

August 17, 2020

RE: Concerns over the Swedish Match Letter Opposing SB 793

Dear Appropriations Committee,

We write to urge you to disregard the August 7, 2020 Norwood Associates letter written on behalf of Swedish Match which requested a No vote on SB 793. This letter was largely based on the fact that the US Food and Drug Administration authorized Swedish Match to market several versions of its Swedish Match snus product. However, the Norwood letter selectively quotes the FDA marketing order and ignores the fact that the market for flavored tobacco products is substantially different now than it was in 2015 when FDA authorized sale of Swedish Match snus. Moreover, the letter glosses over the fact that FDA has *not* authorized the sale of Swedish Match's ZYN flavored nicotine product. Finally, the letter misrepresents youth usage of smokeless tobacco.

1) New data show that mint/menthol/wintergreen flavors are among the most popular for youth

Swedish Match's argument selectively quotes just one section of FDA's 2015 marketing order for Swedish Match snus:

The proposed products are reported to have flavors such as mint, wintergreen, or tobacco character with citrus. These proposed flavors are consistent with traditionally available [smokeless tobacco] flavors and **are not novel flavors that likely increase appeal to youth.**^[1] Additionally, in that ruling the FDA stated that the smokeless tobacco product called snus is low risk. FDA assessed the risk posed to the individual as well as the population as a whole, and judged that the products met the standard in the 2009 US Tobacco Control Act. FDA also considered the fact that the products come in mint and wintergreen flavors. It is significant that the Swedish Match snus products are currently determined by FDA to be "appropriate to the protection of the public health", and that these products are flavored, and are smokeless.

Regardless of whether this statement was reasonable when it was written five years ago (November 2015), it is unsupportable today because the market for flavored tobacco products that appeal to youth is drastically different today. Specifically, FDA's 2015 decision was based on the trends at the time (or more likely on even older trends and studies that Swedish Match had submitted many months before in its PMTA). Newer data, however, show that ***mint/menthol/wintergreen flavors are among the most popular for youth.***

- The 2019 National Youth Tobacco Survey (NYTS) found that ***57.3% of high school tobacco product users use mint or menthol flavors, an increase from 38.1% in 2018.***¹
- Data collected from August to October 2018 among a group of California adolescents and young adults assessed flavors used across tobacco products. The findings showed that 52% had used menthol and 44% had used mint across all used tobacco products and published in a peer-reviewed study.²
- In another peer-reviewed study, participants associated flavored smokeless tobacco with appealing non-tobacco products, such as chewing gum and alcohol. Availability of different varieties and flavors

¹ Cullen KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. *JAMA*. 2019;322(21):2095–2103. doi:10.1001/jama.2019.18387, <https://jamanetwork.com/journals/jama/fullarticle/2755265#:~:text=In%202019%2C%20an%20estimated%2027.5,use%20of%20any%20tobacco%20product.>

² Nguyen N, McKelvey K, Halpern-Felsher B. Popular Flavors Used in Alternative Tobacco Products Among Young Adults. *J Adolesc Health*. 2019;65(2):306-308. doi:10.1016/j.jadohealth.2019.05.004, <https://pubmed.ncbi.nlm.nih.gov/ucsfdm.oclc.org/31331543/>

stimulated interest and curiosity in sampling or switching between smokeless tobacco products. Time-limited promotional flavors and packaging also enhanced product appeal.³

- In a national study of youth who have never used tobacco, those who reported that they thought flavored smokeless tobacco would be "easier to use" than unflavored smokeless tobacco were 50% more likely to be susceptible to smokeless tobacco use.⁴
- In a California rural high school sample, students were asked about different varieties of moist snuff smokeless tobacco. Results showed that compared to "tobacco flavor," all non-tobacco flavors (i.e., wintergreen, mint, and fruit) were associated with greater perceived ease-of-use but lower perceived danger.⁵
- Among youth (age 12-17) who used smokeless tobacco (excluding snus pouches), 81% use a flavored product. Among youth snus users, 80% use a flavored product. This exceeds the percentage of flavored used for cigarettes (60%) and cigars (72%) and nearly matches the percentage for e-cigarettes (85%). National PATH data (baseline: 2013-2014; N > 13,000)⁶
- Among Juul users, a product that was not available in 2015, mint is the most popular flavor. (Leventhal, AM et al., "Flavors of e-Cigarettes Used by Youths in the United States," JAMA, published online November 5, 2019. <<add link>>)
- New national data from Dr. Halpern-Felsher showed that between 58% and 73% of youth under age 21 used mint or menthol e-cigarette products, 37% to 52% under age 21 using fruit, and 27% to 40% using sweet or dessert flavors.

From a less academic perspective, a lawsuit filed by a former Juul employee in October 2019 alleges that Juul's then CEO Kevin Burns told Juul employees, "You need to have an IQ of 5 to know that when customers don't find mango they buy mint."⁷

Independent scientific research confirmed that Burns was right: "After a decline in sales following JUUL's decision to withdraw some flavored products from stores, JUUL sales recovered within weeks and surpassed their previous maximum in those same channels, as consumption shifted to the menthol/mint and tobacco flavors that remained on shelves."⁸

2) FDA did *not* "approve" Swedish Match snus, and it is illegal for Swedish Match to make such a claim

Norwood misrepresented FDA's action, which was to *authorize* the sale, not *approve* Swedish Match snus. Contrary to the statement in the Norwood letter that Swedish Match snus smokeless tobacco products were "approved by the FDA" [page 3] and, "Please note, **two of the eight approved products** are mint flavored and one wintergreen." [page 4, emphasis added], FDA specifically does not *approve* any tobacco products. Indeed, in its marketing order allowing the sale of Swedish Match snus, FDA told Swedish Match:

³ ST product characteristics and relationships with perceptions and behaviors among rural adolescent males: a qualitative study. Health Educ Res. 2017 12 01; 32(6):537-545. Couch ET, Darius EF, Walsh MM, Chaffee BW. PMID: 29112713

⁴ Perceived Flavored Smokeless Tobacco Ease-of-use and Youth Susceptibility. Tob Regul Sci. 2017 Jul; 3(3):367-373. Chaffee BW, Urata J, Couch ET, Gansky SA. PMID: 28781992

⁵ Electronic Cigarette and Moist Snuff Product Characteristics Independently Associated with Youth Tobacco Product Beliefs. Tob Induc Dis. 2020 (Accepted - In Press) Chaffee BW, Couch ET, Urata J, Cash D, Werts M, Halpern-Felsher B

⁶ Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014.

Ambrose BK, Day HR, Rostron B, Conway KP, Borek N, Hyland A, Villanti AC. JAMA. 2015 Nov 3;314(17):1871-3. doi: 10.1001/jama.2015.13802

⁷ <https://www.seattletimes.com/business/former-juul-exec-alleges-company-shipped-tainted-products/>

⁸ Liber A, Cahn Z, Larsen A, Drope J. Flavored E-Cigarette Sales in the United States Under Self-Regulation From January 2015 Through October 2019. Am J Public Health. 2020;110(6):785-787. doi:10.2105/AJPH.2020.305667 <https://pubmed.ncbi.nlm.nih.gov/ucsf.idm.oclc.org/32298169/>

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

3) ZYN has *not* been approved to be used for cessation by FDA’s drug/device authorities, and has *not* been authorized for sale by FDA’s tobacco authorities

The Norwood Associates/Swedish Match letter also makes the unauthorized, unsubstantiated, and illegal claim that its new ZYN product should be used for cessation. Under federal law, such claims can only be made after the FDA has made a specific determination that the product is safe and effective as a cessation aid. FDA has made no such determination. Indeed, Swedish Match has not yet even obtained a PMTA marketing order to sell ZYN in the US. ZYN is available in multiple flavors including four mint flavors popular with youth (Cool Mint, Peppermint, Spearmint, and Wintergreen) and other kid-enticing flavors (Chill, Cinnamon, Citrus, and Coffee). Their brightly colored cans are marketed in convenience stores next to energy drinks popular with youth, and on “power walls” next to Juul and Marlboro.

4) The letter argues that youth don’t use smokeless tobacco. This is imply untrue.

- Nationwide, 4.8% (an estimated 720,000) of high school students and 1.8% (an estimated 280,000) of middle school students were current users of smokeless tobacco in 2019.⁹
- Each day, about 840 youth under 18 years of age used smokeless tobacco for the first time.¹⁰
- Further, and importantly, among U.S. high school boys, use of conventional smokeless tobacco is nearly equal to the prevalence of cigarette smoking (2018 NYTS: smokeless: 8.4%; cigarettes: 8.8%).
- Younger rural males are particularly vulnerable to ST initiation and continued use, with ST use prevalence double that of their urban counterparts
- Expansion in ST use by younger consumers has coincided with increased product differentiation, including the introduction of new ST product types, and steep growth in ST marketing expenditures. ZYN is a new product, not on the market long enough to know its effects on youth use, perceptions or health outcomes.

Further, there is evidence that smokeless tobacco use leads to cigarette use.

- Non-tobacco using youth who try smokeless tobacco are more willing to try cigarettes and e-cigarettes one year later. Nationally representative data (including >7,000 youth from the PATH Study)¹¹
- Non-smoking youth who have tried smokeless tobacco have 2-times higher odds of being a current cigarette smoker one-year later compared to youth who have never tried smokeless tobacco. Nationally representative data (including >10,000 youth from the PATH Study)¹²

⁹ Wang TW, Gentzke AS, Creamer MR, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students – United States, 2019. MMWR Surveill Summ 2019;86(No. SS-12): 1-22.

¹⁰ Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration.

¹¹ Tobacco product initiation is correlated with cross-product changes in tobacco harm perception and susceptibility: Longitudinal analysis of the Population Assessment of Tobacco and Health youth cohort. Prev Med. 2018 09; 114:72-78. Chaffee BW, Cheng J. PMID: 29913179.

¹² Association of Noncigarette Tobacco Product Use With Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015. JAMA Pediatr. 2018 02 01; 172(2):181-187. Watkins SL, Glantz SA, Chaffee BW. PMID: 29297010.



In sum, FDA's authorizing the marketing of Swedish Match snus in the US is an outdated decision which does not reflect current use patterns of flavored tobacco products. Moreover, if smokeless products are the only flavored tobacco products legally available and popular with youth, there is a good chance that youth will migrate to them. We provide some illustrative images below.

The requested exception should be denied, and SB 793 should not include any exemptions for Swedish Match or any smokeless tobacco product.

Thank you.

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