

1310 L Street, NW, 7th Floor  
Washington, DC 20005  
cei.org

202 331 1010 *main*  
202 331 0640 *fax*



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Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Comment on Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry

Docket ID No – FDA-2019-D-0661

Dear Dr. Gottlieb:

The Competitive Enterprise Institute (CEI) welcomes the opportunity to offer the following comments on the Food and Drug Administration's (FDA) proposed modifications to its policy regarding certain deemed tobacco products.

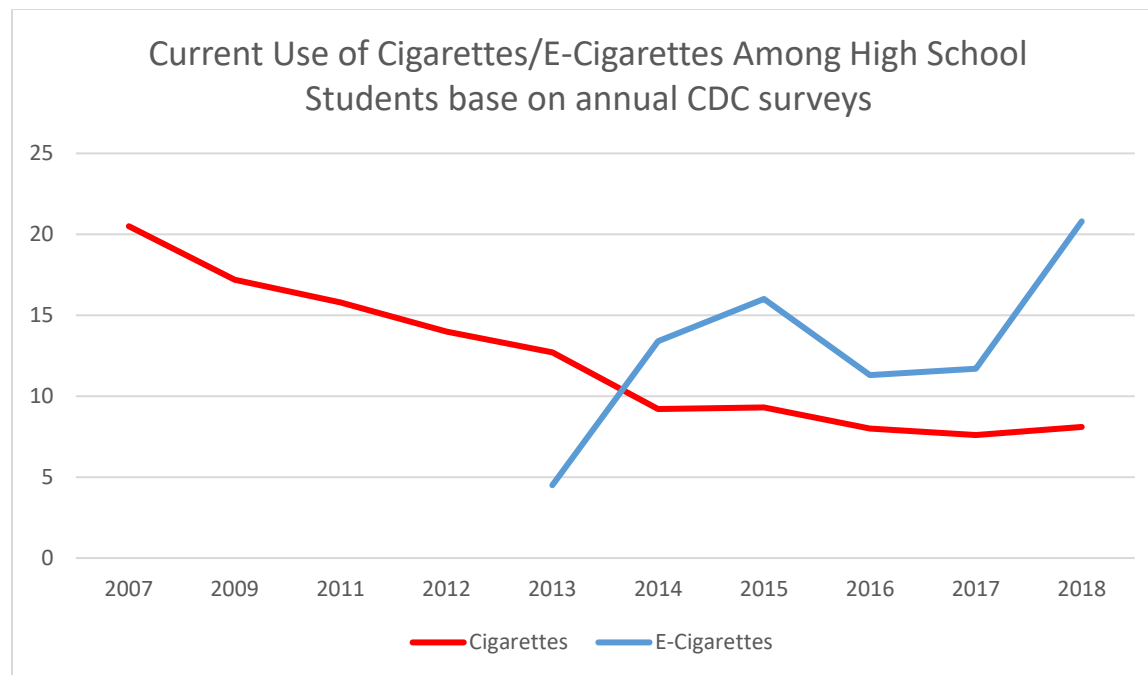
**Interest of the Commenters:** CEI is a non-partisan, non-profit public policy organization with a long history of research and advocacy. Our work on consumer products emphasizes the importance of establishing policies based on an objective analysis of their effects on public health. We believe the FDA is on the brink of making an error that will put millions of American lives at risk and squander one of the greatest public health opportunities of our generation.

**Background:** The evidence is unambiguous: Electronic nicotine delivery systems (ENDS) are a safer alternative to combustible tobacco. Whether one agrees with Public Health England's assessment that e-cigarettes are 95 percent less harmful than cigarettes or not, nobody disputes that e-cigarettes are *safer* to some degree.<sup>1</sup> Therefore, any policy that would make e-cigarettes less available or attractive to smokers ought to be considered carefully, lest it discourage current smokers from switching to safer alternatives.

The FDA's proposed modifications to its compliance policy for ENDS would eliminate certain flavors and shorten the deadline for e-cigarette manufacturers to submit a pre-market tobacco application by up to a year, from August 8, 2022 to August 8, 2021. Both changes are unwarranted and detrimental to the e-cigarette industry's ability to provide customers with the products that many smokers credit with helping them quit.

**E-cigarettes and smoking:** The impetus for the FDA's proposed policy modifications is the idea that there is an "epidemic" of youth vaping that will ultimately lead to higher levels of smoking among adolescents. Based on the government's own data, there is no "epidemic." While annual

surveys show that past 30-day ever-use of e-cigarettes increased between 2017 and 2018, smoking remains at a near all-time low among high school students.<sup>2</sup>



Furthermore, prior to the most recent annual survey, e-cigarette use among adolescents had declined from a high of 16 percent in 2015 to 11.3-11.7 percent in 2016 and 2017. The increase in ever-use during the last year, while concerning, is not a trend; it is for one year. Looking at smoking rates, the overall trend remains positive, with adolescents smoking less than ever before.<sup>3</sup>

**Did Anti-Vaping Campaigns Backfire?** We share the FDA’s concern about the sudden rise in youth vaping. However, the availability of e-cigarettes and e-cigarette flavors does not explain the change in youth e-cigarette use, since the devices and flavors currently available were available in previous years. We believe the most likely explanation for the increase relates to “persuasive backfiring.” In other words, messaging campaigns by agencies like the FDA that teens should not use e-cigarettes and that there is an adolescent e-cigarette “epidemic” may have actually made using e-cigarettes *more attractive* to adolescents.

Our theory rests on two psychological concepts. First, the message that teens should not use e-cigarettes may have incited a negative psychological “reactance” among teenagers who view the messages as a threat to their independence and autonomy.<sup>4</sup> Second, the message that e-cigarette use among adolescents is “epidemic” may have accidentally created “reverse norming”—the perception among adolescents that use of e-cigarettes is a normal behavior among their peers.

Persuasive backfiring has been observed in a number of well-meaning campaigns, including those aimed at reducing adolescent tobacco use. For example, anti-smoking campaigns developed by tobacco companies aimed at raising parental awareness of the issue increased the likelihood of teen smoking. A 2006 study, published in the *American Journal of Public Health*, found that among 10<sup>th</sup>- and 12<sup>th</sup>-graders, each exposure to one of these parent-focused anti-smoking ads increased their likelihood to smoke by 12 percent. The reason why these ads backfired, according

to developmental psychology, is because they focused on parents—authority figures—whom teenagers are apt to rebel against.<sup>5</sup> This sort of backfiring was also observed in a recent Dutch study of secondary schools that showed that smoking rates increased at the schools that had implemented bans on outdoor smoking.<sup>6</sup>

The concept of psychological reactance holds that persuasive communication aimed at discouraging a certain behavior can be perceived by the recipients as a threat to their freedom. In that case, some individuals will try to reassert their autonomy by engaging in the forbidden behavior.<sup>7</sup> Adolescents may particularly be prone to reactance because of their increasing desire for independence, individuality, and disavowal of authority.

Over the last two years, the FDA and other health authorities have made an effort to encourage parents and school officials to take action to prevent adolescent vaping. In some cases, high schools have even removed bathroom doors to discourage the behavior.<sup>8</sup> Even more than bans on smoking on school grounds, removing bathroom doors would certainly be viewed by some students as a threat to their freedom and privacy, likely causing psychological reactance and possibly increasing their interest in vaping.

Anti-vaping messages aimed at teens, rather than authority figures, also have features likely to trigger reactance. Those who are aware of attempts to persuade them are less likely to be persuaded. The more explicit the attempt to persuade, the less persuadable the recipient will be. FDA-funded advertisements in The Real Cost Campaign are not only explicit, but graphic—sometimes laughably so. One titled, “An Epidemic is Spreading,” shows a variety of teen vapers with parasite-like worms crawling over their faces.<sup>9</sup> The transparent intent to persuade makes the advertisement less persuasive, while the message that teen vaping is an “epidemic” may unintentionally communicate that teen vaping is normal.

Commercials produced by the California Tobacco Control Program unintentionally spread the idea, not just that teen vaping is normal, but that teens who vape are more popular. A young woman in the video notes that the “people that I know that [vape] they’re like good students like straight As. It’s a normal thing to do.” Later in the video, describing her fellow teen vapers posting videos of themselves vaping on Snapchat or Instagram, she notes that “they tend to be more popular.” “If you don’t vape you’re looked at as an outsider,” a young man in the same video claims. “So, everybody does it.”<sup>10</sup>

A series of anti-vaping commercials produced by the Truth Initiative features puppets playing the role of teenagers as they discuss the risks of vaping. Not only are these ads likely to be less persuasive because of their overt attempts to persuade, but the use of puppets in an advertisement aimed at high school students would make many young adults feel infantilized and lacking autonomy. These characteristics are likely to increase psychological reactance and potentially increase teens’ interest in vaping as a way to reassert their independence and sense of their own adulthood.<sup>11</sup>

One of the ways in which psychological reactance can be reduced is by communicating that the recipient of persuasive messaging has the ability to disagree.<sup>12</sup> On the other hand, reactance becomes more likely as the threat to freedom increases. This latter scenario is exactly the one that public health authorities and anti-vaping activists have created over the last two years. In addition, adolescents are also likely aware of lawmakers’ attempts to restrict their access to e-cigarettes. Thus, any threat to freedom that teens might have as a result of persuasive messaging

from health agencies would be magnified by *actual* threats to their ability to choose whether to vape from their parents, school administrators, and regulation. This combination of factors almost certainly lead to increased psychological reactance among adolescents when it comes to vaping. For these reasons, we believe the uptick in youth e-cigarette use over the last year can be at least partly explained by the increased attention on the issue from the media, health agencies, school administrators, the FDA, and parents, rather than by the existence of certain e-cigarettes or e-cigarette flavors.

**Do flavors attract children?** The proposal to restrict e-cigarette flavors to tobacco, menthol, and mint is predicated on the idea that other flavors—particularly sweet flavors—attract non-smoking adolescents. However, the scientific evidence indicates that e-cigarette flavors hold little appeal to nonsmoking adolescents. In a small 2015 study (216 nonsmoking teenagers and 432 adult smokers), researchers with the University of Pittsburgh Department of Psychology found no significant variation among nonsmoking teens’ interest in e-cigarettes based on flavor.<sup>13</sup> So, while non-smoking adolescents have shown little interest in e-cigarette flavors, a wide variety of flavors seems to be a key attraction for *adult* smokers who have switched to e-cigarettes.

**Do flavors help adult smokers?** While nonsmoking teens may not be interested in flavors, the University of Pittsburgh study found that interest in flavor varieties was significantly higher among adult smokers, especially among adult e-cigarette users. While these groups rated “classic tobacco” as the most appealing, it was closely followed by “menthol” and “vanilla bean.” Adults also reported a significant interest in fruit and candy flavor options, like butter crunch and cotton candy.

Earlier survey data indicate that the variety of available e-cigarette flavors plays an important role for adults, not only in their willingness to try e-cigarettes as a smoking cessation tool, but in their ability to sustain their attempt to quit smoking. A survey of e-cigarette users in 2014 found that only 22 percent used a single flavor and only 15 percent cited “tobacco” as their primary flavor choice.<sup>14</sup>

The same year, researchers at the Onassis Cardiac Surgery Center in Greece and the Biological and Chemical Toxicology Research Laboratory in Italy published the results of their survey of more than 4,500 adults, of whom 91.1 percent self-identified as a “former smoker.” The study, published in the *International Journal of Environmental Research and Public Health*, found that the tobacco flavor in e-cigarettes seemed to be preferred primarily by those in the earlier stages of smoking cessation, while longer-term ex-smokers preferred non-tobacco flavors. On average, respondents switched between three different flavors, with former smokers switching more frequently than those who self-identified as a “current smoker.”<sup>15</sup>

When asked about how flavor variety in e-cigarettes affected their experience, 73 percent reported that they “liked a variety of choices” and 51.5 percent reported that only using one flavor caused the flavor to become “blunt.” A majority of the respondents noted that flavor variety was “very important” to their efforts to quit or reduce smoking and that eliminating flavors would make vaping less enjoyable (68.9%), more boring (45.7%), increase their cravings for cigarettes (48.5%), and make them less likely to reduce or quit smoking (39.7%). Most importantly, the study found a correlation between the number of flavors regularly used by e-cigarette consumers and complete smoking abstinence.<sup>16</sup>

It is possible that the smokers most motivated to quit are also the ones more likely to try many e-cigarette flavors. But, this study raises the important—and as yet unanswered—question of how e-cigarette flavor variety impacts smoking cessation rates. Given that many former smokers who have switched to e-cigarettes cite flavor variability as an important factor in their cessation attempts, that question must be answered before we can have an idea of how eliminating flavor options might impact public health.

**Reduced-Risk Products and Public Health:** The FDA is statutorily obligated to consider the *net impact* of its regulations on public health. In order to adhere to this standard with regards to its current proposed modifications to policy, the agency must ask the following questions about its proposal to restrict e-cigarette flavors:

- What effect will this have on nonsmoking adults?
- What effect will this have on nonsmoking adolescents?
- What effect will this have on smoking adults?
- What effect will this have on smoking adolescents?

As discussed above, the existing evidence indicates that limiting flavor variety in e-cigarettes will have no effect on the nonsmoking population. However, it would significantly reduce e-cigarettes' attractiveness to existing smokers who might try such devices as a means of reducing or quitting smoking. Therefore, we can safely conclude that such action would have a net negative effect on public health and should be rejected.

Since their introduction into the U.S. market, electronic cigarettes have been viewed by the U.S. public health community as being potentially as or even more harmful than combustible cigarettes and as a ploy by cigarette companies to lure non-smoking minors.<sup>17</sup>

While smokers initially embraced e-cigarettes as a means of reducing their exposure to harmful chemicals, the messaging campaigns of health groups and certain government agencies have led to a decreasing public understanding of relative risk as it pertains to e-cigarettes. Polls conducted by researchers at the Georgia State University School of Public Health found that, while in 2012 only 12.8 percent of adults surveyed believed that e-cigarettes were as or more harmful than traditional cigarettes, by 2017 more than 40 percent of adults held this misguided belief.<sup>18</sup>

Most disturbingly, the change in perception about e-cigarettes' relative harm occurred among those most likely to benefit from using e-cigarettes as a method of cessation. Between 2012 and 2017 the percentage of current smokers who said that e-cigarettes were as or more harmful than cigarettes increased from under 12 percent to nearly 40 percent.<sup>19</sup>

Even as the evidence increasingly demonstrates the reduced risks of e-cigarettes compared to combustible tobacco, the emphasis on their unknown risks by government agencies and public health advocates has led to increased public misinformation. As a result, these well-intentioned efforts have stymied wider adoption of these demonstrably harm-reducing tobacco alternatives by the people who are most in need of such alternatives.

Reports from internationally respected health bodies like the National Academies of Science, Engineering, and Medicine have acknowledged that, based on the available evidence, electronic cigarettes emit significantly fewer harmful and potentially harmful chemicals than traditional cigarettes. According to a recent study, the cancer risk of e-cigarettes is less than 1 percent of that posed by traditional smoking.<sup>20</sup> Given that reality, the FDA should seek to avoid

implementing any policies that might hamper smokers from switching to these demonstrably less harmful products. As the above discussion shows, restricting e-cigarette flavors would do just that.

**Conclusion:** Adult consumers deserve access to a wide array of nicotine-consumption choices. The fear that e-cigarette flavors attract non-smoking adolescents is unsupported by the research literature and should not form the basis for restricting adults' access to e-cigarette flavors. We strongly urge the FDA to reject the exaggerated claims of anti-tobacco advocacy groups and to fulfill its obligation to support tobacco and tobacco-alternative technological innovations by allowing the market to do what decades of public health campaigns have failed to accomplish: provide smokers with satisfying alternatives to fully quit tobacco and greatly reduce tobacco-related harms.

Respectfully,

Michelle Minton  
Senior Fellow  
Competitive Enterprise Institute

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<sup>1</sup> Ann McNeill, Leonie Brose, Robert Calder, Sara Hitchman, Peter Hajek, and Hayden McRobbie, "E-Cigarettes : An Evidence Update," Commissioned by Public Health England, August 28, 2015, <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>.

<sup>2</sup> Andrea S. Gentzke, MeLisa Creamer, Karen A. Cullen, et al., "Vital Signs: Tobacco Product Use Among Middle and High School Students—United States, 2011–2018," *Morbidity and Mortality Weekly Report*, Vol. 68, Issue 6, (February 2019), pp. 157-164, [https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm?s\\_cid=mm6806e1\\_w](https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm?s_cid=mm6806e1_w).

<sup>3</sup> National Youth Tobacco Survey 2007-2018.

<sup>4</sup> Christina Steindl, Eva Jonas, Sandra Sittenthaler, Eva Traut-Mattausch, Jeff Greenberg, "Understanding Psychological Reactance: New Developments and Findings," *Journal of Psychology*, Vol. 223, No. 4, pp. 205-214 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4675534>.

<sup>5</sup> Melanie Wakefield, Yvonne Terry-McElrath, Sheey Emery, et al., "Effect of Televised, Tobacco Company-Funded Smoking Prevention Advertising on Youth Smoking-Related Beliefs, Intentions, and Behavior" *American Journal of Public Health*, Vol. 96, Issue 12 (December 2006), pp. 2154-2160, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1698148>.

<sup>6</sup> Andrea D. Rozema, Marieke Hiemstra, Jolanda J. P. Mathijssen, et al., "Impact of an Outdoor Smoking Ban at Secondary Schools on Cigarettes, E-Cigarettes and Water Pipe Use among Adolescents: An 18-Month Follow-Up," *International Journal of Environmental Research and Public Health*, Vol. 15, No. 2 (February 2018), pp. 205, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5858274>.

<sup>7</sup> Joseph Grandpre, Eusebio M. Alvaro, Michael Burgoon, Claude H. Miller, John R. Hall, "Adolescent Reactance and Anti-Smoking Campaigns: A Theoretical Approach," *Health Communication*, Vol. 15, No. 3, (2003), pp. 349-366, <https://www.ncbi.nlm.nih.gov/pubmed/12788679>.

<sup>8</sup> Pat Warren, "Vaping Prompts Maryland School to Remove Bathroom Doors," CBS Baltimore, April 23, 2018, <https://baltimore.cbslocal.com/2018/04/23/school-removes-bathroom-doors-vaping>.

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- <sup>9</sup> Mari A. Schaefer, “FDA shows ‘real cost’ of vaping with new ad campaign,” *Philadelphia Inquirer*, September 20, 2018 <https://www.philly.com/philly/health/vaping-juul-fda-health-costs-20180920.html>.
- <sup>10</sup> Tobacco Free CA, “Real California teens talk about vaping,” YouTube video, October 25, 2016, <https://www.youtube.com/watch?v=gjYT4YG7jOk>.
- <sup>11</sup> Grandpre, et al., 2003.
- <sup>12</sup> Ibid.
- <sup>13</sup> Saul Shiffman, Mark A. Sembower, Janine L. Pillitteri, Karen K. Gerlach, and Joseph G. Gitchell, “The Impact of Flavor Descriptors on Nonsmoking Teens’ and Adult Smokers’ Interest in Electronic Cigarettes,” *Nicotine & Tobacco Research*, Vol. 17, No. 10, (October 2015), pp. 1255-1262, <https://academic.oup.com/ntr/article-abstract/17/10/1255/1028251?redirectedFrom=fulltext>.
- <sup>14</sup> Niel McLaren, “The Big Survey 2014—Initial Findings Eliquid,” Vaping.com, July 17, 2014, <https://vaping.com/blog/data/big-survey-2014-initial-findings-eliquid>.
- <sup>15</sup> Konstantinos Farsalinos, Giorgio Romagna, Dimitris Tsiapras, Stamatis Kyrzopoulos, Alketa Spyrou, and Vassilis Voudris, “Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey,” *International Journal of Environmental Research and Public Health*, Vol. 10, No. 12 (December 2013), pp. 7272-7282, <https://europepmc.org/abstract/med/24351746>.
- <sup>16</sup> Ibid.
- <sup>17</sup> American Academy of Pediatrics, “Booming Market of Candy-Flavored E-Cigarettes and Cigars Threatens to Hook a New Generation of Kids, New Report Warns,” news release, March 15, 2017, <https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/Booming-Market-of-Candy-Flavored-E-Cigarettes-and-Cigars-Threatens-to-Hook-a-New-Generation-of-Kids,-New-Report-Warns.aspx>.
- <sup>18</sup> Jidong Huang, Bo Feng, Scott R. Weaver, et al., “Changing Perceptions of Harm of e-Cigarette vs Cigarette Use among Adults in 2 U.S. National Surveys From 2012 to 2017,” *Journal of the American Medical Association*, Vol. 2, Issue 3 (March 2019), pp. e191047, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2729471>.
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