

**FDA Tobacco Products Scientific Advisory Committee
February 6-7, 2019
White Oak Conference Center
Building 31, Room 1503
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002**

Comments on modified risk tobacco product applications (MRTPAs) for snus smokeless tobacco products:

Thank you for the opportunity to comment on the Committee's important coming deliberations. The National Center for Health Research (NCHR) is a non-profit organization which analyzes scientific and medical data to provide objective health information to patients, health professionals and policy makers. We accept no funding from drug medical device, tobacco, or e-cigarette companies, so we have no conflicts of interest.

We prefer to submit comments after reviewing the specific Committee background materials, but in this case there is ample evidence that the use of flavors in tobacco products attracts under-aged children and teenagers. The FDA Commissioner has repeatedly warned various tobacco manufacturers about this manufacturing and marketing strategy, many of whose non-cigarette products did not fall under the flavor prohibitions of the 2009 Tobacco Control Act.

For more than twenty years, since the agency's two-year, landmark investigation of the tobacco industry, FDA has known and has documented that tobacco flavorings were a primary driver of recruitment and eventual addiction of young smokers and other non-combustible tobacco product users.

The use of flavors in smokeless tobacco products has greatly increased during the past decade, which has led to more young people trying snus or smokeless tobacco products. A 2013 survey of internet tobacco retailers found that more than forty percent of cigarette-

sized cigars, moist snuff smokeless tobacco and dry snuff smokeless tobacco were flavored, including fruit, sweet and mint/menthol.¹

By 2015, flavored products made up more than half of all smokeless tobacco sales.

Although cigarette smoking among youth has declined since the 2009 Tobacco Control Act went into effect, use of smokeless tobacco among youth has not followed that same trend, and among boys, the prevalence of smokeless tobacco use is now slightly higher than that of cigarettes.²

Moreover, there is no evidence that snus or smokeless tobacco leads to cessation of smoking.

As with cigarettes, characterizing flavors in smokeless products mask the harsh tobacco flavor and can make these products appealing to youth. Tobacco industry documents indicate that smokeless tobacco companies knew that “sweeter, milder flavors could increase appeal to starters by potentially lowering the pH of tobacco.”³

The 2013-2014 PATH study found that 68.9 percent of 12-17 year-olds who had never used smokeless tobacco used flavored smokeless tobacco the first time they tried the product, and 81 percent of current smokeless tobacco users had used a flavored product in the last month.⁴

A 2014 National Youth Tobacco Survey (NYTS) study found that 58.8 percent of middle and high school smokeless tobacco users---a total of nearly 700,000 youth cited in the study---had used flavored smokeless tobacco in the past month.⁵

¹ Morris, DS, Fiala, SC, “Flavored non-cigarette tobacco for sale in the USA; an inventory analysis of Internet retailers, *Tobacco Control*, published on-line August 8, 2013.

² CDC, “Tobacco Use Among Middle and High School Students—United States, 2011-2017”, *MMWR* 67(22), 629-633, June 7 2018.

³ Kostygina, G. and Ling, PM, “Tobacco industry use of flavorings to promote smokeless tobacco products”, *Tobacco Control* 25(Suppl2): ii40-ii49, November, 2016

⁴ Ambrose, BK, et al., 2015.

⁵ Corey, CG, et al., 2015

There also are numerous studies demonstrating that youthful users of smokeless tobacco and other non-combustible tobacco products incorrectly believe that flavored tobacco products are less dangerous or harmful and contain less nicotine than cigarettes. A 2016 systemic review of perceptions of flavored tobacco products included five studies that assessed harm perceptions.

The review concluded that flavored tobacco products were “perceived as less risky or harmful, and those perceptions potentially interact with age, with younger participants appearing more likely to believe that flavored products were less harmful compared with non-flavored products.”⁶

Absent other compelling evidence, the flavors in these products lead to the same initiation to tobacco addiction as the flavors in other, non-combustible tobacco products, such as e-cigarettes and vaping products.

The FDA has emphasized in recent months that it is seriously considering as-yet unspecified action against the industry use of flavors in e-cigarettes and cigars, and the Commissioner is meeting with officials from those industries to get them to explain why they have not actively prevented use of their products among young people. The smokeless tobacco industry should be held to the same standard as its competitors.

The smokeless tobacco industry should be compelled to demonstrate to FDA---as the e-cigarette and vaping manufacturers have been asked to do in recent months---that its flavored tobacco products do not unduly attract youthful consumers, and that the smokeless industry has a credible program for preventing such youthful attraction to its products. Failing that, it is difficult to comprehend why the smokeless tobacco industry is not held to the same standard as other, non-combustible tobacco products.

⁶ Huang, L.L, et al., “Impact of non-Menthol Flavours in Tobacco Products on Perceptions and Use Among Youth, Young Adults and Adults: A Systematic Review,” *Tobacco Control*, 26(6); 709-719, 2017.