguments VTA has advanced in this case.

A. Plaintiffs had no reliance interest in the August 2017 guidance sufficient to preclude FDA from changing it to respond to a public health emergency.

Plaintiffs' argue that their reliance on the August 2017 guidance should preclude FDA from changing it has no merit because they were "promised a path to demonstrate that their products should remain on the market." Pls.' Mem. in Supp. of Prelim. Inj. 6, ECF No 15. This argument is baseless for numerous reasons.

First, Plaintiffs had been on notice for six years prior to the August 2017 guidance that their products would become subject to the premarket review requirements. Any responsible manufacturer would have used those six years to prepare for filing the application. Moreover, in the May 2016 final deeming rule, FDA had informed manufacturers that their applications would have to be submitted by August, 2018 to remain eligible for non-enforcement of the statutory prohibition and thus, by the time the August 2017 guidance was issued responsible manufactures should have been well on their way to compiling the information needed to file the application. 81 Fed. Reg. at 29,006. And given the nearly three additional years manufacturers will have had between August 2017 and the deadline established by the Maryland litigation, responsible manufacturers should be able to file quality applications.

Nor is it true, as Plaintiffs argue, that they lacked sufficient information about the contents of the application. First, the statute itself specifies the major categories of information required in the application. *See* 21 USC § 387j. Second, simultaneous with the issuance of the Deeming Rule, FDA issued a detailed draft guidance informing manufacturers of the information

to be provided in a PMTA application.[20] Recently, FDA issued a final guidance that largely reiterated the contents of the 2016 draft guidance.[21] 84 Fed. Reg. 27,200 (Jun. 12, 2019). In doing so, FDA stated that "the recommendations made in this guidance are substantially similar to those set forth in the draft guidance issued on May 5, 2016." [22] In addition, simultaneous with the issuance of the Deeming Rule FDA also issued a draft guidance designed to greatly simplify the application process by permitting manufacturers who purchase nicotine liquids from commercial manufacturers to rely on Master Files.[23] Pursuant to this approach, manufacturers could simply reference data submitted by their supplier and thereby avoid having to make individual submissions. Moreover, the recent issuance of a draft rule provides still more specificity about the contents of the application. 84 Fed. Reg. 50,566 (Sept. 25, 2019). And despite the Plaintiffs' claims that the filing of applications is impossible, at least two e-cigarette manufacturers, representing a large proportion of the total US e-cigarette market, have publicly announced that they plan to file such applications on the schedule established by the Maryland Supreme Court and one of those manufacturers has publicly stated its disagreement with the Plaintiffs' allegations in this case and withdrawn from the Vapor Technology Association because it disagrees with the representations it has made regarding the barriers to compliance.[24]

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20 *Supra* note 13.

21 FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry (June 2019), https://www.fda.gov/media/127853/download.

22 *Id.* at 3.

23 *Supra* note 14.

24 *See* JUUL, Our Commitment to the PMTA Process (Aug. 20, 2019),https://newsroom.juul.com/2019/08/20/pir-commitment-to-the-pmta-process/; *see also* Juliet Chung and Jennifer Maloney, *E-Cigarette Maker NJOY Changes Funding Plan After Vaping Ban*, Wall St. J., Sept. 13, 2019 (reporting that e-cigarette maker NJOY plans to file [premarket]applications for all of its products early next year"), *available at* https://www.wsj.com/articles/e-cgarette-maker-njoy-changes-funding-plan-after-vaping-ban-11568410278.

On October 11, 2019, Reynolds American Inc. announced that one of its subsidiaries has filed a PMTA for its cartridge-based VUSE electronic cigarettes.[25] Furthermore, Juul Labs recently states that it is prepared to comply with the May 2020 deadline and does not support the lawsuit in this case: "We are fully committed to the current PMTA process and are confident in the content and quality of the materials we will submit with our application by May 2020. We are not appealing the recent federal court case in the District of Maryland and similarly do not support the recent lawsuit against FDA filed by the Vapor Technology Association in the Eastern District of Kentucky."[26]

In addition to providing this information, FDA has consistently and repeatedly urged manufacturers to seek conferences with FDA to discuss application requirements and procedures. Nevertheless, few manufacturers have taken advantage of these opportunities. In issuing its Order on Remedies, the federal court in Maryland found that "the record before me shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so, and it establishes a shockingly low rate of filings." *Am. Acad. of Peds.,* 2019 WL 3067492, at *5.

B. Reliance on an order found to have been issued unlawfully cannot prevent FDA from changing its policy to comply with the law.

FDA cannot be prevented from changing its policy by reliance on an order that was issued unlawfully. The Maryland federal court vacated the August 2017 guidance stating that it was "inconsistent with" and "defeats the purpose of" the Tobacco Control Act, was an

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[25] Reynolds American, Inc., *Reynolds American Inc. submits Premarket Tobacco Product Application for VUSE products*, Press Release, October 11, 2019, https://s2.q4cdn.com/129460998/files/doc_news/2019/10/11/PMTA-Release-FINAL-191011.pdf.

[26] Juul Labs, *Our Commitment to the PMTA Process,* JUUL Labs, August 20, 2019, https://newsroom.juul.com/2019/08/20/our-commitment-to-the-pmta-process/.

"abdication of [FDA's] statutory duty to review new tobacco products in the prompt fashion dictated by Congress in its premarket review requirements;" and was an "ultra vires" action through which FDA "exceeded the authority granted to it by Congress." 379 F. Supp. at 492. A party's reliance on an unlawful order cannot preclude a federal agency from changing its policy to fulfill its statutory obligation. This is particularly true in a case where the conduct at issue—the marketing of a new tobacco product without a premarket order—was concededly unauthorized by the Tobacco Control Act and the only issue was whether FDA had discretion not to enforce the law. *See, e.g., Util. Air Reg. Grp. v. EPA,* 573 U.S. 302, 327 (2014) ("An agency. . .may change its own conduct, but it cannot change the law); *see also*, Zachary S. Price, *Reliance on Nonenforcement*, 58 Wm & Mary L. Rev. 937, 949 (2017) ("The Supreme Court has generally resisted protecting reliance on mistaken assurances about the law or its application" even where "regulated parties relied to the detriment on federal officials' guidance.").

C. For more than one year, FDA has made clear its intention to abandon the August 2017 guidance because of the epidemic of youth e-cigarette usage and addiction and the public health emergency it created.

In support of their reliance argument, Plaintiffs contend that they had no notice that FDA had determined to change the application deadline in the August 2017 guidance, that FDA proposed doing so without taking into consideration the views of manufacturers, and that FDA failed to explain the reasons for determining that the August 2022 application deadline needed to be changed. None of these allegations is true.

Since September 2018, FDA has made clear in a multitude of public statements that it intended to change the application deadline because newly available data demonstrated the existence of an epidemic of youth e-cigarette usage and addiction that it had not foreseen when it established in August 2017. Preliminary data from the National Youth Tobacco Survey showing

the alarming increase in youth e-cigarette usage coupled with an increase in youth smoking of combustible products became available to FDA Commissioner Scott Gottlieb on August 30, 2018. As Commissioner Gottlieb described the data, "this was a dramatic change, this was the biggest one-year change in the history of the surveys that were done looking at youth use of substances of addiction—the biggest change ever recorded in history year-over-year. And so that required us to change course…"[27]

Less than two weeks later, on September 11, 2018, Commissioner Gottlieb publicly stated, "we didn't predict what I now believe is an epidemic of e-cigarette use among teenagers. Today we can see that this epidemic of addiction was emerging when we first announced our plan last summer [i.e., in August 2017]. Hindsight, and the data now available to us, reveal these trends. …The FDA won't tolerate a whole generation of young people becoming addicted to nicotine as a tradeoff for enabling adults to have unfettered access to these same products. . . So we're. . .going to re-visit the compliance policy that we announced last summer to extend the application compliance periods for certain deemed products, including and especially the e-cigarettes that were on the market as of Aug. 8, 2016."[28]

In the same statement Commissioner Gottlieb sharply criticized the behavior of the e-cigarette industry in the face of the mounting evidence of youth addiction. "I've been warning the e-cigarette industry for more than a year that they needed to do much more to stem the youth

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[27] AEI Banter Podcast, Scott Gottlieb on the CBD craze, vaping, and JUUL: A conversation with the former FDA commissioner, No. 374, August 7, 2019, https://ricochet.com/podcast/aei-banter/scott-gottlieb-on-the-cbd-craze-vaping-and-juul-a-conversation-with-the-former-fda-commissioner/.

[28] FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use, September 11, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use.

trends. In my view, they treated these issues like a public relations challenge rather than seriously considering their legal obligations, the public health mandate, and the existential threat to these products. . .Well, I'm here to tell them that this prior approach is over. The FDA is closely watching the trends in youth use. And if, as we expect, preliminary data. . .confirm our present observations that the use of e-cigarettes is rising very sharply, we'll swiftly change course."[29]

Commissioner Gottlieb also debunked the claim that manufacturers were unable to file applications. "We believe there's no excuse for manufacturers not to file applications with the FDA because the agency hasn't told them what they are expected to do. If any manufacturer wants to get direct, precise guidance on a specific product application, just call us. Request a meeting. Our door is open. And our policy is to grant pre-submission meetings to help manufacturers understand our expectations."[30]

In the face of these statements, made more than one year ago, there could be no legitimate reliance on FDA's maintenance of the application deadline referenced in the August 2017 guidance. Moreover, Commissioner Gottlieb's September 2018 statement was followed by a cascade of public announcements affirming FDA's determination to change the deadline, including the possibility of "eliminating any application enforcement discretion to any currently marketed [e-cigarette] product."[31]

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29 *Id.*

30 *Id.*

31 FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018, *available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access.

In March 2019, FDA issued and sought public comments on a draft guidance that proposed shortening the compliance period for e-cigarette applications and called on manufacturers "to do more to keep their products out of the hands of minors."[32]

In May 2019, then-former Commissioner Gottlieb tweeted: "In 2017 we gave ecigs time to prove they could bend death and disease from tobacco. The intervening year and youth risks they helped ignite makes it more urgent ecigs undergo close scrutiny. That's why we committed in March to move up application deadlines. Whether by courts or regulatory action; it's critical that information is demanded earlier in view of the youth epidemic."[33] "By marketing to kids, e-cig makers squandered the opportunity we sought in 2017."[34]

As noted above, results from the 2019 National Youth Tobacco Survey and the Monitoring the Future survey, which both became available in September, show a further substantial increase in youth usage and underscore the urgency of effective FDA enforcement action. Noting these results, Acting FDA Commissioner Norman Sharpless stated, "And as I've said before, responsible manufacturers certainly don't need to wait to act. We encourage industry to use available FDA resources as a guide for their submissions to the agency."[35]

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[32] Plaintiffs' claim that they have not had an opportunity to comment on changes in the compliance period is unfounded. In fact, Plaintiffs submitted comments in this very docket. FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products*, Draft Guidance for Industry, March 2019, https://www.fda.gov/media/121384/download, at 6.

[33] Gottlieb, S (ScottGottliebMD), Twitter Post, May 15, 2019, 7:35 a.m., https://twitter.com/ScottGottliebMD/status/1128987420140220416.

[34] Gottlieb, S (ScottGottliebMD), Twitter Post, July 12, 2019, 5:21 p.m., https://twitter.com/ScottGottliebMD/status/1149790818800144385.

[35] FDA, FDA issues proposed rule for premarket tobacco product applications as part of commitment to continuing strong oversight of e-cigarettes and other tobacco products, News Release, September 20, 2019, https://www.fda.gov/news-events/press-announcements/fda-issues-proposed-rule-premarket-tobacco-product-applications-part-commitment-continuing-strong.

This history makes it abundantly clear that Plaintiffs cannot have reasonably relied on the August 2017 guidance. More disturbingly, their failure to engage constructively with FDA in the face of the epidemic of youth usage and addiction and the dismissive characterization of the epidemic in their filing with this Court demonstrate the disregard for the public health that has embodied their actions.

Plaintiffs have already enjoyed the benefits of FDA's refusal to enforce the law over the course of many years. Despite the fact that they have been on notice since 2011 that they would be subject to premarket review, their products have been permitted to stay on the market with no such review for more than eight years since then—and even under the order of the Maryland federal court applications will not be required to be filed until May 2020. The review of these products that will ultimately take place is anything but "premarket" − and, by Plaintiffs' own admission, they have built a multi-billion industry on the sale of addictive products that have never been subjected to the review required by law. During this period these products have fueled an unprecedented epidemic of youth usage and addiction. And despite this epidemic Plaintiffs continue to resist having to demonstrate, as the Tobacco Control Act requires, that the marketing of their products is appropriate for the protection of the public health. As former Commissioner Gottlieb tweeted recently, "I think it's a fair statement that the vaping and e-cig industry doesn't have a single association, company, or other entity that's engaged consistently and constructively with the regulatory process. The entire apparatus seems focused on fighting FDA. That hurts progress long term."[36]

III. Plaintiffs Greatly Exaggerate What is Being Required of Them.

[36] Gottlieb, S (ScottGottliebMD), Twitter post, Jun. 11, 2019, 12:50 p.m., https://twitter.com/ScottGottliebMD/status/1138488623152738304.

As demonstrated above, the purpose of the Tobacco Control Act was to ensure that new tobacco products are not commercially marketed until they have demonstrated that their commercial marketing is "appropriate for the protection of the public health." Despite this legal requirement, thousands of e-cigarette products are on the market and not one of them has been required to meet the statutory standard. E-cigarette manufacturers claim that their products have a beneficial effect by helping smokers switch to less harmful products. Given that these products have been on the market for years, it is certainly not unreasonable to require that manufacturers document this claim with scientific proof and establish that benefits from the marketing of their product outweigh the very real harms of youth addiction. Finally requiring enforcement of this statutory provision is particularly important because the most authoritative objective analyses of these claims has concluded that the public health benefits manufacturers claim are unproven .[37]

Furthermore, it is important to recognize that what is at issue is not a blanket prohibition on the marketing of products.[38] Rather, the statute simply provides for FDA to make a threshold

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[37] *Supra* note 9, ("Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation); U.S. Preventive Services Task Force, *Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women:* U.S. Preventive Services Task Force Recommendation Statement, Annals of Internal Medicine, Vol. 163, No. 8, October 2015, http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1 ("the current evidence is insufficient to recommend electronic delivery systems for tobacco cessation...); King, BA, et al., *Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011*, Nicotine & Tobacco Research, 15(9):1623-7, 2013 ("There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service"); *See also*, King, BA, et al., *Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults*, 2010-2013, Nicotine & Tobacco Research, first published online September 19, 2014.

[38] Adams, J (Surgeon General), "However per the law and the deeming rule, any company can apply to the FDA for approval of vape products – including flavors. So from a federal standpoint, THERE IS NO "BAN." If manufacturers/ retailers/consumers want continued access, submit an application & make the case." September 29, 2019, 6:41 am. Tweet. Available at https://twitter.com/Surgeon_General/status/1178258597807054855.

determination on a product-by-product basis that the marketing of the product is appropriate for the protection of the public health in order for it to be marketed. For the first time adult smokers will be given a way to distinguish between products that may actually help them switch to a less dangerous alternative and those that do not, and products that addict youth will no longer be permitted on the market. Although this determination is described as "premarket" review, because products have been on the market for years, the review is in fact "postmarket review." Manufacturers that have diligently monitored the use of their products should therefore have an abundance of relevant data and, as noted above, at least two e-cigarette manufacturers have announced that they can and will comply with the application deadline set by the Maryland federal court and one company has already filed an application.[39] Completion of an application for a product that has been marketed for years should be easier than for a product that has never been sold commercially. Moreover, by Plaintiffs' own admission, e-cigarette manufacturers now constitute a multi-billion-dollar industry "comparable in size to the U.S. steel and iron forging and commercial fishing industries." Pls. Mem. In Supp. of Prelim. Inj., at 1, ECF No. 15. Manufacturers in an industry of this size have sufficient resources to permit compliance with the statutory requirements.

[39] *Supra* notes 30, 31.

CONCLUSION

For the reasons stated herein, Amici Curiae urge the Court to deny Plaintiffs' Motion for a Preliminary Injunction and to grant Defendants' Motion in Opposition to the Grant of a Preliminary Injunction and Motion to Dismiss.

Respectfully submitted,

CRAIG HENRY PLC

/s/ Michele Henry
Michele Henry
401 W. Main Street
Suite 1900
Louisville, KY 40202

Of counsel:
Dennis Henigan
Mark Greenwold
Campaign for Tobacco-Free Kids
1400 Eye St., NW
Washington, D.C. 20005

APPENDIX A

Description of *Amici Curiae*

Amicus Curiae American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of the AAP has grown from the original group of 60 physicians specializing in children's health to 67,000 pediatricians. Over the past 89 years, the AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to protect the well-being of America's children. The AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to secondhand tobacco smoke.

Amicus Curiae American Cancer Society Cancer Action Network (ACS CAN) is making cancer a top priority for public officials and candidates at the federal, state and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

Amicus Curiae American Heart Association is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. The association invests in research, professional and public education, community-based programs, and advocacy so people across America can live longer, healthier lives. Preventing and reducing tobacco use is a top priority for the association.

Amicus Curiae American Lung Association is the nation's oldest voluntary health organization. The American Lung Association has long been active in research, education and public policy advocacy regarding the adverse health effects caused by tobacco use, including supporting eliminating the sale of all flavored tobacco products.

Amicus Curiae Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke.

Amicus Curiae Truth Initiative is a 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports programs in the United States to reduce youth tobacco use and to prevent diseases associated with tobacco use. Its nationally recognized truth® campaign has educated hundreds of millions of young people about the health effects and social costs of tobacco.