"Swedish Experience" extolled in this MRTP application is not transferrable to the US because of the dual use with cigarettes and differences in the tobacco advertising environment

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Note: This comment is identical to 1jy-8fot-818d except that the URL for the Trinkets and Trash website has been corrected.

Although snus presents lower health risks to individual users than cigarettes, the benefit of snus as a reduced harm product is only realized if smokers switch to snus completely rather than become dual users. Currently, we have little data on the trajectories of use of combustible and smokeless tobacco products in the US. We do know that in the US, the rates of smokeless tobacco use among cigarette smokers are lower than rates of smoking among smokeless tobacco users. For example, in 2011, ever use of smokeless tobacco among smokers was 25.5% (of snus specifically it was 13.2%), past 30-day was 7.0% (snus 2.3%). Yet rates of smoking among smokeless tobacco users are much higher (20% for daily SLT users and 40% for occasional SLT users in 1998). This indicates that dual use might be a more common pattern of use and a bigger problem than argued in this application. In addition, a high quality longitudinal study of the relationship between snus use and cigarette smoking done in the United States found that smokeless tobacco users were more likely to smoke cigarettes than non-users after a period of tobacco abstinence.

Any change to the warning label must reflect these realities, particularly the likelihood of dual use and the fact that to have a reasonable chance of affecting risk (at both the individual and population level) users would have to completely switch from cigarettes to snus, something that is rare in actual practice in the US.

The application argues for the transferability of the Swedish and Norwegian experience to the United States (Section 2.5.2.3.3); however, the differences in marketing environments are largely ignored. The application extolls the fact that "both the Swedish and Norwegian experiences occurred in the complete absence of a national coordinated advertising campaign" (p. 106), but fails to mention that the absence of the advertising campaign was due to bans on tobacco advertising in both Sweden⁵ and Norway.⁶ In the US, tobacco advertising for both cigarettes and smokeless tobacco is pervasive (see, for example www.trinketsandtrash.org), and any potential change in warning labels need to examine the effects in a context completely different from that of Sweden and Norway. For this reason, it is not reliable to make US regulatory policy based on the Swedish and Norwegian experience until there are comparable changes to the advertising environment in the US.

One way to evaluate potential effects in the absence of existing data on the effects of advertising is to model a variety of scenarios. This is exactly what we did in our 2011 paper⁷ (copy

attached). We estimated the effects of aggressive promotion of snus in the United States. The analyses show that promoting snus as a harm reduction strategy is unlikely to result in substantial net health benefits on a population level, but might instead undermine other tobacco control strategies that are working.

For these reasons, the MRTP application should be denied.

References

- 1. Hatsukami DK, Lemmonds C, Tomar SL. Smokeless tobacco use: harm reduction or induction approach? Preventive Medicine. 2004;38(3):309-17.
- 2. Popova L, Ling, PM. Alternative tobacco product use and smoking cessation: A national study. American Journal of Public Health. 2013;103:923-30.
- 3. Tomar SL. Snuff use and smoking in U.S. men: Implications for harm reduction. National Institutes of Health State-of-the-Science Statement on Tobacco Use Prevention, Cessation, and Control. 2002;23(3):143-9.
- 4. Klesges RC, Sherrill-Mittleman D, Ebbert JO, Talcott GW, Debon M. Tobacco use harm reduction, elimination, and escalation in a large military cohort. Am J Public Health. 2010;100(12):2487-92. Epub 2010/11/12. doi: 100/12/2487 [pii] 10.2105/AJPH.2009.175091.
- 5. Campaign for Tobacco-Free Kids. Tobacco Control Laws. Country Details for: Sweden. 2014. Available from: http://www.tobaccocontrollaws.org/legislation/country/sweden/summary
- 6. Campaign for Tobacco-Free Kids. Tobacco Control Laws. Country Details for: Norway. 2014. Available from: http://www.tobaccocontrollaws.org/legislation/country/norway/summary
- 7. Mejia AB, Ling PM, Glantz SA. Quantifying the effects of promoting smokeless tobacco as a harm reduction strategy in the USA. Tob Control. 2010;19(4):297-305. Epub 2010/06/29. doi: 10.1136/tc.2009.031427.