

Nos. 19-2130 [L], 19-2132, 19-2198, 19-2242

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

AMERICAN ACADEMY OF PEDIATRICS, et al.,

Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants- Appellants,

E-LIQUIDS MANUFACTURING STANDARDS ASSOCIATIONS, et al.,

Intervenors-Appellants,

CIGAR ASSOCIATION OF AMERICA, et al.,

Appellants.

Appeals from the United States District Court
for the District of Maryland
No. 8:18-cv-883 (Grimm, J.)

**BRIEF OF *AMICUS CURIAE* CONSUMER ADVOCATES FOR
SMOKE-FREE ALTERNATIVES ASSOCIATION (CASAA)
in support of Intervenors-Appellants American E-Liquid
Manufacturing Standards Association et al.**

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DISCLOSURE STATEMENT

Pursuant to FRAP 26.1 and Local Rule 26.1, Consumer Advocates for Smoke-Free Alternatives Association, who is amicus curiae, makes the following disclosure:

1. Is party/amicus a publicly held corporation or other publicly held entity? NO
2. Does party/amicus have any parent corporations? NO
3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? NO
4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? NO
5. Is party a trade association? (amici curiae do not complete this question) N/A
6. Does this case arise out of a bankruptcy proceeding? NO
7. Is this a criminal case in which there was an organizational victim? NO

Dated: January 30, 2020

/s/ Keith D. Price

Keith D. Price

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INTRODUCTION AND STATEMENT OF INTEREST OF AMICUS CURIAE

The Consumer Advocates for Smoke-free Alternatives Association (“CASAA”) respectfully submits this amicus curiae brief in support of the Intervenor-Appellants American E-Liquid Manufacturing Standards Association et al. to provide helpful information to the Court about the impact of this case on consumers who use e-cigarettes (“vapor products”) as a low-risk alternative to smoking.

Millions of consumers have found low-risk vapor products to be an acceptable alternative to smoking and use vapor products to eliminate or dramatically reduce their smoking habit. While much attention has been paid to concerns involving youth experimentation and use of vapor products, the needs of adults who rely on these products to quit smoking and to improve their health and well-being have largely been ignored.

Under current circumstances, requiring PMTAs to be filed in May 2020 will result in a dramatic exit of businesses from the vapor sector due to lack of resources in the independent vapor space to file in the next several months. This exit will destroy diversity in the marketplace and will have devastating consequences for consumers and public health: (1) increased smoking, (2) increased risks due to black market

and do-it-yourself activities, and (3) loss of the expertise and social/community support provided by vapor shops.

As required by Federal Rule of Appellate Procedure 29(a)(4)(E), no party's counsel has authored any part of this brief nor has contributed money that was intended to fund preparing or submitting the brief.

Further, no one — other than CASAA and its counsel — have contributed money intended to fund preparing or submitting the brief.

ARGUMENT

I. Vapor products help adults who smoke make the switch to a low-risk alternative.

Vapor product use (“vaping”) is far less risky than smoking. It is indisputable, and even acknowledged by the Food and Drug Administration (“FDA”), that a smoker who switches to a vapor product will dramatically reduce his or her risk. As noted by Director Zeller in a 2016 interview, “If I were a pack-a-day smoker who was unable or unwilling to quit, and I substituted cigarettes for e-cigarettes, there’s no question I’d be significantly reducing my risk.”¹

CASAA surveys its membership from time to time to assess use patterns, consumer behaviors, and various demographic and other information, the most comprehensive survey to date being conducted in late 2015 (“CASAA’s Survey”).² The purpose of the survey was to elicit information from CASAA members to present to the Office of Information and Regulatory Affairs (“OIRA”) in January 2016 to help

¹ Julia Belluz, *FDA Tobacco Czar Explains the Agency’s New Clampdown on E-Cigarettes*, Vox (May 9, 2016), <https://www.vox.com/2016/5/9/11608684/mitch-zeller-e-cigarette-fda>.

² Carl V. Phillips, *CASAA ecig survey results* (Jan. 4, 2016), <https://antithrlies.com/2016/01/04/casaa-ecig-survey-results/>.

inform decisions in connection with FDA's proposed deeming of vapor products as tobacco products.³

The following is a brief overview of the study population (nearly 20,000 CASAA members) and their smoking/quit history. The following data is taken from the CASAA Survey. *See supra* n. 2.

- **Ages of respondents:**

- Age 18-25: 14%
- Age 26-35: 30%
- Age 36-55: 44%
- Age over 55: 12%

- **Smoking history:**

- **87% (17,186 respondents) quit smoking entirely after starting to use vapor products**
 - ***Length of time to quit:***⁴
 - 64% switched within a few days of starting vapor products

³ Carl V. Phillips, *CASAA Report to OMB/OIRA* (Dec. 15, 2015), <http://www.casaa.org/wp-content/uploads/294824711-CASAA-Report-to-OIRA-12-15-15-Final-Submitted-pdf.pdf>. The overview of the methods and nature of the CASAA Survey is included as an appendix to that report. *Id.* at 56.

⁴ This is perhaps best interpreted as a descriptive statistic for the study population rather than a result, and it seems to represent a faster average switching trajectory than CASAA believes is average for the population overall.

- 21% quit smoking within a month
- 11% quit smoking within one to six
- 3% quit smoking more than six months
- ***Role of vapor products for those who quit smoking entirely after starting to use vapor products:***
 - 64% started using vapor products with the intention of quitting smoking
 - 25% started using vapor products with the intention of merely reducing their smoking but wound up switching entirely
 - 11% started using vapor products with no intention of quitting or reducing their smoking but wound up switching entirely.
- **5% (980 respondents) reported some current smoking:**
 - ***Current smoking habit***
 - 34% of them smoke less than one cigarette per day on average
 - 42% of them smoke one to five cigarettes per day on average
 - 23% of them smoke more than five cigarettes per day on average
 - 1% declined to answer

■ ***Role of vapor products for those who are still smoking:***

- 51% credited vapor products with helping them almost quit smoking
 - 44% credited vapor products with helping them smoke a lot less
 - 3% indicated they used vapor products as a partial substitute but still smoke almost as much as they used to (with almost none saying they smoke fully as much as they used to).
- **3% (565 respondents) already quit smoking before starting to use vapor products⁵**
- 48% were concerned they'd start smoking again so sought a substitute
 - 31% missed smoking (but did not predict they'd start smoking again)
 - 21% chose neither and gave open-ended answers
- **3% never regular smokers and 3% "other" answer**

⁵ There is a tendency to view the case of a person who quits smoking before starting to use vapor products as a negative, but this ignores the reality that smokers are at a high risk of relapse. Thus, the fact that a former smoker chooses to use low-risk vapor products rather than begin smoking again is clearly a positive development. An example of one such story can be found at CASAA's collection of testimonials (<http://www.casaa.org/testimonials/glointhedark/>).

- **Quit Attempts - 94% of all survey respondents reported previous attempts to quit smoking before using vapor products:⁶**
 - 71% had tried to quit using NRT
 - 41% had tried other pharmaceutical products (e.g., Chantix)
 - 21% had tried formal counseling
 - 21% had tried calling a quit line
 - 81% had tried unaided quitting
 - 8% other method⁷

II. Flavors and diversity of products play a crucial role in helping smokers transition to vaping and remaining smoke-free.

While there is much discussion about flavors being appealing to teenagers, it is self-evident that flavors appeal to adults as well. To state the obvious, non-tobacco and non-menthol flavors in and of themselves do not constitute marketing to teenagers. Moreover, while teenagers do use flavors, analysis of data from the 2019 National Youth Tobacco Survey (“NYTS”) released on December 6, 2019 by the CDC

⁶ When this analysis of quit attempts is restricted to those who quit completely with vapor products, all of the rates for quit methods increases: 75% NRT, 43% other pharmaceutical product, 24% formal counseling, 24% quit line, 85% unaided, 8% other. This no doubt reflects the fact that those who ultimately quit smoking using vapor products (87% of respondents) had been more intent on quitting before using vapor products. Of the five specific methods listed above, 8% had tried all five, 21% had tried four or five, and 46% had tried at least three.

⁷ See *supra*, n.2.

and FDA⁸ indicates that flavors are not the main reason why teenagers vape. The number one reason (56.1%) why teenagers try vapor products is simple curiosity.⁹ Flavors come in third at 22.4%.¹⁰

Flavors play a vital role in making vapor products an effective alternative to smoking, in helping smokers transition to vapor products, and in helping former smokers who are now vapers continue to refrain from smoking,¹¹ something that CASAA's Survey reflects, as well as the personal, unscripted testimonials our members have submitted to CASAA's Testimonial Project.¹²

⁸ Teresa W. Wang et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019*, Vol. 68 Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report No. 12 (Dec. 6, 2019), <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.

⁹ *Id.* at p. 6.

¹⁰ *Id.*

¹¹ Farsalinos et al., *Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*, *International Journal of Environmental Research and Public Health*, Vol. 10, pp. 7272-7282 (Dec. 17, 2013),

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/>. See also Christopher Russell et al., *Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA*, *Harm Reduction Journal*, Vol. 15:33 (2018), <https://harmreductionjournal.biomedcentral.com/track/pdf/10.1186/s12954-018-0238-6>.

¹² See CASAA Testimonials Project, <http://www.casaa.org/testimonials/>.

Turning to CASAA's Survey (see *supra*, n.2), of those who quit smoking entirely (87% of the respondents), 72% credited interesting flavors with helping them quit. This response very clearly demonstrates that among the CASAA Survey respondents who have been successful in completely replacing their smoking habit with vaping, flavors were instrumental in helping them quit. Of those who still smoke, 53% credited interesting flavors as helping them move toward quitting entirely.¹³

When asked about all the flavors they use regularly, respondents indicated an extremely strong flavor preference for fruit or fruit beverage (83%) and candy/soda/pastry (76%):

- 83% fruit or fruit beverage
- 76% candy, soda, or pastry
- 30% spice or savory
- 19% tobacco
- 18% menthol/mint
- 12% bitter

¹³ While concern is sometimes expressed about so-called dual use, for many who use both vapor products and combustibles, this period is more properly characterized as a transition period.

In addition, 78% indicated that they used sweet flavors (fruit, candy, pastry, soda) most or all of the time,¹⁴ with only 11% indicating that they chose tobacco or menthol flavors most or all of the time. In fact, 48% indicated that they rarely used tobacco or menthol flavors.¹⁵

Also interesting is that 28% of the CASAA Survey respondents reported using more than twenty flavors in a typical month.¹⁶ This is consistent with research conducted by Dr. Konstantinos Farsalinos (“Farsalinos Flavor Survey”), where 68.3% of the participants reported “switching between flavours on a daily basis or within the day, with former smokers switching more frequently.”¹⁷ Farsalinos’ Flavor Survey also reports that more than half of the respondents stated that restricting variability of flavors would make the vaping experience less enjoyable and almost half of them answered that it would increase

¹⁴ 18% indicated they chose sweet flavors always, 35% indicated they chose sweet flavors almost always, and 26% indicated they chose sweet flavors most of the time. 14% indicated they used sweet flavors some of the time, and 7% indicated they rarely or never used sweet flavors.

¹⁵ 25% reported rarely using tobacco or menthol flavors and 14% indicated they used tobacco or menthol flavors some of the time.

¹⁶ See *supra*, n.2.

¹⁷ Farsalinos et al., *supra*, at § 4.2.

craving for tobacco cigarettes and would make reducing or completely substituting smoking less likely.¹⁸

Current research indicates that increasingly, smokers are initiating use of vapor products with sweeter flavors:

Adult frequent e-cigarette users in the USA who have completely switched from smoking cigarettes to using e-cigarettes are increasingly likely to have initiated e-cigarette use with non-tobacco flavors and to have transitioned from tobacco to non-tobacco flavors over time. Restricting access to non-tobacco e-cigarette flavors may discourage smokers from attempting to switch to e-cigarettes.^[19]

Nearly a third of the CASAA Survey respondents stated they started out using tobacco or menthol flavors but now always or almost always use other flavors.

This change in flavor preference away from tobacco or menthol flavors has powerful implications for not only the role of flavors in helping smokers transition from smoking to vaping, but also in connection with helping vapers maintain smoking abstinence and preventing relapse to smoking.

¹⁸ *Id.*

¹⁹ Christopher Russell et al., *supra*, at 1.

For many vapers, the fact that vaping is pleasurable and enjoyable allows them to see vapor products as not merely a substitute for smoking, but actually a preferred alternative to smoking.²⁰ Limiting flavor options would decrease the enjoyment and therefore the acceptability and effectiveness of vapor products, inevitably resulting in fewer smokers successfully transitioning from smoking to vaping and higher smoking rates.

III. Significantly reducing availability of a wide variety of vapor products and/or flavors will have a devastating impact on consumers.

Under current circumstances, requiring PMTAs to be filed in May 2020 will result in a dramatic exit from the sector due to the inability of those in the independent vapor space to access resources (time, money, and expertise) necessary to file. Whether the exit is caused by lack of business resources and/or FDA enforcement actions, the simple fact is that reducing product choices will inevitably lead to fewer smokers

²⁰ Caitlin Notley et al., *The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention*, Harm Reduction Journal, Vol. 15:31 (Jun. 20, 2018), <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0237-7>.

successfully reducing or eliminating their smoking habit by switching to vapor products.

Considering that 72% of the CASAA Survey respondents say that interesting flavors helped them quit smoking and 53% of the CASAA Survey respondents who still smoke credit interesting flavors with helping them move toward quitting entirely, limiting or prohibiting flavored vapor product choices would result in a net-negative for the genuine public health goal of reducing smoking.²¹

By way of background, open-tank products utilizing refillable flavored e-liquids represent about half of the total vapor market and are primarily sold in independent vape shops and online, rather than in convenience stores. The vapor industry is very diverse and complex. Closed-system and pod-based e-cigarettes (like JUUL) make up roughly 57.5% of the \$6.6 billion U.S. vapor products market, with open-system vapor products (e.g., tanks, mods, e-liquids, etc.) making up approximately 42.4% in 2018, according to Wells Fargo.²²

²¹ See *supra*, n.2.

²² See Bonnie Herzog, *Nielsen: Tobacco All Channel Data Through 9/8*, WELLS FARGO SECURITIES (Sept. 8, 2018).

There are now thousands of brick and mortar vapor shops across the United States that sell a wide variety of products, primarily specializing in open-tank products and flavored e-liquids. Vapor shops are an excellent resource, especially for those who are interested in exploring vaping as a means of reducing or eliminating their smoking habit.²³ At a vapor shop, a consumer can receive information about products and advice on their use. CASAA repeatedly hears from its members about the critical role that vapor shops play in helping them successfully transition from smoking.²⁴

²³ See Emma Ward et al., *A Qualitative Exploration of the Role of Vape Shop Environments in Supporting Smoking Abstinence*, *International Journal of Environmental Research and Public Health* Vol. 15:2 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5858366/>, for an excellent examination of the critical role vapor shops play in the lives of the customers they serve.

²⁴ See Kimberly from Atlanta, GA, CASAA Testimonials Project (May 13, 2016), <http://www.casaa.org/testimonials/kimberly-kimmyvapes-from-atlanta-ga/>:

I walked into a local vape shop and asked the guy behind the counter what device is best for a pack a day smoker. I have never seen a group of people who are so involved and so helpful. I spent a good hour there talking with the employees listening to their stories, and staring at the wall of cigarette packs that were left behind as testimony to how well these devices worked. I bought my first good quality device set up and e-liquid that

Vapor shops also form the hub of local vape community activities and socialization. While this may not sound particularly compelling at first blush, in fact, the sense of community among vapers is a vitally important component of helping many vapers remain smoke-free. Social identity is an important factor in smoking, and we call attention to recent research that discusses smoking relapse in terms of recovering a social identity.²⁵ And, in fact, vapor products — and the vape community — seem purpose-built to address this problem:

Our data demonstrates that e-cigarettes may be a unique harm reduction innovation for smoking relapse prevention. E-cigarettes meet the needs of some ex-smokers by substituting physical, psychological, social, cultural and identity-related aspects of tobacco addiction. Some vapers reported that they found vaping pleasurable and enjoyable—being more than a substitute but actually preferred, over time, to tobacco smoking.

day, and I never picked up another tobacco cigarette again.

See also Thomas Morrow, CASAA Testimonial Project (Oct. 2, 2015), <http://www.casaa.org/testimonials/thomas-morrow/>; Lisa J. Mills, CASAA Testimonial Project (Nov. 24, 2015), <http://www.casaa.org/testimonials/lisa-j-mills-aka-thunder-smallfrye/>, and hundreds more at www.casaa.org/testimonials/.

²⁵ Caitlin Notley & Rory Collins, *Redefining smoking relapse as recovered social identity — secondary qualitative analysis of relapse narratives*, *Journal of Substance Use* (Jul. 2, 2018), <https://www.tandfonline.com/doi/full/10.1080/14659891.2018.1489009>.

This clearly suggests that vaping is a viable long-term substitute for smoking^[26]

Obviously, without a diverse range of interesting and appealing products, vapor shops will go out of business. Given the invaluable services vapor shops offer to their customers and to the communities in which they are located, the loss of vapor shops would be devastating from a consumer, as well as public health, perspective.

CASAA is also concerned about the inevitable black market—and all the attendant risks to consumers—that will be created as legitimate businesses are forced to exit the market.²⁷ It is a virtual certainty that there will be an increase in consumers seeking out risky black market

²⁶ Caitlin Notley et al., *The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention*, Harm Reduction Journal, Vol. 15:31 (2018), <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0237-7>.

²⁷ The source of the lung and pulmonary injuries associated with vaping appears to be primarily due to Vitamin E acetate added to tetrahydrocannabinol (THC)-containing products purchased from “informal” sources. See *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, Centers for Disease Control and Prevention, Overview Section (last updated Jan. 28, 2020, at 1:00 PM EST), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html. This is a stark reminder of the risks to consumers of purchasing from informal sources or the black market.

sources and engaging in do-it-yourself (DIY) activities to be able to use the products and flavors they enjoy.

This is not merely a theoretical concern. In the CASAA Survey, respondents were asked how they would respond if the only e-liquids that could be sold were tobacco and menthol flavored. Nearly 90% of respondents said they would continue to use their preferred flavors by purchasing from overseas, purchasing on the domestic black market, and/or via DIY. It is telling that a ban on flavors other than tobacco and menthol prompted almost the same outraged reaction from CASAA Survey respondents as did a ban on all vapor products (93% said they would purchase from overseas or a domestic black market, or engage in DIY activities).

This illustrates in a very concrete fashion the central importance of flavors and diversity in connection with vapor products and the lengths to which consumers will go to obtain the products they enjoy using.

As currently practiced, DIY activity is not an overly risky endeavor. Consumers involved in DIY activities are able to obtain unflavored nicotine at reasonable prices and in various strengths, and

so there is no pressure to purchase very high concentrations (which would increase the risk). The current DIY hobbyists are generally quite well informed about the products they use and actively share information with each other.

CASAA is, however, concerned that if consumers are denied access to the products they enjoy, there will be a significant increase not only in the black market, but also in DIY activity. And, unlike today's DIY community populated by the informed hobbyist, the DIY space likely to be created by increased regulatory pressures would consist of less sophisticated and less informed consumers. This, obviously, increases the risk of what is presently a relatively safe practice.

IV. Issues concerning youth use must be viewed in context and reflect a balance that does not ignore the needs of adults.

While it is important to discourage youth tobacco use, the reality is that there will always be a statistically significant population of youth who engage in risky behavior and who seek out risky products. To put this in perspective, the CDC reports that in the thirty days preceding administration of the 2017 Youth Risk Behavior Survey (conducted every two years), 29.8% of high school students reported current alcohol use, 19.8% current marijuana use, and nearly 1 in 7

high school students reported misusing prescription opioids.²⁸ This is all to say that some youth engage in risky behaviors, and they also find ways to obtain risky products despite regulations prohibiting access (and even in the face of severe criminal punishment for possession or non-compliance in some cases).

Moreover, even as youth use of vapor products has risen, smoking rates among that population have continued to drop: “In 2019, the prevalence of cigarette smoking among youths was the lowest ever captured by the NYTS since 1999.”²⁹ In addition, recent research finds that over 86% of youth do not use vapor products, and among the minority who do vape, most are not regular users.³⁰ In addition, the study finds that most youth who are vaping are also current or former smokers.³¹

²⁸ Laura Kann, et al., *Youth Risk Behavior Surveillance — United States, 2017*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Vol. 67, No. 8, at p. 1 (Jun. 15, 2018), <https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/ss6708.pdf>.

²⁹ Teresa W. Wang et al., *supra*, at p. 8.

³⁰ Allison M. Glasser et al., *Youth Vaping and Tobacco Use in Context in the United States: Results from the 2018 National Youth Tobacco Survey*, *Nicotine & Tobacco Research* (Jan. 13, 2020), <https://doi.org/10.1093/ntr/ntaa010>.

³¹ *Id.*

Also ignored is the fact that the Family Smoking Prevention and Tobacco Control Act (“TCA”) specifically contemplated adults’ continued access to tobacco products (which would include vapor products) and requires FDA to regulate in a manner that would allow adults to access tobacco products that are lower risk than cigarettes.³² Insufficient attention has been given to the denial of access by adults to these potentially life-saving products in light of the TCA’s mandate.

In light of the foregoing, the goal of reducing youth use of vapor products should be balanced against the critical need to provide a variety of effective and satisfying low-risk smoking alternatives to adults.

³² The TCA is designed “to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products.” Tobacco Control Act, Pub. L. No. 111-31, § 3(4), 123 Stat. 1776, 1782 (2009).

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CERTIFICATE OF COMPLIANCE

This brief complies with type-volume limits because, excluding the parts of the document exempted by Fed. R. App. R. 32(f) (cover page, disclosure statement, table of contents, table of citations, statement regarding oral argument, signature block, certificates of counsel, addendum, attachments), this brief contains 3,676 words.

In addition, this brief complies with the typeface and type style requirements because this brief has been prepared in a proportionally spaced typeface (Century Schoolbook), font size 14.

CERTIFICATE OF SERVICE

The undersigned certifies that on January 30, 2020, he filed the foregoing brief 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.

/s/ Keith D. Price

Keith D. Price