



**BEFORE THE FOOD AND DRUG ADMINISTRATION AND THE
TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE**

**In The Matter of The Renewal of a Risk Modification Order
Submitted by Swedish Match USA, Inc.**

Comments by the American Consumer Institute

The American Consumer Institute is an independent 501(c)(3) education and research organization. Its mission is to identify, analyze, and protect the interests of consumers in selected legislative and rulemaking proceedings in information technology, health care, insurance, and other matters.

Cigarettes cost nearly 300,000 lives per year in America.¹ Providing smokers with alternative choices, like Snus, and renewing the risk modification order for tobacco harm reduction tools can help reduce smoking deaths.

Snus is a smokeless tobacco product used in Sweden, Norway, and other European countries. The FDA first allowed the sale of snus in the U.S. in November 2015. Recognizing its harm reduction potential granted it modified risk status in October 2019, the first time FDA granted this status. The FDA's previous approval of a risk modification for snus recognizes the evidence that snus is far less harmful than smoking and is a useful smoking cessation tool.

Snus provides significant harm reduction when compared to smoking. This has resulted in drastically fewer deaths and less impact on tobacco users' health in countries where snus is used. In Sweden, where many smokers have transitioned to snus, there has been a reduction in

¹ Justin Leventhal, "Transition from Tobacco to Vaping: The Health Impacts by State," The American Consumer Institute, March 7, 2024, <https://www.theamericanconsumer.org/2024/03/vaping-study/>.

smoking related deaths such as lung cancer and cardiovascular disease.² The U.K. Royal College of Physicians found that snus is less harmful than smoking on a variety of metrics including cancer and cardiovascular disease.³ Other estimates indicate snus is only 5 percent to 9 percent as harmful as smoking in terms of overall mortality.⁴

Harm reduction products, like snus, provide smokers with an option that not only reduces the risk to themselves but also produces population level health benefits.⁵ Snus and other harm reduction products, also have the potential to reduce overall use of the medical system and save patients from large medical payments. Smokers' medical care costs \$225 billion each year,⁶ a cost born by patients, insurers, Medicare, and Medicaid.

Evidence suggests that not only is snus less harmful than smoking, but it is also a useful tool for smokers trying to quit.⁷ While smoking rates vary across each state, as of 2019, several state's smoking rate exceed 20 percent of the population, resulting in 36.9 million American smokers.⁸ Providing options for smoking cessation is a useful tool in reducing this number. One study in Sweden and Finland found that simply giving smokers the option of snus has been shown to lower smoking rates.⁹

² Elizabeth Clarke, Keith Thompson, Sarah Weaver, Joseph Thompson and Grant O'Connell, "Snus: A Compelling Harm Reduction Alternative to Cigarettes," *Harm Reduction Journal*, 2019, <https://link.springer.com/content/pdf/10.1186/s12954-019-0335-1.pdf>.

³ "Harm Reduction in Nicotine Addiction Helping People Who Can't Quit," The Royal College of Physicians, October, 2007, <https://cdn.shopify.com/s/files/1/0924/4392/files/harm-reduction-nicotine-addiction.pdf?15599436013786148553>.

⁴ David Levy, et al., "The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts," *Cancer Epidemiology Biomarkers and Prevention*, December, 2004 <https://pubmed.ncbi.nlm.nih.gov/15598758/>.

⁵ Coral Gartner et al., "Assessment of Swedish Snus for Tobacco Harm Reduction: an Epidemiological Modelling Study," *Lancet*, June 16, 2007, <https://pubmed.ncbi.nlm.nih.gov/17498798/>.

⁶ "Health Topics – Tobacco, The Centers for Disease Control and Prevention, Reviewed September 30, 2021, <https://www.cdc.gov/policy/polaris/healthtopics/tobacco/index.html>.

⁷ Hans Gilljam and M. Rosaria Galanti, "Role of Snus in Smoking Cessation and Smoking Reduction in Sweden," Department of Public Health Sciences of The Karolinska Institute, July 12, 2002, <https://onlinelibrary.wiley.com/doi/pdf/10.1046/j.1360-0443.2003.00379.x>.

⁸ Justin Leventhal, "Transition from Tobacco to Vaping: The Health Impacts by State," The American Consumer Institute, March 7, 2024, <https://www.theamericanconsumer.org/2024/03/vaping-study/>.

⁹ Jennifer Maki, "The Incentives Created by a Harm Reduction Approach to Smoking Cessation: Snus and Smoking in Sweden and Finland," *International Journal of Drug Policy*, 2014, <https://snusforumet.se/wp-content/uploads/2017/05/maki-snus-in-sweden-and-finland.pdf>.

In Norway, snus is not only the most preferred method to quit smoking but is also the most effective.¹⁰ A Swedish study showed that over 70 percent of smokers who started using snus quit smoking cigarettes entirely.¹¹ In the same study approximately 30 percent quit using all tobacco products.

Contrary to any fears that snus is a gateway to smoking, it has had the opposite effect. Studies in Sweden show snus is associated with smokers quitting, not the uptake of smoking.¹²

Providing smokers with less harmful alternatives increases their lifespan and quality of life. It also lessens the medical costs of American citizens and reduces the burden on the U.S. healthcare system. Since 2019, when snus received modified risk status, the evidence supporting its benefits have only grown. Denying the application for modified risk for snus would not only deprive consumers of choices, but it would also limit smokers' options to quit and may send people who previously quit back to smoking. Keeping snus available as a smoking cessation option for smokers is one step in preventing many of the hundreds of thousands of smoking-related deaths in the U.S. each year.

Respectfully,

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¹⁰ Karl Erik Lund, "Tobacco Harm Reduction in the Real World: Has the Availability of Snus in Norway Increased Smoking Cessation?" Norwegian Institute for Alcohol and Drug Research, 2013, <https://fhi.brage.unit.no/fhi-xmlui/bitstream/handle/11250/281478/LundTobacco%2Bharm%2Bredution2013.pdf?sequence=3>.

¹¹ Lars Ramström, Ron Borland and Tom Wikmans, "Patterns of Smoking and Snus Use in Sweden: Implications for Public Health," *International Journal of Environmental Research and Public Health*, November 9, 2016, <https://pubmed.ncbi.nlm.nih.gov/27834883/>.

¹² Helena Furberg et al., "Is Swedish Snus Associated with Smoking Initiation or Smoking Cessation?" *Tobacco Control*, December 2005, <https://tobaccocontrol.bmj.com/content/14/6/422>.