

## **FDA Should Prohibit Flavors in all Tobacco Products in the Current Rule Making**

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While fruit, candy and alcohol flavored cigarettes have been banned by the 2009 Family Smoking Prevention Tobacco Control Act (TCA)<sup>1</sup>, other flavored tobacco products such as smokeless tobacco, cigars, hookah, and electronic cigarettes (e-cigarettes) continue to be sold. Similar to cigarettes, sales and promotion of flavored alternative tobacco products attract youth and new users to these products and encourage novices and youth to start using tobacco. In addition, use of flavorings contributes to dual use of cigarettes and other tobacco products among those who are trying to quit smoking cigarettes and those who do not distinguish between cigarettes and little cigar products. FDA recognizes in its proposed deeming that it has the authority under sections 906(d) and 907 of the Family Smoking Prevention Tobacco Control Act (TCA)<sup>2</sup> to issue regulations requiring restrictions on the sale and distribution of tobacco products that would be appropriate for the protection of the public health, including adopting tobacco product standards that prohibit the use of flavors in all covered tobacco products; however, the FDA fails to take this essential step.<sup>3</sup> FDA already has more than sufficient evidence (additional evidence overviewed below) demonstrating why flavors that attract youth to a lifetime of addiction to toxic tobacco products in various forms must be banned. FDA should immediately under the current rulemaking establish a product standard prohibiting flavors in e-cigarettes, cigars, hookah, and all other covered tobacco products.

Failing to prohibit all flavors of covered tobacco products would defeat the purpose of the law to reduce the population level public health impact of tobacco use, which inherently includes reducing all tobacco use among youth. In addition, before manufacturers are allowed to market any kind of tobacco product with flavors, including newly deemed products, these companies must provide data to FDA demonstrating the safety of inhaling and ingesting flavor additives, and, most important, that the use of these flavors does not increase use of the products by youth and are appropriate for the protection of public health.

### **1. Flavor additives attract young people to tobacco products**

The FDA recognized that sweet flavors like chocolate and bubble-gum attract young people to initiate and continue using cigarettes; the same is true for other tobacco products like smokeless tobacco, little cigars, e-cigarettes, and hookah. Historically, tobacco industry has utilized the same strategies using candy and fruit flavors to attract youth and novices to tobacco in different forms. As a result, a number of studies show the high prevalence of the use of

flavored products, including little cigars and cigarillos, hookah, and smokeless tobacco, among youth and young adults. FDA acknowledges that although many of these flavored products are especially attractive and marketed to youth<sup>4,5,6</sup>, the prohibition against characterizing flavors established in the TCA applies to cigarettes only.<sup>7</sup>

Use of flavored *cigar and cigarillo* products is on the rise. Data from the 2009-2010 National Adult Tobacco Survey (NATS) suggest that flavored cigar products are more popular among young adults than among older ones. Use of flavored cigars is highest among such groups of cigar smokers as young adults aged 18-24 (57.1 percent), those with incomes below \$20,000 (51.7 percent), those with a GED (65.3 percent), those in the LGBT community (67 percent), and women (60.8 percent).<sup>8</sup> Except for women, all of these groups also have higher overall cigar smoking rates, suggesting that flavored cigars are driving cigar use among these groups.<sup>9</sup> According to the national 2011 Youth Risk Behavior Survey (YRBS), 13.1 percent of all high school students and 17.8 percent of high school boys currently smoke cigars.<sup>10</sup> Every day, about 3,050 adolescents under 18 try cigar smoking for the first time – compared to the 3,650 adolescents who try cigarettes.<sup>11</sup> According to the 2009-2010 NATS 15.9 percent of young adults aged 18-24 smoked cigars in the past month.<sup>12</sup>

As the FDA report notes, manufactured cigars (i.e., most types of small cigars and cigarillos) are most commonly used by teens due to their ease of purchase, low cost, sweetened flavors, and pleasant aromas.<sup>13</sup> More recent surveys have confirmed the popularity of small cigars and cigarillos is due at least in part to the availability of a wide variety of flavors.<sup>14,15,16,17</sup>

Evidence cited in the 2012 Surgeon General report titled “*Preventing Tobacco Use among Youth and Young Adults*” shows that the use of alternative tobacco products that are available in numerous flavors such as, cigars and smokeless tobacco has increased among Black female and White male high school students.<sup>18</sup> It was also reported that with the exception of ‘Black and Mild,’ the top cigars preferred by adolescents and young adults alike include candy and fruit flavorings such as peach, grape, apple, and chocolate (see Figure 1 for examples of cigarillo flavors).

Internal tobacco industry research also demonstrates that the tobacco companies know that sweeter flavors in little cigars increase appeal to starters and mask harsh taste of tobacco. RJ Reynolds’ marketing research conducted in 1972 found, for instance, that describing Winchester Little Cigars as having a mint “frosty-new taste” would intrigue younger respondents who responded that this appeal would lead them to try the product.<sup>19</sup> RJ Reynolds expected the Winchester Little Cigar, which resembled regular cigarette in appearance, to appeal to young smokers.<sup>20</sup> In 1970, Philip Morris considered producing cherry and menthol flavored 100mm slim little cigars that produced a mild smoke flavor.<sup>21</sup> An internal PM memo from Frank Resnik, Director of Research Center Operations to Stephen Fountaine, Director of Marketing Research, contained the following recommendations for the product:

The taste to the smoker would be very mild compared to other cigars because of the air dilution and because of the masking effect of the Cherry and Menthol flavors (masking the heavy cigar taste).<sup>22</sup>

In 1975 United States Smokeless Tobacco Company President Louis Bantle discussed with the President of House of Windsor (USST Subsidiary), Walter Allen, the possibility of

having House of Windsor develop a new cigar product “designed to invade the youth, pipe and cigarette smokers markets” with 100% Borkum Riff (Bourbon) tobacco filler and sweetened wrapper.<sup>23</sup> The cigar was to be “panatela-shaped,” i.e., smaller and slimmer than regular shaped cigars.

With the abundance of flavored products on the market, *smokeless tobacco* has increasing appeal among youth (Figure 2). A decline in smokeless tobacco use between the mid-1990s and early 2000s due to tightening regulations on marketing and the Master Settlement Agreement (MSA) has been followed by an increase in smokeless tobacco use among adolescents.<sup>24</sup> From 2004 to 2007, the rates of ST use initiation increased significantly for males 12 to 25 years of age.<sup>25</sup> Sales of flavored moist snuff products increased 72.1% between 2005 and 2011 and contributed to approximately 60% of the growth in the moist snuff category overall.<sup>26</sup> For the same time period, 73% of portion pouch moist snuff and 65.8% of long cut moist snuff varieties were flavored. According to Nielsen Research Company, the most popular flavor is wintergreen (two-thirds of all flavored snuff sold between 2005 and 2011), followed by spearmint/mint, fruit flavors (e.g., apple, berry, peach) and other characterizing flavors (e.g., vanilla, cinnamon). Sales of fruit flavored products across the same 7 years were largely attributed to Skoal, which accounted for 86.4% of all fruit flavored products sold.<sup>27</sup> Currently, Skoal, which is the smokeless tobacco brand most used by youth according to the National Survey on Drug Use and Health (NSDUH), offers at least 10 varieties of flavoring.<sup>28,29</sup> Flavored products tend to contain lower levels of free nicotine and pH<sup>30,31</sup>, features which are characteristic of initiation products.

Previously secret tobacco industry documents show that tobacco companies know that flavored smokeless products have been associated with young and inexperienced tobacco use. Internal studies confirmed that candy-like sweeter milder flavors (i.e., “candy dips”) increases appeal to starters by evoking a perception of mildness and masking the strong tobacco taste.<sup>32</sup> Thus, according to a 1972 United States Tobacco Company marketing document detailing the “Lotus project”, the company was working on developing a flavored smokeless product that would make it easier for a new user aged 15 to 35 to use tobacco in the mouth.<sup>33</sup> In terms of nicotine level and taste, the product was to have “a flavored taste like mint, cherry or rum, not too strong to give harshness but strong enough to cover any salty bitterness or any unpleasantness for a new user in having tobacco in the mouth.”<sup>34</sup> A focus group study on consumer perceptions of smokeless tobacco conducted by Brown & Williamson in 1985 showed that flavored smokeless tobacco products were perceived to be for starters or kids:

Using flavored brands or ‘candy dips’ was likened to sucking on a candy or a Lifesaver by experienced users; and was considered to be characteristic of beginners; such “candy” flavors were “okay for little kids” but inappropriate for those who wanted a “full, strong taste” of tobacco.<sup>35</sup>

The evidence found in tobacco industry documents complements findings in recent scientific studies. According to a study by Oliver et al.,<sup>36</sup> mint flavoring may play a particularly important role in initiation of smokeless use and subsequent dependence. In their study, a majority of subjects’ first and current choice of product was flavored, specifically mint or wintergreen. According to analyses conducted by Chen, Isabelle, Pickworth and Pankow,<sup>37</sup> smokeless tobacco products are utilizing mint and wintergreen at levels that are highly elevated

compared with those found in candy and gum. They found that the average level of mint in the top five smokeless tobacco products was 50% higher than that of the top five brands of candy and levels of wintergreen additive were eight times higher.<sup>38</sup>

FDA is aware that some *electronic cigarettes* are being marketed with flavors that may be attractive to youth (Figure 3). E-cigarettes are available in numerous flavors including candy flavors, fruit flavors, soda flavors, for example, vanilla, chocolate, peach schnapps, bubblegum, and cola.<sup>39,40</sup> The preference for sugar is strongest among youth and young adults and declines with age,<sup>41,42</sup> therefore sweet flavors like white grape and mint mocha attract young consumers to initiate and maintain tobacco use. FDA cites that according to the 2011 and 2012 National Youth Tobacco Survey (NYTS) given to middle and high school students, e-cigarette use more than doubled.<sup>43,44</sup> Following the release of a 2013 report by CDC noting the increased prevalence of e-cigarette use in middle school and high school students, students have been quoted in newspaper articles noting that classmates use e-cigarettes and that they prefer flavors like gummy bears “because it tastes really good.”<sup>45</sup> Furthermore, a focus group study by Choi et al. conducted with young adults (18-26 years old) on new tobacco products (electronic cigarettes, snus, dissolvable tobacco products) found that participants generally reported positive perceptions of the new products, particularly because they came in flavors.<sup>46</sup>

A 2014 report titled Vaporized: E-Cigarettes, Advertising, and Youth by Legacy,<sup>47</sup> assessed the recent rise in e-cigarette use among teens and young adults and reported that 14% of 13-17 year olds and 39% of 18-21 year olds had ever used e-cigarettes. Teens (aged 12-17) who had ever or currently smoked reported higher rates of e-cigarette use. Rates of e-cigarette use were also higher among young adults who were past or current smokers. This evidence shows a trend toward dual use of both cigarettes and e-cigarettes and could pose a major risk to public health, therefore in the deeming rule the FDA should not only establish a product standard, but also prohibit flavors of all covered products.

As cited by FDA, *hookah* or waterpipe use appears to be increasing among youth in the United States as well.<sup>48,49,50</sup> Hookah users smoke specially made tobacco that comes in a variety of flavors, such as apple, mint, cherry, and candy flavors.<sup>51</sup> Studies have demonstrated the presence of high levels of tobacco related carcinogens such as certain polycyclic aromatic hydrocarbons (PAHs) and tobacco-specific nitrosamines (TSNAs) in hookah users, which increase cancer risk in users.<sup>52</sup>

Marketing of fruit, candy, and alcohol flavors in cigarette products was banned as part of the TCA, prohibiting tobacco manufacturers from targeting youth. Candy, fruit, alcohol, and spice flavors have been found to mask the harshness of tobacco taste in cigarette products, making these cigarettes easier to use and increasing their appeal among youth.<sup>53,54,55</sup> Research on previously secret tobacco industry documents also confirmed that tobacco manufacturers used flavors in cigarette products to attract new users.<sup>56</sup>

The flavors (e.g., cherry, peach, grape, citrus, mint) that are marketed by tobacco companies to promote the above discussed products are attractive to youth. Similar strategies were used by tobacco companies to attract youth and novices by using flavors to mask the harshness of tobacco in cigarettes, cigars, smokeless tobacco. These flavors, in combination with colorful and stylish packaging that are associated with the flavors, mask the harsh and toxic properties of tobacco. Recent studies on nutrition confirm that children and adolescents prefer

products that are sweeter and have more intense flavor than those preferred by adults.<sup>57,58</sup> In addition, flavor is a major factor in promoting products for the youth market. In a study on emotional and rational product appeals in televised food advertisements for children, it was found that more than one-third of all the commercials appearing during children's programming on U.S. broadcast networks used a fruit flavor appeal or fruit association; many of the products used the term "super-charged" or a similar adjective to describe the powerful taste or other characteristics of the product to appeal to children.<sup>59</sup>

## **2. Flavored product use influences long-term patterns of tobacco use**

The effects of flavoring on long-term patterns of use of various tobacco products have also been documented. FDA cites research showing that flavored product use may influence long-term patterns of tobacco use as young adulthood is a critical age when lifelong patterns of tobacco use are often established.<sup>60,61</sup>

Use of flavored products contributes to dual use of cigarettes and other tobacco products among those who are trying to quit smoking and those who do not differentiate among cigarettes and cigar products. Thus, in 2000, Lorillard conducted a Consumer Needs Assessment Study, which included qualitative interviews with cigarette smokers (specifically, the study was conducted by Roper Starch Worldwide for Lorillard).<sup>62,63</sup> The study showed that flavored little cigars were particularly popular among younger women and users who were trying to quit cigarette smoking; as well as the fact that users inhaled cigar smoke. For instance, according to one interviewee:

"A. Cigars are booming. You don't even know how many women are smoking cigars. It's insane.

Q. Oh, really? They're going for the flavored cigars?

A. Flavored cigars, yeah. I just got both my sisters hooked, which is terrible. They won't quit smoking cigarettes, but they're hooked on cigars. They like the vanillas and the cherries. They're smoking the filtered ones."... "My sisters both started smoking them because the[y] quit smoking cigarettes"... "My goofy sisters are inhaling cigars.. They probably think they are less addicted. They probably think it's a temporary thing.."<sup>64</sup>

Another interviewee was not able to differentiate between little cigars and cigarettes and called little cigars "little flavor-tip cigarettes." When probed by the interviewer why the user preferred flavored product to unflavored one, he responded that the flavor "would soothe [his] throat when it does kind of scratch".<sup>65</sup>

Evidence also shows that tobacco manufacturers have used menthol and cherry flavored smokeless products as part of a "graduation strategy" with low free nicotine content to encourage new users to start with particular products and progress to others with higher levels of free nicotine.<sup>66</sup> Oliver and colleagues,<sup>67</sup> combined the data from 5 treatment or product switching studies to examine the choice of brand flavor in the course of smokeless tobacco use and found that treatment seeking smokeless tobacco users began by using mint flavored products and switched from unflavored products to flavored products and were current users of mint flavored products. This study concluded that mint products play a role in the initiation and maintenance of smokeless tobacco use.

Findings from a longitudinal school based survey of middle school and high school students conducted by Nonnemaker et al. reported that initiating smoking with menthol cigarettes was associated with progression to established smoking and higher levels of nicotine dependence.<sup>68</sup> It was concluded that young people in the US who start smoking menthol cigarettes are at a greater risk of progression to regular smoking and nicotine dependence than are young people who start smoking non-menthol cigarettes.

### **3. FDA should immediately in this rulemaking establish a product standard prohibiting flavors in e-cigarettes, cigars, hookah, and all other covered tobacco products**

According to the Proposed Rule,<sup>69</sup>“The prohibition against characterizing flavors established in the Tobacco Control Act applies to cigarettes only. Consequently, when this regulation is finalized and other tobacco products are deemed subject to FDA’s tobacco product authority, the statutory prohibition against characterizing flavors will not apply automatically to those products (p.23147).” The FDA states that they may establish a product standard prohibiting flavors in those products only after the rule has been established and requests information and data that would support establishing such a standard (p. 23147).

The FDA’s decision to not take the necessary steps to adopt tobacco product standards prohibiting the use of flavoring of all covered products under the current rulemaking, as well as other products currently regulated by the FDA, such as smokeless tobacco, is inconsistent with the FDA’s own summary of the scientific evidence on flavored tobacco and its relationship with initiation and maintenance of tobacco use among youth and young adults. Within the deeming rule, the FDA cites scientific evidence that the high prevalence of use of flavored tobacco products among youth and young adults, and that flavored product use may influence long term patterns of use (p. 23146-23147), and notes that according to the 2011 and 2012 NYTS given to middle and high school students, e-cigarette use has more than doubled (p. 23152).

FDA has the authority under sections 906(d) and 907 of the Family Smoking Prevention Tobacco Control Act <sup>70</sup>to issue regulations requiring restrictions on the sale and distribution of tobacco products that would be appropriate for the protection of the public health, including adopting tobacco product stands that prohibit the use of flavors in all covered tobacco products. FDA recognizes this authority in the proposed rule at pages 23143, 23147, and 23149, yet failed to take this essential step. FDA should immediately under the current rulemaking establish a product standard prohibiting flavors including menthol in e-cigarettes, cigars, hookah, and all other covered tobacco products. Failing to do so would defeat the purpose of the law, and thwart any positive effects on public health that might otherwise be gained by the proposed restrictions prohibiting sales to youth under 18. FDA should also require manufacturers to submit data in new tobacco product applications explaining why flavors are not harmful to health or are appropriate for the protection of public health. Before tobacco manufacturers are allowed to market tobacco products, tobacco companies should provide data on the safety of inhaling and ingesting flavor additives.

### **4. FDA should immediately in this rulemaking exercise its authority to prohibit manufacturers from using trade or brand names of candy, soda, bubblegum, and other non-tobacco products as the trade or brand name for a tobacco product, including newly deemed tobacco products such as e-cigarettes and cigars**

FDA already has the authority under 21. C.F.R. section 1140.16(a) to prohibit manufacturers from using trade or brand names of nontobacco products as the trade or brand names for cigarette or smokeless tobacco products. FDA should amend section 1140.16(a) in the current rulemaking to extend its provisions to cover *all tobacco products*, including newly deemed tobacco products such as electronic cigarettes and cigars, by deleting the words, “a cigarette or smokeless tobacco product” and substituting in their place the words, “any tobacco product.”

Many electronic cigarette and cigar companies use flavors and flavor names that are brand and/or trademarked names for candy, cookies, soda, ice cream, and other nontobacco products already on the market such as Gummy Bears, Skittles, Dr. Pepper, Tootsie Roll, Thin Mint, Junior Mint, Froot Loops, Lucky Charms and others that are especially attractive to and deliberately targeted to kids and young adults<sup>71,72</sup>. The provisions of section 1140.16(a) should automatically apply to all tobacco products, including newly deemed products, upon enactment of the final rule.

**Figure 1.** Candy (left) and White Owl and Phillies Cigarillo Flavors (right). In addition to using sweet flavors that appeal to youth, the packaging of these cigarillo products utilizes bright colors and materials similar to candy wrappers. Source:

[http://171.67.24.121/tobacco\\_web/images/tobacco\\_ads/targeting\\_teens/flavored/large/flavor\\_32.jpg](http://171.67.24.121/tobacco_web/images/tobacco_ads/targeting_teens/flavored/large/flavor_32.jpg)



**Figure 2.** Smokeless Tobacco Flavors, Reviewer Video Still Shots. Smokeless tobacco reviews are frequently posted on youtube and other websites by young males; both of these videos are shot with a large array of flavored smokeless tobacco cans in the background. Source:

[https://www.youtube.com/channel/UCVnqt5\\_KShHtBhpxhs6Xe1A](https://www.youtube.com/channel/UCVnqt5_KShHtBhpxhs6Xe1A)



**Figure 3.** E-cigarette Flavors for Youth. Electronic cigarette liquids (“e-juice”) which may or may not contain nicotine are sold in hundred of flavors, including fruit, candy and alcohol, including the popular gummy bear, Skittles, cotton candy, and bubble gum. One of these products also utilized the Skittles brand name and a variant of its slogan. Source:

[http://tobacco.stanford.edu/tobacco\\_main/ecigs.php](http://tobacco.stanford.edu/tobacco_main/ecigs.php)



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<sup>3</sup>79 FR 23142 at 23143, 23147, 23149

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<sup>7</sup>79 FR 23142 at 23144, 23146-147

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