



July 19, 2018

Submitted Electronically (via <http://www.regulations.gov>)

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, RM. 1061
Rockville, Maryland 20852

Re: FDA Docket No. FDA-2017-N-6565; Regulation of Flavors in Tobacco Products; Joint Comment by the Smoke-Free Alternatives Trade Association and the American E-Liquid Manufacturing Standards Association

The Smoke-Free Alternatives Trade Association (SFATA) and the American E-Liquid Manufacturing Standards Association (AEMSA) appreciate this opportunity to respond to the Food and Drug Administration (FDA or Agency) request for comments on the Advanced Notice of Proposed Rulemaking (ANPRM) on the Regulation of Flavors in Tobacco Products (FDA Docket No. FDA-2017-N-6565).

Both SFATA and AEMSA support responsible, science-based and appropriately tailored regulations for Electronic Nicotine Delivery Systems (ENDS) based on the “continuum of risk” of nicotine products. As described herein, ENDS including e-liquids – **all of which are flavored** – are appropriate for the protection of the public health, as they are critical to reducing harm from combustible tobacco by helping cigarette smokers who are otherwise unwilling or unable to quit smoking transition permanently to less harmful sources of nicotine, such as non-combustible ENDS. The SFATA and AEMSA members, which include hundreds of small and large businesses across the United States, rely heavily on the sale of flavored e-liquids and ENDS products to adults; any ban or restriction of such products would likely result in these companies going out of business, and be severely detrimental to public health. We discuss our reasoning below.

I. Background on SFATA and AEMSA

SFATA, a 501(c)(6) organization, is a national trade association of businesses that work in, or in service of, the vapor products industry, including manufacturers, distributors and retailers. SFATA’s mission is to advocate for a reasonably regulated U.S. marketplace which

allows its member companies to provide smoke-free products to adult consumers, while promoting a positive public image for vapor products and educating businesses in our industry. All SFATA members must agree to adhere to the association's Statement of Principles which include, among other things, strict marketing and packaging guidelines and can be found here: http://sfata.org/content.aspx?page_id=22&club_id=89995&module_id=255471.

AEMSA is the first and only trade association of manufacturers dedicated to creating responsible and sustainable standards for the manufacturing of e-liquids used in ENDS, e-liquid components, ENDS hardware devices, as well as distribution and retail standards and best practices. AEMSA is an all-volunteer 501(c)(6) organization, formed to promote safety and responsibility in the vapor industry through self-regulation. One of AEMSA's primary goals is to provide consumers and government regulators with confidence that its members' products are manufactured in a professionally responsible and safe manner until FDA promulgates good manufacturing practices for these products. In this regard, AEMSA has developed manufacturing standards for e-liquids and which may be downloaded from its website at: <http://www.aemsa.org/standards/>.

II. Flavored E-Liquids are Appropriate for the Protection of the Public Health

To be understood, *all* ENDS e-liquids are flavored – there is no such thing as an unflavored e-liquid. Even tobacco and menthol flavors are added to e-liquids to create a characterizing flavor. Unlike cigarettes or other tobacco-containing products, there is simply no “natural” tobacco or other flavors inherent to e-liquids. Rather, all flavors for these products are chemically synthesized and added to the base PG/VG. Thus, unlike cigarettes, a ban on characterizing e-liquid flavors would effectively result in a ban of *all* ENDS.¹

a. ENDS are for Adults Only; SFATA and AEMSA Prohibit Marketing ENDS to Minors

In the ANPRM, FDA requests information on the role of flavors in helping adult smokers reduce cigarette use and/or switch to potentially less harmful tobacco products. First and foremost, both SFATA and AEMSA applaud FDA's recent efforts to curb youth access to ENDS, and agree that there is no place in this industry for companies that use packaging, marketing and advertising gimmicks that may imitate kid-appealing foods or that may otherwise be unnecessarily appealing to children. SFATA and AEMSA members are required to comply with all FDA age restrictions and other requirements, as well as not to market products to minors, taking into consideration product names, cartoons, other imagery and use of promotional items. Both organizations believe that ENDS should be allowed to be marketed responsibly like other flavored adult-only consumable products (e.g., alcohol).

¹ See Dr. Michael Siegel, *Glantz and Colleagues Essentially Call for a Ban on Electronic Cigarettes: Banning Flavors Would Ban All Existing E-Cigarettes*, THE REST OF THE STORY: TOBACCO AND ALCOHOL NEWS ANALYSIS AND COMMENTARY, (July 19, 2018, 12:15 PM), <http://tobaccoanalysis.blogspot.com/2014/06/glantz-and-colleagues-essentially-call.html>.

(continued ...)

b. ENDS Are Less Harmful Than Cigarettes; FDA Acknowledges The Continuum of Risk

That being said, ENDS products are, without a doubt, less harmful than combustible cigarettes, and have been acknowledged as such by FDA. The National Academies of Sciences, Engineering and Medicine², Public Health England, and the Royal College of Physicians, among many other public health advocates and scientists, have repeatedly concluded that ENDS present significantly less health risk than combustible cigarettes. It is critical that these products remain available for adult smokers and consumers.

Indeed, FDA itself concedes that ENDS are less harmful than cigarettes in the Deeming Rule. *See* 81 Fed. Reg. at 29,030 (“FDA recognizes that completely switching from combusted cigarettes to [vapor products] may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products’ comparative placements on the continuum of nicotine-delivering products.”); *id.* at 29,035 (“FDA agrees that use of [vapor products] is likely less hazardous for an individual user than continued smoking of traditional cigarettes.”); *id.* at 28,981 (FDA “believes that the inhalation of nicotine (i.e., nicotine without the products of combustion) is less of a risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products”); *id.* at 29,032, 29,039.

American Cancer Society, which already recommends physicians encourage smokers unable to quit using FDA-approved cessation medicines switch to ENDS, released a statement acknowledging the reduced harm of ENDS and warning about the dangers of misleading consumers – who increasingly believe vaping is just as, if not more harmful than, smoking.³

² *See* National Academies of Science, Engineering and Medicine: Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems, THE PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (Kathleen Stratton et al. eds., 2018), available at <https://tinyurl.com/ya4w37kb>. Public Health Consequences of E-Cigarettes (hereinafter referred to as the “Report”). The Report, which was the result of the Committee’s review of over 800 articles identified from a massive literature search of six different databases, noted that the Committee found sufficient literature to suggest that, “while there are risks associated with e-cigarettes, compared with combustible tobacco cigarettes, e-cigarettes contain fewer toxicants; can deliver nicotine in a manner similar to combustible tobacco cigarettes; show significantly less biological activity in a number of in vitro, animal, and human systems; and might be useful as a cessation aid in smokers who use e-cigarettes exclusively.” *Id.* at 15-16. In sum, the Report acknowledges that vaping is significantly less harmful than smoking traditional combustible tobacco cigarettes.

³ *See* Clifford E. Douglas et al., *American Cancer Society Public Health Statement on Eliminating Combustible Tobacco Use in the United States*, CA: A CANCER JOURNAL FOR CLINICIANS (2018), <https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21455>.

(continued ...)

Even Commissioner Gottlieb has himself made clear on numerous occasions that FDA believes in the “continuum of risk”, stating most recently⁴:

We believe in the concept of a continuum of risk related to tobacco products, and we believe there is a role for modified risk products. Further, we want to preserve e-cigs as one among a number of possible options for adult smokers and believe that fully transitioning smokers to ENDS can reduce the morbidity and mortality associated with tobacco use. If we believe in these concepts, and I do – then we must make sure that kids aren't being initiated on, and becoming addicted to these products.

But if FDA truly recognizes the continuum of risk, statements alone will not suffice. FDA should use its well-established enforcement discretion to not only promulgate science-based and appropriately tailored regulations for ENDS, but also permit the continued marketing of flavored ENDS, which are appropriate for the protection of the public health.

c. ENDS Flavor Variety is Necessary to Protect the Public Health

While it is clear that ENDS are significantly less harmful than cigarettes and that smokers would benefit from switching to vaping, the overall public health utility of ENDS depends on them being attractive enough, through the use of flavors, to appeal to as wide a spectrum of adult smokers as possible.

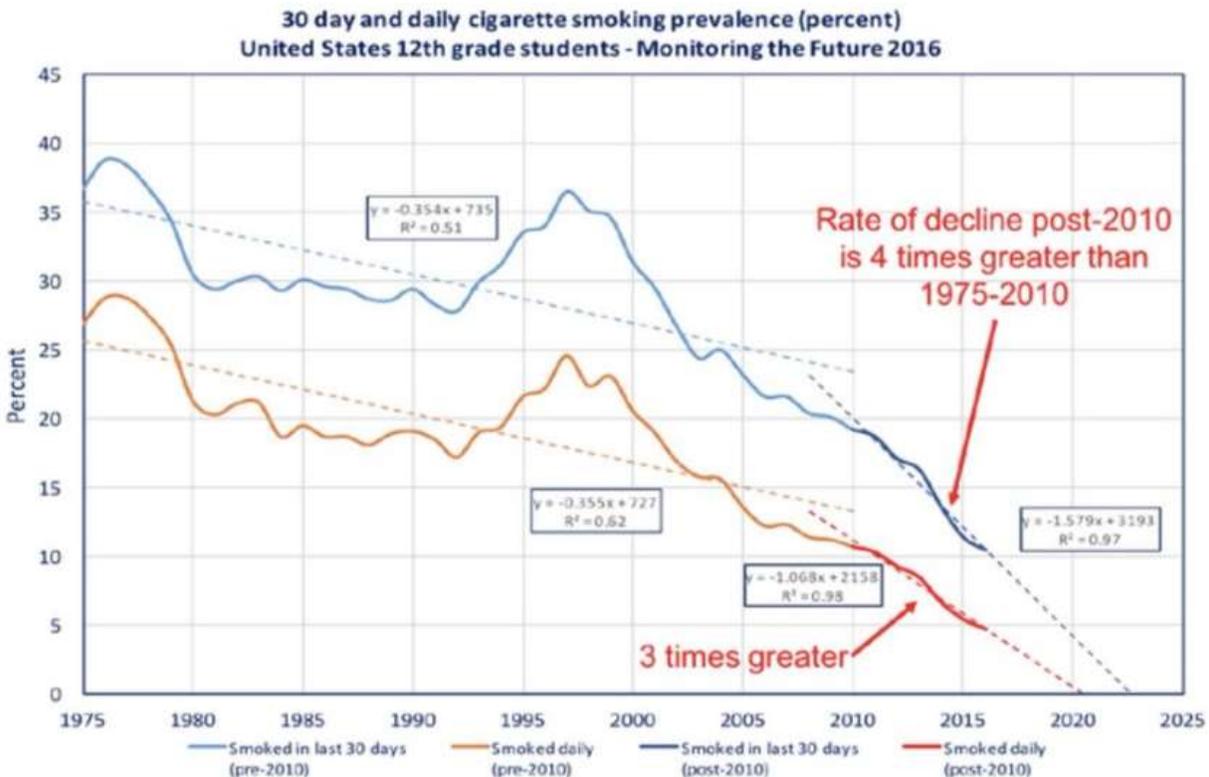
Flavored ENDS are appropriate for the protection of the public health because the availability of these products has undoubtedly played a significant role in the continuously falling U.S. cigarette smoking rate – which hit yet another all-time low (14%) according to the Centers for Disease Control’s National Center for Health Statistics.⁵ Not only has the feared “gateway” effect failed to come to fruition, but quite the opposite has happened. More and more U.S. smokers, including adolescents⁶, are shunning cigarettes and turning to flavored ENDS. Indeed, the rate of decline of smoking prevalence has increased rapidly since flavored ENDS were introduced to the U.S. market⁷:

⁴ See Scott Gottlieb, M.D., Commissioner of Food and Drugs, FDA, FDA’s Nicotine and Tobacco Regulation and the Key Role of Regulatory Science (June 18, 2018) <https://www.fda.gov/NewsEvents/Speeches/UCM611033>.

⁵ See *Smoking rate in U.S. hits all-time low, CDC says*, CBS NEWS, June 19, 2018, <https://www.cbsnews.com/news/smoking-rate-in-u-s-hits-all-time-low/>.

⁶ See Press Release, CDC Newsroom, Cigarette smoking among U.S. high school students at an all-time low, but e-cigarette use a concern, (June 9, 2016) <https://www.cdc.gov/media/releases/2016/p0609-yrbs.html>.

⁷ See Clive Bates, *30 day and daily cigarette smoking prevalence (percent) 1975-2017 United States 12th grade students – Monitoring the Future 2016 and 2017* <https://www.clivebates.com/documents/MTF12thGradeSmokingTrend+.png>.



Numerous published studies demonstrate the important role that flavored ENDS play in this regard. Most recently, the *Harm Reduction Journal* published the results of an extensive online survey which assessed the first e-cigarette flavor and current e-cigarette flavors used by a non-probabilistic sample of 20,836 adult frequent e-cigarette users in the United States.⁸ Differences in e-cigarette flavor preferences between current smokers, former smokers, and never-smokers and trends in the first flavor used across time of e-cigarette use initiation were assessed. The survey demonstrates just how critical ENDS flavors are to protecting the public health – cigarettes smokers who switch to ENDS are doing so increasingly with fruit and other non-tobacco flavored ENDS.

Specifically, the proportion of first e-cigarette purchases that were fruit-flavored increased from 17.8% of first purchases made before 2011 to 33.5% of first purchases made between June 2015 and June 2016. Tobacco-flavored first purchases almost halved during this time (46.0% pre-2011 to 24.0% between 2015 and 2016), possibly because smokers transitioning to vaping are looking to get away from tobacco flavored products. Fruit/fruit beverage (73.9 to 82.9% of sampled users), dessert/pastry (63.5 to 68.5% of sampled users), and candy, chocolate, or sweets (48.7 to 53.4% of sampled users) were the most popular currently used e-cigarette flavors. Tobacco and menthol flavors, the two most popular flavors for initiating e-cigarette use

⁸ See 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*, 15 *Harm Reduction Journal* (2018) <https://doi.org/10.1186/s12954-018-0238-6>. Attached as **Exhibit A** hereto.

prior to 2013, now rank as the 5th and 6th most popular currently used e-cigarette flavors, respectively. Based on this, the study authors concluded that adult frequent e-cigarette users in the United States 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.

Similarly, in 2014 a comprehensive survey of 4,618 dedicated adult vapers was reported in the *International Journal of Environmental Research and Public Health*, and demonstrated that flavors, especially flavor variety, was an important factor in ENDS use by current and former smokers.² Of the 4,515 participants that reported their current cigarette smoking status, the overwhelming majority (91.1%) were former smokers (*i.e.*, vapers who have transitioned completely to e-cigarettes from combustible cigarettes). Of the remaining current smokers (*i.e.*, dual users, or vapers that continue to smoke cigarettes), they had, on average, reduced their cigarette consumption from 20 to 4 units per day. Both subgroups (former smokers and dual users) had a median smoking history of 22 years and had been using e-cigarettes for 12 months at the time of the survey.

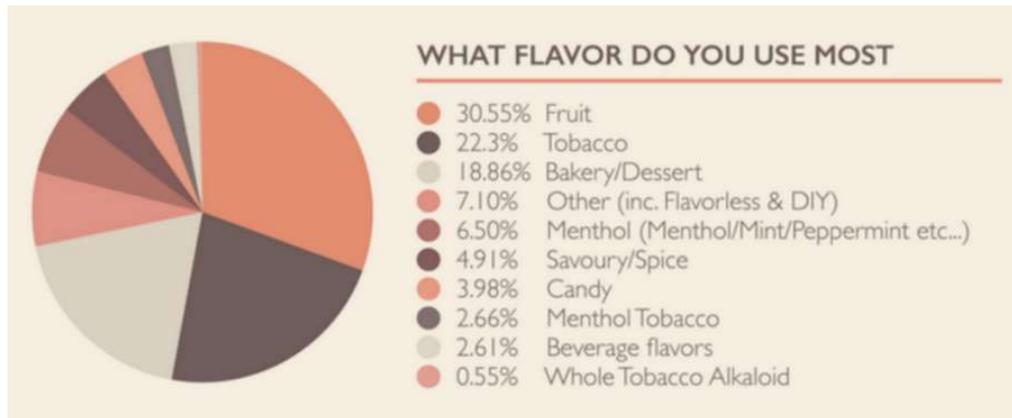
On average, the participants were using three different types of e-liquid flavors on a regular basis, with former smokers switching between flavors more frequently, compared to current smokers. Specifically, 69.2% of the former smokers reported using different e-liquid flavors on a daily basis or during the day. Fruit flavors were more popular at the time of participation, while tobacco flavors were more popular at initiation of e-cigarette use. In other words, smokers making the transition to vaping were like to initially make the switch using tobacco flavored e-liquids, but then began enjoying other flavors. On a scale from 1 (not at all important) to 5 (extremely important) participants answered that variability of flavors was “very important” (score = 4) in their effort to reduce or quit smoking. The majority reported that restricting flavor variability will make e-cigarettes less enjoyable and more boring, while 48.5% mentioned that it would increase craving for combustible cigarettes. Nearly 40% said that it would have been less likely for them to reduce or quit smoking if not for flavored e-liquids. The number of flavors used was independently associated with smoking cessation.¹⁰

² See Konstantinos E. Farsalinos, et al., *Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*, 10 *Int. J. Environ. Res. Public Health* 7272 (2013) <http://www.mdpi.com/1660-4601/10/12/7272>.

¹⁰ Of course, as noted above, none of the e-liquids produced by SFATA or AEMSA members are marketed for use in smoking cessation or as NRTs, but rather only for recreational use by adults. Any smoking cessation or reduced cigarette consumption resulting from the use of e-liquids or ENDS generally is a corollary public health benefit of these products.

(continued ...)

This public health benefit of e-liquid flavors was also reinforced by a survey of 10,000 vapers conducted by the Electronic Cigarette Forum (ECF).¹¹ When asked which e-liquid flavor they used most, only about 25% of the participants indicated tobacco or menthol tobacco. This means that three-quarters of the adult e-cigarette users surveyed actually prefer flavors *other* than tobacco, including fruit (31 percent), bakery/dessert (19 percent), and savory/spice (5 percent)¹²:

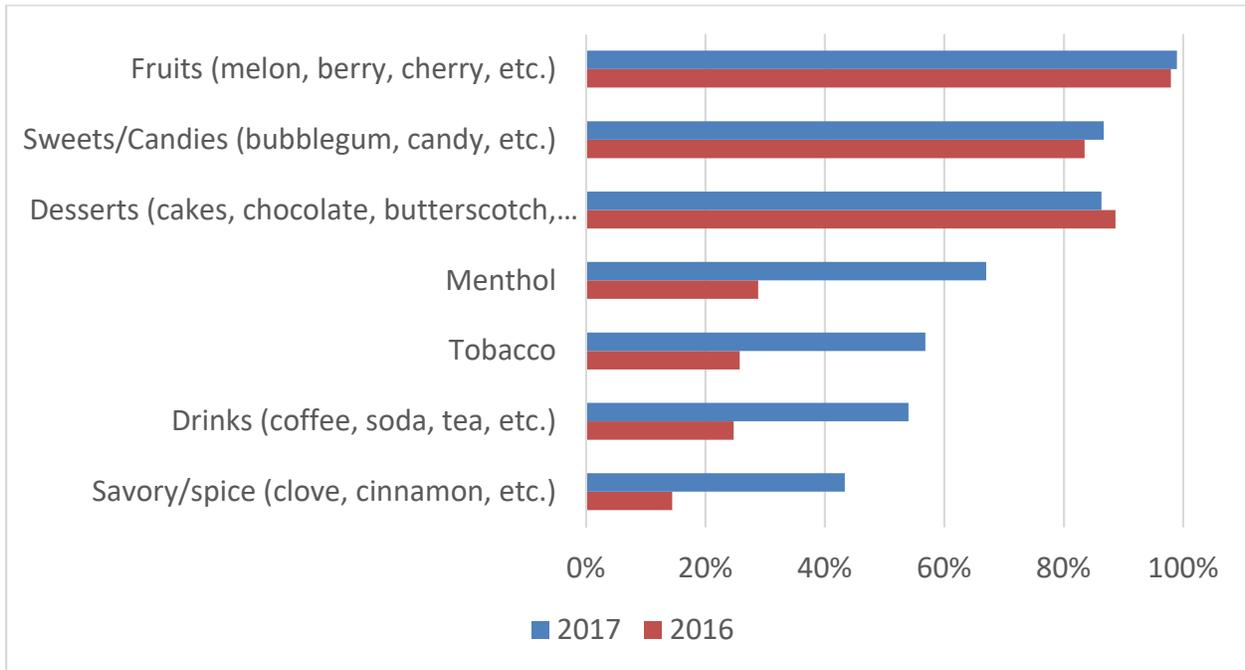


Approximately 65.5% of the former smokers surveyed consider e-liquid flavors important in helping them transition completely to vaping and away from smoking.

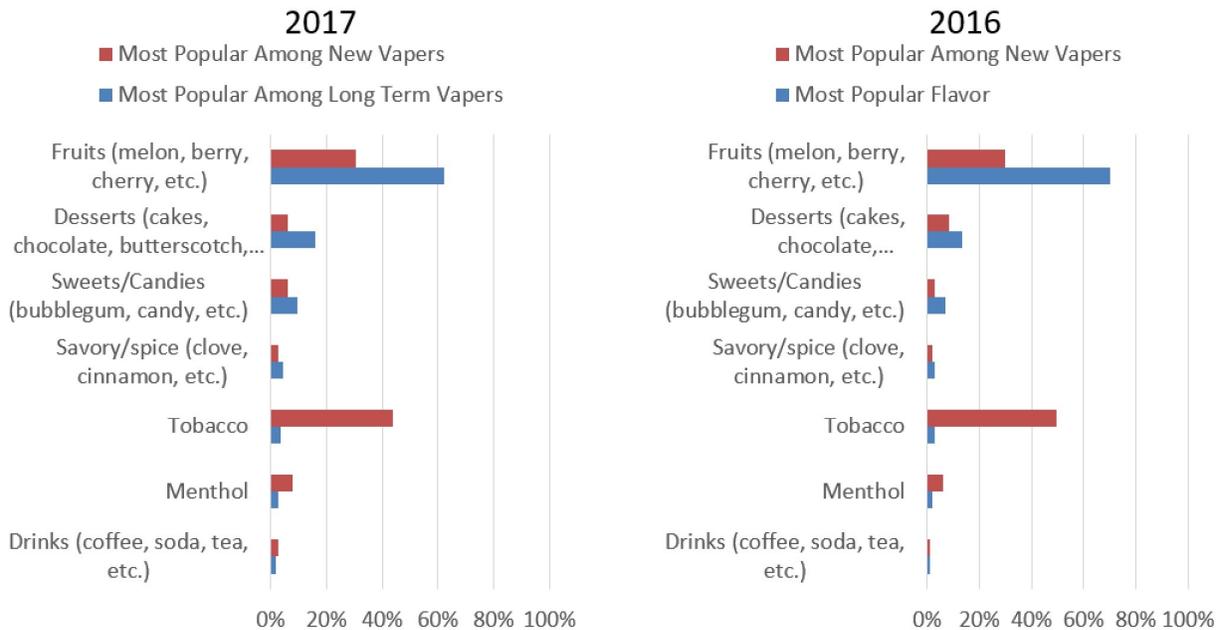
This data is further buttressed by product sales data reported in recent vape shop owner surveys conducted by Management Science Associates, Inc. (see **Exhibit B**) and ECigIntelligence (see **Exhibit C**). The MSA survey of 114 stores found that the top flavors being sold are all on the sweeter end of the spectrum, including fruit, dessert, and sweet/candies; tobacco flavored e-liquids, on the other hand, were less popular.

¹¹ See Neil McLaren, *Vaping.com Big Survey 2014 - Initial Findings General*, VAPING.COM (July 17, 2014), <http://vaping.com/data/vaping-survey-2014-initial-findings>. This survey was conducted in late June and early July 2014. Of the more than 10,000 members of E-Cigarette Forum, 78 percent of whom live in the United States. Their ages ranged from 18 to “65 and over,” with 74 percent between 22 and 54.

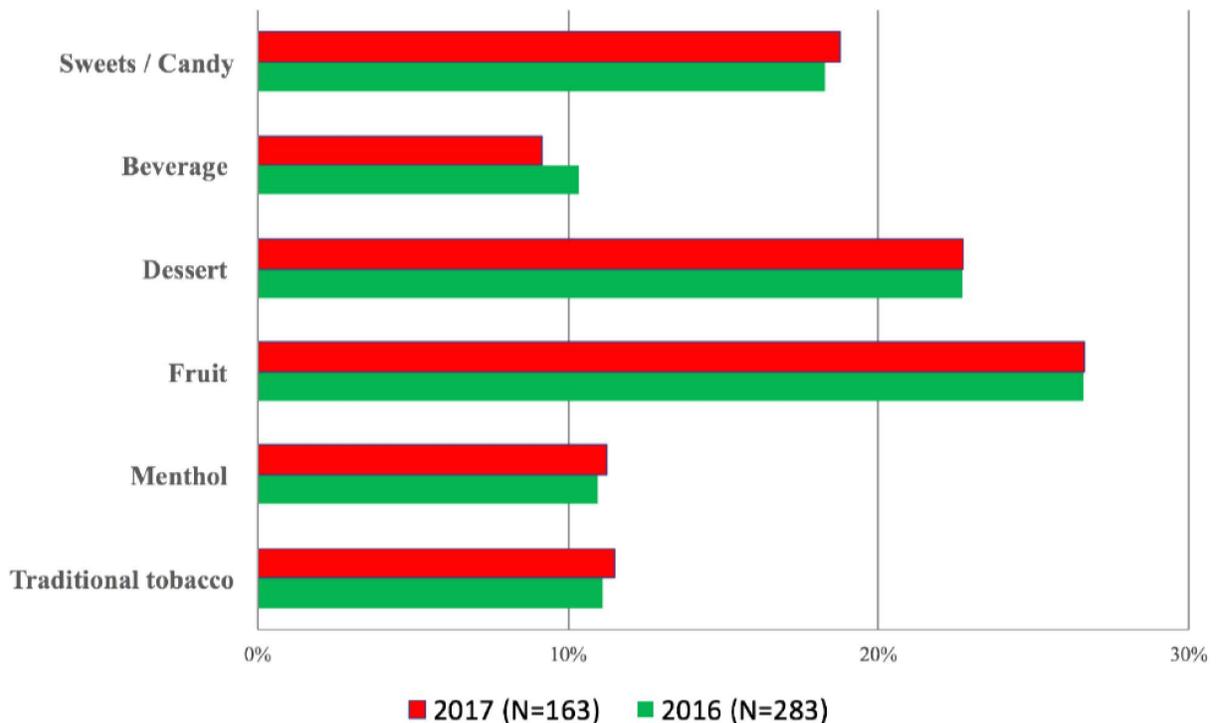
¹² Neil McLaren, *Vaping.com Big Survey 2014 - Initial Findings General*, VAPING.COM (July 17, 2014), <http://vaping.com/data/vaping-survey-2014-initial-findings>. See also Jacob Sullum, *Survey Shows Adults Who Use E-Cigarettes To Quit Smoking Prefer Supposedly Juvenile Flavors*, FORBES.COM, July 17, 2014, available at: <http://www.forbes.com/sites/jacobsullum/2014/07/17/survey-shows-adults-who-use-e-cigarettes-to-quit-smoking-prefer-allegedly-juvenile-flavors/>.



For example, shop owners were asked to select the most popular flavor for long-term customers and new vapers. Not surprisingly, tobacco flavors were preferred by new vapers (accustomed to cigarettes) while sweeter varieties were identified as the most popular among long term users – further supporting the notion that tobacco flavors are a stepping stool that smokers may start with, but graduate from as they transition completely away from cigarettes:



The preference for wide flavor variety among vapers is further supported by the ECigIntelligence survey of 425 vape shops who were asked to rank the popularity of different flavors based on sales data:



As these and many other surveys and studies show, flavor variety is critical for adult vapers.

FDA itself has recognized the importance of having palatable cigarette alternatives available in order to reduce harm. Specifically, FDA has determined that a variety of Nicorette® gum flavors such as White Ice Mint®, Cinnamon Surge™, Fruit Chill™, FreshMint™ and Mint provide a more enjoyable alternative for adult smokers and do not present a significant risk for abuse.¹³ In the case of Nicorette, the Agency clearly determined that the benefit of having a variety of flavored options outweighed the risk that the flavors might attract adolescents or non-smokers to the over-the-counter product, or otherwise lead to the product being abused. In fact, a study published in 2002 in *Pharmacology Biochemistry and Behavior* found that improved flavor of nicotine gum did not increase abuse liability, but may be associated with *enhanced* craving reduction.¹⁴

¹³ See *Find your flavor*, NICORETTE.COM (2017) <http://www.nicorette.com/nicorette-gum>

¹⁴ See EJ Houtsmuller, et al., *Flavor improvement does not increase abuse liability of nicotine chewing gum*, 72 *Pharmacol Biochem Behav* 559 (2002) <https://www.ncbi.nlm.nih.gov/pubmed/12175452>.

Although ENDS are recreational use products and not intended to be smoking cessation devices, the same principle and need for flavor variety applies to these products. Non-tobacco ENDS flavors help smokers transition from cigarettes by helping them disassociate their habit and nicotine addiction with tobacco/tobacco flavor, as the 2018 survey discussed above appears to demonstrate. When switching to vaping, data supports that many smokers may initially try tobacco-flavored ENDS because they are looking to mimic the cigarette flavor they are accustomed to. The process of transitioning from smoking to “dual use” to eventually quitting is a trial-and-error process that requires a smoker to find the right ENDS device, flavor and nicotine concentration that works for them. Many of those newly switching often need to try multiple tobacco flavored e-liquids to find just one or two products that are subjectively satisfactory to replace combustible tobacco use. But as their olfactory and sense of taste return as their cigarette consumption decreases, new vapers often experiment with more pleasant and enjoyable e-liquid flavors which, in turn, keep them from reverting to cigarette use. If *only* tobacco-flavored e-liquids were permitted, smokers would be less likely to disassociate their habit from such flavor. In short, tobacco-flavored e-liquids could re-trigger an urge to smoke cigarettes.

This is further supported by another recent study published in the *Harm Reduction Journal*, which demonstrates how vaping helps even hardened smokers quit.¹⁵ A research team conducted in-depth interviews with 40 vapers, who were asked about their tobacco smoking history and prior quit attempts, about how they started vaping, their vape set up, preferred flavors and nicotine strength, and whether they had switched to vaping in attempt to quit smoking.

The researchers found that ENDS, all of which are flavored, may be a unique harm reduction innovation for smoking relapse prevention, and a viable long-term substitute for smoking, as these products meet the needs of some ex-smokers by substituting physical, psychological, social, cultural and identity-related aspects of tobacco addiction. Flavors and smells, the sensory aspect of vaping, were an important and pleasurable aspect. One of the study subjects noted, “it’s probably one of the most important things in a way, in a sense, that if it was flavourless I don’t think it would really have, it’s actively pleasurable, it’s a nice thing. It’s that bit that means it’s fundamentally different in my mind between a patch or chewing gum or the spray.”

d. Banning Flavors in ENDS Will be Detrimental to the Public Health and Will Likely Result in an Increase in Cigarette Smoking

FDA must consider the likely impact any ban on flavors in ENDS will have on the use of other tobacco products, especially combustible cigarettes (and look beyond the presumed and anecdotal impact flavors have on youth initiation). A 2017 FDA-funded study by Yale University for the National Bureau of Economic Research (NBER), the working paper of which is attached hereto as **Exhibit D** – but was inexplicably excluded from the background materials of this ANPRM – modeled the impact of flavor bans on the use of ENDS as well as cigarettes.

¹⁵ See Caitlan Notley, et al., *The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention*, 15 *Harm Reduction Journal* (2018) <https://doi.org/10.1186/s12954-018-0237-7>.

The researchers conducted a discrete choice experiment on a nationally representative sample of 2,031 adult smokers and recent quitters. They estimated preferences for flavors and other attributes, and use these preferences to predict the demand for both ENDS and cigarettes.

More specifically, the researchers were able to predict the demand for combustibles and e-cigarettes under alternative policies banning flavors while controlling for other product characteristics. Critically, the study concludes that restricting flavors in ENDS (as proposed by FDA in the original proposed Deeming Rule) would *increase* smoking of combustibles, and decrease ENDS use:

We find that flavors themselves serve as an attribute that drives choices across combustibles and e-cigarettes and choosing none. We conclude that flavor bans can be effective levers that affect smokers' choices. Alternative flavor bans can either enhance protection of the health of the public or worsen it. Specifically, our results indicate that banning flavors in e-cigarettes, while allowing them to remain in combustibles, would result in the greatest increase in smoking of combustible cigarettes; and the use of e-cigarettes would decline (10.3 percent).

The study reflects on the role flavors play in the preference among people who attempt to quit, noting that “[t]hose who have attempted quitting show a preference for e-cigarettes (all flavors), which is in keeping with the use of e-cigarettes as a cessation aid (Beard et al., 2016; Marti et al., 2016; Hartman-Boyce et al., 2016; Zhu et al., 2017).”

The study also observed that how policymakers personally view the use of ENDS as tools for harm reduction can impact the development of an optimal flavor policy. This is a valid point, as any decision FDA makes needs to be based not only on science, but weighed by the objectivity of the policymaker. To ban flavors is, ultimately, a policy decision and the evidence as pointed out by this study is the first of its kind in showing the potential for public harm in the event the FDA chooses to ban all ENDS flavors.

Finally, as the Yale study points out, the availability of fruit and sweet flavors is an important factor for people looking for an alternative to combustible products and must remain available for the good of the public health.

Ultimately, as traditional cigarette use continues to decrease, without sufficient scientific data to support a product standard restricting or banning the use of characterizing flavors in ENDS and e-liquids, the Agency must proceed with extreme caution before promulgating any such standard. If FDA were to move too quickly in this regard, such a move could be detrimental to the public health, as smokers who prefer flavor variety while vaping would have no palatable recreational alternatives to turn to. Such smokers could switch back to harmful cigarettes.

The growing body of evidence supports that flavored ENDS are appropriate for the protection of the public health as they help adult smokers disassociate their nicotine addiction and smoking habit from the taste of tobacco, creating a “gateway” *away* from smoking, which is

July 19, 2018

Page 12 of 12

supported by CDC's data on falling smoking rates amongst all populations. Moreover, both SFATA and AEMSA agree that in order to minimize any potential harm, preventing adolescents from accessing these products is paramount, and supports and prohibiting marketing, advertising and packaging that is unnecessarily attractive to minors.

* * * *

Thank you for considering these comments on behalf of SFATA and AEMSA. Should FDA have any follow-up questions or if you would like to meet to discuss, please do not hesitate to let us know.

Respectfully yours,



Mark Anton
Executive Director
SFATA



Scott Eley
President
AEMSA

Enclosures

- Exhibit A – 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*, 15 Harm Reduction Journal (2018) <https://doi.org/10.1186/s12954-018-0238-6>.
- Exhibit B – 2017 Management Science Associates, Inc. Vape Shop Survey
- Exhibit C – 2017 ECigIntelligence Vape Shop Survey
- Exhibit D – Bucknell, J., et al., *Should flavors be banned in e-cigarettes? Evidence on adult smokers and recent quitters from a discrete choice experiment*, National Bureau of Economic Research Working Paper Series