

**FDA must address youth tobacco addiction now by restricting technology and marketing strategies that appeal to and addict youth**

Docket No. FDA-2019-N-1107  
Youth Tobacco Cessation: Science and Treatment Strategies

Lauren Kass Lempert, JD, MPH;<sup>1</sup> Bonnie Halpern-Felsher, PhD;<sup>1,2</sup>  
Shannon Lea Watkins, PhD;<sup>1</sup> Lucy Popova, PhD;<sup>3</sup> Benjamin Chaffee, DDS, PhD;<sup>1</sup>  
Julia Mcquoid, PhD;<sup>1</sup> Wendy Max, PhD;<sup>1</sup> Pamela Ling, MD, MPH;<sup>1</sup> Stanton Glantz, PhD<sup>1</sup>

<sup>1</sup> UCSF Tobacco Centers of Regulatory Science  
<sup>2</sup> Stanford University, Department of Pediatrics, Division of Adolescent Medicine  
<sup>3</sup> Georgia State University  
<sup>4</sup> Stanford University School of Medicine

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FDA held a second public scientific workshop on May 15, 2019 and requested comments about tackling youth tobacco addiction and cessation, with a focus on e-cigarette cessation. In response to a previous request for similar information, we appeared at the January 18, 2019 public hearing and submitted comments dated February 1, 2019, which we attach and incorporate herein.<sup>1</sup>

In the four months since we submitted our written comments, evidence has continued to rapidly accumulate that e-cigarettes are designed to and successfully do attract and addict youth to nicotine products, but no new strategies to address this youth epidemic have emerged. “Juuling” has become a crisis in schools, with teachers and school administrators spending time monitoring bathroom use instead of focusing on teaching academic curricula, and there is no sign that the epidemic is abating. *FDA should use its existing authority to aggressively enforce against companies using marketing strategies designed to appeal to youth, create new youth customers, and keep youth addicted to nicotine.*

**1. FDA should prohibit e-cigarette design features that maximize addiction potential and appeal to youth**

Bluetooth-enabled or other technologies have the potential to allow manufacturers to customize the dose, speed of delivery, and frequency of use of nicotine to maximize the additive

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<sup>1</sup> Lempert LK, Halpern-Felsher B, Glantz S, FDA should use its regulatory authority and take immediate steps to tackle the youth e-cigarette epidemic, February 1, 2019, Docket No. FDA-2018-N-3952. Available at: <https://www.regulations.gov/document?D=FDA-2018-N-3952-0394>

potential for individual users.<sup>2</sup> For example, some devices (e.g., IQOS) have features that allow the device to communicate with the manufacturer that would automatically remind consumers to use the device and to reorder nicotine liquids or pods. Juul's chief executive Kevin Burns said Juul will soon be testing new Bluetooth technology that will let users monitor on their smartphones how many puffs they are taking and will allow Juul to have "a much more intimate relationship" with customers and help "coach" them to manage their nicotine intake.<sup>3</sup> This kind of technology featuring two-way communication raises significant privacy as well as health concerns. It has the potential to allow IQOS, Juul, and other e-cigarette companies to manipulate nicotine delivery in a way that would increase abuse potential and maximize nicotine addiction (while at the same time also maximizing product sales). ***FDA should prohibit these kinds of technologies and two-way communications in e-cigarettes and other new tobacco products.***

FDA's April 30, 2019 issuance of a marketing order<sup>4</sup> permitting Philip Morris International (PMI) to market its IQOS heated tobacco product in the United States is disconcerting because the IQOS device contains Bluetooth technology that allows PMI to monitor consumers' puffing behavior and remind them to purchase more nicotine Heatsticks.<sup>5</sup> ***FDA's failure to even mention this issue should be corrected by amending the IQOS marketing order to prohibit two-way communication between the IQOS and PMI or any other party.***

In addition to technological design features in devices that could create and maintain nicotine addiction in youth, the physical design of some products are especially attractive to youth and could encourage youth and other non-users to initiate with e-cigarettes and become addicted to nicotine.

For example, the "tech appeal" of pod devices and in particular the slick design of Juul that resembles USB memory sticks and other user-friendly personal electronics could encourage uptake among young people.<sup>6</sup> Additionally, because the pod devices are discrete, portable, and create discreet clouds of aerosol, they are convenient and lend themselves to inconspicuous use in places where tobacco use is generally prohibited.<sup>6</sup> Moreover, the pod devices may reduce the social stigma previously associated with conventional cigarettes and with earlier generation large "box mod" devices.<sup>6</sup> Because these devices are associated with personal electronic devices instead of with tobacco products that are deadly and stigmatized, and are

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<sup>2</sup> Lempert LK, Glantz SA, Heated tobacco product regulation under US law and the FCTC. Tob Control. 2018 Nov;27(suppl1): s118-s125. DOI 10.1136/tobaccocontrol-2018-054560

<sup>3</sup> Gray A and Edgecliffe-Johnson, Financial Times, Juul tests puff-tracking app for growing army of vapers, May 10, 2019. <https://www.ft.com/content/07eb3e20-72bf-11e9-bbfb-5c68069fbd15>

<sup>4</sup> FDA News Release, April 30, 2019: FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway, <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>

<sup>5</sup> Lassetter T, Wilson D, et al. Reuters Investigates, Philip Morris device knows a lot about your smoking habit, May 15, 2018. <https://www.reuters.com/investigates/special-report/tobacco-iqos-device/>

<sup>6</sup> Keamy-Minor E, McQuoid J, Ling PM. Young adult perceptions of JUUL and other electronic cigarette pod devices. BMJ Open 2019;9:e026306. doi: 10.1136/bmjopen-2018-026306

supported by aggressive social media advertising, use of these products have become normalized.<sup>6</sup>

Moreover, the Bluetooth, chip, and other electronic features that have been added to e-cigarettes and other new tobacco products have exacerbated environmental concerns. Burgeoning e-cigarette use is creating problems with disposal of hazardous waste in addition to health problems related to tobacco use and nicotine addiction.

## **2. FDA should regulate social media advertising by tobacco companies**

A May 10, 2019 investigative report by Reuters<sup>7</sup> exposed how PMI aggressively marketed their IQOS heated tobacco product on Instagram and other social media platforms,<sup>8</sup> reaching millions of young people across the globe. This report “demonstrates Philip Morris’ utter lack of sincerity when they promise to market IQOS only to existing smokers and not to youth and nonsmokers – a promise the FDA relied on when it recently authorized the sale of IQOS in the United States.”<sup>9</sup> *FDA must put teeth behind marketing restrictions to ensure that PMI and other e-cigarette companies do not use similar strategies to market their products to kids by prohibiting any use of social media influencers.*

## **3. FDA should halt Juul’s “Switch” campaign because it has high potential to confuse youth and makes unauthorized cessation and modified risk claims**

On their face, the ads and testimonials on Juul’s website violate the FDA rules requiring a company to receive FDA authorization from its drug/device authorities before marketing its products for cessation or other "therapeutic" purposes. However, Juul seems to be taking advantage of some murky language in the preamble to FDA's final rule on what it considers the "intended use" of a tobacco product.<sup>10</sup> However, that imprecise language (in particular, the "switching" language at 82 FR 2193, 2214) must be read in the context of the rest of the rule. Looking at the plain meaning of the words and common sense understanding, "switching" and "smoking cessation" are interchangeable notions that both communicate the same thing to their

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<sup>7</sup> Kirkham C, Reuters. Exclusive: Philip Morris suspends social media campaign after Reuters exposes young 'influencers,' May 10, 2019. <https://www.reuters.com/article/us-philipmorris-ecigs-instagram-exclusiv/exclusive-philip-morris-suspends-social-media-campaign-after-reuters-exposes-young-influencers-idUSKCN1SH02K>

<sup>8</sup> Campaign for Tobacco Free Kids, IQOS Social Media Examples. May 10, 2019. <https://www.tobaccofreekids.org/media/2019/iqos-marketing>

<sup>9</sup> Statement of Matthew L. Myers, President, Campaign for Tobacco-Free Kids, Philip Morris Caught Red-Handed Marketing IQOS to Young People on Social Media, May 10, 2019, [https://www.tobaccofreekids.org/press-releases/2019\\_05\\_10\\_pmi\\_iqos\\_socialmedia\\_marketing](https://www.tobaccofreekids.org/press-releases/2019_05_10_pmi_iqos_socialmedia_marketing)

<sup>10</sup> Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses” AGENCY: Food and Drug Administration, HHS. ACTION: Final rule. 21 CFR Parts 201, 801, and 1100 [Docket No. FDA–2015–N–2002]. 82 FR 2193 Available at: <https://www.federalregister.gov/documents/2017/01/09/2016-31950/clarification-of-when-products-made-or-derived-from-tobacco-are-regulated-as-drugs-devices-or>

audience: Juul will help you quit smoking. ***FDA should immediately clamp down on unauthorized cessation and modified risk claims being made by Juul and other e-cigarette companies.***

Importantly, the final rule clearly states that claims made by companies that their product cures or treats nicotine addiction, helps prevent relapse by treating nicotine craving, or provides nicotine addiction relief are all therapeutic claims that would require FDA approval as a drug or device. The language of the final rule itself at section 21 CFR 1100.5(a) says a tobacco product will be subject to regulation as a drug, device, or combination product if the intended use is for "the cure or treatment of nicotine addiction (e.g., smoking cessation), relapse prevention, or relief of nicotine withdrawal symptoms", and FDA explains in the preamble to the final rule that a claim that a product could be used to "wean yourself off of nicotine" would also suggest that its intended use is as a drug or device.<sup>11</sup> FDA provides some examples "for purposes of illustration," but explicitly states that this is not an exhaustive list. (see 82 FR at p. 2205 and footnote 14). Many of the testimonials on Juul's website talk about how customers use Juul to get their "nicotine fix," and this seems to fit under that category. See also discussion about Comment 23 at 82 FR p. 2211.

At the very least, these claims are confusing. FDA's says it has "skepticism" about claims that could confuse consumers into believing FDA approves the product for therapeutic uses. FDA said in the final rule preamble, "Where products making claims related to quitting smoking also attempt to disclaim that use in some way, FDA intends to view such disclaimers skeptically because of the likelihood of consumer confusion." This language is repeated at 82 FR at p. 2199, 2203, and 2212.

Of particular and timely concern, FDA stated that "unsubstantiated cessation claims that reach adolescents may confuse teens and lead teens to believe that these products are FDA-approved smoking cessation products." 82 FR at 2212. Many of these issues were raised in a lawsuit recently filed on behalf of the parents of a 15-year-old girl who became addicted to Juul in part because she was confused and misled by Juul's marketing campaign.<sup>12</sup>

Finally, Juul's stated mission is to "improve the lives" of the world's billion adult smokers. Because the law prohibits Juul from making unsubstantiated health claims, it is indisputable that Juul would not be permitted to state that its product "improves the health" of smokers. We are skeptical that there is a plausible difference between "improving the lives" of smokers and "improving the health" of smokers. Juul may argue that they only mean that their company is "improving the lives of smokers" by giving them a product that doesn't smell as bad, thereby putting Juul in the "non-therapeutic" category. But that kind of claim would hardly be credible, especially since Juul's founders Adam Bowen and James Monsees, who were both longtime smokers, originally said they started experimenting with vaping technology to help themselves

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<sup>11</sup> (see attached final rule - 82 FR at p. 2217)

<sup>12</sup> NesSmith et al. v. Juul et al., U.S. District Court, Middle District of Florida, Case 8:19-cv-00884, Filed April 15, 2019. Available at: <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/Juul%20lawsuit%20-%20Florida%20April%202019.pdf>

and other adults quit smoking.<sup>13</sup>

***The FDA has the responsibility and authority to take enforcement action to require Juul to stop running the ads with unsubstantiated cessation and modified risk claims unless and until Juul gets authorization under FDA’s drug/device authorities to market its products as cessation or therapeutic aids, or authorization under FDA’s tobacco authorities to market them with modified risk tobacco product (MRTP) claims.*** In the United States, companies are prohibited from marketing products with unsubstantiated health claims. We discussed this issue in our public comment submitted to Docket No. FDA-2019-D-0661 on March 21, 2019, which we attach and incorporate herein.<sup>14</sup>

#### **4. Strong evidence shows flavors attract youth to initiate with and continue using tobacco products and there is not good evidence supporting industry claims that flavors are necessary to help adults quit smoking**

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>15</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>16</sup> Exposure to ads for flavored products is positively associated with youth consumption,<sup>17</sup> and most money spent by youth is on food or beverages, particularly sweets.<sup>18</sup> Research on e-cigarettes is consistent with these findings, concluding: flavors play an important role for online e-cigarette marketing and boosts user interaction and positive emotion;<sup>19</sup> flavored (vs. unflavored) e-cigarette ads elicit greater

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<sup>13</sup> <https://www.theringer.com/tech/2019/1/10/18167364/juul-big-tobacco-tech-startup-long-cons>

<sup>14</sup> FDA’s proposed modifications to its compliance policy for e-cigarettes leaves millions of youth at risk for starting to use e-cigarettes; FDA needs to remove these products from the market now and clamp down on illegal therapeutic and modified risk claims in Juul and other e-cigarette advertising, Docket No. FDA-2019-D-0661 March 21, 2019. Available at: <https://www.regulations.gov/document?D=FDA-2019-D-0661-0313>

<sup>15</sup> Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. *N Engl J Med.* 2014;370(23):2250-2252.

<sup>16</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>17</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>18</sup> Kraak VI, Gootman JA, McGinnis JM. *Food marketing to children and youth: Threat or opportunity?* National Academies Press; 2006.

<sup>19</sup> Liang Y, Zheng X, Zeng DD, Zhou X. Impact of flavor on electronic cigarette marketing in social media. 2015:278-283.

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>20</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>21</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>22</sup> Flavor preferences are associated with higher e-cigarette use among adolescents.<sup>23</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>24</sup>

Youth and young adult tobacco users are more likely than older adult tobacco users to use flavored products, including menthol cigarettes,<sup>25</sup> flavored smokeless tobacco,<sup>26</sup> and flavored cigars.<sup>27</sup> Young smokers (12-17 years of age) are three times as likely to smoke menthol cigarettes than smokers 35 years and older.<sup>28</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>20</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>21</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>22</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>23</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>24</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>25</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>26</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>27</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>28</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>29</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>30</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>31</sup> What is most important is that youth believe flavored e-cigarette ads target them.

In a study<sup>32</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.



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.

<sup>29</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>30</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>31</sup> Zhu SH, Sun JY, Bonnevie 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>32</sup> McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Youth Say Ads for Flavored E-liquids are for Them. *Addictive Behaviors*, in press.

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

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>33</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 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>34</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>35</sup> Finally, there is compelling recent evidence showing that youth use mint and menthol

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<sup>33</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>

<sup>34</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>

<sup>35</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>



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>36</sup> McKelvey and colleagues also showed that mint and menthol are used widely by youth, as noted earlier.<sup>37</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>38</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 flavors.<sup>39,40</sup> Additionally, tobacco products with a characterizing flavor including fruit-flavored e-cigarettes<sup>41</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>42,43</sup>

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<sup>36</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>37</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>38</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.

<sup>39</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>40</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>41</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>42</sup> Pletcher MJ, Hulley BJ, Houston T, Kiefe CI, Benowitz N, Sidney S. Menthol cigarettes, smoking cessation, atherosclerosis, and pulmonary function. 2006;166.

<sup>43</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.

***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>44</sup> Menthol use is also higher among female smokers;<sup>27</sup> Lesbian, Gay, and Bisexual smokers<sup>45</sup> (although see Rath et al 2013<sup>46</sup>); people with severe psychological distress; people with fewer years of education and lower income; and those who are unmarried or uninsured.<sup>47</sup>

The tobacco industry cultivated menthol use among African Americans by manipulating social factors of the civil rights era,<sup>48</sup> advertising menthol brand cigarettes, little cigars, and cigarillos in African American media and retail settings in African American neighborhoods,<sup>49,50</sup> and donating to African American leadership organizations.<sup>51</sup> The strategy has been so successful that even by 6<sup>th</sup> grade, African American youth were three times more likely to recognize menthol brands than their peers.<sup>52</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

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<sup>44</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>45</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>46</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>47</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>48</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>49</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>50</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>51</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.

<sup>52</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.

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>53</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>54</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 ceiling) effects.<sup>55,56</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>57</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

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<sup>53</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>54</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

<sup>55</sup> Martin P, Bateson PPG. *Measuring behaviour: An introductory guide*: Cambridge University Press; 1993.

<sup>56</sup> Newman AB, Cauley JA. *The epidemiology of aging*: Springer; 2012.

<sup>57</sup> Pinney Associates. Tobacco harm reduction. <http://www.pinneyassociates.com/our-practices/tobacco-harm-reduction/>

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>58</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>59</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).

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>60</sup> 43.8% of youth listed "good flavors" as the reason they tried e-cigarettes.<sup>61</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

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<sup>58</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>59</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

<sup>60</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>61</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

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***

A recent randomized control trial<sup>62</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. While the e-cigarettes used in the trial included flavors, the effect of flavors on cessation was not addressed. 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 health providers' care. Importantly, this study does not suggest that e-cigarettes are effective at helping all adult smokers quit smoking or are effective at aiding youth cessation, nor does it support having e-cigarettes available on the mass market.

### **Summary:**

- (1) Many modern e-cigarettes, including Juul, are capable of two-way communication with the manufacturer, which creates the possibility that the e-cigarette company could “tune” the device by adjusting the nicotine delivery to maximize addictive potential and consumption on an individual level.
- (2) Social media advertising is especially effective among youth and has been used by tobacco companies (including Philip Morris International) to attract new users.
- (3) Juul's “Switch” campaign that has the potential to confuse youth and makes unauthorized cessation and modified risk claims.
- (4) There is a large body of strong and consistent scientific evidence that flavors play a central role in attracting youth to e-cigarettes. In contrast, there is not good evidence to support industry claims that flavors are necessary to help adults quit smoking.

(continued)

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<sup>62</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, 2019 Feb 14;380(7):629-637.

Because of these facts, FDA should adopt the following measures to address the burgeoning vaping crisis and youth e-cigarette epidemic:

- (1) Prohibit any two-way communications between e-cigarette devices and any individual (including the user and manufacturer) for any purpose, including through Bluetooth technology and apps on smart phones;
- (2) Adopt rigorous advertising and promotion restrictions that prohibit use of social media influencers and protect youth;
- (3) Enforce against Juul's and other e-cigarette manufacturers' unauthorized cessation and modified risk claims, including so-called "switching" claims that confuse youth;
- (4) Prohibit *all* flavors in all e-cigarette products, including mint and menthol.