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June 18, 2024

Dr. Brian King
Director
Center for Tobacco Products (CTP)
United States Food and Drug Administration
Rockville, MD 20852

Re: Docket No. **FDA-2024-N-0008**

Dear Members of the Tobacco Products Scientific Advisory Committee,

The R Street Institute (R Street) respectfully submits the following comments in response to the Tobacco Products Scientific Advisory Committee (TPSAC) Meeting on modified risk tobacco product (MRTP) Renewal Applications for Swedish Match USA, Inc. R Street is a nonprofit, nonpartisan public policy organization focused on advancing free markets and limited, effective government in various areas, including Integrated Harm Reduction. Our work is based on the belief that health policy rooted in harm reduction can greatly lessen negative outcomes of harmful behaviors and alleviate healthcare cost burdens. Decades of research show that abstinence-only methods are ineffective at a population level for risky behaviors. Policies that criminalize behaviors like smoking lead to unintended negative consequences.

We want to begin by commending the CTP for critically reviewing the scientific rationale behind the reduced risk claims associated with the applicant's snus products and allowing the company to provide messaging to help consumers make appropriate personal health decisions. The history of potential risks associated with snus products is long and deep, with a clear evidence base that supports the General Snus MRTP reduced-risk claim currently under review.¹

As the current renewal review process proceeds, from the current TPSAC meeting through the conclusion of the process, evaluating the impact of both the modified risk messaging on consumer use patterns and how those use patterns impact behavioral change by the consumers should be considered. The snus marketplace has generally compressed in the United States over

¹ Daniel Roth, H, Adam B Roth, and Xiao Liu. "Health Risks of Smoking Compared to Swedish Snus." *Inhalation toxicology* 17, no. 13 (2005): 741-48. <https://link.springer.com/article/10.1186/1477-7517-10-36>

the past 5 years. The shift in consumer adoption can be primarily attributed to new modern oral tobacco-free nicotine pouches entering the market. However, following the dissemination of the MRTP-related advertising by General Snus within the traditional snus category, researchers have determined that General Snus sales have better withstood the shrinking market as compared to other traditional snus products.² This suggests that the MRTP message has had some impact on product choice by snus consumers and has, at least, some effectiveness in driving behavioral change.

Additionally, at the time of initial consideration, there were concerns that awarding an MRTP would lead to a misunderstanding of what that message entails, suggesting that the product had been deemed safe instead of the relative risk compared to cigarettes. Investigators directly pursued this question and determined that adult—including young adult—smokers clearly understood the meaning of the MRTP messaging on the packaging but expressed that the message carried the needed credibility in order to influence their choices.³ Concerns were primarily directed toward the fact that the messaging required more details and how much inherent risk these products may possess. To strengthen the impact of the MRTP messaging related to the General Snus product and more strongly encourage those who smoke to transition to this product, the CTP and the manufacturer should work together to attempt to resolve this information gap.

One question TPSAC evaluators should explore is the potential benefits of revising FDA-required warning labels. The lack of specificity to the snus product itself appears to generate uncertainty in the consumer and potentially hamper the credibility of the MRTP claim itself.⁴ A potential change that would greatly clarify this for the consumer would be to reconsider the wording of the FDA-required warnings so that they do not reflect identical risk information as other oral tobacco products such as snuff (dip). Providing snus-specific warnings based on epidemiology and other clinical studies suggests that the risks associated with the FDA-required warnings would act to reduce confusion and improve consumer switch behavior.⁵ To be clear, snus is a different product as compared to other traditional oral tobacco products (let alone

² Liber, Alex C, Andrew B Seidenberg, and Michael F Pesko. "Mrtp Claim Authorisation and General Snus Sales in the USA: Evidence from a Difference-in-Differences Model." *Tobacco Control* (2023). <https://tobaccocontrol.bmj.com/content/early/2023/06/20/tc-2022-057890.abstract>

³ Wackowski, Olivia A, Mariam Rashid, Kathryn L Greene, M Jane Lewis, and Richard J O'connor. "Smokers' and Young Adult Non-Smokers' Perceptions and Perceived Impact of Snus and E-Cigarette Modified Risk Messages." *International journal of environmental research and public health* 17, no. 18 (2020): 6807. <https://www.mdpi.com/1660-4601/17/18/6807>

⁴ Katz, Sherri Jean, Bruce Lindgren, and Dorothy Hatsukami. "E-Cigarettes Warning Labels and Modified Risk Statements: Tests of Messages to Reduce Recreational Use." *Tobacco regulatory science* 3, no. 4 (2017): 445. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6141046/>

⁵ "Retailers: Chart of Required Warning Statements on Tobacco Product Packaging and Advertising", FDA, 2015, <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/retailers-chart-required-warning-statements-tobacco-product-packaging-and-advertising>

cigarettes). The evidence related to snus use over decades in Sweden has provided real-world evidence that risks associated with snus use are low, similar to what is seen by those who use patch-based nicotine replacement therapy.⁶ Additionally, meta-analyses have been conducted to show the same low prevalence of risk in other countries across the globe.⁷ Though snuff (dip) carries less risk than the use of combustible products, additional clarity related to the difference in risk when comparing snus and snuff (dip) use may greatly enhance consumer understanding of both the modified risk messaging and the levels of inherent risk the snus product itself may carry.⁸

Summary of Recommendations

The R Street Institute profoundly appreciates the opportunity to comment on the review of the General Snus MRTP application and hopes these comments help support the renewal of the MRTP application and motivate the CTP to review and amend tobacco product warnings so that they are specific to the product category. To be clear, the fewer people who smoke, the better. The CTP should focus on providing consumers with the clearest information in the swiftest manner possible to encourage behavioral change in their personal health choices. Tobacco harm reduction is the most efficient approach to tackling smoking disparities as compared to product prohibition and the potential adverse outcomes associated with trying to regulate human behavior.

Respectfully submitted,



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⁶ Lee, Peter N. "Summary of the Epidemiological Evidence Relating Snus to Health." *Regulatory Toxicology and Pharmacology* 59, no. 2 (2011): 197-214.

<https://www.sciencedirect.com/science/article/abs/pii/S0273230010002229>

⁷ Lee, Peter Nicholas, Katharine Jane Coombs, and Janette Susan Hamling. "Review with Meta-Analysis Relating North American, European and Japanese Snus or Smokeless Tobacco Use to Major Smoking-Related Diseases." *World Journal of Meta-Analysis* 10, no. 3 (2022): 130-42. <https://www.wjgnet.com/2308-3840/full/v10/i3/130.htm>

⁸ Huhtasaari, F, K Asplund, V Lundberg, B Stegmayr, and PO Wester. "Tobacco and Myocardial Infarction: Is Snuff Less Dangerous Than Cigarettes?". *British Medical Journal* 305, no. 6864 (1992): 1252-56. <https://www.bmj.com/content/305/6864/1252.short>, Carlens, Cecilia, Maria-Pia Hergens, Johan Grunewald, Anders Ekblom, Anders Eklund, Caroline Olgart Hoglund, and Johan Askling. "Smoking, Use of Moist Snuff, and Risk of Chronic Inflammatory Diseases." *American journal of respiratory and critical care medicine* 181, no. 11 (2010): 1217-22. <https://www.atsjournals.org/doi/full/10.1164/rccm.200909-1338OC>