

FDA Should Prohibit Flavors in all Tobacco Products including Electronic Cigarettes

Docket No. FDA-2014-N-0189

Emily Anne McDonald, PhD
Lauren K. Lempert, JD
Ganna Kostygina, PhD MPH
Pamela M. Ling, MPH, MD

Center for Tobacco Control Research and Education
University of California San Francisco

August 6, 2014

Although flavored cigarettes were banned under the 2009 Family Smoking Prevention Tobacco Control Act (TCA)¹, flavored tobacco products, including electronic cigarettes (e-cigarettes), continue to be widely available.

The FDA acknowledges that although many of these flavored products are especially attractive and marketed to youth^{2,3,4}. The prohibition against characterizing flavors established in the TCA, however, applies to cigarettes only, leaving unaddressed the use of flavors in other tobacco products.⁵ This is especially worrisome in the case of electronic cigarettes, which may be particularly appealing to youth and young adults. Further research addressing the use, experience of and attraction to flavors in electronic cigarettes is needed, however, our qualitative research indicates that flavors used in electronic cigarettes are especially appealing to youth and therefore should be prohibited.

We conducted 18 focus groups (N=87) and 12 semi-structured interviews to with young adults (age 18-27) recruited from bars located in the boroughs of Manhattan, Brooklyn, and Queens in New York City. We described the motivations participants had when using e-cigarettes. This study is currently under revision and review for publication; we received permission from the journal editor to submit the full manuscript as part of this comment due to its relevance to the proposed rule (see attached manuscript).

The research found:

Flavor additives attract young people to electronic cigarettes

Flavored solutions were one of the most attractive e-cigarette characteristics identified by our participants. A 26-year-old conventional cigarette and e-cigarette smoker commented:

“It's just like the feeling of having a cigarette...but...didn't have the smoke taste, because you can put...different flavors in there. I just remember the one...was sweet kind of. I was like, ‘oh...I would do this.’”

A 20-year-old African-American male participant was similarly drawn to the sweetness of electronic cigarettes. As he recalled, “I bought an e-cigarette, oh it tastes like a cigarette, but the vapor, it's sweeter...that's why I like it, because it tasted sweet.”

Commenting specifically on menthol-flavored e-cigarettes, a male participant commented:

“I had a menthol flavored [electronic cigarette]...It just tasted like a mint, basically. I think it was for the relief if I wanted to smoke. One hit or two hits, and you were fine. It was like smoking an entire cigarette. So, I did it while I was at work.”

Similar to cigarettes, sales and promotion of flavored electronic cigarettes may attract youth to these products. Historically, the tobacco industry has utilized the same strategies using candy and fruit flavors to attract youth, with flavored products especially marketed to youth^{6,7,8}. The FDA has previously recognized that sweet flavors attract young people to initiate and continue using cigarettes; the same is likely true for other tobacco products, including e-cigarettes.

FDA should immediately in this rulemaking establish a product standard prohibiting flavors in e-cigarettes along with all other covered tobacco products

According to the Proposed Rule,⁹ “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).

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 Act¹⁰ 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. 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 prior to the use of flavors demonstrating how the use of 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 flavor additives.

FDA should act now to limit youth and young adult experimentation with e-cigarettes.

In addition, our research found that young adults have easy access to electronic cigarettes, and easy access, low prices, and free samples all promote experimentation by young users. Young people lack information about e-cigarettes and rely on advertising messages, the

lack of warning labels or their own bodily sensations to judge the safety of the product. They report using e-cigarettes in addition to smoking cigarettes, not as a substitute, and some reported that e-cigarettes increased their nicotine and cigarette consumption over time. Please review the attached manuscript for data supporting these findings. FDA should act within the current rulemaking to stop the current aggressive youth-oriented promotion of e-cigarettes and prevent the ongoing expansion of experimentation with e-cigarettes among the young.

Attachment: Mcdonald EA, Ling PM, “One of several “toys” for smoking: Young adult experiences with electronic cigarettes in New York City” Tobacco Control (revise and resubmission in process).

¹Pub.L. 111-31, H.R. 1256 (June 22, 2009)

² Villanti, A. C., A. Richardson, D. M. Vallone, et al., “Flavored Tobacco Product Use Among U.S. Young Adults,”

American Journal of Preventive Medicine, 44(4):388–391, 2013.

³ Johnston, M. L., B. C. Daniel, C. J. Levy, et al., “Young Smokers—Prevalence, Trends, Implications, and Related Demographic Trends,” Philip Morris USA Research Center; March 31, 1981. Report No.: Bates No. 1000390803/0855.

⁴ Cullen, J., P. Mowery, C. Delnevo, et al., “Seven-Year Patterns in U.S. Cigar Use Epidemiology Among Young Adults Aged 18–25 Years: A Focus on Race/Ethnicity and Brand,” American Journal of Public Health, 101:1955–1962, 2011.

⁵79 FR 23142 at 23144, 23146–147

⁶ Villanti, A. C., A. Richardson, D. M. Vallone, et al., “Flavored Tobacco Product Use Among U.S. Young Adults,”

American Journal of Preventive Medicine, 44(4):388–391, 2013.

⁷ Johnston, M. L., B. C. Daniel, C. J. Levy, et al., “Young Smokers—Prevalence, Trends, Implications, and Related Demographic Trends,” Philip Morris USA Research Center; March 31, 1981. Report No.: Bates No. 1000390803/0855.

⁸ Cullen, J., P. Mowery, C. Delnevo, et al., “Seven-Year Patterns in U.S. Cigar Use Epidemiology Among Young Adults Aged 18–25 Years: A Focus on Race/Ethnicity and Brand,” American Journal of Public Health, 101:1955–1962, 2011.

⁹ Food and Drug Administration, Department of Health and Human Services. Federal Register Vol. 79, No. 80. Proposed Rules. 21 CFR Parts 1100, 1140, and 1143 (April 25, 2014)

¹⁰ Pub.L. 111-31, H.R. 1256 (June 22, 2009)