

Swedish Match's Consumer Perception Study Provides No Evidence for the Population-Level Effects of Modified Snus Labels

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According to the Modified Risk Tobacco Product Applications Guidance for the Industry, "FDA shall issue an order under section 911(g)(1) of the FD&C Act (risk modification order) only if it determines the applicant has demonstrated that the product, as it is actually used by consumers, will:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
- Benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products" (p. 3)

The Swedish Match's MRTP application attempts to demonstrate the benefit to the population by presenting the results of an online experiment (section 6.4.2 and appendices). Their "Consumer Perception Study" evaluated the effects of the proposed labels compared to existing labels on adults' perceptions of harm and willingness to purchase or use the product. Contrary to Swedish Match's the claims, this study does not evaluate the effects of the proposed label on "subjects' tobacco use behavior" (p. 689) nor can it evaluate the effects of "removal" of current warnings (p. 689).

An online experimental study with a brief exposure to the picture of the products with the new warning labels is hardly equivalent to evaluating how the product is actually used by consumers.

The selection of the proposed label is problematic. As the Swedish Match's own study reports, significantly lower proportion of participants exposed to modified labels found them easy or very easy to understand, compared to those who saw current labels. This could be due to the longer text on the proposed label or the smaller size of the font to fit the longer label. Why not select a different label, such as "This product may not be as dangerous as smoking"? Or something even simpler? There is no information provided on why this label was chosen and what other alternatives were researched.

Recently, Popova and Ling conducted a study with a national US sample of non-users of tobacco, smokers, and dual users, exposing them to advertisements for moist snuff, snus, and

e-cigarettes with different warning labels. The data from non-users of tobacco have been published in BMC Public Health (see Popova and Ling, Nonsmokers' responses to new warning labels on smokeless tobacco and electronic cigarettes: an experimental study, BMC Public Health 2014, 14:997 <http://www.biomedcentral.com/1471-2458/14/997>) and the data from smokers have been presented at the National Conference on Health Communication, Marketing and Media. In brief, we found that the proposed warning label ("WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes"):

- 1) significantly lowered perceptions of harm of snus among exclusive smokers
- 2) significantly increased positive attitudes towards moist snuff among dual snuff/cigarette users
- 3) significantly lowered perceptions of harm of moist snuff among non-users of tobacco

These results demonstrate that while the modified label might benefit current exclusive smokers, the effects might not be beneficial for dual users (by promoting continued dual use) and would not be beneficial to non-users of tobacco (by encouraging them to start using snus).

This result, combined with the many problems with the Swedish Match study demonstrate that the evidence submitted by Swedish Match is not sufficient to demonstrate the proposed new warning labels would benefit the health of the population as a whole.

For these reasons, the FDA should deny the requested petition to change the warning labels.