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RJR consumer perceptions studies are poorly designed and fail to provide sufficient evidence to evaluate the effects the proposed modified risk advertisements on consumer comprehension and behavioral intentions

Lucy Popova, PhD, Stanton A. Glantz, PhD, Lauren K. Lempert, JD MPH,
Pamela M. Ling, MD MPH
GSU and UCSF TCORS
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RJ Reynolds Tobacco Company's (RJR) Consumer Reactions studies submitted as part of the RJR's Modified Risk Tobacco Product (MRTP) Applications for Camel Snus are poorly designed so **do not provide sufficient evidence for the FDA to evaluate the effects of the proposed modified risk claims and advertisement materials on consumer comprehension and behavioral intentions**.

- "Consumer Comprehension and Persuasion" studies did not use randomized experimental design, making the assessment of the actual effects of the marketing materials impossible.
- "Likelihood of Use" studies selectively asked different behavioral intentions questions of smokers with and without quitting intentions, preventing the comparison between the groups and evaluation of the effects of modified risk claims on dual use behavioral intentions among smokers with quitting intentions.

Throughout the application materials made public by the FDA, the applicants make unsubstantiated claims (e.g., their advertisements "further educate smokers about the risks of cigarette smoking"), base their claims on incomplete literature review, and misrepresent their own findings. Because of these shortcomings, the MRTP applications do not provide sufficient evidence that introduction of these modified risk claims would have population level benefits and, therefore, should be denied.

Background

On December 18, 2017, FDA filed for substantive scientific review six RJ Reynolds Tobacco Company's (RJR) Modified Risk Tobacco Product (MRTP) Applications for the following six varieties of its Camel Snus smokeless tobacco products: Camel Snus Frost, Camel Snus Frost Large, Camel Snus Mellow, Camel Snus Mint, Camel Snus Robust Camel Snus Winterchill. RJR proposed three different modified risk advertising executions for each of the six Camel Snus styles, and thus requested a total of 18 MRTP orders.

RJR's three proposed MRTP advertising executions are:

- **Modified risk execution #1**

Smokers who **switch completely** from cigarettes to Camel SNUS can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.

- **Modified risk execution #2**

Smokers who **SWITCH COMPLETELY** from cigarettes to Camel SNUS greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.

- **Modified risk execution #3**

Smokers who **SWITCH COMPLETELY** from cigarettes to Camel SNUS can greatly reduce their risk of lung cancer and respiratory disease.

RJR's proposed advertising plan includes print advertising, direct mail, e-mail, a branded website (snusnation.com), and direct consumer engagement.

To evaluate consumer reactions to these modified risk claims, RJR conducted six studies: three "Comprehension & Persuasion" studies and three "Likelihood of Use" studies (Table 1).

Table 1. Consumer reactions studies that RJR submitted as part of the MRTP applications.

Study Name	Study Design	Study Timeline	Study Participants
Execution 1 Comprehension & Persuasion Study	Online survey (non-randomized)	October 20 - October 30, 2014	8,404 adults drawn from a national web panel
Execution 2 Comprehension & Persuasion Study	Online survey (non-randomized)	June 24, 2015 - July 21, 2015	4,924 adults drawn from a national web panel
Execution 3 Comprehension & Persuasion Study	Online survey (non-randomized)	June 16 - July 21, 2015	4,906 adults drawn from a national web panel
Execution 1 Likelihood of Use Study	Online randomized experiment	November 24 - December 22, 2014	14,511 adults drawn from a national web panel
Execution 2 Likelihood of Use Study	Online randomized experiment	August 11 - September 30, 2015	11,302 adults drawn from a national web panel
Execution 3 Likelihood of Use Study	Online randomized experiment	August 11 - September 30, 2015	11,305 adults drawn from a national web panel

1. RJR's "Consumer Comprehension and Persuasion" studies do not demonstrate how the advertisement materials affected understanding and consumer comprehension because they did not use randomized experimental design.

The Family Smoking Prevention and Tobacco Control Act (FSPTCA)[1] requires that for FDA to issue an order allowing for a tobacco product to be marketed as a modified risk tobacco product, it must establish "that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products." The use of causal language in the FSPTCA ("enable") means that the evidence submitted in support of this requirement should establish that advertisement or labeling under consideration have an effect on

[1] Family Smoking Prevention and Tobacco Control Act§ 911(h)(1), 21 U.S.C. § 387k{h}{1}. Retrieved from http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf .

or cause the consumers to understand the modified risk information. In the application, RJR similarly states that the goal of the "Comprehension and Perceptions" studies was "to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' (both former users and never users) understanding and application of the modified risk information" (p. 196, Executive Summary).

To address the effect of marketing on consumer understanding and perception, FDA recommends in its Guidance on MRTP applications[2] that applicants submit human studies regarding consumer understanding of the product, including its labeling, marketing and advertising. The scientific studies submitted by the applicant should inform FDA's evaluation of the product's marketing on consumer perception and understanding, including:

- The ability of consumers to understand the modified risk claims and the significance of the information in the context of one's health;
- Consumers' beliefs about the health risks of using the product relative to other tobacco products, including those within the same class of products;
- Consumer beliefs about the health risks of using the product relative to cessation aids; and
- Consumer beliefs about the risks of using the product relative to quitting all tobacco use.

However, "Comprehension and Perceptions among Tobacco Users and Non-Users" studies submitted by RJR as part of the MRTP application cannot be used to support the causal claim because they did not use an experimental design that allows for the establishment of causality.

The RJR makes at least four causal claims about the results of its studies:

- "RJRT's studies show that the proposed advertising will be successful in communicating reduced risk information to consumers while avoiding overgeneralization of the risk messaging, which in turn would be expected to mitigate any potential for the advertising to deter tobacco quitting or promote tobacco initiation." (p. 193, Executive Summary).
- "Respondents did not develop a misperception that it had no risk at all. […] In sum, the proposed advertisements communicated conservative risk reduction messaging, and did not promote misconceptions that might lead to inappropriate use of Camel Snus or lead to unintended effects that would reduce the population benefit of having smokers switch completely to Camel Snus." (p. 203, Executive Summary).
- "Taken together, these findings support the conclusion that, overall, consumers understand - and are not mislead by - the proposed Camel SNUS modified risk messaging materials." (p. 24, in Amended Final Report – Execution 1 Comprehension & Persuasion Study, p. 24 in Amended Final Report – Execution 2 Comprehension & Persuasion Study, p. 24 in Amended Final Report – Execution 3 Comprehension & Persuasion Study).
- "The research measured the effects of a single exposure to the proposed Camel SNUS modified risk messaging materials" (p. 26, Amended Final Report – Execution 1 Comprehension & Persuasion Study, p. 26, Amended Final Report – Execution 2 Comprehension & Persuasion Study, p. 26, Amended Final Report – Execution 3 Comprehension & Persuasion Study).

[2] FDA, Guidance for Industry, Modified Risk Tobacco Product Applications, Draft Guidance (March 2012).

These causal claims cannot be made because the "Comprehension and Perceptions" studies did not use a randomized experimental design. These studies did not randomize participants to groups in which one group saw the proposed messages while another (control) group saw content not related to modified tobacco risks. Instead, in these studies the administrators simply showed the same advertising materials to all participants and then asked them about their beliefs. Because they did not use an appropriate experimental design, it is impossible to evaluate if it was the ads that caused these perceptions or if people already had them. It might be that ads actually made people LESS LIKELY to correctly understand the information, but without a control group it is impossible to exclude these possibilities.

2. Contrary to the RJR's claims, the proposed Camel Snus modified risk advertising materials do not "further educate smokers about the risks of cigarette smoking."

In the Executive Summary, RJR claims: "RJRT has designed the proposed Camel Snus modified risk advertising materials to further educate smokers about the risks of cigarette smoking, in more detail than the statutory warning labels" (p. 84) On the next page, they further state, "RJRT believes that the worst case scenario should FDA issue MRTP orders for Camel Snus is that smokers will not switch to Camel Snus in significant numbers, but will have increased opportunities to learn more about the risks of continuing to smoke."

What content on the proposed advertisements "educates smokers about the risks of cigarette smoking?" The RJR refers to the "balancing information" that contains the following: "The proposed print advertising also provides health-related balancing information stressing the importance of quitting and not starting tobacco use: 'Like all tobacco products, Camel SNUS contains nicotine and is addictive. Adults who do not use or have quit using tobacco products should not start. Minors and pregnant women should never use tobacco products. If you're a smoker concerned about the health risks from smoking, the best choice is to quit. If you're a smoker concerned about the health risks from smoking, the best choice is to quit. A good place to begin is talking with a healthcare provider.'"

RJR claims the comparative risk information (such as "reduced risks", "no smoke = less risk", "less risk", "fewer carcinogens", "less of the harmful chemicals than cigarette smoke", "smoke-free, so there are no secondhand smoke risks for those around you", and the full modified risk claim) also indirectly communicates the risks of smoking.

However, these statements do little to educate smokers about the devastating effects of smoking. Extensive research has shown that to effectively communicate harms of smoking and make people really understand the risks,[3] messages need to be graphic, emotional, and hard-hitting.[4]

[3] Slovic P, Finucane ML, Peters E, MacGregor DG. Risk as analysis and risk as feelings: Some thoughts about affect, reason, risk, and rationality. *Risk Analysis.* 2004;24(2):311-322. Weinstein ND. What does it mean to understand a risk? Evaluating risk comprehension. JNCI Monographs. 1999;1999(25):15-20.

[4] Noar SM, Hall MG, Francis DB, Ribisl KM, Pepper JK, Brewer NT. Pictorial cigarette pack warnings: a meta-analysis of experimental studies. *Tobacco Control.* 2016;25:341-354. Noar SM, Francis DB, Bridges C, Sontag J, Ribisl KM, Brewer NT. The impact of strengthening cigarette pack warnings: Systematic review of longitudinal observational studies. Social Science & Medicine. 2016;164:118-129. Hammond D. Health warning messages on tobacco products: a review. Tobacco Control. 2011;20:327-337. Wong NC, Cappella JN. Antismoking threat and efficacy appeals: effects on smoking cessation intentions for smokers with low and high readiness to quit. *J Appl Commun*

The informational bits in the proposed Camel SNUS advertisements do very little to increase the smokers' perceived risks of smoking.

In the "Comprehension and perceptions" studies, participants' perceived risks of smoking were measured. However, because these studies did not employ randomized experimental design with a control group, it is impossible to tell if the ads had any effect on the perceived risks of smoking. Indeed, they likely did not; in our recently published study,[5] we found that comparative risk messages about e-cigarettes, even when they emphasized harmful effects of smoking, did not increase perceived risks of smoking among smokers, probably because they were already high.

Thus, the RJR's claim that the modified risk marketing materials "further educate smokers about the risks of cigarettes smoking" is unsubstantiated and cannot be used as a justification for allowing these claims.

3. RJR presents an incomplete literature to support their claim that consumers overestimate risks of smokeless tobacco compared to cigarettes.

Similar to their arguments and literature review in RJR's 2011 Citizen Petition requesting that FDA change one of the smokeless tobacco warning labels from "WARNING: This product is not a safe alternative to cigarettes" to "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes",[6] RJR claims that "the overwhelming majority of U.S. adults incorrectly believe smokeless tobacco and snus to be either just as harmful or more harmful than traditional cigarettes" (p. 194, Executive Summary). In contrast, based on a nationally representative sample of adult smokers,[7] we found that "whether people perceive smokeless tobacco products (including snus) as less harmful than cigarettes depends on how the question is framed." Specifically, in our survey of a nationally representative sample of 1,836 smokers, we found that when we asked a single question about comparative risk (e.g., "Compared to smoking cigarettes, using new smokeless tobacco, such as snus, is… less harmful/equally as harmful/more harmful"), only 22.1% of respondents reported snus as less harmful. However, when we asked two separate questions (e.g., "In your opinion, how harmful are new smokeless tobacco products, such as snus, to general health?" and "In your opinion, how harmful is smoking cigarettes for health" with answers on 1-7 scales), and then compared the answers to the two questions, we found that 51.6% of participants reported snus as less harmful (Figure 1).

Res 2009;37:1–20. Farrelly MC, Duke JC, Davis KC, et al. Promotion of smoking cessation with emotional and/or graphic antismoking advertising. American journal of preventive medicine. 2012;43(5):475-482.

[5] Yang B, Owusu D, Popova L. Testing messages about comparative risk of electronic cigarettes and combusted cigarettes *Tobacco Control* Published Online First: 13 August 2018. doi: 10.1136/tobaccocontrol-2018-054404

[6] Reynolds R.J. Citizen petition. 2011 Available at: http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0573-0001. Accessed August 20, 2018.

[7] Popova L, Ling PM. Perceptions of Relative Risk of Snus and Cigarettes Among US Smokers. *American Journal of Public Health.* 2013;103(11):e21-e23.

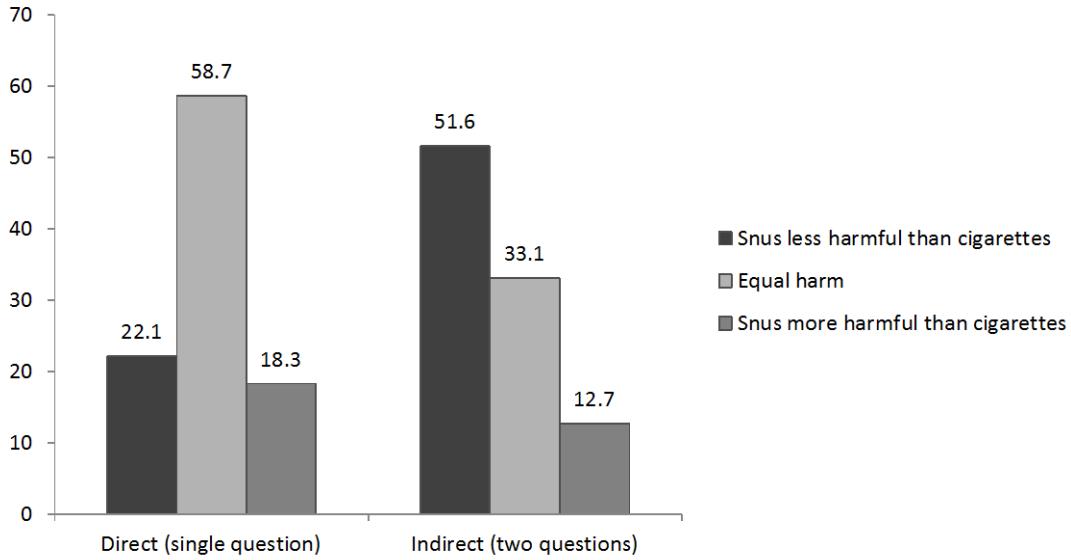

Figure 1. Percentage distribution of US adult current and recently former smokers by relative degree of perceived harm from using snus or smoking cigarettes: November 2011. (Source: Popova L, Ling PM. Perceptions of Relative Risk of Snus and Cigarettes Among US Smokers. *American Journal of Public Health.* 2013;103(11):e21-e23.)

These data show that the proportion of people believing that smokeless tobacco is less harmful than are cigarettes may be substantially larger than RJ Reynolds claims because most of the studies cited in the RJ Reynolds petition measured comparative risk perceptions with a single question. In its Camel SNUS MRTP application, RJR once again uses primarily studies that used a single question to assess comparative risk perceptions. Therefore, their claim that consumers misperceive the relative harm of snus and cigarettes is not supported to the extent that they claim.

4. RJR's executive summary misrepresents the RJR's own findings: The executive summary claims that advertisements did not increase interest among smokers who are likely to quit, but the reports for actual studies demonstrate that advertisements increased interest in both smokers who are and are not likely to quit.

In summarizing the results of the "Likelihood of Use" studies, RJR's Executive Summary claims that for "smokers likely to quit", "their interest was not increased among those who viewed the modified risk advertising" (p. 212, Executive Summary). However, in "Execution 1 – Likelihood of Use Study", "among self-defined current regular cigarette smokers by potential quitter status (refer to Table A-7 in Appendix A for distributions of intent ratings) a two-factor ANOVA reveals significant main effects of potential quitter status ($p<.0001$) and arm ($p<.05$), but no interaction between those two factors ($p>.05$)" (p. 27, Execution 1 – Likelihood of Use Study. The results were the same for current regular cigarette smokers, p. 27 in Execution 2 – Likelihood of Use Study and p. 27 in Execution 3 – Likelihood of Use Study). Thus, RJR's own data show that ratings of likelihood to purchase Camel SNUS for personal trial among potential cigarette quitters are significantly lower than among consumers who are not likely to quit cigarettes in both the test and control arms, and ratings are higher in the test arm than in the control arm" (p. 28, Execution 1 – Likelihood of Use Study). (Similar findings are reported on p. 22 and p. 28 Execution 2 – Likelihood of Use Study and on p. 22, 26, and 26 Execution 3 –

Likelihood of Use Study). ***Thus, RJR's own results indicate the proposed modified risk advertising increases interest in trying snus among both smokers who do and do not plan to quit smoking (Figure 2).***

Table 9B: Weighted Mean Likelihood to Purchase for Personal Trial Ratings - Test versus Control Camel SNUS Advertising Materials among Current Regular Tobacco Users by Potential Quitter Status† -

	Current Regular Tobacco Users	Potential Tobacco Quitters	Not Potential Tobacco Quitters
Test (with modified risk messaging)	**3.7^ (.19)** (n*=1,735)	**2.6 (.39)** (n*=253)	**3.8 (.20)** (n*=1,482)
Control (without modified risk messaging)	**3.3 (.18)** (n*=1,733)	**2.2 (.33)** (n*=226)	**3.5 (.19)** (n*=1,507)

† Tobacco status is based on self-reported tobacco usage.

* Unweighted sample size (on which the weighted data are based).

^ Statistically significantly higher than control (denotes significance from previous analysis; *refer to Table 9A*).

Numbers in parentheses represent the 95% confidence interval half-width (± mean estimate).

Figure 2. Mean likelihood of purchase is significantly higher among current regular tobacco users exposed to the modified risk advertisements regardless of whether they are potential quitters or not[8]. (Source: p. 22, Execution 3 – Likelihood of use study).

Increased interest in snus among smokers with quitting intentions represents a population level harm because in the absence of product promoted as lower risk they would try to quit smoking. RJR tries to gloss over these findings by arguing that potential quitters interested in trying snus are not going to diverge from their quitting trajectory because about half of them state they "envisioned" using snus to help them quit. In addition, RJR states that "(20-36%) just wanted to try it out of curiosity, also suggesting it would be unlikely to deter quitting." It is unclear how trying it out of curiosity has no negative effects of quitting. Most kids start using tobacco products "out of curiosity" and then continue to become lifetime smokers. Importantly, there are a lot more smokers with quitting intentions than without (our recent study found that 86% of smokers plan to quit while only 14% never plan to quit)[9], which indicates that increased interest in snus among potential quitters would have a population-level harm.

[8] On p. 22, Execution 3 – Likelihood of use studies, the report states: "A two-factor ANOVA reveals significant main effects of potential quitter status ($p<.0001$) and arm ($p<.05$), but no interaction between those two factors ($p>.05$). Thus, ratings of likelihood to purchase Camel SNUS for personal trial among potential tobacco quitters are significantly lower than among consumers who are not likely to quit tobacco in both the test and control arms; and, ratings are higher in the test arm than the control arm." The findings are the same for Execution 2 (p. 22, Execution 2 – Likelihood of use studies). For Execution 1, there was no significant main effect of arm (p. 22, Execution 2 – Likelihood of use studies).

[9] Popova L, Majeed B, Owusu D, Spears CA, Ashley DL. Who are the smokers who never plan to quit and what do they think about the risks of using tobacco products? *Addictive behaviors.* 2018;87:62-68.

5. "Likelihood of use" studies selectively asked some questions of smokers with and without quitting intentions in a way that obfuscates the effects of these advertisements on different groups.

In determining whether the modified risk order would have a population level benefit, it is important to evaluate the potential extent of dual use – use of snus in addition to smoking or other tobacco product use. RJR's "Likelihood of use" studies aim to measure self-reported dual use intentions. They ask the question, but only of smokers who are "current regular users" of tobacco who are not intending to quit (if they showed some interest in trying Camel snus, specifically, if they rated likelihood to purchase as "2" or greater). These smokers were asked:

"You indicated you have some interest in purchasing Camel SNUS in order to try it. How would you envision using Camel SNUS?

- Instead of current tobacco (stop using current tobacco completely)
- In addition to current tobacco (overall increase in tobacco use)
- In place of some of current tobacco (no net increase in tobacco use)
- Don't know"

Current regular tobacco users who have intentions to quit (i.e., "potential quitters") were not asked this question. Instead, they were asked the reasons for being interested in trying snus:

"You indicated that you plan to quit using tobacco, but that you have at least some interest in purchasing Camel SNUS in order to try it (that is, you did not rate your intention to try Camel SNUS a "1" in the previous question). Which one of the following reasons best explains why you have some interest in trying Camel SNUS? (Select one.)

- To help me quit
- It will allow me to use tobacco in situations where I cannot use my current product
- I'm just curious about it
- Don't know"

The studies should have measured dual use intentions among all smokers, regardless of the quitting intentions. All smokers should have been asked both questions. It would have allowed to demonstrate the level of dual use intentions among smokers with and without quitting intentions. Currently, the second question (the one that was asked of potential quitters only) is used by RJR to argue that even though interest in snus increased in potential quitters after seeing the modified risk advertisements, because about half of them selected "to help me quit" as the reason, modified risk advertisements will not suppress their quitting. However, without asking how they envision using snus, it is not possible to claim that they will not engage in dual use in large numbers.

6. Additional comments.

It is impossible to evaluate how these advertising materials were developed since this information on the application is redacted (e.g., all content on pp. 5-53 of the "Section 4 – Labels, Labeling, and Advertising" is not available. It should be made available for comment and evaluation by the public.)

Further, it appears that RJR collected but did not present data related to health literacy in their research, which may be relevant to the impact of the advertising on vulnerable populations; this data should be made available for comment and evaluation by the public.

RJR tries to downplay the evidence that snus serves as a gateway to cigarette smoking. In discussing the role of smokeless tobacco as a gateway to smoking, the application cites some studies that found the evidence of this gateway. They explain this finding by claiming that smoking is prohibited during basic military training, but smokeless tobacco is not:

> "A study of U.S. Air Force recruits found an increased odds of smoking initiation (OR=2.33; 1.84-2.94) among current smokeless tobacco users compared to non-users, and also among former smokeless tobacco users compared to never users (OR=2.27; 1.64-3.15) (Haddock et al. 2001). It is possible that there are differences between the national samples and the military cohort that account for the different conclusions. Particularly important may be the prohibition of any smoking during military training, which might have resulted in use of smokeless tobacco as a default product until cigarette use was again permitted, leading to what can be viewed as gateway but might actually be an artifact of the controlled environment" (RJR, p. 209, Executive Summary).

However, all tobacco products, including smokeless tobacco, are prohibited during basic military training.[10] Thus, ***RJR is either ill-informed or deliberately distorting the truth. Both of these options raise doubt about the validity of other claims in the application.***

FDA should make all application materials public and the **Camel Snus MRTP Applications should not be approved without sufficient opportunity to examine their contents in their entirety.**

Summary

RJR consumer perceptions studies are poorly designed and do not provide sufficient evidence to evaluate the effects the proposed modified risk advertisements on consumer understanding of claims and behavioral intentions, particularly regarding dual use intentions among potential quitters. These MRTP applications should be denied.

[10] Department of Defense Instruction 1010.15: Smoke-Free Workplace. Washington, DC, Department of Defense, 2001. Available at http://www.dtic.mil/whs/directives/corres/pdf/i101015_010201/i101015p.pdf; accessed March 13, 2007.