

FDA should prohibit of use of flavors in deemed tobacco products as part of the current rulemaking

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Page 23147 of the proposed Rule the FDA states: “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 deemed products (147).”

The FDA specifically 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 (147).

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, including its relationship with initiation and maintenance of tobacco use among youth and young adults.

A logical consequence of the evidence that FDA itself presents in the proposed rule justifies including a flavor ban as part of the present rulemaking process in order to meet the law’s mandate to issue regulations to protect the public health.

Specifically, in the proposed rule, the FDA cites scientific evidence indicating 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 (146-147). According to the 2011 and 2012 National Youth Tobacco Survey given to middle and high school students, use of frequently flavored products such as e-cigarettes, hookahs, cigars, and smokeless tobacco is on the rise among adolescents (152).

We offer additional evidence that flavored tobacco products, including flavored smokeless tobacco and flavored electronic cigarettes, are extremely popular among young tobacco users.

We are currently conducting a cohort study of tobacco-related behaviors among adolescent males in California. We have commenced survey piloting and recruitment for the cohort study. Piloting took place during physical education classes at an urban high school. After completing this pilot, the cohort study enrolled baseball team members at nine rural high schools. Results are preliminary, because recruitment is ongoing for the cohort study. Participants completed survey items regarding the use of seven types of tobacco products: cigarettes, conventional smokeless tobacco (chewing tobacco or oral snuff also known as dip), compressed dissolvable tobacco (tablets, strips(films) and/or tooth-pick-like sticks), snus, hookah/waterpipe, cigars (including little cigars and cigarillos), and electronic cigarettes. In total, 210 high school boys (mean age = 15.6 years) completed standardized questionnaires in 2014.

Responses regarding flavorings in tobacco products did not differ appreciably from urban to rural settings and were therefore pooled.

The preliminary results regarding flavoring and tobacco product use among this population are included below to provide the FDA with the most recent information supporting the adoption of 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.

Among the participants in our study to date, 55% of respondents had ever tried a tobacco product, and 33% had used tobacco in the previous 30 days. In this sample, of which the majority were high school baseball athletes in rural California, the most commonly used products (past 30 days) were smokeless tobacco (18%), electronic cigarettes (13%), hookah (12%), and cigars, little cigars, and cigarillos (9%). Less commonly used were cigarettes (6%), snus (6%), and compressed dissolvable tobacco (1%). Approximately half of boys who reported tobacco use in the past 30 days reported using more than one type of tobacco product (51%).

Flavored tobacco products were overwhelming preferred over unflavored products. For electronic cigarettes, 100% of individuals who reported use in the past 30 days reported using flavored electronic cigarettes or e-liquid. All snus and dissolvable compressed tobacco users also used flavored products. Use of flavored products predominated for past-30 day users of hookah (96%), smokeless tobacco (76%), and cigars, little cigars, and cigarillos (68%), as well. Preference for flavored products was observed even while use of menthol cigarettes was relatively less common (15%).

In the rural sample, participants were able to indicate which, if any, flavors of electronic cigarettes and/or e-liquid they had used in the previous 30 days. **Of 18 electronic cigarette users, the most commonly reported flavors were fruit (peach, apple, berry blend, cherry, grape, or citrus; 14 users), coffee or cola (8 users), mint (ice, peppermint, spearmint, or frost; 5 users), spice (cinnamon or vanilla; 5 users), and candy (butterscotch, bubble gum, or cotton candy; 4 users).**

Flavored products were also overwhelming reported when participants were asked to recall the first time they had ever tried each tobacco product. The vast majority of first-time users of electronic cigarettes started with a flavored product (90% flavored, 6% not sure). Flavored products were also widely popular with first-time users of snus (86% flavored, 14% not sure), hookah (79% flavored, 16% not sure), smokeless tobacco (70% flavored, 15% not sure), dissolvable compressed tobacco (50% flavored, 33% not sure), and cigars, little cigars, and cigarillos (48% flavored, 25% not sure).

Based on these preliminary results, it is clear that **flavored tobacco products are an extremely common feature of tobacco initiation and use in this high school male population.**

These findings are consistent with other studies that have been reported in the literature. The preference for sugar is strongest among youth and young adults and declines with age.¹⁻² Therefore, sweet flavors like white grape and mint mocha attract young consumers to initiate and maintain tobacco use. Evidence cited in the 2012 Surgeon General report, *Preventing Tobacco Use Among Youth and Young Adults* shows that the use of certain products that are available in numerous flavors such as, cigars and smokeless tobacco have increased among certain subgroups of high school students. It was also reported that with the exception of 'Black and Mild,' the top cigars preferred by adolescents and young adults include flavorings such as peach, grape, apple, and chocolate.³

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.³ With many of these flavors available on the market, smokeless tobacco use has been increasing among adolescents.⁴ A study conducted by Oliver and colleagues,⁵ found that mint flavored smokeless tobacco products play a role in the initiation and maintenance of smokeless tobacco use. In their study they found that a majority of their subjects first and current choice of smokeless tobacco product was flavored and that a significant number of those who initiated use with unflavored products eventually switched from unflavored products to flavored products, specifically mint or wintergreen, helping to sustain use.

Researchers from Portland State University in Oregon compared the chemical

flavorings in cigars, and levels of those flavorings, in candy, Kool-Aid, and flavored tobacco products. There was overlap in flavorings used in all three products and **some tobacco products had much higher levels of flavoring than the candies and Kool-Aid products.**⁶ Moreover, in 2014, King and colleagues obtained data from the 2011 National Youth Tobacco Survey, a nationally representative school based survey of U.S. middle and high school students and reported that **more than two fifths of middle and high school smokers used flavored little cigars or flavored cigarettes.**⁷

A July 15, 2014 article in the *New York Times* reported that nearly 250 flavors of e-liquid are being introduced every month totaling 7,000 flavors now available to the public⁸. **The marketing and availability of e-cigarettes in kid-friendly flavors is a strong factor in their appeal and use among young people.** A new report titled *Vaporized: E-Cigarettes, Advertising, and Youth* by Legacy, 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 (age 12-17) who had ever or currently smoked reported higher rates of e-cigarette use and rates of e-cigarette use were higher among young adults who had ever smoked or who were current smokers.⁹ This evidence shows a trend toward dual use of both cigarettes and e-cigarettes, posing a major risk to public health. Reducing the youth appeal of e-cigarettes is pivotal for the prevention of later dual use with cigarettes.

Efforts are needed to reduce flavored tobacco product use, especially among youth. **Delaying addressing this problem will mean that more youth will initiate tobacco use with the products included in the proposed deeming rule while deliberation continues on any subsequent product standard on flavors. Such delay will do irreparable damage to public health.**

The FDA should prohibit flavors, including menthol, as part of the deeming rule for all included products, including, but not limited to, electronic cigarettes, cigars, dissolvable compressed tobacco, and hookah.

For the same reasons, **the FDA should move expeditiously to extend the flavor ban to all regulated products, including all smokeless products.**

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