

**FDA must use its existing authority to combat the youth e-cigarette use epidemic by preventing addiction now, rather than by seeking to treat it after the fact**

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The number of youth using e-cigarettes and other new vaping products (herein: e-cigarettes) has reversed progress in reducing youth nicotine addiction, and continues to grow. Over the past year, high school students' use of e-cigarettes including pod-based products has increased by 78%, with 1 in 5 high school students reporting current use. Middle school students' use increased by 48%, with 1 in 20 middle school students reporting recent use.<sup>1,2</sup>

FDA's public statements about the growing epidemic of youth e-cigarette use suggest the agency recognizes the enormity of the problem. For example, speaking of the proposed new steps to reduce youth vaping by preventing their access to flavored tobacco products, FDA Commissioner Scott Gottlieb, MD, said:

"Today, I'm pursuing actions aimed at addressing the disturbing trend of youth nicotine use and continuing to advance the historic declines we've achieved in recent years in the rates of combustible cigarette use among kids."

"[A]ny policy accommodation to advance the innovations that could present an alternative to smoking – particularly as it relates to e-cigarettes – cannot, and will not, come at the expense of addicting a generation of children to nicotine through these same delivery vehicles. This simply will not happen. I will take whatever steps I must to prevent this."<sup>3</sup>

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<sup>1</sup> CDC, National Youth Tobacco Survey (NYTS). Cullen KA, Ambrose BK, Gentske AS, Apelberg BJ, Jamal A, King BA. Notes from the field; Use of electronic cigarettes and any tobacco product among middle and high school students – United States, 2011-2018. MMWR Morb Mortal Wkly Rep 2018; 67:1276-1277. DOI: <http://dx.doi.org/10.15585/mmwr.mm6745a5>

<sup>2</sup> Wang TW, Gentzke A, Sharapova S, Cullen KA, Ambrose BK, Jamal A. Tobacco product use among middle and high school students — United States, 2011-2017. MMWR Morb Mortal Wkly Rep. 2018;67(22).

<sup>3</sup>November 15, 2018;<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>

While helping youth who are already addicted to e-cigarettes is a necessary part of any response, it is not sufficient, particularly since ***there are not yet any treatments for nicotine addiction that have been demonstrated to be effective for youth.*** As a result, ***FDA’s immediate and primary focus should be on quickly using its regulatory authority to prevent youth from becoming addicted in the first place.***

In particular, ***FDA should use its current enforcement authority*** to prohibit the sale of any e-cigarette product (including mint, menthol, and tobacco-flavored e-cigarettes and e-liquids) that has not received FDA premarket review and authorization based on demonstrated public health benefits. Further, the FDA should aggressively enforce against unauthorized modified risk and cessation claims; prohibit all flavors in e-cigarettes, including mint and menthol; prohibit Internet sales of e-cigarettes; and prohibit e-cigarette advertising that targets youth.<sup>4</sup>

***FDA should also stop making unsupported statements*** that (1) e-cigarettes are safer than conventional cigarettes (an MTRP claim), and that (2) e-cigarettes help adults quit smoking (a therapeutic claim) unless evidence to support these claims has been submitted and properly vetted. While many e-cigarette companies are making or implying such claims, they violate the law. FDA should not be making statements that, if made by a company, would be illegal. As discussed in detail below, ***these statements by the FDA are making the problem worse by inadvertently promoting youth use of e-cigarettes.***

If FDA’s ultimate goal is to eliminate e-cigarette and other tobacco product use among youth, it must take these immediate steps to prevent youth from initiating tobacco or other nicotine use with e-cigarettes by making them less appealing to youth. The first question posed by FDA in its request for comments acknowledges that “the factors driving e-cigarette use among youth likely differ from those in the adult population.” FDA must take these factors into consideration to achieve regulatory solutions that are evidence-based and most effective.

***The steps outlined above do not require any additional rulemaking and can and should be taken immediately.***

This public comment discusses the following in support of these critical steps that the FDA can and should take immediately:

- the lack of effective pharmacological approaches for youth e-cigarette cessation
- the problems inherent in discussing addiction with youth, including their lack of acknowledgement that they are addicted, and their lack of understanding of what “addiction” actually means
- why it is important for the FDA to stop its unfounded messaging that e-cigarettes, and in particular flavored e-cigarettes, help adults quit smoking cigarettes

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<sup>4</sup>We have submitted another comment that details these regulatory tools which we incorporate by reference. Lemper LK, Halpern-Felsher B, Glantz S. FDA should use its regulatory authority and take immediate steps to tackle the youth e-cigarette epidemic. Docket No. FDA-2018-N-3952.

- the importance of sound regulation that will be instrumental in preventing youth addiction in the first place, including banning all flavors including mint and menthol
- prohibiting Internet sales of e-cigarettes
- prohibiting e-cigarette advertising targeting kids
- removing from the market all e-cigarettes that have not obtained FDA premarket review and authorization
- the importance of education

## 1. There is No Evidence for Using Pharmacological Approaches for Youth E-cigarette Cessation

Currently, there are no FDA-approved pharmacological approaches for youth e-cigarette cessation, including no studies examining the effectiveness of nicotine replacement therapies (NRTs) on reducing e-cigarette use. While there are studies showing that NRTs are effective at reducing adult cigarette smoking,<sup>5</sup> *when used in conjunction with counselling* such as cognitive behavior therapy,<sup>6</sup> there are currently no studies conducted on the effectiveness of NRTs with youth under age 18.

We can also look to the young adult literature for further information. Studies have shown that young adult smokers who try to quit smoking cigarettes are less likely to use evidence-based cessation strategies than their older adult counterparts and more likely to try to quit unassisted.<sup>7,8,9,10,11,12</sup> It is likely that youth would be even less likely to use suggested cessation devices, in part because they do not recognize that they are addicted, as noted below. Further, young adults trying to quit cigarettes used e-cigarettes substantially more than any other

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<sup>5</sup> West R, Zhou X. Is nicotine replacement therapy for smoking cessation effective in the “real world”? Findings from a prospective multinational cohort study. *Thorax*. 2007;62(11):998-1002. doi:10.1136/thx.2007.078758.

<sup>6</sup> Kotz D, Brown J, West R. “Real-world” effectiveness of smoking cessation treatments: a population study. *Addiction*. 2014;109(3):491-499. doi:10.1111/add.12429

<sup>7</sup> Watkins SL, Thrul J, Max W, Ling P. Cold Turkey and Hot Vapes? A national study of young adult cigarette cessation strategies. *Nicotine Tob Res*. 2018;1-9. doi:10.1093/ntr/nty270.

<sup>8</sup> Curry SJ, Sporer AK, Pugach O, Campbell RT, Emery S. Use of tobacco cessation treatments among young adult smokers: 2005 National Health Interview Survey. *Am J Public Health*. 2007;97(8):1464-1469. doi:10.2105/AJPH.2006.103788.

<sup>9</sup> Hughes JR, Cohen B, Callas PW. Treatment seeking for smoking cessation among young adults. *J Subst Abuse Treat*. 2009;37(2):211-213.

<sup>10</sup> McCarthy M, Siahpush M, Shaikh RA, Kessler AS, Tibbits M. Social disparities in unaided quit attempts among daily current and former smokers: Results from the 2010-2011 tobacco use supplement to the current population survey. *Nicotine Tob Res*. 2016;18(8):1705-1710. doi:10.1093/ntr/ntw007.

<sup>11</sup> McCarthy M, Siahpush M, Shaikh RA, Kessler AS, Tibbits M. Social disparities in unaided quit attempts among daily current and former smokers: Results from the 2010-2011 tobacco use supplement to the current population survey. *Nicotine Tob Res*. 2016;18(8):1705-1710. doi:10.1093/ntr/ntw007.

<sup>12</sup> Solberg LI, Asche SE, Boyle R, McCarty MC, Thoele MJ. Smoking and cessation behaviors among young adults of various educational backgrounds. *Am J Public Health*. 2007;97(8):1421-1426. doi:10.2105/AJPH.2006.098491.

cessation therapy<sup>13</sup> despite the fact that population-based studies of actual use show that, overall, smokers who use e-cigarettes are less likely to quit than smokers who do not use e-cigarettes.<sup>14</sup>

Given concerns about providing nicotine to adolescents whose brains are still developing and therefore most susceptible to addiction, use of non-nicotine pharmacological therapy would probably be best. Based on mechanism of action, varenicline is intriguing because it has agonist effects, which relieves withdrawal symptoms, but also has antagonist effects, potentially making nicotine from an e-cigarette less rewarding.<sup>15</sup> Varenicline is, however, meant for heavily addicted users and many youth using e-cigarettes may not meet this standard. Varenicline also may not be as effective a cessation aid for non-cigarette tobacco products. Recent trials suggest mixed effectiveness for varenicline as a cessation for conventional smokeless tobacco.<sup>16</sup> As it stands, any rationale for varenicline use by nicotine addicted adolescent e-cigarette users is largely theoretical and not supported by actual clinical data.

## **2. FDA Must Recognize that Youth Do Not Understand Nicotine Addiction, Nor Do They Acknowledge their Own Addiction**

Studies clearly show that adolescents have a poor understanding of what addiction – and in particular nicotine addiction – means. In a mixed-methods study in which adolescents were surveyed and interviewed about their perceptions and understandings of addiction, the authors found that adolescent participants did not recognize the association between being addicted, the chance of still being a smoker in five years, and the ability to quit. Further, the qualitative data describing how youth conceptualize and understand addiction revealed skepticism and uncertainty about addiction.<sup>17</sup> While adolescents have received the message that tobacco products can be addictive, they are uncertain regarding the definition of addiction and have not recognized that addiction means experiencing difficulty quitting and continuing to smoke longer than expected.

Further, in a study of youth's use of and attitudes towards Juuls, McKelvey, Baiocchi, and Halpern-Felsher found that youth perceive Juuls as less addictive than other e-cigarettes and cigarettes, although they contain equal or greater amounts of nicotine. Further, despite perceiving lower levels of nicotine in these products, and not identifying themselves as addicted,

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<sup>13</sup> Watkins, S. L., Thrul, J., Max, W., & Ling, P. (2018). Cold Turkey and Hot Vapes? A national study of young adult cigarette cessation strategies. *Nicotine & Tobacco Research*.

<sup>14</sup> Kalkhoran S, Glantz SA. E-cigarettes and smoking cessation in real-world and clinical settings: A systematic review and meta-analysis. *Lancet Respir Med* 2016 Feb;4(2):116-28.

<sup>15</sup> Coe JW, Brooks PR, Vetelino MG, Wirtz MC, Arnold EP, Huang J, Sands SB, Davis TI, Lebel LA, Fox CB, Shrikhande A. Varenicline: an  $\alpha 4\beta 2$  nicotinic receptor partial agonist for smoking cessation. *Journal of medicinal chemistry*. 2005 May 19;48(10):3474-7.

<sup>16</sup> Schwartz J, Fadahunsi O, Hingorani R, Mainali NR, Oluwasanjo A, Aryal MR, Donato A. Use of varenicline in smokeless tobacco cessation: a systematic review and meta-analysis. *Nicotine & Tobacco Research*. 2015 Feb 2;18(1):10-6.

<sup>17</sup> Roditis, M, Lee, J., Halpern-Felsher, B. (2015). Adolescent (Mis)Perceptions About Nicotine Addiction: Results From a Mixed-Methods Study. *Health Educ Behav*. 2016 Apr;43(2):156-64. doi: 10.1177/1090198115598985.

youth themselves were showing signs of addiction as measured by the Hooked on Nicotine Checklist.<sup>18</sup>

Taken together, these studies and others show that youth do not fully understand the addictive nature of nicotine, do not recognize the level of nicotine in the various e-cigarette devices, and are therefore more subject to misperceptions and usage of e-cigarettes. ***The FDA therefore needs to take steps to ensure that labels and packaging clearly explain what addiction means in terms that are meaningful to youth.*** For example, the legally mandated<sup>19</sup> warning label shown on a Juul package in Figure 1 will not be fully understood by youth, and can lead to their initiation and usage with this product. Further, the 5.0% strength noted on the package is misleading, as nowhere on the Juul package is it made clear that the 5% is referring to nicotine or what amount of nicotine 5% entails.

### **3. The FDA should prohibit all flavors, including mint and menthol, in all e-cigarette products, not only in pod-style e-cigarettes**

In order to attract young and new users, the tobacco industry adds characterizing flavors like mint, menthol, fruit, and candy to tobacco, often using the same flavorants that are in fruit-flavored candy, and sometimes at higher doses.<sup>20</sup> These flavors appeal to new users by masking the harsh taste of tobacco, and in the case of e-cigarettes, resulting in a more pleasant smell than that found with tobacco alone.

Flavor or “taste” is one of the most common persuasive marketing techniques used to promote food (mostly candy and snacks) to children on TV.<sup>21</sup> Exposure to ads for flavored products is positively associated with youth consumption,<sup>22</sup> and most money spent by youth is on food or beverages, particularly sweets.<sup>23</sup> Research on e-cigarettes is consistent with these findings, concluding: flavors play an important role for online e-cigarette marketing and boosts user



Figure 1. Warning that simply says a product is addictive or contains an addictive chemical will not be understood by youth.

<sup>18</sup>WheelerKC,FletcherKE,WellmanRJ,DifranzaJR.Screeningadolescentsfornicotinedependence:the Hooked On Nicotine Checklist. *J Adolesc Health*. 2004;35(3):225-230. doi:[10.1016/S1054-139X\(03\)00531-7](https://doi.org/10.1016/S1054-139X(03)00531-7)

<sup>19</sup> 21 CFR 1143.3(a)

<sup>20</sup> Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. *N Engl J Med*. 2014;370(23):2250-2252.

<sup>21</sup> Jenkin G, Madhvani N, Signal L, Bowers S. A systematic review of persuasive marketing techniques to promote food to children on television. *Obesity reviews*. 2014;15(4):281-293.

<sup>22</sup> Cairns G, Angus K, Hastings G, Caraher M. Systematic reviews of the evidence on the nature, extent and effects of food marketing to children. A retrospective summary. *Appetite*. 2013;62:209-215.

<sup>23</sup> Kraak VI, Gootman JA, McGinnis JM. *Food marketing to children and youth: Threat or opportunity?* National Academies Press; 2006.

interaction and positive emotion;<sup>24</sup> flavored (vs. unflavored) e-cigarette ads elicit greater appeal and interest in buying and trying e-cigarettes; and the appeal of ads marketing flavors is linked to rapid and persistent adoption of e-cigarettes among youth.<sup>25</sup>

### Youth are Attracted to Flavored Tobacco Products

The vast majority of youth in the US who try tobacco initiate with flavored tobacco products, including 81% of e-cigarette ever users, 65% of cigar ever users, and 50% of cigarette ever smokers.<sup>26</sup> Adolescents are more likely to report interest in trying an e-cigarette from a friend if it is menthol-, candy-, or fruit-flavored than if unflavored.<sup>27</sup> Flavor preferences are associated with higher e-cigarette use among adolescents.<sup>28</sup> Most adolescent current tobacco users cite flavors as a reason for use (including 81% for past 30-day e-cigarette users; 74% for past 30-day cigar users).<sup>10</sup> Three quarters of adolescent and young adult flavored tobacco product users reported they would quit if flavors were unavailable.<sup>29</sup>

Youth and young adult tobacco users are more likely than older adult tobacco users to use flavored products, including menthol cigarettes,<sup>30</sup> flavored smokeless tobacco,<sup>31</sup> and flavored cigars.<sup>32</sup> Young smokers (12-17 years of age) are three times as likely to smoke menthol cigarettes than smokers 35 years and older.<sup>33</sup> Research among approximately 4000 school-going youth shows that for 98% of them, first e-cigarettes used were flavored to taste like something other than tobacco, compared to 44.1% of older adults nationwide. Fruit and candy flavors predominated for all groups; and, for youth, flavors were an especially salient reason to use e-

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<sup>24</sup> Liang Y, Zheng X, Zeng DD, Zhou X. Impact of flavor on electronic cigarette marketing in social media. 2015;278-283.

<sup>25</sup> Vasiljevic M, Petrescu DC, Marteau TM. Impact of advertisements promoting candy-like flavoured e-cigarettes on appeal of tobacco smoking among children: An experimental study. *Tob Control*. 2016;25(e2):e107-e112.

<sup>26</sup> Ambrose B, Day H, Rostron B, et al. Flavored tobacco product use among us youth aged 12-17 years, 2013-2014. *J Am Med Assoc*. 2015;314(17):1-3. doi:10.1001/jama.2015.13802.

<sup>27</sup> Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. *Tob Control*. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.

<sup>28</sup> Morean ME, Butler ER, Bold KW, Kong G, Camenga DR, Cavallo DA, Simon P, O'Malley SS, Krishnan-Sarin S. Preferring more e-cigarette flavors is associated with e-cigarette use frequency among adolescents but not adults. *PloS one*. 2018 Jan 4;13(1):e0189015

<sup>29</sup> Loukas A, Jackson CD, Marti CN, Perry CL. Flavored tobacco product use among youth and young adults: What if flavors didn't exist? *Tob Regul Sci*. 2017;3(2):168-173.

<sup>30</sup> Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control*. 2016;25(Suppl 2):ii14-ii20. doi:10.1136/tobaccocontrol-2016-053329.

<sup>31</sup> Oliver AJ, Jensen JA, Vogel RI, Anderson AJ, Hatsukami DK. Flavored and nonflavored smokeless tobacco products: Rate, pattern of use, and effects. *Nicotine Tob Res*. 2013;15(1):88-92. doi:10.1093/ntr/nts093.

<sup>32</sup> Delnevo CD, Giovenco DP, Ambrose BK, Corey CG, Conway KP. Preference for flavoured cigar brands among youth, young adults and adults in the USA. *Tob Control*. 2014;24(4):389-394. doi:10.1136/tobaccocontrol-2013-051408.

<sup>33</sup> Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control*. 2016:1-7. doi:10.1136/tobaccocontrol-2016-053329.

cigarettes.<sup>34</sup> Finally, a recent study showed that only 1.5% of adolescent and young adult e-cigarette users used tobacco flavored-Juuls and .9% used tobacco-flavored other e-cigarette products. Instead, the majority used fruit or dessert flavors (33% for Juul users and 64% for other e-cigarette users) and 27% of Juul users and 12% of other e-cigarette users used mint or menthol flavors.<sup>35</sup>

## Youth Believe Ads for Flavored E-cigarettes Target Them

Using flavors in e-cigarettes is a key marketing strategy to reach and recruit youth. In 2014, over 7,700 flavors for e-cigarettes were available, with greater than 240 new flavors being added per month.<sup>36</sup> What is most important is that youth believe flavored e-cigarette ads target them.

In a study<sup>37</sup> of California youth and young adults (mean age 17.5, SD = 1.7), participants were asked to indicate whether eight different ads for flavored e-cigarette products (Figure 2), randomly displayed, target someone younger than them, their age, someone a little older, or someone much older like their parents. Participants felt the ads were for someone just a little older than them (age 18 – 26; not for someone much older). More than half of participants felt ads for *cherry*, *vanilla cupcake*, *caramel*, and *smoothie* flavors were for someone their age. Ads were also seen as targeting an audience younger than them. These findings suggest that while the tobacco industry argues that flavored tobacco products, including sweet and fruit flavored products, are not meant to attract youth, youth see them as aimed at them. ***These and similar findings indicate that the FDA should immediately stop exercising enforcement discretion that allows these products to remain on the market without FDA premarket review. FDA should instead remove from the market all e-cigarettes that have not submitted premarket approval applications and have not obtained FDA authorization based on a demonstration that these flavors are good for the public health.***<sup>38</sup>

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<sup>34</sup> Harrell MB, Weaver SR, Loukas A, Creamer M, Marti CN, Jackson CD, Heath JW, Nayak P, Perry CL, Pechacek TF, Eriksen MP. Flavored e-cigarette use: Characterizing youth, young adult, and adult users. Preventive medicine reports. 2017 Mar 1;5:33-40

<sup>35</sup> McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. JAMA Network Open, 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

<sup>36</sup> Zhu SH, Sun JY, Bonnie E, Cummins SE, Gamst A, Yin L, Lee M. Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. Tobacco control. 2014 Jul 1;23(suppl 3):iii3-9

<sup>37</sup> McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Youth Say Ads for Flavored E-liquids are for Them. Addictive Behaviors, in press.

<sup>38</sup> Had the premarket review and authorization provisions of the Tobacco Control Act been enforced as intended, all e-cigarettes would have been removed from the market by the effective date of the Deeming Rule (i.e., August 8, 2016). Instead, the FDA submitted to the OMB a proposed Deeming Rule that included a compliance or grace period of 12 months from the date a final rule is promulgated. However, OMB doubled the length of the compliance period to twenty-four months from the date a final rule is promulgated, i.e., to August 8, 2018. We submitted public comments to the Deeming Rule docket opposing that extension.

<https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA-comment-2014-06-06%20Dutra%20Glantz%20cost%20of%202-year%20compliance%20period-%201jy-8cis-skj5.pdf>  
<https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA%20comment-Substantial%20Equiv-%201jy-8cos-3k4o.pdf>





Figure 2. Flavored e-cigarette ads shown to adolescents and young adults to elicit perceptions of the age of audience being targeted for each ad.

## FDA Should Use its Regulatory Authority to Ban All Flavors in E-cigarettes, Including Mint and Menthol

Over the longer term, FDA should use its authority under section 907 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) to prohibit *all* flavors in electronic cigarettes, *including mint and menthol*.

On November 15, 2018, FDA announced<sup>39</sup> a proposed policy that would restrict youth access to flavored e-cigarettes and e-liquids, but the proposed policy specifically excluded mint, menthol, and tobacco-flavored e-cigarette products. Specifically, FDA Commissioner Gotlieb said:

“These changes will not include mint- and menthol-flavored ENDS. This reflects a careful balancing of public health considerations. Among all ENDS users, data suggests that mint- and menthol-flavored ENDS are more popular with adults than with kids. One nationally representative survey showed that, among ENDS users aged 12-17 years old, 20 percent used mint- and menthol-flavored ENDS while, among adult ENDS users, 41 percent used mint- and menthol-flavored ENDS. Any approach to mint- and menthol-flavored ENDS must acknowledge the possibility that the availability of these flavors in ENDS may be important to adult smokers seeking to transition away from cigarettes. Moreover, I recognize that combustible cigarettes are still sold in menthol flavor, including in convenience stores. I don’t want to create a situation where the combustible products have features that make them more attractive than the non-combustible products. Or a situation where those who currently use menthol-flavored cigarettes might

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In August 2017, FDA announced that it would use its discretion and further extend the compliance date for e-cigarettes to August 8, 2022.  
<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf>

<sup>39</sup> FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018.  
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>



find it less attractive to switch completely to an e-cigarette. This is a difficult compromise that I'm trying to strike, recognizing the public health risk posed by cigarettes still being available in menthol flavor.”<sup>40</sup>

This proposed policy is inadequate.

Data from the most recent National Youth Tobacco Survey released on that same day show that “Among high school students, during 2017–2018, current use of any flavored e-cigarettes increased among current e-cigarette users (from 60.9% to 67.8%,  $p = 0.02$ ); current use of menthol- or mint-flavored e-cigarettes increased among all current e-cigarette users (from 42.3% to 51.2%,  $p = 0.04$ ) and current exclusive e-cigarette users (from 21.4% to 38.1%,  $p = 0.002$ ).”<sup>41</sup> Finally, there is compelling recent evidence showing that youth use mint and menthol e-cigarettes. In a recent study published in JAMA Online Network, the authors found that almost 27% of youth in their study used mint or menthol flavored Juuls, and 12% used mint or menthol other e-cigarette styles.<sup>42</sup> McKelvey and colleagues also showed that mint and menthol are used widely by youth, as noted earlier.<sup>43</sup>

Under FDA's proposal, mint and menthol flavored e-cigarettes and e-liquids would still be widely available to youth, despite these data showing that the majority of high school students who use e-cigarettes use mint- or menthol-flavored products.

**There is no scientific basis to keep mint and menthol flavored e-cigarettes and e-liquids on the market.**

To successfully tackle youth e-cigarette use, FDA must ensure that all flavored e-cigarettes are prohibited. FDA should immediately propose, finalize, and enforce regulations banning all flavors in all products as part of its overall effort to protect youth.

Despite historic tobacco industry claims that menthol simply adds flavor, tobacco industry documents have revealed that the industry manipulates menthol levels to control a cigarette's intensity to cater to new and long-term smokers.<sup>44</sup>

Menthol and other characterizing flavors appeal to new users by masking the harsh taste of tobacco, and bright packaging associates flavored tobacco products with candy and other

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<sup>40</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>

<sup>41</sup> CDC, National Youth Tobacco Survey (NYTS). Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018*. MMWR Morb Mortal Wkly Rep 2018;67:1276–1277. DOI: <http://dx.doi.org/10.15585/mmwr.mm6745a5>

<sup>42</sup> McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. JAMA Network Open, 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

<sup>43</sup> McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. JAMA Network Open, 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

<sup>44</sup> Kreslake JM, Wayne GF, Alpert HR, Koh HK, Connolly GN. Tobacco industry control of menthol in cigarettes and targeting of adolescents and young adults. Am J Public Health. 2008;98(9):1685-1692. doi:10.2105/AJPH.2007.125542.

flavors.<sup>45,46</sup> Additionally, tobacco products with a characterizing flavor including fruit-flavored e-cigarettes<sup>47</sup> and menthol cigarettes<sup>14</sup> are perceived to be less harmful than unflavored or tobacco-flavored products. In addition, there is some evidence that menthol cigarettes are harder to quit.<sup>48,49</sup>

***Mint and menthol target vulnerable youth.*** In the general population, differences in menthol use exist across race, gender, age, and sexual orientation. Rates of use of menthol flavored tobacco products are often higher in marginalized populations. African American smokers consistently have the highest menthol use rate.<sup>50</sup> Menthol use is also higher among female smokers;<sup>27</sup> Lesbian, Gay, and Bisexual smokers<sup>51</sup> (although see Rath et al 2013<sup>52</sup>); people with severe psychological distress; people with fewer years of education and lower income; and those who are unmarried or uninsured.<sup>53</sup>

The tobacco industry cultivated menthol use among African Americans by manipulating social factors of the civil rights era,<sup>54</sup> advertising menthol brand cigarettes, little cigars, and cigarillos in African American media and retail settings in African American neighborhoods,<sup>55,56</sup> and donating to African American leadership organizations.<sup>57</sup> The strategy has been so successful

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<sup>45</sup> Yerger VB. Menthol's potential effects on nicotine dependence: a tobacco industry perspective. *Tob Control*. 2011;20(Suppl 2):ii29-ii36. doi:10.1136/tc.2010.041970.

<sup>46</sup> Lewis MJ, Wackowski O. Dealing with an innovative industry: A look at flavored cigarettes promoted by mainstream brands. *Am J Public Health*. 2006;96(2):244-251. doi:10.2105/AJPH.2004.061200.

<sup>47</sup> Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. *Tob Control*. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.

<sup>48</sup> Pletcher MJ, Hulle BJ, Houston T, Kiefe CI, Benowitz N, Sidney S. Menthol cigarettes, smoking cessation, atherosclerosis, and pulmonary function. 2006;166.

<sup>49</sup> Trinidad DR, Pérez-Stable EJ, Messer K, White MM, Pierce JP. Menthol cigarettes and smoking cessation among racial/ethnic groups in the United States. *Addiction*. 2010;105(SUPPL.1):84-94. doi:10.1111/j.1360-0443.2010.03187.x.

<sup>50</sup> Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control*. 2016:1-7. doi:10.1136/tobaccocontrol-2016-053329.

<sup>51</sup> Fallin A, Goodin AJ, King BA. Menthol cigarette smoking among lesbian, gay, bisexual, and transgender adults. *Am J Prev Med*. 2015;48(1):93-97. doi:10.1016/j.amepre.2014.07.044.

<sup>52</sup> Rath JM, Villanti AC, Rubenstein RA, Vallone DM. Tobacco use by sexual identity among young adults in the united states. *Nicotine Tob Res*. 2013;15(11):1822-1831. doi:10.1093/ntr/ntt062.

<sup>53</sup> Hickman NJ, Delucchi KL, Prochaska JJ. Menthol use among smokers with psychological distress: findings from the 2008 and 2009 National Survey on Drug Use and Health. *Tob Control*. 2014;23(1):7-13. doi:10.1136/tobaccocontrol-2012-050479.

<sup>54</sup> Gardiner PS. The African Americanization of menthol cigarette use in the United States. *Nicotine Tob Res*. 2004;6 Suppl 1:S55-65. doi:10.1080/14622200310001649478.

<sup>55</sup> Henriksen L, Schleicher NC, Dauphinee AL, Fortmann SP. Targeted advertising, promotion, and price for menthol cigarettes in California high school neighborhoods. *Nicotine Tob Res*. 2012;14(1):116-121. doi:10.1093/ntr/ntr122.

<sup>56</sup> Kostygina G, Glantz SA, Ling PM. Tobacco industry use of flavours to recruit new users of little cigars and cigarillos. *Tob Control*. 2014:tobaccocontrol-2014-051830-. doi:10.1136/tobaccocontrol-2014-051830.

<sup>57</sup> Yerger VB, Malone RE. African American leadership groups: Smoking with the enemy. *Tob Control*. 2002;11(4):336-345. doi:10.1136/tc.11.4.336.

that even by 6<sup>th</sup> grade, African American youth were three times more likely to recognize menthol brands than their peers.<sup>58</sup>

FDA had stated in its Deeming Rule submitted to the Obama Office of Management and Budget (OMB) that menthol products would be treated the same as other flavored products, and therefore all newly deemed menthol products would have been ordered off the market by November 6, 2016. FDA presented overwhelming evidence, supported by comments it received on the then-proposed deeming rule, that menthol, as well as candy and fruit-flavored tobacco products attract youth to tobacco use and deter quitting. In particular, FDA presented evidence in the draft submitted to the Obama OMB demonstrating the impact of menthol and other flavors in enticing African Americans to begin and continue smoking:

“FDA expects that the tobacco flavor in a tobacco product need not be naturally inherent to the product in order for a manufacturer to fall within the compliance policy described here, but rather may result from the addition of ingredients or other measures by the manufacturer to result in the presence of tobacco as a characterizing flavor. However, menthol flavored products will be treated the same as products with characterizing flavors other than tobacco for the purpose of this policy, because when it is used as a characterizing flavor, menthol has a similar impact on a product’s appeal to youth and young adults as such other characterizing flavors. We note that newly-deemed flavored tobacco products that are not grandfathered may still need to address the public health implications of any added flavors, including tobacco flavor, in their pre-market review submissions.”<sup>59</sup>

***Taken together, these data clearly show that youth do use mint and menthol flavors, that such flavorants are purposely added to attract both users and non-users, and that mint and menthol attract youth. As such, a ban on flavored e-cigarette products must include mint and menthol.***

### **The Evidence that Flavors Attract Youth is Strong**

As discussed above, the evidence that flavors attract youth is very strong and consistent. In contrast, the evidence to the contrary is limited to industry-funded research that has an obvious conflict of interest. Shiffman et al.<sup>60</sup> reported the results of an online survey in which they concluded that “interest in e-cigarettes is very low among nonsmoking teens and is not affected by flavor descriptors.” This conclusion is unlikely to be reliable because it is based on responses to a single question on interest in flavors that makes the results likely affected by floor (and

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<sup>58</sup> Dauphinee AL, Doxey JR, Schleicher NC, Fortmann SP, Henriksen L. Racial differences in cigarette brand recognition and impact on youth smoking. *BMC Public Health*. 2013;13(1):170. doi:10.1186/1471-2458-13-170.

<sup>59</sup> TAB B 2014-850 Deeming Final Rule Redline Changes, p.169. Available at: <https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>

<sup>60</sup> Shiffman S, Sembower MA, Pillitteri JL, Gerlach KK, Gitchell JG. The impact of flavor descriptors on nonsmoking teens’ and adult smokers’ interest in electronic cigarettes. *Nicotine Tob Res* 2015:ntu333. doi: 10.1093/ntr/ntu333

ceiling) effects.<sup>61,62</sup> This paper was funded by the NJOY e-cigarette company and whose authors all work for Pinney Associates on projects with Reynolds American Inc. on smoking cessation and reduced risk tobacco products.<sup>63</sup> The paper suffers from serious methodological problems that biased the results against finding an effect of flavors. Contrary to Shiffman et al.'s findings, the impact of flavor descriptors on nonsmoking teens' and adult smokers' interest in e-cigarettes is not a reliable estimate of the effects of e-cigarette flavors on product desirability.

One of the largest problems with the findings from Shiffman et al. was the measures used. Floor and ceiling effects occur when a measuring instrument is not sensitive enough to detect the real differences between participants when their answers are clumped at the low or high end of the possible range of values. An example of a floor effect would be testing mathematical knowledge using a problem that is so difficult that no one can solve it; thus, it will not reveal the true differences in mathematical knowledge. Shiffman et al. found almost no interest in any flavors of electronic cigarettes among teenagers who have never tried tobacco products (including e-cigarettes) and very low interest among adult smokers based on responses to a single question (albeit about 24 different flavors/products): "How interested would you be in using a [flavor] [product]?" The problem with just using a single question is that most people (especially those who are not yet tobacco users) are not interested in using a product even though they might be interested in trying it or using it in a specific situation, thus resulting in a floor effect.

To avoid the problem of a single question not measuring the variable of interest, surveys typically use more than one question to assess smoking behavior and intentions. For example, openness to smoking (or interest in smoking) is typically measured by at least two questions in most large surveys, such as the following questions from the National Youth Tobacco Survey:<sup>64</sup>

"Do you think you will smoke a cigarette anytime during the next year? If one of your best friends offered you a cigarette, would you smoke it?"

As a result, Shiffman et al.'s findings of limited interest in flavors, especially among youth, is likely to be the result of an insensitive measurement method rather than a real effect.

A study of smokers' interest in smokeless tobacco illustrates the importance of how the question is worded.<sup>65</sup> Smokers reported very low interest in smokeless tobacco products (mean 1.5 on a 1-9 scale) when asked about use in general. However, when they were asked about smokeless tobacco use in specific situations, such as "How interested would you be in using this product when in a smokefree environment?" (mean=3.2) or for a specific reason, such as "to reduce health risk," they reported greater interest (mean interest=4.2).

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<sup>61</sup> Martin P, Bateson PPG. *Measuring behaviour: An introductory guide*: Cambridge University Press; 1993.

<sup>62</sup> Newman AB, Cauley JA. *The epidemiology of aging*: Springer; 2012.

<sup>63</sup> Pinney Associates. Tobacco harm reduction. <http://www.pinneyassociates.com/our-practices/tobacco-harm-reduction/>

<sup>64</sup> Centers for Disease Control and Prevention. National Youth Tobacco Survey (NYTS).

Retrieved January 15, 2015 from [http://www.cdc.gov/tobacco/data\\_statistics/surveys/nyts/index.htm](http://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm).

<sup>65</sup> Popova L, Ling P. Alternative tobacco product use and smoking cessation: A national study. *Am J Pub Health*. 2013;103:923-930. doi: 10.2105/AJPH.2012.3010

In contrast to the hypothetical interest Shiffman et al. assessed, real world behavior indicates that while under 10% of the of adults who ever tried e-cigarettes reported that they tried them because of “appealing flavors,”<sup>66</sup> 43.8% of youth listed “good flavors” as the reason they tried e-cigarettes.<sup>67</sup>

There are also serious concerns about the ethics of the study. The authors state that the work was “exempt” from human subjects because they were using de-identified data collected by a third-party internet survey firm. While subject confidentiality is certainly an issue, so is the fact that Shiffman et al. were subjecting youth (as well as adults) to stimuli that could increase the respondents’ likelihood to try an e-cigarette, thereby possibly introducing them to nicotine addiction. There is no acknowledgement of this risk to the subjects or steps taken after the survey was completed to mitigate these risks. Further, there is no discussion that informed consent from the minors’ parents or the adults participating in the study was not obtained. The Shiffman study also suffers from poor quality because it fails to report or describe any of these issues as limitations. Such studies typically include anti-tobacco education at the end to try and blunt the effect of any pro-tobacco or pro-e-cigarette effects of collecting the data. Finally, even studies conducted using a third-party and with data collected using Internet-based surveys usually have some form of IRB approval and consent process.

***For these reasons, the FDA should not rely on the results in Shiffman et al.’s paper to dismiss the overwhelming evidence that flavors attract youth to e-cigarette use.***

#### **4. FDA’s Messaging that E-cigarettes are Good for Adults Has The Unintended Consequence of Attracting Kids**

FDA has issued a variety of statements characterizing e-cigarettes as less harmful nicotine delivery devices. These statements may be misinterpreted by youth to suggest that youth should use e-cigarettes to help them quit smoking, or that e-cigarettes are generally safe for youth to use.

For example, on March 15, 2018, FDA Commissioner Scott Gottlieb said, “... to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and ***less harmful sources.***”<sup>68</sup> On November 15, 2018, Dr. Gottlieb said, “We must recognize the potential for innovative, ***less harmful products*** that can efficiently deliver satisfying levels of nicotine to adults who want them.”<sup>69</sup>

The claims that e-cigarettes are “less harmful” nicotine delivery devices have not been substantiated. In fact, as discussed above, if e-cigarette companies made these exact statements,

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<sup>66</sup> Pepper JK, Ribisl KM, Emery SL, Brewer NT. Reasons for starting and stopping electronic cigarette use. *Int J Environ Res Pub Health* 2014;11(10):10345-10361. doi: 10.3390/ijerph111010345

<sup>67</sup> Kong G, Morean ME, Cavallo DA, Camenga DR, Krishnan-Sarin S. Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults. *Nicotine Tob Res* 2014;ntu257. doi: 10.1093/ntr/ntu257

<sup>68</sup> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm601039.htm>

<sup>69</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>

they would be illegal modified risk claims because they have not been proven with rigorous scientific evidence.

***FDA should not assume that e-cigarettes help adult smokers quit***

Before discussing the evidence related to FDA's presumption that flavorings help adult tobacco smokers quit smoking combustible tobacco products, it is important to emphasize that, while some smokers have successfully quit smoking using e-cigarettes (notably daily users of high nicotine delivery systems), most smokers who use e-cigarettes are *less* not more likely to quit smoking. A meta-analysis of existing studies reports that the odds of quitting cigarettes are significantly reduced (OR 0.77, 95% CI 0.06-0.99) among smokers who use e-cigarettes compared to smokers who do not use e-cigarettes.<sup>70</sup> ***In other words, the overall effect of e-cigarette use is to depress smoking cessation, and thus flavored e-cigarettes do not increase likelihood of cigarette cessation.***

A recent randomized control trial<sup>71</sup> randomized adult cigarette smokers to either nicotine replacement therapy or second-generation e-cigarettes, both coupled with behavioral support, to determine which product best helped adults quit smoking. They did find that while neither NRTs or the e-cigarettes helped the majority of adult smokers quit, the e-cigarettes were more effective overall, compared to the NRTs. Overall, the results suggest that e-cigarettes, ***used as part of a structured cessation program along with intensive counseling***, could be effective at reducing cigarette use among adults already seeking or interested in cessation.

***These recent findings argue that e-cigarettes should be used only in structured medically supervised environments and only through a prescription.*** This would keep e-cigarettes out of the hands of youth and ensure that only adult smokers are using the products, and are doing so under a providers' care. As such, the FDA should require that e-cigarette companies apply to FDA's Center for Drug Evaluation and Research to have them approved as cessation devices. Importantly, this study does not suggest that e-cigarettes are effective at helping all adult smokers quit smoking, nor does it support having e-cigarettes available on the mass market.

***The FDA must stop saying that flavors help adults quit smoking cigarettes until there has been a formal regulatory decision to support this claim***

FDA notes the existence of preliminary data that some adults may use flavored noncombusted tobacco products (e.g., flavored e-cigarettes) to transition away from combusted tobacco, and

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<sup>70</sup> Glantz S. While several studies have been published showing some e-cig users quit more, the overall picture remains negative. <https://tobacco.ucsf.edu/while-several-studies-have-been-published-showing-some-e-cig-users-quit-more-overall-picture-remains-negative> April 9, 2018; Kalkhoran S, Glantz SA. E-cigarettes and smoking cessation in real-world and clinical settings: A systematic review and meta-analysis. *Lancet Respir Med* 2016 Feb;4(2):116-28. The 2018 analysis updates the Kalkhoran, Glantz meta-analysis published in 2016, which is updated every time a new study is published. The conclusion that, overall, e-cigarettes depress quitting has remained stable.

<sup>71</sup> Hajek, P, Phillips-Waller, A., Przulj, D., Pesola, F., Myers Smith, K., Bisal, N., Li, J, Parrott, S., Sasieni, P., Dawkins, L., Ross, L., Goniewicz, M., Wu, Q, and McRobbie, H. A randomized trial of e-cigarettes versus nicotine replacement therapy. *NEJM*, January 29, 2019

believes that “under a properly regulated framework that protects youth,”<sup>72</sup> flavors may help some currently addicted adult cigarette smokers switch to non-combustible forms of tobacco products.

In a nationally-representative sample of US tobacco users, Smith and colleagues found that among current users of non-cigarette tobacco products, those who reported using a flavored tobacco product were less likely to have made a past-year quit attempt than those who used unflavored tobacco.<sup>73</sup> Tackett et al.<sup>74</sup> conducted a cross-sectional study of a convenience sample of 215 adult e-cigarette users recruited in vape shops in “a large metropolitan city in the Midwestern United States” in 2013. They found that most customers (86%) started using e-cigarettes as an aid to stopping smoking. While most started with tobacco flavored e-liquids, the authors found that those using non-tobacco and non-menthol flavored e-liquids (fruity, coffee, candy, etc.) were significantly more likely to have stopped smoking cigarettes (OR 2.95, 95% CI 1.04-8.40) compared to e-cigarette users who used tobacco or menthol flavored e-liquids. Strengths of this study are that it observed the relationship between smoking behavior and flavors, and that most participants had their smoking status verified with exhaled CO. Weaknesses are that the study was cross-sectional and that there was no control group of smokers who did not use e-cigarettes. In addition, the authors note that “specialty vapor stores may be serving individuals with vaping characteristics distinct from those purchasing their products from convenience stores, gas stations, or online.”

A PubMed search using “(e-cigarette or ENDS) and flavor and (quit or cessation)” conducted on May 1, 2018 identified 32 papers. Only two included evidence on the effect of flavors on adult cigarette cessation. Chen<sup>75</sup> found that young adults (age 18-34) in Waves 1 and 2 of the Population Assessment of Tobacco and Health (PATH) Study who used e-cigarette flavors (sweet and fruity or tobacco and menthol/mint) were more likely to have reduced or stopped smoking cigarettes. In particular, e-cigarette users with one (AOR = 2.5,  $p < 0.001$ ) and multiple nontobacco or menthol flavors (AOR = 3.0,  $p < 0.001$ ) were more likely to have reduced or quit smoking over the past year compared to non-e-cigarette users. (It is not clear how “smoking reduction” was defined.) While the longitudinal nature of this study is a strength, the failure to distinguish between reduction of number of cigarettes smoked and smoking cessation is a serious limitation.

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<sup>72</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm601690.htm>

<sup>73</sup> Smith DM, Bansal-Travers M, Huang J, Barker D, Hyland AJ, Chaloupka F. Association between use of flavoured tobacco products and quit behaviours: findings from a cross-sectional survey of US adult tobacco users. *Tob Control*. 2016 Nov;25(Suppl 2):ii73-ii80.

<sup>74</sup> Tackett AP, Lechner WV, Meier E, Grant DM, Driskill LM, Tahirkheli NN, Wagener TL. Biochemically verified smoking cessation and vaping beliefs among vape store customers. *Addiction*. 2015 May;110(5):868-74. doi: 10.1111/add.12878

<sup>75</sup> Chen J. Flavored E-cigarette Use and Cigarette Smoking Reduction and Cessation-A Large National Study among Young Adult Smokers. *Subst Use Misuse*. 2018 Apr 6:1-15. doi: 10.1080/10826084.2018.1455704. [Epub ahead of print]



Smith et al.<sup>76</sup> reported results of a nationally representative, telephone-based survey completed in 2012 by 1443 US adult tobacco users asked about use of 9 tobacco products: cigarettes, e-cigarettes, cigars, cigarillos, little filtered cigars, pipes, hookah, smokeless tobacco and snus. They found that first use of a flavored tobacco product was associated with current flavored tobacco use and polytobacco use. Users of flavored non-cigarette products were less likely to have made a cigarette quit attempt than those who did not use flavored non-cigarette products (OR 0.45 95% CI 0.30-0.67), and were more likely to be current cigarette smokers (OR 1.55, 95% CI 1.08-2.22) than people who used non-flavored tobacco products (including cigarettes). Thus, this cross-sectional study shows that ***the presence of flavors was associated with less cigarette cessation.***

The FDA noted in the version of its Deeming rule submitted to the Obama OMB<sup>77</sup> and posted in May 2016 that flavored tobacco products have the potential to lower barriers to nicotine addiction for youth and young adults. At page 170, FDA stated, “Flavoring also can make these products easier to use and increases their appeal among new users, most notably among young people (Ref. 9, Carpenter; Ref. 10, Cummings; Ref. 11, Manning).”<sup>78</sup>

As noted above, the OMB deleted the provisions ending the use of menthol and other flavors from the final Deeming Rule. ***The FDA’s conclusions were correct then and remain correct now. Precisely the same logic and even more scientific evidence should be used today to advance a rule eliminating menthol and other flavors from all tobacco products, except in cases where a manufacturer makes a good case that using a specific flavor would promote public health.***

## **5) All forms of E-cigarettes Must be Regulated.**

If only pod-style e-cigarettes are regulated, kids who currently use pods might switch to tanks and other kinds of e-cigarettes. Figure 3, which shows rates of youth use of cigarettes, e-cigarettes (excluding Juul), and Juuls, separately and in combination, clearly shows that youth who use Juul style pod-based e-cigarettes also use other forms of e-cigarettes.<sup>79</sup>

Other studies also demonstrate the range of e-cigarette products used. In a study using eight local and national datasets, Barrington-Trimis and colleagues showed that among adolescent and

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<sup>76</sup> Smith DM, Bansal-Travers M, Huang J, Barker D, Hyland AJ, Chaloupka F. Association between use of flavoured tobacco products and quit behaviours: findings from a cross-sectional survey of US adult tobacco users. *Tob Control*. 2016 Nov;25(Suppl 2):ii73-ii80. doi: 10.1136/tobaccocontrol-2016-053313. Epub 2016 Oct 5.

<sup>77</sup> TAB B 2014-850 Deeming Final Rule Redline Changes, pp. 167-183. Available at: <https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>

<sup>78</sup> TAB B 2014-850 Deeming Final Rule Redline Changes, p. 170. Available at: <https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>

<sup>79</sup> McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents’ and young adults’ use and perceptions of pod-based electronic cigarettes. *JAMA Network Open*, 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

young adult users of e-cigarettes, use of the disposable or cigalike devices was rare. Instead, most youth used later generation device such as mods and tanks.<sup>80</sup>

## 6) FDA Should Restrict Marketing that Appeals to Kids.

The FDA must restrict ads that obviously target youth, and must address social media forms of advertising. As was done with respect to combustible cigarettes,<sup>82</sup> the FDA should ban all forms of e-cigarette ads, including those on television, radio, print, the Internet, and social media, that can in any way entice youth. This includes banning ads for flavored e-cigarette products,<sup>83</sup> ads that use youthful images and colors, and ads that use models who appear to be under the legal age of tobacco purchase (age 21 to be safe).

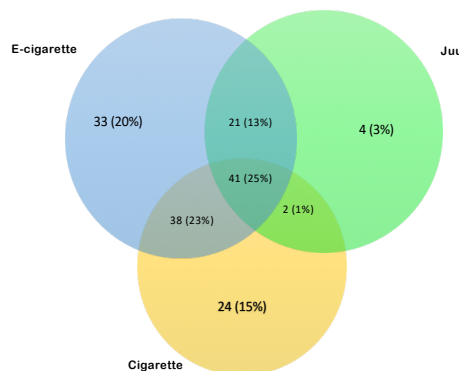


Figure 3. Adolescents' and young adults' use of e-cigarettes, Juuls, and cigarettes.<sup>81</sup>

The FDA should also ban the use of “influencers,” or people who are paid to blog or post on social media or otherwise influence use of a product.<sup>84</sup>

In a recent study of polyuser young adults, it was found that showing younger models (vs. older adults) in e-cigarette ad was a definite cue for greater identification and liking the ad. Restricting showing youthful models and activities in the ad on channels often used by youth (including social media) needs to be considered.<sup>85</sup>

## 7) The FDA Should Regulate and Ban Sales of E-cigarettes on the Internet

<sup>80</sup> Barrington-Trimis, J., Gibson, LA., Halpern-Felsher, B., Harrell, M., Kong, G., Krishnan-Sarin, S., Leventhal, AM., Loukas, A., McConnell, R., Weaver, SR. Type of E-Cigarette Device Used Among Adolescents and Young Adults: Findings From a Pooled Analysis of Eight Studies of 2166 Vapers. *Nicotine and Tobacco Research*, 2018; 271-274.

<sup>81</sup> McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. *JAMA Network Open*, 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

<sup>82</sup> Federal Cigarette Labeling and Advertising Act, <https://www.govinfo.gov/content/pkg/USCODE-2008-title15/html/USCODE-2008-title15-chap36.htm>; Master Settlement Agreement, <https://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf>

<sup>83</sup> McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Youth Say Ads for Flavored E-liquids are for Them. *Addictive Behaviors*, in press.

<sup>84</sup> <https://www.cnn.com/2018/12/17/health/juul-social-media-influencers/index.html>

<sup>85</sup> Kim, M., Rosen, S., Jordan, J., Ling, P. (2017) Recognizing Peer Crowd-Based Targeting in E-Cigarette Advertisements: Interviews with Poly-Tobacco Users. Annual Conference of International Communication Association. Prague, Czech Republic.

FDA announced in November 2018<sup>86</sup> that it would propose a policy requiring that certain flavored e-cigarettes and e-liquids could be sold only in age-restricted in-person locations. ***Notably, mint, menthol, and tobacco-flavored e-cigarettes and e-liquids are specifically excluded from the proposed policy.*** Also, the proposed policy does not apply to so-called “age-restricted locations” such as vape shops and stand alone retailers that “adequately prevent persons under the age of 18 from entering” or from sections of retail establishments that “adequately prevent persons under the age of 18 from entering” AND the flavored e-cigarette products are not visible or accessible to under-age customers at any time. **Of particular concern, tobacco, mint, and menthol flavored e-cigarettes products may continue to be sold online so long as they use “heightened age verification processes” that FDA has yet to describe.** While a good first step, FDA’s proposed policy is inadequate. There is ample evidence that youth access e-cigarettes mostly from their friends, but then from smoke/vape shops and online.<sup>87</sup>

### ***Youth Under Age 18 Purchase Tobacco on the Internet.***

There is strong evidence demonstrating that youth under age 18 purchase tobacco products on the Internet.<sup>88,89</sup> Indeed, the Internet serves as a significant means of acquiring tobacco for youth, with Internet sales serving as a way to circumvent the age restrictions and face-to-face age verification requirements. Fix et al. (2006) showed that Internet sales of tobacco increased significantly among 9<sup>th</sup> grade students living in New York State. In 2004- 2005, youth were 2.6 times more likely to purchase cigarettes over the Internet than were similar students just 4-5 years earlier. The rates went from 1.6% in 2001 to 5.2% in 2005. Moreover, 9% reported that they intended on purchasing cigarettes through the Internet (see also Abrams et al., 2003). Using a large representative sample of 10<sup>th</sup> and 12<sup>th</sup> graders in California, Unger and colleagues showed that 2.2% of the youth had tried to buy cigarettes on the Internet, and 32% of those who had tried cigarettes rated the Internet as their most recent source for cigarettes. Internet sales were highest among younger adolescents, males and frequent smokers. As Internet use explodes among youth, these numbers are almost certainly much larger today.

Additional evidence for the importance of full restriction of Internet sales of tobacco products has been provided to the FDA over the past year (Docket Number: FDA-2011- N-0467; <http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0467>). In particular, Williams, Ribisl, and Jo, from the University of North Carolina, provide ample evidence that youth do

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<sup>86</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>

<sup>87</sup> Meyers, M.J., Delucchi, K., Halpern-Felsher, B. Access to Tobacco Among California High School Students: The Role of Family Members, Peers, and Retail Venues. *J of Adol Hlth*, 61 (2017) 385e388

<sup>88</sup> Pepper, J. K., Coats, E. M., Nonnemaker, J. M., & Loomis, B. R. (2018). How Do Adolescents Get Their E-Cigarettes and Other Electronic Vaping Devices? *American Journal of Health Promotion*, 0890117118790366

<sup>89</sup> Kong, G., Morean, M. E., Cavallo, D. A., Camenga, D. R., & Krishnan-Sarin, S. (2017). Sources of electronic cigarette acquisition among adolescents in Connecticut. *Tobacco regulatory science*, 3(1), 10-16.

purchase tobacco on the Internet, and can do so easily without age verification. The FDA has had this evidence, yet did not apply the findings to their deeming rule.

### ***It is Easy to Circumvent Age Restrictions***

While age verification for Internet sales can occur in a number of ways, it is extremely easy for an adolescent under age 18 to circumvent these age restrictions. For example, some websites simply require the user to click on a button verifying that he/she is over 18, or to enter his/her birth date and click on a button to verify or certify this date. These processes are the most common methods for age verification; however, it is easy for anyone under age 18 to bypass the age restriction by simply lying about their age. Other websites require online age verification via entering a driver's license number, or copying their actual license and submitting those through the website. While somewhat more effective than the simple check or click system, this process is used and enforced less often, and still allows for an adolescent under age 18 to submit a false driver's license or ID card. Still other Internet tobacco sales websites require age verification at the time of delivery. However, these policies are rarely enforced, and when they are, it is still easy for an adolescent to provide false proof of age (see Ribisl et al., 2002;<sup>90</sup> Williams, 2014<sup>91</sup>).

Williams and colleagues (2006)<sup>92</sup> examined compliance with state laws explicitly regulating the sales of cigarettes via the Internet, and found little compliance of the law. Another study noted that almost all (96.7%) of underage youth were easily able to purchase tobacco online, compared with 12%-17% being able to purchase tobacco from other commercial venues (Jensen et al., 2004). Malone and Bero (2000)<sup>93</sup> reported that only 36 of the 141 Internet sites examined prohibited the purchase of cigars to minors. Adolescents 11-15 years old were easily able to purchase cigarettes on the Internet, 93.6% were successful at obtaining cigarettes on the Internet using credit cards, and 88.9% were able to complete their Internet sales using money orders. Age was never verified in these transactions (Ribisl et al., 2003).<sup>94</sup> Ribisl and colleagues (2002)<sup>95</sup> reported that almost 20% of cigarette-selling websites do not say sales to minors are prohibited, more than half require only that the buyer say they are of legal age (e.g., by clicking a button that says "I am over age 18"), another 15% require only that the buyer types in their date of birth, and only 7% require any driver's license information. Attorneys general from at least 15 states have conducted Internet stings and found that children as young as 9 years old were able to purchase cigarettes easily, with a New York sting operation finding that 24 of 26 websites sold to kids

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<sup>90</sup> Ribisl KM, Kim AE, Williams RS. 2002. Are the sales practices of Internet cigarette vendors good enough to present sales to minors? *American Journal of Public Health* 92(6):940-941

<sup>91</sup> Williams RS, Ribisl KM. 2014. Internet cigarette vendor compliance with credit card payment and shipping bans. *Nicotine & Tobacco Research* 16(2): 243-246.

<sup>92</sup> Williams, RS, et al., "Internet cigarette vendors' lack of compliance with a California state law designed to prevent tobacco sales to minors," *Archives of Pediatrics and Adolescent Medicine* 2006; 160:988-989

<sup>93</sup> Malone RE, Bero LA (2000). Cigars, youth and the Internet link. *American Journal of Public Health*, 90:790-792

<sup>94</sup> Ribisl KM, Williams RS, Kim AE. 2003. Internet sales of cigarettes to minors. *JAMA* 290: 1356-1359

<sup>95</sup> Ribisl KM, Kim AE, Williams RS. 2002. Are the sales practices of Internet cigarette vendors good enough to present sales to minors? *American Journal of Public Health* 92(6):940-941

under 18 (Unger et al., 2001).<sup>96</sup> A *JAMA* study found that more than 96% of minors aged 15-16 were able to find an Internet cigarette vendor and place an order in less than 25 minutes, with most completing the order in seven minutes (Jensen et al., 2004).<sup>97</sup>

### ***Internet Advertisement is Pervasive***

Failing to restrict Internet sales of all tobacco products is also problematic given that youth are constantly exposed to advertising of these products on the Internet. Of particular concern is the advertisement of e-cigarettes, and especially ads with particular appeal to youth, such as those promoting candy and other flavored e-cigarettes (see also the Stanford Research into the Impact of Tobacco Advertising (SRITA); <http://srita.stanford.edu>).

Internet and social media marketing of tobacco products, including the more recent addition of e-cigarettes and other new products, is exploding, causing Internet sales of e-cigarettes and other tobacco products to skyrocket. Most social media content is industry-generated, which is carefully planned with specific keywords and mostly directed at youth to adopt a particular lifestyle. For example, a study found that 80% of all tweets were automated or promotional in nature.<sup>98</sup>

Further, there is pervasive false or unsubstantiated claims on products received online, that youth may not have the health literacy or access to information to be able to see through. Another study showed that the contents of packages received through online sales were rarely indicated on package exteriors. More than half of products received online did not include a health warning, and some had unsupported claims, such as lack of secondhand smoke exposure.<sup>99</sup>

Finally, internet marketing appeals to sensations. All e-cigarette liquids included a description that promotes flavor. Most descriptions included images that are associated with a sensation (e.g., 43% of menthol E-cig liquid images included mint leaves or ice). Menthol and apple descriptions or images were more likely than tobacco descriptions or images to promote appeals related to chemesthesis (e.g., cool, warm, moist;  $p < .05$ ).<sup>100</sup>

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<sup>96</sup> Unger, JB, et al., "Are adolescents attempting to buy cigarettes on the Internet," *Tobacco Control* 2001; 10:360-63 [citing Sherer, R, "States crack down on Web tobacco sales," *The Christian Science Monitor*, Nov. 8, 2000 and ABC News, "Getting smokes online: Children buying cigarette with click of mouse," March 6, 2001

<sup>97</sup> Jensen JA, Hickman NJ, Landrine H, Klonoff EA (2004). Letters: Availability of tobacco to youth via the Internet *JAMA*: 291(15):1837

<sup>98</sup> Clark EM, Jones CA, Williams JR, et al. Vaporous marketing: uncovering pervasive electronic cigarette advertisements on Twitter. *PLoS One*. 2016;11(7):e0157304.) and (Vandewater EA, Clendennen SL, Hébert ET, Bigman G, Jackson CD, Wilkinson AV, Perry CL. Whose Post Is It? Predicting E-cigarette Brand from Social Media Posts. *Tobacco Regulatory Science*. 2018 Mar 1;4(2):30-43

<sup>99</sup> Kong AY, Derrick JC, Abrantes AS, Williams RS. What is included with your online e-cigarette order? An analysis of e-cigarette shipping, product and packaging features. *Tobacco control*. 2018 Nov 1;27(6):699-702

<sup>100</sup> Soule EK, Sakuma KL, Palafox S, Pokhrel P, Herzog TA, Thompson N, Fagan P. Content analysis of internet marketing strategies used to promote flavored electronic cigarettes. *Addictive behaviors*. 2018 Nov 14

**8) FDA should use education and advertising techniques similar to Truth Initiative's to denormalize the industry, change the social environment, and get youth to recognize that the companies are trying to addict them**

The most effective forms of tobacco-prevention education involves showing youth that they are being manipulated by the tobacco industry to use their product, and that the industry is using colors, appealing packaging, flavors, and youthful looking models to attract them. Programs that use counter-marketing techniques to change attitudes towards the tobacco industry are also effective.<sup>101</sup>

**No tobacco company should do their own education**

At no time should ANY tobacco industry do their own education.<sup>102,103</sup> There is ample evidence that when the industry does their own education, they omit critical components of successful education, such as discussing the role of flavors and marketing in attracting new youth initiates. Tobacco-industry produced curriculums also fail to discuss the role that these industries have played in promoting tobacco/nicotine use, nor do they use any counter-marketing techniques to change attitudes towards the tobacco/nicotine industry.<sup>104</sup>

**Summary**

The evidence is clear. Youth are using e-cigarettes, including pod-based products, in record numbers. The increase in use of e-cigarettes is undermining and repealing the great progress that has been made by tobacco control efforts over the past two decades. Such increases in e-cigarette use come at a time when youth have negative views of cigarettes, compared to even 10 years ago.<sup>105</sup>

Treating e-cigarette addiction in youth, while necessary, is an insufficient response to the e-cigarette epidemic, particularly since there are currently no treatments for nicotine addiction that have been demonstrated to be effective for youth. ***FDA has the regulatory authority to take immediate actions that will reduce and prevent youth e-cigarette use.*** FDA should:

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<sup>101</sup> Hershey JC, Niederdeppe J, Evans WD, et al. The theory of "truth": how counter industry campaigns affect smoking behavior among teens. *Health Psychol* 2005;24(1):22–31. Jan.

<sup>102</sup> Liu, J., & Halpern-Felsher, B. The Juul Curriculum is not the Jewel of Tobacco Prevention Education. *J of Adolescent Health*, 63, 527-528 (2018).

<sup>103</sup> Landman A, Ling PM, Glantz SA. Tobacco industry youth smoking prevention programs: protecting the industry and hurting tobacco control. *Am J Public Health* 2002;92(6):917–30. <https://doi.org/10.2105/ajph.92.6.917>

<sup>104</sup> Hershey JC, Niederdeppe J, Evans WD, et al. The theory of "truth": how counterindustry campaigns affect smoking behavior among teens. *Health Psychol* 2005;24(1):22–31. Jan.

<sup>105</sup> McKelvey, K., & Halpern-Felsher, B. Adolescent cigarette smoking perceptions and behavior: Tobacco control gains and gaps amidst the rapidly expanding tobacco products market from 2001-2015. *J of Adol Health*, 60 (2017) 226e228

- Ensure that all messaging and warning labels regarding addiction are clear and include terms understood by youth;
- Stop messaging that e-cigarettes, and in particular flavored e-cigarettes, help adults stop smoking until we have ample, generalizable, and well-vetted studies to make these claims. Allowing such claims of reduced harm and exposure has unintended consequences of increasing youth use;
- Ban all flavored e-cigarettes – including mint and menthol – because these flavors are used by youth;
- Ban Internet sales. It is false to believe that banning sales in gas stations and convenience stores will have much benefit on youth, when they are most likely getting them from peers, vape shops, and the Internet;
- Regulate all ads that appeal to youth;
- Enforce FDA premarket rules; and
- Ensure that any and all education campaigns use techniques that help youth understand that the tobacco industry is targeting them, and prohibit the industry from conducting its own education programs.