



The Consumer Advocates for Smoke-free Alternatives Association

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**To:** U.S. Food and Drug Administration

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**Re:** CASAA comments on Docket No. FDA-2017-N-6565, "Regulation of Flavors in Tobacco Products"

VIA REGULATIONS.GOV

## **I. Introduction**

This comment on Docket No. FDA-2017-N-6565, "Regulation of Flavors in Tobacco Products," is submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association ("CASAA"). CASAA is a 501(c)(4) nonprofit public health and education organization and is the leading representative of consumers who use--or who may in the future choose to use--low-risk, smoke-free alternatives to smoking. CASAA is a U.S. membership organization with an all-volunteer Board of Directors and a grassroots membership of more than 200,000 members. CASAA is not an industry group and does not represent the interests of industry. Rather, CASAA represents consumers and is dedicated to ensuring the availability of a wide variety of reduced harm alternatives to smoking and to ensuring that smokers and non-smokers alike receive honest information about those alternatives so that they can make informed choices.

These low-risk smoking alternatives at present primarily include vapor products (sometimes referred to as e-cigarettes), low-risk smokeless tobacco products (including snus), and heated tobacco products (which are currently not available in the U.S. market). These products are collectively referred to as “tobacco harm reduction products” or “THR products.” We are writing to comment on the regulation of flavors in THR products, and we are specifically not commenting on the regulation of flavors in combustible tobacco products.

While FDA will hear from many stakeholders (and from some who are not stakeholders but who merely have opinions), we submit that CASAA’s comment--and the comments being submitted by thousands of consumers, individually--should be given serious and primary consideration given that consumers are in a very real sense the most important stakeholders. It is our lives and our health that are most profoundly impacted by the decisions FDA makes in connection with THR products. In fact, we consider the right of consumers to obtain honest information about the full range of THR products (and access to those THR products) to be a human rights issue.

It is indisputable, and even acknowledged by FDA, that a smoker who switches to a THR 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 my cigarettes for e-cigarettes, there’s no question I’d be significantly reducing my risk.”<sup>1</sup> Likewise, there is no doubt that smokeless tobacco poses a far lower risk than smoking, something that has been known for well more than a decade.<sup>2</sup>

Any examination of the role of flavors in connection with THR products must be conducted with full appreciation that (i) sales to minors (persons under age 18) of all tobacco products--including low-risk THR products--are illegal, (ii) THR products are incredibly low risk as compared to combustible tobacco products, (iii) smokers who make the switch to THR products dramatically reduce their risks, and (iv) anything that FDA does to make THR products less attractive to adult consumers will harm and work against the interests of those consumers, many of whom have tried repeatedly to quit smoking but never found any success until they tried a flavored THR product.

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<sup>1</sup> 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>).

<sup>2</sup> Brad Rodu and Christer Jansson, “Smokeless Tobacco and Oral Cancer: A Review of the Risks and Determinants,” *Critical Reviews in Oral Biology & Medicine*, Volume 15, Issue 5 (2004) (<http://journals.sagepub.com/doi/10.1177/154411130401500502>). See also Tobacco Advisory Group of the Royal College of Physicians, “Protecting Smokers, Saving Lives,” (2002) ([https://www.hri.global/files/2011/07/13/RCP\\_-\\_Protecting\\_Smokers.pdf](https://www.hri.global/files/2011/07/13/RCP_-_Protecting_Smokers.pdf)): “As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10–1,000 times less hazardous than smoking, depending on the product.” See also Farhad Islami, et al., “Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States,” *CA: A Cancer Journal for Clinicians*, Volume 8, Issue 1 (2017) (<https://doi.org/10.3322/caac.21440>), where American Cancer Society researchers identified 17 potentially modifiable risk factors that cause cancer, and while cigarette smoking was listed as the highest risk factor, smokeless tobacco use did not even make the list.

## **II. Is there a need for dramatic regulatory intervention regarding flavors in connection with THR products?**

Should it be determined that a particular flavor poses a nontrivial risk to consumers, certainly that issue should be addressed with appropriate restrictions (e.g., limiting the amount used or, in extreme cases, banning the use of the particular flavoring). We also agree that consideration should be given to restricting the marketing of products that are potentially confusing to very young children (e.g., packaging that resembles a food or beverage container), a project that FDA has already begun.<sup>3</sup> But with standards or regulations that reach beyond these types of reasonable interventions, the harms will outweigh any potential or perceived benefits.

### **A. THR products should not be made less effective**

As previously noted, THR products are indisputably low risk as compared with smoking. It is therefore self-evident that extraordinary care should be taken to regulate THR products lightly and to do nothing that would make them less accessible, less affordable, less effective, or less enjoyable to adult consumers. As discussed later in this comment, flavor restrictions (including restrictions involving marketing and labeling) will negatively affect the accessibility, effectiveness, enjoyment, and possibly even the cost of these low-risk products. While we express no opinion on how combustible tobacco products should be regulated in connection with flavors, we specifically reject the notion that flavors in THR products should be restricted or eliminated (except in the case of a particular flavor that is shown to cause non-trivial harm to consumers). We likewise object to any marketing or labeling restrictions that would make THR products less appealing to consumers. Simply stated, THR products should not be treated as if the risks associated with them are in any way comparable to the high-risk combustible tobacco products.

### **B. Dramatic regulatory intervention regarding flavors is not necessary to protect youth.**

We question the need for intervention and restrictions (other than those noted in the first paragraph of this Section), not only because the risk associated with THR products is very low as compared to smoking, but also because the “problem” of youth use of THR products is not nearly the crisis that it is being portrayed as in the media and by public health activists.<sup>4</sup>

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<sup>3</sup> FDA, “E-Liquids Misleadingly Labeled or Advertised as Food Products,” (May 10, 2018) (<https://www.fda.gov/tobaccoproducts/newsevents/ucm605729.htm>).

<sup>4</sup> Dr. Brad Rodu, “CDC Data Shows That E-Cigarette Use Declined Again in 2017,” (July 19, 2018) (<https://rodutobaccotruth.blogspot.com/2018/07/cdc-data-shows-that-e-cigarette-use.html>).

Smoking rates in the U.S. are declining. According to recent figures released by the Centers for Disease Control and Prevention (“CDC”), the smoking rate for U.S. adults has dropped to an all-time low of 14.8%.<sup>5</sup> Likewise, cigarette smoking among high school students has declined to 7.6%, and use of any tobacco product continues to decline.<sup>6</sup> We note that these numbers reflect *all* use, including experimental use (defined as use even once on one day in the last thirty days), so the percentage of actual regular users is substantially lower. By any measure, these numbers are good news. Far from youth tobacco use being a public health crisis, we are seeing a very steady decline in use. And even though there is a modest uptick in use of low-risk THR products, use of the most dangerous products is decreasing.

Despite this, regulators and anti-tobacco groups insist on burying the lead on the good news, and they continue to conflate dramatically differential health risks across the broad category of “tobacco products.” For example, CDC Director Robert R. Redfield recently opined, “Despite promising declines in tobacco use, far too many young people continue to use tobacco products, including e-cigarettes. Comprehensive, sustained strategies can help prevent and reduce tobacco use and protect our nation’s youth from this preventable health risk.”<sup>7</sup> This suggests that the health risks of using any tobacco product are similar and ignores the reality that there is a dramatic differential in health risks associated with various tobacco products.

While it is important to discourage youth tobacco use, we must also acknowledge the reality that there will always be a statistically significant population of young people who engage in risky behavior and seek out risky products. To put this in perspective, the CDC reports that 11.7% of high school students used vapor products at least one day in the last thirty days.<sup>8</sup> However the CDC also reports that in the thirty days preceding administration of the 2017 Youth Risk Behavior Survey, 39.2% of high school students nationwide reported having texted or emailed while driving, 29.8% reported current alcohol use, and 19.8% reported current marijuana use.<sup>9</sup> Condom use among sexually active high school students has decreased from 62% to 54%, and

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<sup>5</sup> CDC, “Early Release of Selected Estimates Based on Data From the National Health Interview Survey, January–March 2017” ([https://www.cdc.gov/nchs/data/nhis/earlyrelease/Earlyrelease201709\\_08.pdf](https://www.cdc.gov/nchs/data/nhis/earlyrelease/Earlyrelease201709_08.pdf)).

<sup>6</sup> CDC, “Tobacco Product Use Among Middle and High School Students--United States, 2011-2017,” Morbidity and Mortality Weekly Report, June 8, 2018 (<https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm>).

<sup>7</sup> CDC, “Youth tobacco use drops during 2011-2017,” June 7, 2018 (<https://www.cdc.gov/media/releases/2018/p0607-youth-tobacco-use.html>).

<sup>8</sup> CDC, “Tobacco Product Use Among Middle and High School Students--United States, 2011-2017,” Morbidity and Mortality Weekly Report, June 8, 2018 (<https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm>).

<sup>9</sup> Laura Kann, et al., CDC, “Youth Risk Behavior Surveillance--United States, 2017, Surveillance Summaries, Morbidity and Mortality Weekly Report, Vol. 67, No. 8 (June 15, 2018). (<https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/ss6708.pdf>).

nearly 1 in 7 high school students reported misusing prescription opioids.<sup>10</sup> 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).

To date, most of the debate surrounding flavored tobacco products is centered on marketing tactics and retail sources (illicit and legal), but we must also consider social sources of tobacco products and the influence these sources play in a young person's decision to try a tobacco product, particularly in connection with use of high-risk combustible tobacco products. We note that adolescents whose parents smoke are at greater risk of becoming smokers.<sup>11</sup> While policies like raising the minimum legal purchase age and restricting where flavored tobacco products can be sold limit a young person's access and exposure to tobacco in a retail environment, such interventions ignore the most influential social sources of family, close family friends, and adult co-workers who continue to smoke. The collateral harm of making THR products less attractive and less available to adult consumers is that the most risky tobacco products, combustible cigarettes, remain the most popular and visible products to young people. Parents and close family friends, in turn, act as unknowing sources of both product and marketing for smoking.

Given that THR products are low risk, the goal of reducing youth use of tobacco products generally (and of THR products specifically) should not outweigh the critical need to provide effective and satisfying low-risk smoking alternatives to adults. While much attention has been paid to interventions involving youth, when one considers the influence of social sources of tobacco products, it is likely that placing more significance on allowing--and encouraging--adults to choose safer alternatives will yield more positive outcomes. With this in mind, we should not make it more difficult for adults to dramatically reduce their risks, especially when we are seeing a decline in combustible tobacco use as well as a decline in overall tobacco use by youth. Regulators do both adults and youth a disservice by viewing all tobacco products through the same lens and by ignoring or conflating risk differentials.

We also note that a concern about consigning youth to a "lifetime of nicotine addiction" is in large part what drives much of the policy concerning youth use of tobacco products. We respectfully submit that such concerns are largely misplaced in connection with low-risk THR

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<sup>10</sup> Id.

<sup>11</sup> "Parental smoking was associated with a significantly higher risk of smoking initiation in adolescent offspring (odds ratio=2.81, 95% CI=1.78, 4.41). In addition, the likelihood of offspring smoking initiation increased with the number of smoking parents and the duration of exposure to parental smoking, suggesting a dose-response relation between parental smoking and offspring smoking. Offspring of parents who had quit smoking were no more likely to smoke than offspring of parents who had never smoked." Stephen F. Gilman et al., "Parental smoking and adolescent smoking initiation: an intergenerational perspective on tobacco control," *Pediatrics*. Vol. 123(2) (2009) (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2632764/>). See also Darren Mays et al., "Parental Smoking Exposure and Adolescent Smoking Trajectories," *Pediatrics* Vol. 133:6 (June 2014) (<http://pediatrics.aappublications.org/content/133/6/983>).

products. As a preliminary matter, we note that there really has not been a serious exploration of just how “addictive” nicotine is for various methods of delivery beyond FDA-approved nicotine replacement therapies (NRT), and there is substantial evidence that vapers (those who use vapor products) exhibit less dependence on vapor product use than they did as compared to smoking.<sup>12</sup>

Whatever one might think of the validity of defining “addiction” as a “disease” in connection with smoking, such a definition has no place or applicability when discussing low-risk THR products. Moreover, there is no definition of “addiction” itself that is applicable with the use of low-risk THR products. A fundamental component of “addiction” is *serious harm*, something that is not relevant when discussing incredibly *low-risk* THR products. Nicotine use alone is not particularly risky, with NRTs being considered “safe.”<sup>13</sup> In fact, for some consumers, there may be substantial benefits associated with nicotine use.<sup>14</sup> And far from creating harm, we note that smokers who switch to a THR product dramatically reduce their risk and experience improvements in their health and well-being.<sup>15</sup> Moreover, preliminary data suggests that long-term use of vapor products is unlikely to raise significant health concerns in relatively young users.<sup>16</sup>

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<sup>12</sup> See, for example, Konstantinos Farsalinos, Alketa Spyrou, Kalliroi Tsimopoulou, Christos Stefopoulos, Giorgio Romagna, and Vassilis Voudris, “Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices,” *Scientific Reports*, Vol 4, Art. No. 4133 (2014) (<https://www.nature.com/articles/srep04133>). See also Jean-Francois Etter and Thomas Eissenberg, “Dependence levels in users of electronic cigarettes, nicotine gums and tobacco cigarettes,” *Drug and Alcohol Dependence*, Vol. 147, pp. 68-75 (2015) (<https://www.ncbi.nlm.nih.gov/pubmed/25561385>).

<sup>13</sup> Clinical Guidelines for Prescribing Pharmacotherapy for Smoking Cessation. Content last reviewed December 2012. Agency for Healthcare Research and Quality, Rockville, MD. (<http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/prescrib.html>)

<sup>14</sup> “In human studies, acute administration of nicotine can have positive effects on cognitive processes, such as improving attention, fine motor coordination, concentration, memory, speed of information processing, and alleviation of boredom or drowsiness. Some nicotine users benefit from self-medication effects for alleviation of stress, anxiety, depression, and other mental health and medical conditions, including schizophrenia and Parkinson’s Disease. Nicotine also reverses cognitive deficits caused by withdrawal. It is not clear if chronic use of nicotine enhances cognitive function.” Raymond Niaura, “Re-thinking nicotine and its effects,” The Schroeder Institute at Truth Initiative, published online December 2, 2016 (<https://truthinitiative.org/sites/default/files/ReThinking-Nicotine.pdf>)

<sup>15</sup> For example, see Joanna Astrid Miller, Bernhard Mayer, and Peter Hajek, “Changes in the Frequency of Airway Infections in Smokers Who Switched to Vaping: Results of an Online Survey,” *Journal of Addiction Research & Therapy*, Vol. 7:4 (2016) (<https://pdfs.semanticscholar.org/bf98/94e87ed9d6eb51d377e1a43c0dff6b50d90c.pdf>).

<sup>16</sup> Riccardo Polosa et al., “Health impact of E-cigarettes: a prospective 3.5-year study of regular daily users who have never smoked,” *Scientific Reports*, Volume 7, Article No. 13825 (2017) (<https://www.nature.com/articles/s41598-017-14043-2>).

There is no compelling evidence that experimentation with, or even regular use of, THR products is causing youth to become addicted to such products, let alone that they are moving from use of the low-risk products to the far more dangerous combustibles.<sup>17</sup> Contrary to notions that THR products might serve as a gateway to the most harmful combustible products, the declining smoking rates would suggest low-risk products are acting as a path *away from* smoking.

We are, however, concerned that a gateway might inadvertently be created if extraordinary care is not taken in messaging to youth. As mentioned previously, there is a great deal of emphasis on eliminating youth initiation and use of all tobacco products. As a result, anti-tobacco campaigns and the policy agendas they support lump all tobacco products together as if they carry the same risk. In fact, we see what we feel are misplaced concerns being expressed about how youth who perceive vaping as a less harmful alternative to smoking may begin using vapor products.<sup>18</sup> Specifically, researchers with the Office of Science, Center for Tobacco Products opined, “Youth who perceive gradations in harm--both by frequency and intensity of cigarette use and by type of product--may be particularly susceptible to e-cigarette use.”<sup>19</sup> This concern--namely, that youth perceptions about the low-risk nature of THR products might align with the truth and increase use of those products--is what drives so much policy. But this concern misses the mark because it ignores positive outcomes attributable to young people who know the truth about THR products and who are therefore less likely to smoke, or, if currently smoking, more likely to quit or move to a low-risk THR product. One possible negative outcome resulting from this lack of emphasis on the truth is that young people choose to transition to combustible products because they do not perceive a risk differential.

It is important to empower young people with truthful, accurate information, and it would be public health malpractice to mislead youth to believe that all tobacco products carry similar risks. As noted by Iowa Attorney General Tom Miller, “People making misstatements about e-cigarettes have the best of intentions — to keep kids from being addicted to nicotine through e-cigarettes. But adults misleading kids to get them to do what we want has always been a failed strategy.”<sup>20</sup> Regulatory and legislative actions addressing youth tobacco use should be

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<sup>17</sup> Lynn T. Kozlowski and Kenneth E. Warner, “Adolescents and e-cigarettes: Objects of concern may appear larger than they are,” *Drug and Alcohol Dependence*, 2017 May 1;174:209-214. (<https://www.buffalo.edu/content/dam/www/news/documents/Study%20PDFs/Kozlowski-Warner-DAD-2017-inpress.pdf>)

<sup>18</sup> Bridget K. Ambrose, et al., “Perceptions of the Relative Harm of Cigarettes and E-cigarettes Among U.S. Youth,” *American Journal of Preventive Medicine*, Vol 47:2S1 (2014) (<https://www.ncbi.nlm.nih.gov/pubmed/25044196>).

<sup>19</sup> *Id.*

<sup>20</sup> Iowa Attorney General Tom Miller, “Statement by Attorney General Tom Miller on Electronic Cigarettes,” December 23, 2015. (<https://www.iowaattorneygeneral.gov/newsroom/statement-by-attorney-general-tom-miller-on-electronic-cigarettes/>).

focused on high-risk combustible tobacco products and in providing truthful and accurate information about quitting and also about low-risk alternatives.

We also note that federal law requires age verification and prohibits sales of all tobacco products, including low-risk THR products, to anyone under the age of 18. It is within FDA's power to strictly enforce these laws in order to reduce youth access.

With this in mind, we firmly believe that restrictions (other than those noted in the first paragraph of this Section II) on flavors, marketing, labeling, etc. are not only unnecessary, but they will most certainly result in a great deal of harm both on the individual and population level.

### **III. CASAA's Survey**

#### **A. Summary of the methods and nature of the CASAA Survey.**

Throughout this comment, data from a survey CASAA conducted of its membership in November and December of 2015 ("CASAA Survey") will be discussed. This section provides a summary of the methods and nature of the CASAA Survey.<sup>21</sup> Subjects were asked slightly different questions depending on their smoking history.

The survey was prepared by Dr. Carl Phillips, and a detailed discussion of the survey results can be found at <https://antithrlies.com/2016/01/04/casaa-ecig-survey-results/>. The purpose of the survey was to elicit information from our members to present to the Office of Information and Regulatory Affairs ("OIRA") in January 2016 to help inform their decisions in connection with FDA's proposed deeming of vapor products as tobacco products.<sup>22</sup>

The target population was adults living in the U.S. who are CASAA members; CASAA membership was approximately 120,000 at the time of the survey. We were able to directly contact approximately 77,000 members by email (the others did not opt in for receiving emails from CASAA) to invite them to participate. An initial invitation and several reminders were sent via email. CASAA members who did not receive the email could take the survey, but would need to find out about it via invitations on our social media accounts or website.

There were 18,398 respondents who received the email and 2,056 others who were (based on self-report) CASAA members who did not. Of those, 259 indicated they had never been vapor product users (defined based on having spent a minimum of \$100 on e-cigarette products for

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<sup>21</sup> The survey can be viewed, as seen by the subjects, at <https://www.surveymonkey.com/r/Z5ZZCRM>.

<sup>22</sup> The text of CASAA's submission to OIRA can be found at <http://www.casaa.org/casaa-guidance/casaa-report-to-omboira-dated-december-15-2015/>, and the overview of the methods and nature of the CASAA Survey was included as an appendix to that report. The discussion of the CASAA Survey in this comment is taken, in some cases verbatim, from Dr. Phillip's report at <https://antithrlies.com/2016/01/04/casaa-ecig-survey-results/>.

personal use) and are excluded. (The CASAA membership includes users of other smoke-free products and interested non-users; they were also asked to take the survey, though presumably many of them did not bother because they knew it was about vapor products.) An additional 5,416 respondents indicated they were not CASAA members and are excluded from this analysis to better define the survey population. Invitations and the survey introduction made clear who the target population was and questions were asked to confirm that status, but respondents who were not in the target population were allowed to complete the survey to minimize the chance someone would misrepresent their status in order to be able to complete the survey.

Because this survey targeted the CASAA membership (99% American), it is a well-defined population. They are clearly not representative of all U.S. vapers given that they self-selected to participate in CASAA Calls to Action (advocacy alerts) or were otherwise interested in joining the organization. They are probably representative of Americans who will be most affected by policy action targeted at vapor products and are sufficiently socially and politically connected to be aware of such actions. The response rate was far higher, as a portion of the target population, than any previous e-cigarette survey, though it was still low enough that there was presumably selection based on enthusiasm within the CASAA population.

We believe the results are reasonably representative of the subset of U.S. vapers (estimated at 1-2 million during the survey timeframe, and obviously much higher now) who are actively enthusiastic about vapor products, though some results will represent other vapers in the U.S. In particular, the percentage who achieved particular levels of smoking cessation are clearly not representative of all vapers (most of the survey respondents quit smoking entirely using vapor products, while most U.S. vapers have only used them to substitute for some, but not all, of their smoking). However, within the subpopulation who quit entirely using vapor products or merely cut down, the responses are probably reasonably representative. The responses to the questions about planned actions in the event of bans are probably only representative of the enthusiast population, given that plans to seek alternative markets requires knowledge and social connections in the vapor space.

We note that this particular defined population, CASAA members, while not typical of all vapers, is still an important population in that it reflects a pool of vapers for whom vaping helped them quit smoking entirely (87% of survey respondents), and we believe the information they have on what worked for them is useful in any serious exploration of how to reduce the smoking rate.

## B. Brief Overview of CASAA Survey Results

The results of the CASAA survey, particularly in connection with flavors, will be discussed in some detail throughout this comment, but this section contains a brief overview of the study population and their smoking/quit history.

- **Sex of respondents:**
  - 75% male
- **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) reported quitting smoking entirely after starting to use vapor products**
    - ***Length of time to quit:***<sup>23</sup>
      - 64% switched within a few days of starting vapor products
      - 21% quit smoking within a month of starting vapor products
      - 11% quit smoking within one to six months of starting vapor products
      - 3% quit smoking more than six months after starting vapor products
    - ***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.

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<sup>23</sup> 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 we believe is average for the population overall.

- **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 products<sup>24</sup>**
  - 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<sup>25</sup> and 3% "other" answer**
- **Quit Attempts - 94% of all survey respondents reported previous attempts to quit smoking before using vapor products.<sup>26</sup>**
  - 71% had tried to quit using NRT
  - 41% using some other pharmaceutical product (e.g., Chantix)
  - 21% had tried formal counseling
  - 21% had tried calling a quitline
  - 81% had tried unaided quitting
  - 8% other method

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<sup>24</sup> There is a tendency for public health activists to view the case of a person who quits smoking before starting to use vapor products as a negative, but that ignores the reality that smokers are at a high risk of relapse. Thus, the fact that a former smoker chooses to use a low-risk THR product rather than begin smoking again is clearly a positive development. An example of one such former smoker's story can be found at CASAA's collection of testimonials (<http://www.casaa.org/testimonials/glointhedark/>).

<sup>25</sup> "Regular smoker" here is defined based on smoking an average of more than one cigarette per day on most days for at least a year, which we believe is a narrower and more meaningful measure of having been a smoker than is typically used.

<sup>26</sup> 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% quitline, 85% unaided, 8% other. This no doubt reflects the fact that those who ultimately quit smoking using vapor products (87% of our respondents) had been more intent on quitting before using vapor products. Interestingly, 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.

## IV. The role of flavors in harm reduction products

### A. Flavors in general

At the onset, we note that the definition of “flavors” is far from simple. Because vapor products contain no tobacco, even “tobacco-flavored” vapor products contain added flavorings. Moreover, “tobacco-flavored” vapor products, while in many cases reminiscent of some tobacco notes, do not replicate the taste of smoking a cigarette since there is no combustion to impart the taste, sensation, and aroma of smoke. Even completely unflavored liquids designed for use with vapor products impart a flavor since vegetable glycerin and propylene glycol (common ingredients) have a slightly sweet taste.

While there is much talk about flavors being appealing to children, 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 children. If this were a genuine issue, the pharmaceutical industry would be under fire for producing NRT gums and lozenges (which can be used without detection in schools and other places in order to circumvent smoking bans) that come in trendy flavors like Fruit Chill™, Cinnamon Surge™, White Ice Mint® and Spearmint Burst™, to name a few.<sup>27</sup> Certainly, those flavors sound more exciting and edgy than offerings by JUUL Labs, Inc. (“JUUL”) of Creme Brulee, Cool Cucumber, Mango, Cool Mint, and Fruit Medley. Nicorette even offers mini lozenges that are conveniently packaged to look like candy mints:



Frankly, we believe that much of the public outrage over youth use of THR products (particularly vaping) expressed by regulators, legislators, and public health activists--and the ensuing media sensationalism--is not so much highlighting a problem as it is creating the appearance of a crisis. Moreover, many of the accusations leveled at the vapor industry--and JUUL in

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<sup>27</sup> Fruit Chill™, Cinnamon Surge™, White Ice Mint®, and Spearmint Burst™ are Nicorette gum flavors.

particular--are patently ridiculous, actively harmful, and reflect a profound lack of understanding about the low-risk nature of vapor products.<sup>28</sup>

It is indisputable that flavors play a vital role in making THR products an effective alternative to smoking, in helping smokers transition to a THR product, and in helping former smokers who are now THR product users continue to refrain from smoking,<sup>29</sup> something that CASAA's own survey of its membership reflects, as well as the personal, unscripted testimonies our members have submitted to CASAA's Testimonial Project.<sup>30</sup> To date, more than 11,000 people have submitted their success stories, often volunteering great detail about the specific brands and flavors of e-liquids that they find most satisfying and sharing how important access to a variety of products and flavors is in connection with their success.

## **B. The role of flavors in connection with smoking cessation and smoking reduction**

In Section III of this comment, we provided a brief overview of the CASAA Survey respondents and their smoking/quit attempt history. Respondents were also asked to share information about their flavor preferences as well as information about the role of flavors in helping them eliminate or substantially reduce their smoking habit.

Of those who quit smoking entirely (87% of the CASAA Survey respondents), 72% credited interesting flavors with helping them quit.<sup>31</sup> This response very clearly demonstrates that among

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<sup>28</sup> See, for example, assertions made by Senator Durbin (D-IL) and ten other senators in a letter to JUUL, publicized in a press release issued by Senator Durbin's office: "Your company's popular vaping device (JUUL) and its accompanying flavored nicotine cartridges (JUULpods) are undermining our nation's efforts to reduce tobacco use among youth and putting an entire new generation of children at risk of nicotine addiction and other health consequences," Durbin and the senators write to JUUL Labs, Inc. CEO Kevin Burns. "Despite significant progress in reducing smoking, tobacco use is still the leading cause of preventable death in the United States, killing more than 480,000 people every year. Your company's product purports to help people quit smoking cigarettes, yet we are concerned that JUUL—with its kid-appealing design and flavorings—will only lead to further nicotine addiction and adverse health consequences." (March 18, 2018) (<https://www.durbin.senate.gov/newsroom/press-releases/durbin-and-senators-press-juul-labs-inc-for-answers-on-marketing-addictive-e-cigarette-vaping-product-to-teens-urge-fda-to-take-swift-action->).

<sup>29</sup> Farsalinos et al., "Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey, *International Journal of Environmental Research and Public Health*, Volume 10, pp. 7272-7282 (2013) (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/>). See also Christopher Russell, Neil McKeganey, Tiffany Dickson, and Mitchell Nides, "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*, Volume 15:33 (2018) (<https://harmreductionjournal.biomedcentral.com/track/pdf/10.1186/s12954-018-0238-6>).

<sup>30</sup> CASAA Testimonials Project: <http://www.casaa.org/testimonials/>

<sup>31</sup> These figures are also consistent with research conducted by Dr. Konstantinos Farsalinos in 2013: "On a scale from 1 (not at all important) to 5 (extremely important) participants answered that variability of

the CASAA Survey respondents who have been successful in completely replaced 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 towards quitting entirely.<sup>32</sup>

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 (e.g., cinnamon, clove, pepper)
- 19% tobacco
- 18% menthol/mint
- 12% bitter (e.g., unsweetened coffee, whiskey)

In addition, 78% indicated that they used sweet flavors (fruit, candy, pastry, soda) most or all of the time.<sup>33</sup> This contrasts starkly with the responses involving tobacco or menthol flavors, 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.<sup>34</sup>

Also interesting, 28% of the CASAA Survey respondents reported using more than twenty flavors in a typical month. This is consistent with research conducted by Dr. Konstantinos Farsalinos (“Farsalinos’ 2013 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.”<sup>35</sup>

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flavours was ‘very important’ (score = 4) in their effort to reduce or quit smoking.” Farsalinos et al., “Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey, International Journal of Environmental Research and Public Health, Volume 10, pp. 7272-7282 (2013) (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/>).

<sup>32</sup> While regulators and public health activists often express concern about so-called dual use, we note that for many who use both THR products and combustibles, this period is more properly characterized as a transition period. Moreover, when a smoker starts also using a THR product, there is no appreciable increase in risk to the smoker.

<sup>33</sup> 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.

<sup>34</sup> 25% reported rarely using tobacco or menthol flavors and 14% indicated they used tobacco or menthol flavors some of the time.

<sup>35</sup> Farsalinos’ 2013 Flavor Survey included 4,618 participants, with 91% reporting they were former smokers, and participants who were current smokers reported a reduction in smoking from 20 to 4 cigarettes per day. Farsalinos et al., “Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey, International Journal of Environmental Research and Public Health, Volume 10, pp. 7272-7282 (2013) (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/>).

Switching flavors is, of course, in part because vapers enjoy a variety of flavors. More than half of the respondents of Farsalinos' 2013 Flavor Survey mentioned that they like the variety of flavors. But there is also a very practical reasons why many vapers switch flavors: More than half of the respondents of Farsalinos' 2013 Flavor Survey reported that "the taste gets blunt from long-term use of the same flavour."<sup>36</sup>

Farsalinos' 2013 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 craving for tobacco cigarettes and would make reducing or completely substituting smoking less likely.<sup>37</sup> Also noteworthy, the average score for importance of flavor variability in reducing or quitting smoking was 4 ("very important").<sup>38</sup>

Clearly, flavors other than tobacco and menthol play a critical role in terms of helping smokers successfully transition from smoking to vaping. And, as discussed in the following section, these same flavors play a powerful role in helping THR product users maintain smoking abstinence and prevent relapse to smoking.

### **C. The role of flavors in connection with maintaining smoking abstinence and preventing relapse to smoking**

Interestingly, 31% of the CASAA Survey respondents stated they started out using tobacco or menthol flavors but now always or almost always use other flavors. We also note current research indicating that increasingly, smokers are initiating use of vapor products with sweeter flavors, and initiation with tobacco flavors is decreasing. "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."<sup>39</sup>

This change in flavor preference away from tobacco or menthol flavors (both in terms of switching from tobacco or menthol flavors as well as increasing initiation of vaping by smokers

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<sup>36</sup> Id.

<sup>37</sup> Id.

<sup>38</sup> Id.

<sup>39</sup> Christopher Russell, Neil McKeganey, Tiffany Dickson, and Mitchell Nides, "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*, Volume 15:33 (2018) (<https://harmreductionjournal.biomedcentral.com/track/pdf/10.1186/s12954-018-0238-6>).

using non-tobacco and non-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.

As noted in connection with Farsalinos' 2013 Flavor Survey, almost half of the respondents reported that restricting the availability of flavors would increase craving for tobacco cigarettes and would make it more difficult to reduce or eliminate their smoking habit.

Current research confirms what vapers have known for quite some time: 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 preferred to smoking.<sup>40</sup> Limiting flavor options would decrease the enjoyment, the pleasure, and therefore the acceptability and effectiveness of THR products.

## **V. Unintended Consequences**

### **A. Reduction in pleasure and enjoyment of THR products will lead to more smoking**

As discussed previously in great detail, reducing flavor choices will reduce overall enjoyment of THR products for many consumers. This loss of enjoyment is not only detrimental to consumers, it will inevitably lead to fewer smokers successfully reducing or eliminating their smoking habit by switching to THR 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 towards quitting entirely, limiting or prohibiting flavored THR product choices would result in a net-negative for the genuine public health goal of reducing smoking.

### **B. Loss of the independent vapor market and, in particular, vapor shops**

There are now thousands of brick and mortar vapor shops across the United States which sell a wide variety of products. As discussed in more detail below, these shops play a vital role in the fabric of the vaping community and are instrumental in helping smokers who are interested in reducing or eliminating their smoking habit. Anything but a relatively trivial intervention by FDA

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<sup>40</sup> Caitlin Notley, Emma Ward, Lynn Dawkins, and Richard Holland, "The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention," *Harm Reduction Journal* 15:31 (2018) (<https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0237-7>).

in connection with flavors will have a devastating impact on those vapor shops and on the consumers who rely on them to become or remain smoke-free.

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.<sup>41</sup> At a vapor shop, a consumer can receive information about products and advice on their use, and also try various products so that they can find exactly what works best for them. CASAA repeatedly hears from its members about the critical role that dedicated vapor shops play in helping them successfully transition from smoking.<sup>42</sup>

Vapor shops not only provide products, but they form the hub of local vape community activities and socialization. While this may not sound particularly important 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 would call FDA's attention to recent research which discusses smoking relapse in terms of recovering a social identity.<sup>43</sup> 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. This clearly

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<sup>41</sup> See Emma Ward, Sharon Cox, Lynne Dawkins, Sarah Jakes, Richard Holland, and Caitlin Notley, "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.

<sup>42</sup> Kimberly from Atlanta, GA, CASAA Testimonials Project, May 13, 2016, "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 day, and I never picked up another tobacco cigarette again." (<http://www.casaa.org/testimonials/kimberly-kimmyvapes-from-atlanta-ga/>). See also Thomas Morrow, CASAA Testimonial Project, October 2, 2015 (<http://www.casaa.org/testimonials/thomas-morrow/>) and Lisa J. Mills, CASAA Testimonial Project, November 24, 2015 (<http://www.casaa.org/testimonials/lisa-j-mills-aka-thunder-smallfrye/>), and hundreds more at [www.casaa.org/testimonials/](http://www.casaa.org/testimonials/).

<sup>43</sup> Caitlin Notley & Rory Collins, "Redefining smoking relapse as recovered social identity--secondary qualitative analysis of relapse narratives," *Journal of Substance Use*, published online July 2, 2018 (<https://www.tandfonline.com/doi/full/10.1080/14659891.2018.1489009>).

suggests that vaping is a viable long-term substitute for smoking, with substantial implications for tobacco harm reduction.”<sup>44</sup>

We note that before FDA deemed vapor products as tobacco products, vapor shops freely offered advice and information to consumers in order to assist in the transition process. Consumers who were considering making the switch from smoking to vaping were given information and support so that they could make informed choices and have the best chance of successfully making the transition. This information was especially important to smokers who were uncertain as to whether vaping was a less risky alternative than their current smoking habit.

Once vapor products were deemed tobacco products, vapor shops were prohibited from giving what CASAA considers basic (but critical) information to consumers. Most importantly, vapor shops can no longer provide information or answer questions posed by consumers about whether a smoker can potentially reduce his or her individual health risks by switching to vapor products. While CASAA appreciates the need to protect the public from misleading and deceptive information, we note that the effect of FDA’s deeming is to prevent industry from communicating truthful and relevant information to consumers, information that could help consumers make informed choices that would reduce their risks and improve their lives. And, of course, because FDA perversely considers smoking to be a “disease,” vapor shops are prohibited from communicating information about quitting smoking using vapor products, surely a huge net negative from a genuine public health standpoint.

Given the low-risk nature of vaping as compared to smoking, there is nothing misleading in informing consumers that vaping poses fewer risks than smoking. Yet vapor companies are prohibited from even *suggesting* to consumers that vaping is *likely* less hazardous than smoking. From a consumer rights standpoint, it is simply indefensible that the government would prohibit consumers from receiving this basic, truthful information from vapor companies. This is especially troubling given that the general public has been misled into believing that vaping is as risky--or even more risky--than smoking. And even more troubling is the fact that over the years, those misconceptions have increased such that in 2017, approximately 55.6% of the general public believed (wrongfully) that vapor products were as harmful or more harmful than smoking, representing a dramatic increase from the approximately 39.8% who held that view in 2013.<sup>45</sup>

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<sup>44</sup> Caitlin Notley, Emma Ward, Lynn Dawkins, and Richard Holland, “The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention,” *Harm Reduction Journal* 15:31 (2018)

(<https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0237-7>).

<sup>45</sup> National Cancer Institute, Health Information National Trends Survey 2017

([https://hints.cancer.gov/view-questions-topics/question-details.aspx?red=1&qid=1282&PK\\_Cycle=10](https://hints.cancer.gov/view-questions-topics/question-details.aspx?red=1&qid=1282&PK_Cycle=10)).

See also Marc T. Kiviniemi and Lynn T. Kozlowski, “Deficiencies in public understanding about tobacco harm reduction: results from a United States national survey,” *Harm Reduction Journal* Vol 12:21 (2015)

(<https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-015-0055-0>) re the concern that a large proportion of the population holds inaccurate harm reduction beliefs.

Despite FDA regulation prohibiting vapor businesses from providing risk communication and information about quitting smoking using vapor products, vapor shops provide a space where peer-to-peer support for former and transitioning smokers can develop organically. Although vapor shop employees are restricted to attending to customer service and technical assistance issues, customers are bound by no such law. It is not uncommon to hear successful quit smoking stories exchanged between customers in a vapor shop.<sup>46</sup> To the casual observer, sharing such a story might not seem like much, but between people who are struggling, it can mean the difference between living a smoke-free life or returning to the devil they know.

Even while FDA deeming of vapor products has hampered vapor shops in their mission to provide information and support to consumers, these shops continue to offer invaluable services to their customers and to the communities in which they are located. It is imperative that any regulatory actions contemplated in connection with vapor products not negatively impact the ability of these vapor shops to survive. And, obviously, without a diverse range of interesting and appealing products--products with a variety of flavors--vapor shops will go out of business.

We also note that while the traditional tobacco market is dominated by a few major companies, the vapor market has hundreds (if not thousands) of manufacturers and distributors. Anything FDA does to limit the availability of flavors in vapor products will necessarily cause damage to the independent vapor market sector and cause of loss of diversity that would harm consumers.

While CASAA does not represent these business, we represent the consumers that rely on them, and the effect on consumers of massive vapor shop closings would be devastating.

### **C. The black market and increased risk to consumers with DIY**

Limiting the supply will not eliminate the demand. Any non-trivial restriction on flavors will result in an increase in consumers seeking out black market sources and engaging in Do It Yourself (DIY) activities in order to be able to use the flavors they enjoy. The impact of a black market is explored in great detail in both CASAA's comment to FDA in connection with deeming<sup>47</sup> and in CASAA's report to OIRA<sup>48</sup>, both of which are incorporated herein by this reference.

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<sup>46</sup> CASAA Testimonials Project, Jennifer Chumbley, May 23, 2015, "Mostly in the vape community you will find a group of kind, caring people who are ready to help, educate and learn all there is about vaping. When new vapers walk into most small vape shops, they receive a warm welcome and friendly advice and most of all encouragement." (<http://www.casaa.org/testimonials/jennifer-chumbley/>)

<sup>47</sup> <http://www.casaa.org/wp-content/uploads/CASAA-FDA-Comment-8-7-14.pdf>.

<sup>48</sup> <http://www.casaa.org/casaa-guidance/casaa-report-to-omboira-dated-december-15-2015/>.

This is not merely a theoretical concern. In the CASAA Survey, respondents were asked how they would respond if the only e-liquid that could be sold were tobacco and menthol flavored. The vast majority of respondents--89%--indicated that they would continue to use their preferred flavors by purchasing from overseas, purchasing on the domestic black market, and/or by making or flavoring e-liquid themselves. We note that a ban on interesting flavors (i.e., flavors other than tobacco and menthol) prompted almost the same outraged reaction from CASAA Survey respondents as did a ban on all vapor products.<sup>49</sup> This, obviously, illustrates in a very concrete fashion the central importance of flavors in connection with THR products and the lengths to which consumers will go in order to obtain the products they enjoy using.

There is currently a segment of the vaping population that engages in DIY activities. For some, it's a matter of cost since the raw materials for the production of e-liquid are relatively inexpensive as compared to the cost of the finished product at retail. For others, it reflects a desire to have more control over what they choose to consume. But for the vast majority, it has become a hobby, and they derive a great deal of satisfaction in creating new flavor combinations and in sharing information and support with their fellow hobbyists.

As currently practiced, DIY activity is not an overly risky endeavor. Consumers involved in DIY activities today are able to obtain unflavored nicotine at reasonable prices and in various strengths, and because of that, there is no pressure to purchase very high concentrations. The current DIY hobbyists are generally quite well informed about the products they use and actively share information with each other.

We are, however, concerned that if regulatory interference limits consumers' access to the products they enjoy, there will be a significant increase 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.

To the extent FDA would try to reduce DIY activities by limiting access to the raw materials, we note that any such effort would be impossible because flavorings are readily obtainable for other uses such as food or beverages. A significant restriction on flavors will result in flavors being sold as a "shots" for other uses (e.g., flavoring for drinking water) with the understanding that consumers will add them to the legal (but not interesting or enjoyable) e-liquid they are able to purchase.

Any attempts by FDA to limit consumer access to unflavored nicotine would have disastrous consequences. For example, if the unflavored nicotine supply becomes difficult to obtain because of regulatory interference, there will be an incentive for DIY consumers to purchase

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<sup>49</sup> When asked what they would do in response to a total ban on all vapor products--the entire product category--93% of the CASAA Survey respondents indicated they would continue to use the products they enjoy by either purchasing from overseas or a domestic black market, or by engaging in DIY activities.

nicotine in extremely high concentrations so as to reduce the number of orders they'd have to place (and products that would be at risk of seizure). Use of extremely high concentrations of nicotine is obviously risky, far more risky than the current practice which primarily relies on nicotine concentrations of 10% or less.<sup>50</sup>

The vapor industry was born in kitchens and garages by backyard innovators and weekend engineers--consumers who were driven by a passion to design and improve effective and enjoyable alternatives to smoking. Although it has evolved into a sophisticated industry with a well-defined and traceable supply chain from constituent ingredients to end user, much of the original infrastructure still exists. It would be folly to think that consumers, who started the industry by tinkering with unsatisfactory products in order to make them better, would not naturally return to these roots in response to newly created demand resulting from overbearing regulation.

#### **D. Restrictions on marketing will suppress overall THR product use**

A theme throughout our comment is that policies and regulations are structural communications to the public that influence purchasing decisions as well as beliefs about tobacco products. We note here, again, that conflating the risks of smoking with using THR products by way of subjecting THR manufacturers and retailers to the same marketing restrictions applied to combustible products miscommunicates risk and, again, will discourage smokers from making safer choices.

Concurrently, we acknowledge that irresponsible marketing exists and that THR products mimicking trademarked food and beverage brands should be prohibited. We agree with FDA's recent enforcement action against vapor companies that sold e-liquid confusingly resembling food and beverage products popular among very young children. There is an obvious and immediate safety concern associated with these confusingly packaged products.

We further recognize that a balance must be struck between discouraging youth from initiating tobacco use and allowing manufacturers of THR products to communicate obvious characteristics and advantages of THR products. That being said, marketing of THR products should be allowed to appeal to a broad population of smokers and THR product users. In many cases, as observed in voluntary testimonials provided to CASAA, smokers initially believe that the most effective THR product for them will be one that replicates the flavor experience of smoking. However, after some measure of dedication to sampling various products, most find that flavors other than tobacco and menthol are more enjoyable and help distance them from

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<sup>50</sup>For an excellent discussion of the problems associated with restricting access to unflavored nicotine, see Clive Bates, "Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China," The Counterfactual, May 4, 2016  
<https://www.clivebates.com/regulators-and-the-compliance-fallacy-buying-99-nicotine-e-liquid-from-china/>

the experience of smoking.<sup>51</sup> It is simply not enough to state that a variety of flavors are available. THR product marketing, particularly to smokers, must encourage them to explore their options.

When contemplating marketing standards for THR products, FDA must consider the necessary confluence of appealing packaging, flavors and flavor descriptors, and risk communication that is vital to convincing smokers that safer products are viable alternatives to smoking. Removing or prohibiting any one of these marketing devices diminishes both the appeal and availability of products that smokers should be encouraged and excited about switching to.

### **E. Erosion of public trust**

There is a general mistrust in people of government interventions enacted for their own good. It does not help that people (in this case, people who use THR products) perceive many of those who would impose such policies as also being dishonest about the factual support for these policies. Government agencies and a distressing number of public health organizations and activists are deliberately conflating the lower risks of noncombustible tobacco products with the considerably higher risk of combustibles.

Limiting or eliminating flavors in THR products would constitute a massive and unwarranted intrusion on the lives of millions of current THR users.

## **VI. Conclusion**

In their purest form, product standards exist to provide consumers with confidence that the products they choose to purchase and use are of high quality and do not expose them to unreasonable or unnecessary risks. In contemplating a standard for low-risk tobacco and nicotine products, the FDA must separate the needs and rights of consumers from the politics of behavior modification and weigh them accordingly.

In our comment, CASAA is providing evidence which supports our assertion that consumers have a fundamental right to access low-risk products that are enjoyable; that these products are indeed low-risk, and; that consumers are motivated to find sources of THR products despite burdensome or otherwise prohibitive regulation. The challenge for FDA is to promulgate a standard that preserves both consumer choice of effective THR products and a retail environment that is conducive to smokers successfully transitioning to smoke-free products.

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<sup>51</sup> CASAA Testimonials Project, Nate from North Dakota, Nov. 25, 2015, "I thought at first that I would want a mentholy/tobaccoy flavor, but to my surprise my favorite juices are more on the fruity side of things, sweet with maybe a touch of sour."

(<http://www.casaa.org/testimonials/nate-x3m157-from-north-dakota/>)

CASAA strongly urges FDA to allow for further study of flavored vapor products through market surveillance and credible toxicology research on flavorings. Additionally, CASAA encourages FDA to work cooperatively with state departments of health and local vapor retailers to develop messaging and behavioral support for smokers likely to benefit from switching to a THR product. Neither of these recommendations are possible in a regulatory environment where access to a variety of enjoyable and effective THR products is severely limited.