

FILED
Court of Appeals
Division II
State of Washington
2/13/2020 3:22 PM

NO. 54358-3-II

**COURT OF APPEALS, DIVISION II
STATE OF WASHINGTON**

VAPOR TECHNOLOGY ASSOCIATION; AND BARON
ENTERPRISES, LLC D/B/A THE VAPORIUM

Plaintiffs/Petitioners,

v.

WASHINGTON STATE BOARD OF HEALTH; STATE OF
WASHINGTON DEPARTMENT OF HEALTH

Defendants/Respondents.

BRIEF OF AMICI CURIAE

ARETE LAW GROUP
Jonah O. Harrison (WSBA #)
1218 Third Avenue, Suite 2100
Seattle, WA 98101
Telephone: (206) 428-3250

CAMPAIGN FOR TOBACCO-FREE KIDS
Dennis A. Henigan
Swati V. Rawani
1400 I Street NW, Suite 1200
Washington, DC 20005
Telephone: (202) 296-5469

Attorneys for Amici Curiae

TABLE OF CONTENTS

INDEX OF AUTHORITIES..... II

INTRODUCTION AND STATEMENT OF INTEREST1

SUMMARY OF ARGUMENT2

ARGUMENT3

I. The State of Washington Faces a Vaping Crisis Among Youth.....3

II. Vaping Products Available in Thousands of Flavors Increase Youth Usage and Pose Serious Health Risks to Youth.....7

III. Petitioners Exaggerate the Scientific Evidence of Claimed Health Benefits of E-Cigarettes Relative to Conventional Cigarettes and Ignore the Real Health Risks E-Cigarettes Pose.....10

IV. E-Cigarettes Have Not Been Approved as a Smoking Cessation Drug or Device in the U.S.....12

V. The Washington Board of Health Has the Authority to Adopt Rules to Control and Prevent Vaping-Associated Diseases.13

VI. FDA’s Regulatory Authority Over E-Cigarettes Has Been Largely Unused15

CONCLUSION.....19

INDEX OF AUTHORITIES

Cases

Am. Acad. of Peds. et. al. v. FDA,
399 F.Supp.3d 479 (D. Md. 2019), *appeal docketed*, No. 19-2130
(4th Cir. Oct. 18, 2019)..... 4, 17

Statutes

21 U.S.C §387(j)..... 16, 17

21 U.S.C. § 387(p)..... 20

Family Smoking Prevention and Tobacco Control A,
Pub. L. No. 111-31, 123 Stat. 1777 (2009)(codified at 21 U.S.C. §§
387-387u)..... 16

RCW 43.20.050(2)(f)..... 14

Regulations

81 Fed. Reg. 28,978..... 16

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and
Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016) (“Deeming
Rule”)..... 16

WAC 246-80-001..... 4

INTRODUCTION AND STATEMENT OF INTEREST

Amici curiae are filing this brief in support of the court order denying Petitioners' request for a preliminary injunction against the Washington State Board of Health's (Board of Health or Board) Emergency Rules (Emergency Rules).¹ The amici are the following organizations: American Lung Association, Asian Pacific Islander Coalition Advocating Together for Health, Association of Washington School Principals, Campaign for Tobacco-Free Kids, Foundation for Healthy Generations, Gay City: Seattle's LGBTQ Center, Kaiser Permanente, Parents Against Vaping e-cigarettes, Tacoma-Pierce County Health Department, Truth Initiative, Washington State Public Health Association. A description of these organizations is provided in Attachment A.

By this filing, amici seek to demonstrate that the Board of Health acted within its broad statutory authority in promulgating Emergency Rules barring the sale of flavored vapor products to reduce youth exposure to the on-going outbreak of vaping-associated lung disease. Moreover, amici will argue that the Board's exercise of that authority was critical to address the seriousness of the youth vaping crisis that is facing this State and the adverse health effects associated with e-cigarette use.²

¹ Respondents have consented through counsel to the filing of this amici curiae brief.

² Amici are aware that Respondents have suggested that the expiration of the Emergency Rules renders this case moot. Res. Br. at 9. Amici offer the arguments in this brief should

The amici have a strong interest in the implementation of tobacco control policies that will prevent the initiation of tobacco use by young people and reduce the disease and death caused by tobacco products. Reducing the availability of flavored vaping products that are especially appealing to young people is one such policy. The amici have an interest in enhancing this Court’s understanding of the vaping crisis and the public health benefits of the Emergency Rules under attack.

SUMMARY OF ARGUMENT

Youth e-cigarette use in the United States has skyrocketed to what the U.S. Surgeon General and the U.S. Food and Drug Administration (FDA) have called “epidemic” levels. It is a public health crisis and *it is getting worse*. Altogether, five million middle and high school students used e-cigarettes in 2019 – an increase of nearly three million users in two years.³ “Against this backdrop, the United States is seeing what can be considered two distinct but related epidemics connected with vaping: the recent outbreak of lung injuries and the continued surge in use by young people.”⁴ The Emergency Rules constitute a proper and appropriate use of

the Court determine that the case is not moot and thereby addresses the merits of this appeal.

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 King, B., et. al., *The EVALI and Youth Vaping Epidemics – Implications for Public Health*, NEJM, Jan. 17, 2020.

the State's statutory authority to protect the health of Washington's children by prohibiting the sale of flavored vaping products and thereby reducing the use of highly-addictive and hazardous e-cigarettes by Washington youth. As the lower court found, the Emergency Rules are plainly within the rulemaking authority of the Board of Health.

ARGUMENT

I. The State of Washington Faces a Vaping Crisis Among Youth.

The Emergency Rules respond to an epidemic of youth usage of flavored e-cigarettes and the outbreak of vaping related lung disease by prohibiting the sale of flavored vaping products in Washington (except tobacco flavored products). E-cigarettes have become by far the most commonly used tobacco products among U.S. youth. Whereas the 2019 National Youth Tobacco Survey (NYTS) showed that 5.8 percent of high school students smoked regular cigarettes, use of e-cigarettes by high school students soared to 27.5 percent in 2019, up from 20.8 percent in 2018 and 11.7 percent in 2017.⁵

Trends in e-cigarette use in Washington mirror the epidemic levels that are seen nationwide. In 2018, 30 percent of 12th grade students in Washington used vapor products, a 50 percent increase since 2016 (up from

⁵ 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.

20 percent). The numbers are just as alarming among 10th graders, with the use of vapor products increasing 61 percent since 2016 (from 13 percent to 21 percent).⁶ In stark contrast, in 2017, only 4.3 percent of Washington adults were current e-cigarette users.⁷

In December 2018, the Surgeon General issued an advisory on e-cigarette use among youth, declaring the growing problem an epidemic.⁸ A U.S. District Court recently declared e-cigarettes to constitute a “clear public health emergency.” *See Am. Acad. of Peds. et. al. v. FDA*, 399 F.Supp.3d 479, 486 (D. Md. 2019), *appeal docketed*, No. 19-2130 (4th Cir. Oct. 18, 2019) (citing “the uncertainty in the efficacy of e-cigarettes as smoking cessation devices,” the “recalcitrance” of the e-cigarette industry, “the continued availability of e-cigarettes,” and “their acknowledged appeal to youth.”).

The increasing number of serious vaping related lung diseases, a central justification for the Emergency Rules, makes even more serious the concern about initiation of vaping by youth.⁹ Petitioners misrepresent the

⁶2018 Washington State Healthy Youth Survey, and cite the results here: <https://www.askhys.net/Docs/HYS%202018%20tobacco%20and%20vape%20data%20brief%20Final.pdf>.

⁷ CDC, 2017 Behavioral Risk Factor Surveillance System (BRFSS) Prevalence & Trends Data, Washington.

⁸ Office of the Surgeon General, *Surgeon General's Advisory on E-Cigarette Use Among Youth*, December 18, 2018, <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

⁹ WAC 246-80-001, Purpose and Necessity (“The immediate adoption of a rule prohibiting the sale of flavored vaping products....is necessary to prevent and reduce exposure,

demographics of vaping-related lung injuries and users of nicotine vapor products, as well as the status of the Centers for Disease Control's (CDC) investigation into e-cigarette or vaping, product use-associated lung injury (EVALI). Petitioners ignore the youth vaping crisis, and its connection to EVALI, in claiming that "'nicotine-vapor-product' users tend to be adults between the ages of 25 and 64." Pet'rs' Op. Br. at 5-6. The most recent data indicates there are 5.3 million middle and high school students that are current e-cigarette users¹⁰ while 8.1 million adults are current users (about 2.3 million of whom are young adults).¹¹ As noted above, a far higher percentage of high school students use e-cigarettes than adults. Moreover, as Petitioners acknowledge, "patients with vaping-related lung injuries are disproportionately young." Pet'rs' Op. Br. at 6. Indeed, according to the CDC, the *median* patient age for the outbreak of vaping associated lung injury is 24.¹² Thus, both the nicotine vaping epidemic and the vaping related lung injuries disproportionately affect youth.

especially of youth and young adults, to severe lung disease associated with the use of vapor products.").

¹⁰ Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online November 5, 2019.

¹¹ Creamer, MR, et al., "Tobacco Product Use and Cessation Indicators Among Adults—United States, 2018," *Morbidity and Mortality Weekly Report (MMWR)*, 68(45): 1013-1019, November 15, 2019, <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6845a2-H.pdf>. Number of adult e-cigarette users calculated using 2018 American Community Survey 1-Year Estimates, <https://www.census.gov/programs-surveys/acs>.

¹² Centers for Disease Control and Prevention. Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion. Outbreak of Lung Injury

According to CDC's most recent report, as of February 4, 2020, 2,758 confirmed or probable cases of acute lung illness associated with the use of e-cigarette or vaping products have been reported to CDC from all 50 states, and two U.S. territories, and 64 deaths have been confirmed in 27 states.¹³ While vitamin E acetate, an additive to THC-containing e-cigarette or vaping products, is strongly linked to the lung injury outbreak, CDC stated that the "evidence is not sufficient to rule out the contribution of other chemicals of concern," and "the contributing cause or causes of EVALI for persons reporting exclusive use of nicotine-only products warrants further investigation."¹⁴

According to the Washington State Department of Health (DOH), as of January 15, 2020, there have been 25 cases of vaping associated lung injury reported in Washington.¹⁵ Of those cases, 20 percent of the patients are under 20 years old and 28 percent of patients are between the ages of 20-29.¹⁶ About 13 percent of patients nationally and about half of patients

Associated with the Use of E-Cigarette, or Vaping, Products. January 28, 2020. Available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

¹³ *Id.*

¹⁴ CDC, Update: Characteristics of a Nationwide Outbreak of E-cigarette, or Vaping, Product Use – Associated Lung Injury – United States, August 2019 – January 2020, MMWR, 69(3); 90-94 (Jan. 24, 2020).

¹⁵ Washington State Department of Health, Vaping Associated Lung Injury, <https://www.doh.wa.gov/emergencies/vapingassociatedlunginjury> (last visited January 28, 2020).

¹⁶ *Id.*

in Washington report using non-THC products.¹⁷ DOH notes on its website that “while it appears that vitamin E acetate is associated with lung injury, there are many different substances and product sources that are being investigated, and there may be more than one cause.”¹⁸

These statistics establish that Washington, like other states across the nation, faces a vaping crisis among youth. Not only does the epidemic of youth vaping expose young people to the risk of serious lung disease, but as described more fully *infra*, the epidemic threatens youth in this State with a lifetime of nicotine addiction and other adverse health effects.

II. Vaping Products Available in Thousands of Flavors Increase Youth Usage and Pose Serious Health Risks to Youth.

In recent years, companies have extended the tobacco industry strategy of using flavored products to attract kids to the emerging market for e-cigarettes. As of 2017, researchers had identified more than 15,500 unique e-cigarette flavors available online.¹⁹ An earlier study of e-cigarette flavors found that among the more than 400 brands available online in 2014, 84 percent offered fruit flavors and 80 percent offered candy and dessert flavors.²⁰ These products are widely available through convenience stores,

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Zhu, S-H, et al., *Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites*, *Journal of Medical Internet Research*, 20(3), J Med Internet Res 2018;20(3):e80, <https://www.jmir.org/2018/3/e80/>.

²⁰ Zhu, S-H, et al., *Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation*, *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.

other retail outlets and online retailers. Data from the 2016-17 wave of the government's Population Assessment of Tobacco and Health (PATH) study found that 70.3 percent of current youth e-cigarette users say they use e-cigarettes "because they come in flavors I like."²¹ The PATH study also found that 97 percent of current youth e-cigarette users had used a flavored e-cigarette in the past month.²²

Flavored tobacco products play a key role in enticing new users, particularly kids, to a lifetime of addiction. There is growing concern that use of e-cigarettes may function as a gateway to the use of conventional cigarettes and other combustible tobacco products, thereby undermining decades of progress in curbing youth smoking. A 2018 report by the National Academies of Science, Engineering and Medicine (NASEM) concluded that, "There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults."²³ Use of e-cigarettes is not limited to youth who are likely to become cigarette smokers. E-cigarette use is associated with trying cigarettes even among youth who are unlikely to smoke. Several studies

²¹ FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance*, at 9, March 13, 2019, <https://www.fda.gov/media/121384/download>.

²² *Id.*

²³ NASEM, *Public health consequences of e-cigarettes*, 2018, Washington, DC: The National Academies Press, <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

have found that the link between e-cigarette use and starting to smoke cigarettes is stronger for youth who had lower risk factors for smoking.²⁴

E-cigarettes and refill liquids contain widely varying levels of nicotine, and the nicotine delivered through the aerosol can also vary depending on the device characteristics and user practices.²⁵ Nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development²⁶ and the cardiovascular system.²⁷ According to the 2020 Surgeon General’s Report, “[O]nce erroneously considered a habit that could be broken by simply deciding to stop, nicotine addiction is now recognized as a chronic, relapsing condition.”²⁸

Flavorings in e-cigarettes can pose additional health hazards. The risk of serious lung conditions had been linked to these flavorings long before the recent outbreak of EVALI. According to the Surgeon General,

²⁴ *Id.* See also, Barrington-Trimis, JL, et al., *E-Cigarettes and Future Cigarette Use, Pediatrics*, 138(1), July 2016; Wills, TA, et al., *E-cigarette use is differentially related to smoking onset among lower risk adolescents*, *Tobacco Control*, published online August 19, 2016.

²⁵ NASEM, *supra* note 23.

²⁶ HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, CDC, Office of Smoking and Health (OSH), 2014, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>. See also, CDC Office on Smoking and Health, *Electronic Nicotine Delivery Systems: Key Facts*, July 2015.

²⁷ HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, Centers for Disease Control and Prevention, Office on Smoking and Health, 2010 <http://www.ncbi.nlm.nih.gov/books/NBK53017/>.

²⁸ HHS, *Smoking Cessation, A Report of the Surgeon General, 2020 (2020 SG Report)*, <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

“while some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are generally unknown” and noted that some of the flavorings found in e-cigarettes have been shown to cause serious lung disease when inhaled.²⁹

Thus, given the fast-spreading epidemic of youth e-cigarette use, caused in large part by the appeal of flavored products, the Emergency Rules are critical to this State’s efforts to protect its young people from the addictive and other harmful effects of e-cigarettes.

III. Petitioners Exaggerate the Scientific Evidence of Claimed Health Benefits of E-Cigarettes Relative to Conventional Cigarettes and Ignore the Real Health Risks E-Cigarettes Pose.

Petitioners’ “Brief Primer on Vapor Products” utterly ignores the health risks of e-cigarettes, particularly to young people. Pet.’s Op. Br. at 3-4. Petitioners greatly exaggerate what is known about the safety of e-cigarettes relative to cigarettes and oversimplify the relative health effects of using e-cigarettes.

Petitioners’ evidence in support of the conclusion that vaping is significantly less harmful, relies upon a statement by Public Health England (PHE), England’s public health agency, that cites one group’s unscientific assertion that e-cigarettes are 95 percent safer than traditional cigarettes.

²⁹ *Id.*

Pls. Pet. for Decl. and Inj. Relief at 4-5. *Significantly, not a single U.S. health authority or government resource has supported this claim.*

The FDA examined and rejected the “95 percent safer” claim. FDA noted that the panelists conducting the underlying harm analysis “were selected without any formal criterion,” and that the methodology for arriving at the relative harm assessments underlying the “95 percent safer” conclusion was “unclear.” 81 Fed. Reg. at 29,029-30 (internal quotations omitted). One recent analysis concluded, “The “95 percent safer” estimate is a “factoid”: unreliable information repeated so often that it becomes accepted as fact.”³⁰ Significantly, the article raises concern about relying on the 95 percent statistic today, given that the range of e-cigarette products available on the market is drastically different from those available in 2013 when this estimate was made.³¹ For example, currently available e-cigarettes use different materials and heating devices, have power output that exceeds that of most 2013 models by 10 to 20 times, and are available in thousands of new flavors.³² Thus, the 95 percent figure was based on little evidence when it was made and is even less valid today.

³⁰ Eissenberg, T., et al., “Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes,” *AJPH*, published online January 8, 2020, <https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305424>

³¹ *Id.*

³² *Id.*

IV. E-Cigarettes Have Not Been Approved as a Smoking Cessation Drug or Device in the U.S.

Although Petitioners have asserted in this litigation that flavored e-cigarettes facilitate smoking cessation,³³ and imply that e-cigarettes are responsible for the decline in smoking of combustible cigarettes,³⁴ the fact is that no e-cigarette has been approved, or even reviewed, as a smoking cessation drug or device by the FDA. Indeed, according to FDA, “systematic reviews found insufficient evidence to conclude that e-cigarettes aid smoking cessation. *See* 81 Fed. Reg. at 29,037. The U.S. Preventive Services Task Force concluded that “the current evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation...”³⁵ The recent Surgeon General’s report on smoking cessation notes that whether e-cigarettes “produce[s] an effective method of cessation is presently inconclusive from the emerging base of empirical evidence.”³⁶

Moreover, there is no evidence that flavors in e-cigarettes play any role in smoking cessation. While there are surveys showing that many adults enjoy using flavored products, and anecdotal reports of smokers who

³³ *See e.g.*, Pet. for Decl. and Inj. Relief at 5, ¶ 16.

³⁴ Pet’rs’. Op. Br. at 3.

³⁵ 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>.

³⁶ 2020 SG Report, *supra* note 28, at 23.

say flavored e-cigarettes helped them quit, there is no evidence that smokers could not have quit without non-tobacco flavors.

Because the benefits of e-cigarettes are largely anecdotal and speculative, while the risks of e-cigarettes, including addiction and other health harms, are well-documented and real, the Board of Health had a compelling basis to exercise its authority to meet this threat to public health.

V. The Washington State Board of Health Has the Authority to Adopt Rules to Control and Prevent Vaping-Associated Diseases.

Under RCW 43.20.050(2)(f), the powers and duties of the Board of Health include the authority to “[A]dopt rules for the prevention and control of infectious and noninfectious diseases, including food and vector borne illness.” The Emergency Rules, adopted for the prevention and control of vaping related diseases, fall within the plain meaning of the statute. As explained by the State Respondents, the statute “*directs* the Board to adopt rules for the prevention and control of disease,” and “is not a discretionary grant of authority.” Br. of Resp’t. at 21. According to the Respondents, “the use of examples can be read as the Legislature making clear that food and vector borne illnesses were among the conditions the Legislature expected the Board to address.” *Id.* Given that vaping related lung diseases are undeniably “noninfectious diseases,” the Emergency Rule plainly fits within the Board’s statutory authority.

Petitioners insist, however, that only rules for the prevention and control of diseases akin to “food and vector borne illness” are authorized by the statute. Any other interpretation, they argue, would render the reference to “food and vector borne illness” superfluous. Pet’rs’ Br. at 19. However, one reason the legislature may have sought to make clear that food and vector borne illnesses fall within the Board of Health’s authority, even apart from the reference to “infectious and noninfectious diseases,” is derived from understanding the surveillance mechanism for such outbreaks. According to the CDC, “surveillance of outbreaks of foodborne and waterborne illness seeks to identify clusters of sick persons with a common exposure (as opposed to persons with a specific disease). Foodborne disease outbreaks are defined as two or more cases of similar illness resulting from common ingestion of food.”³⁷ Thus, contrary to Petitioners’ arguments, food and vector borne illness are not “subsumed entirely in ‘infectious and noninfectious diseases’” prong of the statute. Pet’rs’ Op. Br. at 18. Because it is likely that foodborne illnesses may be identified based on a common exposure and not a specific identified disease, the legislature may well have sought to make clear that such an illness falls

³⁷ CDC, National Notifiable Diseases Surveillance System (NNDSS), About Notifiable Noninfectious Disease and Conditions Data, <https://wwwn.cdc.gov/nndss/noninfectious.html>.

under the statute even if it is not clearly identified as a specific infectious or noninfectious disease.

Thus, a central premise of Petitioners' statutory argument – that the phrase “food and vector borne illness” would necessarily be superfluous unless it is read to limit the scope of “infectious and noninfectious diseases” -- is simply invalid.

VI. FDA's Regulatory Authority Over E-Cigarettes Has Been Largely Unused.

Contrary to the suggestion of Petitioners,³⁸ the existence of federal regulatory authority over e-cigarettes does not obviate the need for emergency action by Washington. Although Congress gave FDA broad regulatory authority over tobacco products in the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), the agency has largely failed to use that authority to regulate e-cigarettes. Pub. L. No. 111-31, 123 Stat. 1777 (2009)(codified at 21 U.S.C. §§ 387-387u). Despite the requirement in the Tobacco Control Act that new tobacco products (i.e., those introduced after February 15, 2007) obtain an FDA order authorizing their marketing, not a single e-cigarette product currently on the market has been reviewed and authorized by the FDA. 21 U.S.C

³⁸ Pet. for Decl. and Inj. Relief 7-8.

§387j. Thus, it is essential for Washington and other states to utilize their authority to protect the health of their residents and especially their youth.

E-cigarettes were entirely unregulated by FDA until the 2016 issuance of a final rule “deeming” e-cigarettes and other previously unregulated tobacco products subject to FDA regulation. *See Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act*, 81 Fed. Reg. 28,974 (May 10, 2016) (Deeming Rule). Even after the Deeming Rule was issued, FDA’s regulatory power has been severely underutilized.

Most significantly, FDA has failed to implement the required premarket review of “new tobacco products” (i.e. products marketed after February 15, 2007), in which manufacturers generally would be required to demonstrate that their products are “appropriate for the protection of public health” in order to stay on the market or enter the market. 21 U.S.C. § 387(j). At the time it issued the Deeming Rule in August 2016, FDA exercised its enforcement discretion as to e-cigarettes already on the market, to give their manufacturers a two-year period, until August 2018, to file applications for premarket review. 81 Fed. Reg. 28,978. Then, in an August 2017 Guidance, FDA announced it would further defer enforcement of the premarket review requirements for e-cigarettes four additional years until 2022. Thus, FDA allowed thousands of flavored e-cigarettes to remain on

the market until 2022 without even having to submit an application demonstrating that they met the public health standard in the statute. As the result of a lawsuit brought against FDA by several public health groups, a federal court held that FDA was “abdicating its statutory duty” to engage in premarket review³⁹ and later established a ten-month deadline (until May 2020) for industry marketing applications and a one-year deadline for completion of FDA review. *See Am. Acad. of Peds. et. al. v. FDA*, 399 F.Supp.3d 479 (D. Md. 2019), *appeal docketed*, No. 19-2130 (4th Cir. Oct. 18, 2019).

FDA’s enforcement policy announced on January 2, 2020 is also wholly inadequate to clear the market of the appealing e-cigarette flavors that are widely sold and targeted to youth.⁴⁰ The policy only restricts flavors in some cartridge-based e-cigarettes,⁴¹ leaving over 15,000 flavored e-liquids in every imaginable flavor widely available.⁴² The policy also

³⁹ *Am. Acad. of Peds. v. FDA*, 379 F.Supp.3d 461,492 (D .Md. 2019), *appeal docketed*, No. 19-2130 (4th Cir. Oct. 18, 2019).

⁴⁰ FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on Market Without Premarket Authorization, Guidance for Industry (Jan. 2, 2020) (“FDA 2020 Guidance”).

⁴¹ *Id.* at 3, 9.

⁴² Letter to FDA from 30 U.S. Senators re: FDA E-Cigarette Policy, Jan. 13, 2020, (“In other words, FDA will continue to allow all menthol-flavored e-cigarettes and all flavored e-liquids used in “open tank” e-cigarettes, including those in fruit and candy flavors, as well as single-use products, to remain on the market even though these products have not undergone an FDA review.”); Convenience Stores News, *New Flavored E-Cigarette Cartridge Policy Goes into Effect Feb. 6*, Jan. 10, 2020, https://csnews.com/new-flavored-e-cigarette-cartridge-policy-goes-effect-feb-6?utm_source=omeda&utm_medium=email&utm_campaign=NL_CVN+Backbar&utm_keyword=&oly_enc_id=4902I9478178C9Y (“Though the FDA’s policy affects flavored

exempts all menthol flavored e-cigarettes.⁴³ Menthol tobacco products are uniquely appealing to youth. Half (50.1 percent) of youth who have ever tried smoking initiated with menthol flavored cigarettes⁴⁴ and over half (54 percent) of current youth smokers ages 12-17 smoke menthol cigarettes.⁴⁵ There is no reason to believe that menthol e-cigarettes are not equally appealing to kids—especially if they are the only available flavor for cartridge-based products. Data from the 2019 NYTS show that over half (57.3 percent) of high school e-cigarette users use mint or menthol flavored e-cigarettes. This is an increase from just 16 percent in 2016.⁴⁶ Furthermore, the policy also exempts refillable pod systems like Suorin and Smok and disposable e-cigarettes like Puff Bar, Mojo, and Stig,⁴⁷ all which are immensely popular among youth.⁴⁸ Because FDA’s policy falls far

cartridges, retailers can still sell e-liquid flavors used in open vaping systems and in disposable single-use vape products.”); Campaign for Tobacco-Free Kids, *Administration’s E-Cigarette Policy Leaves Thousands of Flavored E-Cigarettes on the Market*, https://www.tobaccofreekids.org/media/2020/2020_01_15_what-isnt-covered.

⁴³ FDA 2020 Guidance, *supra* note 40, at 3 (“FDA intends to prioritize enforcement against: Any flavored, cartridge-based ENDS product (other than tobacco- or menthol-flavored ENDS product”).

⁴⁴ Ambrose, BK, et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, *Journal of the American Medical Association*, published online October 26, 2015, <https://jamanetwork.com/journals/jama/fullarticle/2464690>.

⁴⁵ Villanti, A., et al., *Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014*, *Tobacco Control*, published online October 20, 2016.

⁴⁶ Leventhal, AM, et al., *Flavors of e-Cigarettes Used by Youths in the United States*, *JAMA*, published online November 5, 2019.

⁴⁷ FDA 2020 Guidance, *supra* note 40, at 9, Fn 20 (“An example of products that would not be captured by this definition include completely self-contained, disposable products”).

⁴⁸ *Supra* note 10; Kaplan, S., *Teens Find a Big Loophole in the New Flavored Vaping Ban*, *The New York Time*, Jan. 31, 2020.

short of clearing the market of flavored e-cigarettes, they will remain widely available to youth.

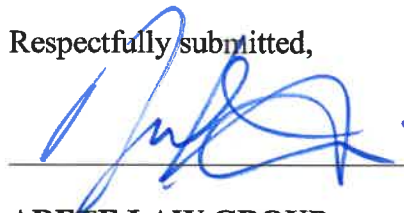
In light of the absence of effective federal regulation, it is vital for states to take action to protect their residents from the harms of e-cigarettes. Moreover, nothing in the Tobacco Control Act prohibits the Board of Health from promulgating regulations to prohibit the sale and distribution of flavored e-cigarette products to consumers in Washington. Section 916 of the Tobacco Control Act specifically preserves broad state and local authority with respect to tobacco products. 21 U.S.C. § 387(p). Thus, the existence of federal regulatory authority over e-cigarettes in no way diminishes Washington's authority to prohibit the sale of flavored e-cigarettes, nor does it diminish the public health importance of doing so.

CONCLUSION

The United States and the State of Washington are seeing two closely related public health crises connected with vaping – the recent outbreak of lung injuries and the continued surge in youth vaping. Washington and several other states have implemented emergency regulations seeking to respond to these crises by prohibiting the sale of flavored e-cigarettes – the products most likely to appeal to youth and expose them to the health risks associated with vaping. At least 200 localities also have passed restrictions or complete prohibitions on the sale

of flavored e-cigarettes.⁴⁹ The Emergency Rules are clearly within the statutory authority of the State Board of Health and Washington children and families should not be deprived of the benefits of this necessary and appropriate response to the serious and rapidly spreading public health hazards of these products. The denial of a preliminary injunction should be upheld.

Respectfully submitted,



ARETE LAW GROUP

Jonah O. Harrison (WSBA #34576)
1218 Third Avenue, Suite 2100
Seattle, WA 98101
Telephone: (206) 428-3250

**CAMPAIGN FOR TOBACCO-FREE
KIDS**

Dennis A. Henigan
Swati V. Rawani
1400 I Street NW, Suite 1200
Washington, DC 20005
Telephone: (202) 296-5469
Attorneys for Amici Curiae

⁴⁹ Campaign for Tobacco-Free Kids, *States & Localities That Have Restricted the Sale of Flavored Tobacco Products*, <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

CERTIFICATE OF SERVICE

Annabel Barnes, being first duly sworn deposes and says that on February 13, 2020, she filed the foregoing Brief of Amici Curiae and this Certificate of Service with the Clerk of the Court using the Court's electronic filing system which will electronically serve all counsel of record:

Jordan Caine Harris
Davis Wright Tremaine LLP
920 Fifth Avenue, Suite 3300
Seattle, WA 98104

Steven P. Caplow
Davis Wright Tremaine LLP
920 Fifth Avenue, Suite 3300
Seattle, WA 98104

Eric A. Sonju
Washington State Office of the
Attorney
P.O. Box 40109
7141 Cleanwater Drive SW
Olympia, WA 98504

Lilia Lopez
Wash. State Attorney General's
Office
P.O. Box 40109
7141 Cleanwater Drive SW
Olympia, WA 98504

Christopher Phillip Wright
Washington State Office of the
Attorney
P.O. Box 40109
7141 Cleanwater Drive SW
Olympia, WA 98504

ATTACHMENT A

Description of Amici Curiae

1. American Lung Association

The American Lung Association is the nation's oldest voluntary and the leading organization working to save lives by improving lung health and preventing lung disease, through research, education and advocacy. Our work is focused on four strategic imperatives: to defeat lung cancer; to improve the air we breathe; to reduce the burden of lung disease on individuals and their families; and to eliminate tobacco use and tobacco-related diseases.

2. Asian Pacific Islander Coalition Advocating Together (APICAT) for Health

APICAT for Health began organizing in 1997 to address tobacco prevention and control issues impacting the Asian American Native Hawaiian & Pacific Islander (AANHPI) community. With over 25 coalition partners APICAT's mission is "building healthy AANHPI communities through leadership development, education and advocacy while advancing policy, systems, and environmental change to ensure equity and social justice."

3. Association of Washington School Principals

The Association of Washington School Principals (AWSP) serves over 3,800 members from elementary, middle, and high schools in Washington. Established in 1972, our membership includes over 96% of all principals and assistant principals in our state. We work closely with principals statewide through boards and committees to plan and coordinate professional learning, advocacy efforts, member support, diversity and equity resources, and student leadership opportunities. Our mission is to support principals and the principalship in the education of all students.

4. Campaign for Tobacco-Free Kids

The 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 dead 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.

5. Foundation for Healthy Generations

We transform systems, policies, and practices to create equitable health outcomes and enduring health equity. We work to ensure all people have the equal opportunity for a healthy life. We address the critical social, economic, and environmental conditions that impact health in communities with the poorest health outcomes by engaging communities, fostering learning and innovation, and advocating for system-wide changes

6. Gay City: Seattle's LGBTQ Center

Celebrating 25 years of supporting and advocating for LGBTQ communities, Gay City: Seattle's LGBTQ Center has evolved into an organization impacting both the Greater Seattle Area and beyond. We provide a space for LGBTQ people to grow, thrive, and be themselves. Gay City's Wellness Center, our LGBTQ Resource & Referral Program, our Gay City Volunteer Crew, our Youth Advocacy programs, and Gay City Arts all provide multiple ways for our community to gather, connect, find voice and serve.

7. Kaiser Permanente

Kaiser Permanente is committed to helping shape the future of health care. We are recognized as one of America's leading health care providers and not-for-profit health plans. Founded in 1945, Kaiser Permanente has a mission to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve. We currently serve 12.2 million members in eight states and the District of Columbia.

8. PAVe – Parents Against Vaping e-cigarettes

PAVe is a grassroots organization founded by three concerned New York City mothers as a response to the current youth vaping epidemic, the most serious adolescent public-health crisis our country has faced in decades. PAVe's volunteer parent advocates operate in multiple states, working in partnership with other stakeholders including public-health groups and community-based organizations. PAVe believes that regulatory and legislative change at the federal/national and/or state and local levels (e.g., a ban on all e-cigarette flavors

including mint and menthol and Tobacco 21 Laws without exceptions) are key to slowing the explosive growth of teen vaping and will prevent younger kids from starting to use flavored e-cigarettes. In cities and states where PAVe works as part of a broader anti-tobacco coalition—such as in New York City, its home base—it fully supports a ban on all flavored tobacco products including menthol cigarettes.

9. Tacoma-Pierce County Health Department

Tacoma-Pierce County Health Department tackles known and emerging health risks through policy, programs and treatment to protect public health. We are one of only 134 accredited health departments in the country and among five in the state to have met or exceed the Public Health Accreditation Board's quality standards.

10. Truth Initiative

Truth Initiative Foundation, d/b/a Truth Initiative ("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 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.

11. Washington State Public Health Association

The Washington State Public Health Association has been around for 85 years. It has a mission of working together to improve the health of all people, places, and communities in Washington.

ARETE LAW GROUP

February 13, 2020 - 3:22 PM

Transmittal Information

Filed with Court: Court of Appeals Division II
Appellate Court Case Number: 54358-3
Appellate Court Case Title: Vapor Technology Association, et al, Appellant v. State Board of Health,
Respondent
Superior Court Case Number: 19-2-05196-2

The following documents have been uploaded:

- 543583_Briefs_20200213151743D2471842_0680.pdf
This File Contains:
Briefs - Amicus Curiae
The Original File Name was 2020 02 13 Amici Final.pdf
- 543583_Motion_20200213151743D2471842_4161.pdf
This File Contains:
Motion 1 - Other
The Original File Name was 2020 02 13 Motion for Leave to File Amici Final.pdf

A copy of the uploaded files will be sent to:

- Eric.Sonju@atg.wa.gov
- abarnes@aretelaw.com
- ahdolyef@atg.wa.gov
- christopher.wright@atg.wa.gov
- jharrison@aretelaw.com
- jordanharris@dwt.com
- lilia.lopez@atg.wa.gov
- lisabass@dwt.com
- stevenaplow@dwt.com

Comments:

Sender Name: Annabel Barnes - Email: abarnes@aretelaw.com

Filing on Behalf of: Jonah Harrison - Email: jharrison@aretelaw.com (Alternate Email: abarnes@aretelaw.com)

Address:
1218 Third Avenue
Suite 2100
Seattle, WA, 98101
Phone: (206) 428-3250

Note: The Filing Id is 20200213151743D2471842