The Consumer Advocates for Smoke-free Alternatives Association

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From: Alex Clark
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The Consumer Advocates for Smoke-free Alternatives Association (CASAA)

RE: Modified risk tobacco product applications (MRTPAs), submitted by R.J. Reynolds Tobacco Company (RJRT) for six Camel SNUS tobacco products.

I. Introduction

The following comments are submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association (CASAA) regarding the modified risk tobacco product applications ("MRTP applications") submitted by R.J. Reynolds Tobacco Company ("RJRT") for six Camel SNUS products. CASAA is a 501(c)(4) nonprofit public health and education NGO and is the leading representative of consumers who use or might in the future use smoke-free tobacco and nicotine products. It is a U.S. membership organization with over 200,000 members. CASAA advocates on behalf of consumers and does not represent the interests of industry.

We are writing in full support of RJRT's application to make certain modified risk marketing claims about Camel SNUS. Consumer awareness of and access to very low-risk alternatives to smoking is critical to improving public health. We believe that snus and other smoke-free tobacco products are a vital part of the overall strategy to reduce the early death and disease attributed to smoking. Truthful marketing statements about the low risk of using smokeless tobacco are timely and crucial, and people who smoke should have been made aware of the lifesaving benefits of switching to snus decades ago.

We note that in the executive summary section 2.5.7 "Modified risk messaging and smoker misperceptions," RJRT goes into great detail with regard to prevailing public misperceptions about the risks of using smokeless tobacco.[1] We believe this is a thoughtful and thorough consideration of the ways in which modified risk messaging can be undermined and provides convincing arguments as to why public health organizations and the FDA can do more to accurately inform consumers about the continuum of risk associated with tobacco and nicotine products and to encourage people who smoke to switch to safer, smoke-free alternatives. This is especially important given how grossly misinformed the public is about the relative risk of smokeless tobacco as compared to smoking.[2]

II. Camel SNUS meets the standards for a modified risk order

The Family Smoking Prevention and Tobacco Control Act ("TCA") requires the MRTP application to demonstrate that "such products, as it is actually used by consumers, will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both the users of tobacco products and persons who do not currently use tobacco products."[3]

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[1] R.J. Reynolds Tobacco Company Modified Risk Tobacco Product (MRTP) Applications, Executive Summary (PDF). Accessed from https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm564399.htm .

[2] Feirman SP, Donaldson EA, Parascandola M, Snyder K, Tworek C, "Monitoring harm perceptions of smokeless tobacco products among U.S. adults: Health Information National Trends Survey 2012, 2014, 2015," Addict Behav. 2018 Feb;77:7-15. doi: 10.1016/j.addbeh.2017.09.002. Epub 2017 Sep 9 Accessed from https://www.ncbi.nlm.nih.gov/pubmed/28938110.

[3] Section 911(g)(1) of the TCA.

It its MRTP application, RJRT convincingly demonstrates that Camel SNUS presents lower risks to individuals and at the population level. The evidence presented goes on to demonstrate that people who smoke who switch completely to Camel SNUS can significantly reduce their risks of developing lung cancer, oral cancer, respiratory disease, and heart disease.

III. The modified risk claims for which approval is sought are appropriate

RJRT seeks to make the following truthful claims:

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

We note the emphasis on encouraging people who smoke to completely transition to a smoke-free product. However, the reality is that many people who smoke and who try smokeless tobacco will engage in a period where they both smoke and use a smoke-free product. We are concerned that government-supported messages about the risks of so-called "dual use" may undermine truthful marketing statements about reduced harm in a way that is counter productive and actually harmful. Specifically, it is imperative that FDA and CDC measure their risk communications to consumers by recognizing that dual use is oftentimes a transitory phase rather than a pattern of use to be avoided. And even when so-called "dual use" constitutes a pattern of use for some consumers, those consumers should not be discouraged from reducing their smoking habit since a substantial reduction in smoking will reduce certain risks. Our recommendation here is consistent with FDA's revised guidance to manufacturers of nicotine replacement therapies which encourages people attempting to quit smoking to start using NRT even if they continue to smoke.

IV. Accurate risk communication from RJRT is directly undermined by required government warnings on smokeless tobacco

By way of background, rotating warning labels on smokeless tobacco products are mandated by Congress in accordance with Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402). Support for requiring these warnings on smokeless tobacco products is based largely on an epidemiologic study published in 1981 that looked at women living in the American South who had oral and pharyngeal cancer.[4] While this study

[4] Kozlowzki, Lynn T., "Origins in the USA in the 1980s of the warning that smokeless tobacco is not a safe alternative to cigarettes: a historical, documents-based assessment with implications for the comparative

ostensibly revealed a link between oral tobacco use and oral cancer, the findings are exaggerated.[5] Moreover, due to the fact that the study focused on use of one oral tobacco product in particular, dry powdered tobacco, the results cannot be broadly applied to all smoke-free tobacco products.

We note that since 1981 the literature regarding health outcomes of smokeless tobacco use has grown to include decades of data from Sweden, where people who smoke are successfully using snus as a means to quit smoking and reduce their risk of developing tobacco attributable diseases.[6] While we acknowledge that changing the warning labels on smokeless tobacco products is not the subject of RJRT's MRTP application, we are highlighting the critical need for modified risk messages to not be contradicted by government-supported campaigns and communications to consumers.

In their application, RJRT presents data suggesting "that modified risk messaging will need to be repeated over time and not contradicted by messages from public health agencies such as FDA, in order to overcome deeply ingrained smokeless tobacco attitudes and beliefs and misperceptions." Should FDA approve RJRT's MRTP application, we are confident that marketing for Camel SNUS will be strategically placed to maximize exposure to people who smoke. Concurrently, we believe the FDA must take bold steps to support RJRT's modified risk communications. While many people exposed to these marketing statements will take either the modified risk claims or required warning messages at face value, a not insignificant number of people, likely motivated by a justifiable mistrust of tobacco companies, will be inclined to investigate further. It is vital that curious and skeptical consumers are able to easily find information provided by FDA that supports RJRT's modified risk claims and that plainly explains why these statements are accurate.

We are not suggesting that FDA should provide supplementary marketing materials specifically promoting Camel SNUS. Rather, we believe the agency has a duty to feature the low-risk nature of Camel SNUS as part of an overall campaign to remediate consumer misperceptions about smoke-free tobacco products and nicotine. Consistent with RJRT's conclusion that modified risk statements will need to be repeated over time in order to correct prevailing misperceptions, FDA will need to do more than produce one or two obligatory press releases or blog posts announcing approval of a modified risk order for Camel SNUS.

In light of the data presented by RJRT and our own request that FDA act to mitigate messaging that undermines any shaky public trust of modified risk statements regarding smokeless tobacco

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warnings on less harmful tobacco/nicotine products." April 2018, Harm Reduction Journal. Accessed from https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0228-8#CR17.

[5] Rodu, B., "Three Decades of Smokeless Tobacco Misinformation." April 2010, Tobacco Truth Blog. Accessed from https://rodutobaccotruth.blogspot.com/2010/04/three-decades-of-smokeless-tobacco.html.

[6] Ramstrom, L., Borland, R., Wikmans, T., "Patterns of Smoking and Snus Use in Sweden: Implications for Public Health." Nov. 2016, International Journal of Environmental Research and Public Health. Accessed from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5129320/#.

products, we urge FDA to acknowledge that snus and American moist snuff as a category presents lower risks to consumers and that by completely switching to smokeless tobacco, people who smoke can reduce their risk of developing diseases attributed to smoking.

V. Conclusion

We are keenly aware that regulators have a responsibility to balance the promotion of modified risk messages about tobacco products with the need to protect young people from initiating risky behaviors. We also believe that these seemingly polar opposite goals are not mutually exclusive. While we agree that young people need the tools and education to find more productive ways to avoid risky behaviors like tobacco use, empowering young people to make better decisions cannot come at the expense of adults who smoke or at the expense of the truth.

We believe that concerns over youth access to and appeal of any tobacco products are weighted disproportionately heavier than the demonstrable potential for smoke-free tobacco products to improve public health. The Tobacco Product Scientific Advisory Committee (TPSAC) is establishing a pattern of allowing concerns about youth use to act as a barrier to moving forward. We believe there is a deep cynicism in such a calculation that treats people who smoke as hopeless victims who are incapable of making better decisions about how they consume nicotine. In the worst case, this very dark perspective dismisses people who smoke and resigns them to “quit or die.” We feel very strongly that this primitive belief-turned-public-health-strategy is, ultimately, a gross violation of human rights. People who smoke deserve to know the truth about all of their options for improving their health.

For the foregoing reasons, we respectfully urge this committee to favorably recommend FDA approval of RJRT’s MRTP applications for Camel SNUS. Just as important, we strongly encourage TPSAC to acknowledge that people who smoke are capable of understanding risk differentials between tobacco products. Every MRTP application that this committee considers is an opportunity to begin remediating the harm of misperceptions about nicotine and smoke-free tobacco products.

Disclosure:

CASAA accepts donations from many sources and has no financial or policy agreements with industry stakeholders. In 2017, CASAA received a one-time, completely unrestricted donation from RAI Services Company. CASAA’s policy for allocating resources is that all contributions are used for efforts that will maximize consumer access to and awareness of low-risk, smoke-free nicotine and tobacco products.