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U.S. Food and Drug Administration
Center for Tobacco Products
Office of the Center Director
10903 New Hampshire Avenue
Silver Spring, MD 20993

February 11, 2019

Re: Smoke-Free Alternatives Trade Association Response to January 23, 2019 Meeting at the Center for Tobacco Products; Impact of Flavored Vapor Products on the Public Health and Youth Surge

Dear Director Zeller,

On behalf of the Smoke-Free Alternatives Trade Association (SFATA), we would like to thank you and your team for taking the time to meet with us on January 23, 2019, to discuss important issues regarding the vapor industry. We especially appreciate the opportunity to present our ideas for how we can work together to protect youth from tobacco while encouraging harm reduction for adult smokers. The purpose of this email is to follow-up on a particular topic that came up during our conversation; namely, the impact of flavors on the public health and the recent surge in underage use of certain types of e-cigarettes.

Appropriate Marketing for Vapor Products

At the outset, as we discussed, SFATA and its members are vehemently opposed to underage use of any vapor or tobacco product. Our *Statement of Principles* makes clear that vapor products are intended for adults of legal age only, and that companies should avoid any marketing that may be viewed as targeting minors. Indeed, for the reasons noted herein, SFATA maintains that the use of flavors in vapor products should not, in and of itself, be considered an attempt to target minors, but rather as a necessary tool to help adult smokers make the switch. More critical to the youth issue, as evidenced by the recent Food and Drug Administration (FDA) and Federal Trade Commission (FTC) warning letters, is *how* such flavored products are packaged, labeled and marketed. In this regard, we are developing marketing guidelines for our members to help ensure that their products do not, for example, overly appeal to children or inappropriately imitate youth-oriented products. We would be glad to keep you updated on this and would appreciate any FDA feedback on our marketing guidelines.

Public Health Benefit of Flavored Vapor Products

With respect to the use of flavors in vapor products (beyond how they are packaged and marketed), we are concerned that any regulatory action that could (1) restrict access to these products by adults or (2) result in these products being effectively banned, will be severely



detrimental to the public health. The growing body of scientific evidence supports not only that vapor products are far less harmful than combustible cigarettes and nearly twice as effective as cessation aids compared to existing nicotine replacement therapies (NRTs)¹, but that flavors are *crucial* to getting adult smokers to make the switch and stay away from cigarettes. We encourage you to review the thousands of personal stories from former smokers who now use flavored vapor products that were submitted to the docket for the Advance Notice of Proposed Rulemaking (ANPRM) on the *Regulation of Flavors in Tobacco Products*, FDA-2017-N-6565 (Mar. 21, 2018)² at Commissioner Gottlieb’s request.³

Moreover, as detailed in SFATA’s own comment to the ANPRM⁴, numerous published studies also support these anecdotes and highlight the important role of flavored vapor products for harm reduction. Recently, for example, the *Harm Reduction Journal* published the results of an extensive online survey which assessed the first and current vapor product flavors used by a non-probabilistic sample of 20,836 adult frequent vapers in the United States.⁵ Differences in vapor product flavor preferences between current smokers, former smokers, and never-smokers, as well as trends in the first flavor used when initiating vapor products, were assessed. The results were telling – cigarette smokers who switch to vapor products are doing so increasingly with a variety of fruit and other non-tobacco flavors. These results were buttressed by another recently completed survey of more than 69,000 adult vapers, the largest survey ever on e-

¹ We note that on January 30, 2019, the New England Journal of Medicine published a new UK study that reported the results of a one-year randomized, clinical trial in which e-cigarettes were compared to NRT to aid smoking cessation. The study found that e-cigarettes were more effective for smoking cessation than NRT when both products were accompanied by behavioral support. Specifically, the “1-year abstinence rate was 18.0% in the e-cigarette group, as compared with 9.9% in the nicotine-replacement group (relative risk, 1.83; 95% confidence interval [CI], 1.30 to 2.58).” See *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy*, available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1808779?query=featured_home.

² Regulations.gov: Docket comments available at <https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&D=FDA-2017-N-6565>.

³ See U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to reduce tobacco use, especially among youth, by exploring options to address the role of flavors – including menthol – in tobacco products*, (March 20, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm601690.htm>.

⁴ See Regulations.gov: <https://www.regulations.gov/document?D=FDA-2017-N-6565-22951> (ID: FDA-2017-N-6565-22951; Tracking Number: 1k2-94dd-ewp5).

⁵ 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), available at: <https://doi.org/10.1186/s12954-018-0238-6>.



cigarette use by sample size. In this survey, just 16 percent identified tobacco, menthol, or mint as flavors they used most often; the vast majority preferred fruit and dessert flavors.⁶

Recent Surge of Past 30-Day E-Cig Use Among Youth

The above surveys are just a few pieces of the growing body of research that shows that flavors in vapor products play a critical role in attracting and retaining smokers into the reduced-harm vaping category. Nevertheless, as important as flavors are for adult smokers, we acknowledge that non-tobacco characterizing e-liquid flavors likely play a role in youth experimentation. In this regard, you noted during our meeting that early Population Assessment of Tobacco and Health (PATH) survey data indicated that “flavors” was one of the top reasons cited by minors for trying e-cigarettes, which have become the most-used “tobacco product” among youth.⁷

The initial interest in e-cigarettes in the early years of vaping (by both youth and adults) was likely due, at least in part, to the curiosity factor observed when any innovative technology product is introduced to the market, be it smart phones, hover boards or e-cigarettes. Importantly, among high school students, that early interest in e-cigarettes was seen primarily among students who were already smoking.⁸ But after the (expected) swell in youth experimentation from 2011-2015, beginning in 2016 the percentage of high school students who used an e-cigarette at least once in the past 30 days started to fall, nearly cutting *in half* in just one year, from 15.8 to 8.0

⁶ See Konstantinos Farsalinos, *Submitting to the FDA the Findings of the Largest Ever Survey on E-Cigarette Flavors Use by US Vapers*, E-Cigarette Research: Blog (August 11, 2018, 6:54 p.m.), <http://www.ecigarette-research.org/research/index.php/whats-new/2018-2/266-us-flav>

⁷ Of course, it must be noted that while vaping has become more common, the cigarette smoking rate continues to fall to *all-time* lows among all age groups. According to the CDC, in 2017, 7.6 percent of high school students reported smoking cigarettes in the past 30 days—a decrease from 15.8 percent in 2011. See https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm. Among young adults aged 18-24, 10.4 percent smoked cigarettes in 2017 – 21 percent decline since 2016, when the young adult smoking rate was 13.1 percent, and a 45 percent decrease since 2011, when 18.9 percent young adults smoked. See <https://truthinitiative.org/news/young-adult-smoking-rate-drops-10>. Among adults (older than 24), only 14 percent reported smoking “every day” or “someday” – the lowest level ever recorded, down from 15.5 percent in 2016, and a 67 percent decrease since 1965. See TW Wang, et al., *CDC: Smoking Rate Among US Adults Reaches All-time Low*, Helio.com (November 8, 2018), <https://www.healio.com/family-medicine/addiction/news/online/%7B448d408a-6056-4376-be89-a7f2eb468284%7D/cdc-smoking-rate-among-us-adults-reaches-all-time-low>

⁸ See Jacob Sullum, *CDC Belatedly Reveals That Smoking by Teenagers Dropped While Vaping Rose*, Forbes.com (November 20, 2013), available online at: <http://www.forbes.com/sites/jacobsullum/2013/11/20/cdc-belatedly-reveals-that-smoking-by-teenagers-dropped-while-vaping-rose/>



percent.⁹ This potentially indicated that (1) industry-implemented age-verification and youth prevention methods were working, and (2) the novelty of the available products, including the flavored products that have been around since the very nascent stages of the industry, was beginning to wane among minors.

But by mid-2018, FDA announced that early NYTS data revealed a sudden shift in past 30-day e-cigarette use among high schoolers, which had jumped to 20.8%.¹⁰ SFATA and its members were just as alarmed by this as FDA, particularly because our membership, which includes hundreds of small vapor businesses, retail shop owners and e-liquid manufacturers, had not reported any similar increase in sales or illegal purchase attempts by minors. We reached out to our members “on the ground” and quickly realized that the youth surge appeared to be confined to a particular pod-based e-cigarette – the JUUL – that had gained access to the convenience store distribution network normally reserved for Big Tobacco products.¹¹ Commissioner Gottlieb acknowledged this in his September 2018 announcement when he noted that “open-tank” vapor products are *not* the source of rising underage use.¹² As you know, open-tank products utilize refillable flavored e-liquids, represent about half of the total vapor market¹³, and are primarily sold in independent vape shops and online, rather than in convenience stores, pharmacies and gas stations – the recipients of the majority of FDA retailer warning letters and No Tobacco Sale Orders (NTSOs) for illegal sales to minors.¹⁴

⁹ See Ahmed Jamal, et al., *Tobacco Use Among Middle and High School Students – United States, 2011-2016*, MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR) (2017), Figure 1, available at: https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm#F1_down.

¹⁰ See Karen A. Cullen, et al., *Notes From the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students – United States, 2011-2018*, MORBIDITY AND MORTALITY WEEKLY REPORT, MMWR) (2018): <https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm>.

¹¹ A review of Nielson data from 2017-18 indicates that the reported surge in underage e-cigarette use corresponds almost exactly with JUUL’s rise to dominance of the convenience store channel. See Bonnie Herzog, Nielsen: C-Store Data Through 1/27/18, 2/24/18, and 10/6/18; WELLS FARGO SECURITIES.

¹² U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, (September 12, 2018)” See <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>

¹³ 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. See Bonnie Herzog, Nielsen: Tobacco All Channel Data Through 9/8, WELLS FARGO SECURITIES, (Sept. 8, 2018).

¹⁴ U.S. Food and Drug Administration, *FDA pursues order barring specific retailers from selling tobacco products as part of its continuing efforts to target youth tobacco use* (February 7, 2019): https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630913.htm?utm_source=Eloqua&utm_me



If Not the Flavors, Then What?

But while the JUUL comes in a handful of non-tobacco and non-menthol flavors, it was clear to our members who have the unique ability to interact with young adults in their stores (and have tried the product themselves), that flavors are *not* what is driving youth to the JUUL. Rather, in the same way teenagers were never interested in smoking cigarettes for the tobacco flavor, adolescents appear to be coming back to the JUUL because of the “buzz” that, in this case, comes from the high concentrations (*i.e.*, up to 50 mg) of protonated nicotine, commonly referred to as nicotine salts, in the pre-filled e-liquid pods.

In addition, nicotine salts in e-liquid may actually play the role that flavor prohibitionists assign to flavors. In other words, tobacco control advocates often assume that flavors are added to e-liquids for the same reason they are added to combustible tobacco products – to reduce the harshness of the “smoke” when inhaled. But this is based on a fundamental misunderstanding of vapor products, which do not produce smoke or tar. To the extent there is a harshness or “throat hit” associated with vaping freebase nicotine e-liquids, flavors simply do not do much to guise that sensation, which adult smokers making the switch are used to.

Rather, the ability to vape non-tobacco flavors is what drove the development of these products by industry entrepreneurs. Vapor products were invented by smokers for smokers looking for less risky products that, put simply, did not smell or taste like combustible cigarettes.¹⁵ Whether any particular e-liquid flavors allow for a smoother delivery compared to others is unclear, and an area that needs to be researched. What does appear to be clear, however, is that rather than flavors, the use of nicotine salts reduces the throat hit from vaping compared to freebase nicotine. Combined with a host of other factors, *e.g.*, the pod-based format, access at all-age retailers like gas stations and convenience stores, user-driven social media and viral memes, straw purchases by older friends and family, and lack of enforcement of existing age

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¹⁵ As a practical matter, we note that there is no such thing as an unflavored e-liquid. 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, including tobacco and menthol, are chemically synthesized and added to the base solution. Thus, unlike cigarettes, a ban on characterizing e-liquid flavors would effectively result in a ban of *all* vapor products. 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>



restrictions, among other things, the popularity and growth of the JUUL skyrocketed into what FDA quickly termed a youth e-cigarette “epidemic”.¹⁶

Nicotine Salts

Our concern with the JUUL and the nicotine salt concentration in that product does not mean that we do not believe that nicotine salts, which have become popular among adult users of open-system vapor products, cannot play a significant role in tobacco harm reduction. A study published in *Internal and Emergency Medicine*, for example, found that while delivering less nicotine than a conventional cigarette, the use of nicotine salts in e-cigarettes enables cigarette-like pulmonary delivery of nicotine that reduces the desire to smoke.¹⁷ For many adult smokers, nicotine salt products could present an effective reduced-harm alternative.

In light of this, instead of focusing entirely on flavors to address the youth issue, we encourage FDA to examine carefully the public health questions raised by the use of nicotine salts, such as:

- Does a smoother nicotine “hit” from nicotine salts impact addictiveness and consumer perceptions and initiation?
- Does a harsher nicotine hit from free base nicotine prevent “never users” from initiating use of vapor products?
- Does the availability of a product with a higher nicotine concentration and greater nicotine delivery attract current smokers to switch to vaping?
- Are nicotine salts a way to mitigate exposure to other aerosol constituents (*i.e.*, if exposed to a higher nicotine concentration per hit, will less liquid be consumed daily)?
- What nicotine salt concentration in e-liquid is appropriate for the protection of the public health? While nicotine salt concentrations of 50 mg may be too high considering the potential impact on youth initiation, we believe lower concentrations up to 36 mg may provide effective alternatives for adults while not being as potentially addictive to minors.

Next Steps

SFATA shares FDA’s serious concerns about underage e-cigarette use, but maintains that flavors are not the primary cause of the recent rise in past 30-day use among teenagers. Flavored

¹⁶ See Clive Bates, *The Great American Youth Vaping Epidemic. Really?* Clivebates.com (January 23, 2019), <https://www.clivebates.com/the-great-american-youth-vaping-epidemic-really/> for a detailed analysis on the current adolescent vaping situation in the United States.

¹⁷ See O’Connell G., Pritchard, J.D., Prue, C. et al. *Intern Emerg Med* (2019). <http://doi.org/10.1007/s11739-019-02025-3>.



vapor products are an important tobacco harm reduction tool for adult smokers, who typically prefer a variety of fruit, dessert and other vapor product flavors. Accordingly, for the reasons noted above, we believe the Agency’s efforts to restrict access to all flavored vapor products, as well as threats to eliminate the August 8, 2022 Premarket Tobacco Product Application (PMTA) compliance policy deadline for products on the market, is misplaced – and will ultimately harm the public health. Attempting to solve the problem of youth use by focusing on flavors, rather than examining other potential causes of the recent surge, risks losing out on all the upside of vaping technology. Rather, a broader approach considering all of the likely causes of increased youth initiation (*e.g.*, high nicotine salt concentrations, social media, retailer access, straw purchases, etc.), as well as enforcement of existing age-restrictions and FDA requirements, would better protect vulnerable youth without eliminating a major “off ramp” for adult smokers.

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We thank you again for taking the time to meet with us last month and for considering this response. We look forward to continuing to work together and hope that we can meet again soon to discuss these important public health issues.

Respectfully submitted,

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