June 20, 2024

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Via email: TPSAC@fda.hhs.gov

Comments re: Tobacco Products Scientific Advisory Committee Meeting, June 26, 2024
I'm writing to submit my comment to the Tobacco Products Scientific Advisory Committee (TPSAC) for Docket No. FDA-2024-N-0008. As Executive Director of the Burley and Dark Tobacco Producer Association (BDTPA) I believe the TPSAC should recommend renewal of the U.S. Food and Drug Administration's (FDA) authorization for General Snus products as submitted by Swedish Match USA, Inc.

General Snus products have already received FDA authorization through both the Premarket Tobacco Application (PMTA) and Modified Risk Tobacco Product (MRTP) processes. Both pre-market evidence and post-market surveillance and studies performed by Swedish Match support continued FDA authorization of these products. Not only do these studies reflect relatively low levels of harmful and potentially harmful constituents (HPHCs), but they also show that consumers continue to understand the FDA-authorized reduced exposure claim.

Moreover, the adult tobacco consumer experience in Sweden continues to provide more real-world evidence supporting FDA authorization of General Snus with the current reduced risk information. According to public health data, tobacco-related illnesses and mortality is lower in Sweden than in any other European country. This comes as smoking rates in the country have fallen to the lowest levels in Europe, even as smoke-free tobacco product use, including Snus, continues to increase.

If transitioning to less harmful tobacco products is working to protect public health in Sweden, then the FDA should continue to prioritize authorization of smoke-free tobacco products,

including General Snus here in the United States. As you know, that is why Congress authorized the MRTP process, which enables tobacco manufacturers to provide accurate communication about the relative risks of tobacco products to inform adult consumers and help them make more informed, less harmful decisions.

Smoking remains the leading cause of preventable death and disease in the United States, making it even more urgent for the FDA to help ensure a larger market of reduced harm, smokeless tobacco options. If the overwhelming evidence supporting FDA authorization of General Snus products is somehow insufficient, then it is likely that no tobacco products would receive authorization moving forward. That would be a clear indicator that the FDA's review process is broken beyond repair.

To continue providing adult smokers in the United States with more options that help them make reduced-risk choices, the TPSAC must recommend FDA authorization of General Snus products with the same modified risk information currently available to consumers. Please help ensure that happens.

Sincerely,

(b) (6)

Joe Cain
Executive Director
Burley and Dark Tobacco Producer Association (BDTPA)

Commentary to the U.S. Food and Drug Administration's
Tobacco Product Scientific Advisory Committee
Regarding Modified Risk Tobacco Product Orders
June 20, 2024

Center for Tobacco Products
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Thank you for your time today to discuss the issue of renewing the modified risk tobacco product order for Swedish Match's General Snus tobacco products. My name is Lindsey Stroud and I am a senior fellow at the Taxpayers Protection Alliance. TPA is a non-profit, non-partisan organization dedicated to educating the public through the research, analysis and dissemination of information on the government's effects on the economy.

Introduction

The regulation of tobacco products in the United States underwent a significant transformation in 2009 with the enactment of the Family Smoking Prevention and Tobacco Control Act (TCA). This legislation granted the U.S. Food and Drug Administration (FDA) comprehensive authority over the oversight of tobacco products, including their manufacturing, distribution, and marketing. The TCA was particularly notable for its focus on modified risk tobacco products (MRTPs), which are marketed as less harmful alternatives to conventional tobacco products. The FDA should continue to permit Swedish Match's MRTP order while also examining the need for regulatory reform to streamline tobacco regulatory processes and enhance public understanding of the risks associated with various tobacco and tobacco harm reduction products.

Modified Risk Tobacco Products and Tobacco Product Regulation

In 2009, Congress granted the FDA the authority to regulate tobacco products through the TCA. The TCA not only allows the FDA to regulate tobacco products but also gives it oversight over the manufacturing, distribution, and marketing of these products, including "specific restrictions on marketing tobacco products to children."[i] Companies producing new tobacco products—those introduced after 2007—must submit an application to the FDA for authorization to sell those products.

The TCA also addressed the then-growing category of safer alternatives to cigarettes by requiring that "modified risk" claims are supported by robust evidence showing that they are less harmful than combustible cigarettes. Section 911 of the TCA defines modified risk tobacco

products as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."[ii]

The Secretary of the Department of Health and Human Services is tasked with issuing all modified risk tobacco product orders, provided that the manufacturer demonstrates the products 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."

Additionally, companies must submit further findings before an order is issued, including:

- "the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substances or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a measurable reduction in overall morbidity and mortality among individual tobacco users;
- … issuance of an order with respect to the application is expected to 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.
- … the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users."

In essence, tobacco companies must provide robust evidence that the modified risk tobacco product reduces the harms associated with tobacco use.

Further, the FDA has ongoing oversight authority through postmarket surveillance data and studies, as required by Section 911. After issuing a modified risk order, the applicant must "conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health … and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product." These results "shall be submitted to the Secretary on an annual basis."

The FDA also has exclusive authority to withdraw the modified risk order marketing authorization at any time after the order has been issued. The FDA can remove the order for several reasons, including:

- "the applicant, based on new information, can no longer make the demonstrations required
- … the application failed to include material information or included any unture statement of material fact;
- any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if
- … any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;
- the application failed to conduct or submit the postmarket surveillance and studies required…"

The TCA provides the FDA with comprehensive authority to recognize and permit the marketing of tobacco products that have reduced harm. Companies must not only submit rigorous scientific evidence proving the product is less harmful than current tobacco products, but they must also monitor those products. Should youth use become an issue, or if long-term evidence suggests the product may not be less harmful, the FDA can withdraw the modified risk order, and the company must cease marketing the product as such.

As of December 31, 2023, the FDA has granted only 16 modified risk orders for tobacco products. Nine of these orders were for smokeless tobacco products, and the remaining orders were for combustible and heated cigarette tobacco products.

Swedish Match's PMTA and MRTP Orders

In 2015, Swedish Match's portioned snus products (defined as smokeless tobacco products) were the first ever-tobacco products to be granted a marketing order through the premarket tobacco product application (PMTA). The FDA's PMTA process requires the manufacturer to demonstrate to the agency that its product is appropriate for the "appropriate for the protection of public health," or the APPH standard.

In issuing the first-ever PMTAs, the FDA announced that the decision "reflects evidence showing that these products, marketed as described in the manufacturers' application, would result in a low likelihood of new initiation, delayed cessation or relapses."[iii] Further, the FDA "also determined that [the new] products would likely provide less toxic options if current adult smokeless tobacco users used them exclusively."[iv]

As emphasized by the FDA, the PMTA did not permit the company to "market a product with claims of reduce exposure or reduced risk," including the FDA finding the products being less toxic. As such, Swedish Match first applied for a MRTP order in 2014.

According to the company, Swedish Match provided "an abundance of Swedish and international evidence on the health effects of snus. This evidence stretches over three decades and includes governmental cohort studies and clinical trial results."[v] The company's MRTP application consisted of "more than 100,000 pages."[vi]

Youth Use of Snus & Other Smokeless Tobacco Products Is at Record Lows

The Monitoring the Future (MTF) Study is conducted annually by the University of Michigan, with support from the National Institute on Drug Abuse. The MTF is "an ongoing study that uses annual surveys to track the behaviors, attitudes, and values of U.S. secondary school students, college students, and adults through age 60."[vii]

The MTF has been tracking snus among youth in 8th, 10th, and 12th grades since 2012, while the study first asked 12th graders about use in 2011. That year, 5.7 percent of youth in the MTF study reported past-year use of snus products. Since 2012, the percentage of youth reporting past-year use of snus products has only decreased. In 2023, only 1.1 percent of youth had used snus in the past year. This was a 30.6 percent decline from 1.6 percent of youth who had used snus in 2022, and a whopping 80.2 percent decline from 2012.

TCA Is in Dire Need of Reform

The FDA has claimed that the agency is working to educate the public (and especially adults who smoke) of the continuum of risk that exists among tobacco products, yet the very process to bring products to market is fundamentally flawed.

All products undergoing a PMTA must be found to be "appropriate for the protection of public health" and in Swedish Match's PMTA, the FDA found the use of such products to be less harmful than combustible cigarettes. Yet, Swedish Match was prohibited from relaying the FDA's findings without first obtaining a MRTP after it received marketing authorization. Such processes are redundant and a waste of taxpayer dollars.

The FDA should examine reforms to both reduce the costs associated with MRTPs and informing the public about the continuum of risk among tobacco products. An agency that is founded in science should not be constrained by bureaucratic processes that fail to address the issue.

TAXPAYERS PROTECTION ALLIANCE

Conclusion

The case of Swedish Match highlights both the challenges and the potential benefits of the regulatory pathway. Despite providing extensive evidence on the health effects of snus, Swedish Match faced significant hurdles in communicating the reduced risk of its products due to regulatory constraints. This case underscores the need for clearer and more streamlined regulatory processes that can more effectively convey the relative risks of different tobacco products to the public.

Furthermore, the ongoing decline in youth use of snus and other smokeless tobacco products, as reported by the MTF Study, suggests that effective regulation can contribute to reducing tobacco use among vulnerable populations. However, the FDA's efforts to educate the public about the risk continuum of tobacco products have fallen short, leaving many adults confused about nicotine's role and the harm reduction potential of various products.

In light of these challenges, there is a pressing need for reform within the TCA framework. Simplifying the application processes and improving public communication strategies could enhance the effectiveness of tobacco regulation and better support public health goals. As the FDA continues to navigate the complexities of tobacco product regulation, it must strive to balance rigorous oversight with practical measures that facilitate informed decision-making among consumers.

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[i] U.S. Food and Drug Administration, "Family Smoking Prevention and Tobacco Control Act - An Overview," Jun. 3, 2020, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview.

[ii] U.S. Food and Drug Administration, "Section 911 of the Federal Food, Drug, and Cosmetic Act - Modified Risk Tobacco Products," Jan. 7, 2018, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-911-federal-food-drug-and-cosmetic-act-modified-risk-tobacco-products.

[iii] U.S. Food and Drug Administration, "FDA issues first product marketing orders through premarket tobacco application pathway," Nov. 10, 2015, https://wayback.archive-it.org/7993/20170111122117/http:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472026.htm/

[iv] *Ibid.*

[v] Swedish Match, "Swedish Match submits a Modified Risk Tobacco Product (MRTP) application," Jun. 11, 2014, https://www.swedishmatch.com/Media/Pressreleases-and-news/Press-releases/2014/Swedish-Match-submits-a-Modified-Risk-Tobacco-Product-MRTP-application/.

[vi] *Ibid*.

[vii] U.S. Centers for Disease Control and Prevention, "Monitoring the Future (MTF) Study," *National Center for Health Statistics*, Jun. 26, 2023, https://www.cdc.gov/nchs/hus/sources-definitions/mtf.htm.

CMSA

Coalition of Manufacturers of Smoking Alternatives

June 20, 2024

Via Email

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Re: Written Comments to Docket No. FDA-2024-N-008

Dear Capt. Serina Hunter-Thomas,

The Coalition of Manufacturers of Smoking Alternatives (CMSA) provides this written submission for the forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC) to be held on June 26, 2024. In this submission, CMSA provides input regarding (1) the renewal of the risk modification order, submitted by Swedish Match USA, Inc., (Swedish Match) for General Snus products[1]; and (2) broader Modified Risk Tobacco Products (MRTP) program developments, with emphasis on those related to the conceptualization and measurement of consumer understanding.

CMSA is a trade coalition group that represents responsible manufacturers of smoking alternatives. CMSA members focus on products that are considered potentially reduced risk on the tobacco/nicotine risk continuum, e.g., modern oral white pouch products and electronic nicotine delivery system (ENDS) products. CMSA is comprised of companies that have invested significant resources to file premarket tobacco product applications (PMTAs) that are either still pending or have resulted in Marketing Granted Orders (MGOs). Some CMSA members also have direct experience with the MRTP program.[2] CMSA members share the important goals of advancing tobacco harm reduction through product innovation and accurate communication about the relative risks of tobacco products to help move current adult smokers down the continuum of risk.

[1] MR0000020: General Loose, MR0000021: General Dry Mint Portion Original Mini, MR0000022: General Portion Original Large, MR0000024: General Classic Blend Portion White Large—12 ct, MR0000025: General Mint Portion White Large, MR0000027: General Nordic Mint Portion White Large—12 ct, MR0000028: General Portion White Large, MR0000029: General Wintergreen Portion White Large.

[2] Swedish Match USA, Inc. and Philip Morris International are members of CMSA.

Renewal of Risk Modification Order for General Snus Products

CMSA strongly supports the renewal of the Risk Modification Order for the General Snus products with the following reduced risk information:

> "*Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."*

The US Food and Drug Administration (FDA) may renew a risk modification order if the applicant files a new application and FDA finds that the requirements for such order under section 911(g)(1) continue to be satisfied. Here, the science and evidence continue to demonstrate the General Snus products meet the statutory standard by (1) significantly reducing the risk of tobacco-related disease – including mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis associated with cigarettes; and (2) benefiting 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. Specifically:

- In authorizing the claim, FDA stated that its review determined that the claim is "**supported by scientific evidence ,that consumers understand the claim and appropriately perceive the relative risk of these products compared to cigarettes, and that the modified risk products, as 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**." The underlying and overwhelming science about General Snus has not changed since FDA's initial evaluation.
- In accordance with Section 911(i)(1) of the FD&C Act, the renewal application complies with the requirements by providing results from the required postmarket surveillance conducted pursuant to the Risk Modification Order. That reporting demonstrates:
    - During almost ten years of post-market reporting to FDA, no issues have arisen.
    - Post-Market Surveillance Studies have shown that consumers continue to understand and are not misled by the authorized claim.
    - Surveillance during the post-market period conducted by FDA and Centers for Disease Control and Prevention (CDC) continues to demonstrate extremely low youth uptake of General Snus products.
    - Annual literature reviews of external scientific research directly assessing snus products support the conclusions made in the original applications regarding low disease risk of snus use relative to combustible use, patterns of use of the authorized products indicating a move away from combustible cigarettes, low youth use, and continued understanding of the claim.
- Since initial authorization, converging lines of evidence continue to build upon the decades of scientific evidence supporting products like General Snus being lower in risk than combusted products.

- General Snus products have significantly lower levels of harmful chemicals compared to combustible cigarettes. In particular, the GOTHIATEK standard[3] remains well adhered to as evidenced by results of extensive testing, confirming General Snus products maintain their exceptionally low HPHC levels.
- Decades of epidemiological data through the "Swedish Experience" with snus demonstrate that the health risks associated with snus are considerably lower than those associated with cigarette smoking.
- Overall, FDA itself has concluded that the available scientific data shows that switching from cigarettes to products smokeless tobacco products like General Snus reduces the risk of cancers, cardiovascular disease, and respiratory disease.[4]

The historic decision to authorize the marketing of the General Snus products as reduced risk products followed five years of rigorous review. Swedish Match continued the MRTP journey with robust post-market surveillance and reporting. The data collectively show that having General Snus on the market with the authorized MRTP claim benefits the population as a whole, and support the conclusion that maintaining authorization of the claim will be appropriate for the protection of public health. While authorization of the claim for the General Snus products demonstrated that the MRTP process can work, a denial would suggest that the MRTP process is fundamentally broken. Most importantly, a denial of the renewal of this Risk Modification Order would deny adult consumers truthful information they could use to make better decisions about their health.

MRTP Program Developments

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The MRTP program as it currently exists appears difficult, time-consuming, and cost-prohibitive for many manufacturers. The long journey to obtain the Risk Modification Order for General Snus products was instructive for would-be applicants considering the MRTP pathway, and FDA must do more to make the MRTP program approachable. Specifically, FDA should develop a more clear and predictable framework for high-quality MRTP application submissions and reviews. CTP should not only prioritize timely development and completion of policies and scientific standards necessary for high quality submissions, but also simplify, standardize, document, and publicly disseminate review procedures.

Regarding the conceptualization and measurement of consumer understanding in support of MRTPAs, specifically mentioned on the docket for TPSAC's consideration,

[3] https://www.swedishmatch.com/Snus-and-health/GOTHIATEK/GOTHIATEK-standard/

[4] See, e.g., FDA Memorandum, "Summary of Health Effects of Smokeless Tobacco Products for Epidemiology Branch Product Application Review" (September 10, 2020) ("the overall epidemiological literature supports that cigarette smokers who completely switch to SLT products are likely to substantially lower their risks of cardiovascular disease, lung cancer, and respiratory disease compared to smoking.")

FDA should carefully consider the following:

- *Added specificity to FDA's existing guidance for industry regarding principles for designing and conducting tobacco product perceptions and intentions studies (TPPI Guidance).* The TPPI guidance provides helpful general principles to consider regarding study design and methodologies. While the guidance recognizes that Applicants are faced with many options that each have their own strengths and weaknesses, it lacks detail on the tradeoffs in the eyes of the FDA, specifically in the context of consumer understanding studies to be used in support of MRTP submissions. FDA may consider incorporating references to existing standards and materials, such as widely used measures. Additionally, the TPPI guidance provides little information on potential bridging across product portfolios. Applicants would benefit from information on specific product attributes FDA believes may impact MRTP study outcomes and why.
- *Communication of claims in context*. MRTP claims do not exist in a vacuum. Rather, baseline knowledge and beliefs, total health information, and warnings conveyed regarding a product all influence consumer understanding. The Swedish Match consumer perception study highlighted this, and ultimately required substantial revision based on FDA feedback. FDA should be mindful of how existing information may conflict with or detract from the overall message that a modified risk or exposure claim may otherwise deliver. Additionally, FDA could provide guidance to industry on when and how to adjust claims based on findings from consumer understanding studies and what retesting may be required as claims are perfected, as appropriate.
- *Claims stimuli*. FDA must consider the various modes in which claims information may be communicated to consumers. It is likely not feasible or necessary to proactively test all potential claims communications, and FDA should provide guidance on best formats for test stimuli – like the video ad used by Swedish Match in its Perception and Behavioral Intentions Study – that could be considered representative of the claim's understanding by consumers. Additionally, FDA should be explicit about limitations on claims collateral and channels for dissemination that could result from test stimuli.
- *Validation*. The TPPI guidance recognizes that MRTP studies will likely require new or adapted measures and survey instruments because the information conveyed is typically product-specific. Applicants could benefit from additional guidance on what information FDA is looking for to support the validity, particularly of quantitative measures and survey methods, in order to demonstrate that participant answers are based on a correct understanding of the information presented and are not biased.

Additionally, rather than expecting perfect information about consumer understanding of a product before issuing an authorization, CTP should embrace the value of post-authorization surveillance data and information. Such data can be used to evaluate certain population-level trends and unintended consequences and, where appropriate, support CTP in renewing or withdrawing an authorization.

Currently, consumer understanding regarding the continuum of risk for nicotine-containing products and the role of nicotine in the harms caused by tobacco products is detached from reality. Significantly, former CTP Director Mitch Zeller repeatedly highlighted the prevalence of misperceptions about the health impacts of nicotine over his term, but CTP has yet to address these widespread misperceptions – which are held not just by the general public, but also by a majority of physicians.[5] For example, the misperception that ENDS products are at least as harmful as cigarettes has been growing over time.[6] Indeed, this misperception has been actively promoted by numerous state and local government entities as well as public health groups.[7]

As the public misperception of potentially reduced risk products like ENDS continues to worsen, effective educational efforts and evidence-backed interventions are more critical than ever. Research shows that smokers who believed ENDS were less harmful than smoking were significantly more likely to start using ENDS a year later and also more likely to stop smoking and switch completely to ENDS. Additionally, the belief that ENDS are less harmful than smoking was associated with maintaining switching.[8] Consumers need access to truthful information regarding the relative risks of tobacco products, and the only avenue through which manufacturers can communicate the relative risk of their products is the MRTP pathway.

It is essential to public health that CTP provide useful guidance to potential applicants so that evidence-based information regarding the relative risks of nicotine-containing products can reach consumers. We believe that for tobacco harm reduction to succeed, there must be a diverse marketplace of innovative FDA-authorized, reduced-risk products—and this is the first critical step to making that vision a reality.

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[5] Bover Manderski MT, Steinberg MB, Wackowski OA, Singh B, Young WJ, Delnevo CD. Persistent Misperceptions about Nicotine among US Physicians: Results from a Randomized Survey Experiment. Int J Environ Res Public Health. 2021 Jul 21;18(14):7713. doi: 10.3390/ijerph18147713. PMID: 34300168; PMCID: PMC8306881; Steinberg, M.B., Bover Manderski, M.T., Wackowski, O.A. *et al.* Nicotine Risk Misperception Among US Physicians. *J GEN INTERN MED* 36, 3888–3890 (2021). https://doi.org/10.1007/s11606-020-06172-8.

[6] See, e.g., Huang J, Feng B, Weaver SR, Pechacek TF, Slovic P, Eriksen MP. Changing perceptions of harm of e-cigarette vs cigarette use among adults in 2 US national surveys from 2012 to 2017. JAMA Netw Open. 2019;2(3):e191047; Malt L, Verron T, Cahours X, Guo M, Weaver S, Walele T, O'Connell G. Perception of the relative harm of electronic cigarettes compared to cigarettes amongst US adults from 2013 to 2016: analysis of the Population Assessment of Tobacco and Health (PATH) study data. Harm Reduct J. 2020;17(1):65.

[7] See, e.g., Vaping Post, US: Idaho Launches Inaccurate Statewide Anti-Vape Campaign (February 21, 2023); The Chronicle of Philanthropy, Bloomberg's Millions Funded an Effective Campaign Against Vaping. Could It Do More Harm Than Good? (March 23, 2021); Reason Foundation, The American Heart Association's 'Quit Lying' Campaign Spreads Misinformation About E-Cigarettes (November 20, 2019).

[8] See Kim, S., Shiffman, S. & Sembower, M.A. US adult smokers' perceived relative risk on ENDS and its effects on their transitions between cigarettes and ENDS. *BMC Public Health* 22, 1771 (2022). https://doi.org/10.1186/s12889-022-14168-8.

Thank you for the opportunity to comment on these important topics. Should you have any questions, please do not hesitate to contact me at (b) (6)

Sincerely,

(b) (6)

Brittani Cushman
President

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Thank you for the opportunity to provide testimony to the U.S. Food and Drug Administration's Tobacco Advisory Committee's meeting on renewing the modified risk tobacco product order for Swedish Match's general snus products.

The Independent Women's Forum has long promoted tobacco harm reduction products and we know these products are especially important for women because women have a harder time quitting smoking.

In fact, researchers at Uppsala University in Sweden discovered that nicotine can impede the production of an enzyme that regulates estrogen production, which can impact women's emotion and motivation. Research has also found that women also deal with the fear of weight gain and changes in mood.

Similarly, researchers at the University of Montreal found that women's menstruation cycle increases neural activity related to cravings, which often hamper a woman's attempt to quit smoking. As we all know, and while this might be an unfashionable statement today, it is a biological fact that men *do not* have a menstruation cycle. As such, men do not have to deal with the added monthly cravings that come with menstruation.

Other studies have shown women have much more severe symptoms of withdrawal than men, and that women are more likely than men to begin smoking again when faced with stress and anxiety.

We know that the FDA does not intend to punish women, simply for their sex. Yet, that is precisely what's going to happen if women are limited to smoking cessation products that biologically cannot provide them with the help they need to quit traditional cigarettes. Women want and need a variety of choices in the marketplace in order to find a harm reduction product that works for them.

Therefore, we believe that TPSAC and FDA should renew the MRTP marketing orders.

Modified Risk Tobacco Products and Tobacco Product Regulation

In 2009, Congress gave the U.S. Food and Drug Administration the authority to regulate tobacco products under the Family Smoking Prevention and Tobacco Control Act (TCA). In addition to regulating tobacco products, the TCA authorizes the FDA to oversee manufacturing, distribution

and marketing of tobacco products, including "specific restrictions on marketing tobacco products to children."[i] Under the TCA, companies manufacturing new tobacco products – those that were introduced to market after 2007 – are required to submit an application to the FDA for authorization to sell those products.

In addition to regulations, the TCA addressed the then-growing product category of safer alternatives to cigarettes by requiring that "modified risk" claims are backed by robust evidence to show that they are less harmful than combustible cigarettes.

Section 911 of the TCA defines modified risk tobacco products as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."[ii]

The Secretary of Health and Human Services is responsible for issuing all modified risk tobacco product orders, provided that the manufacturer is able to demonstrate that the products 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."
- In addition, companies must also submit additional findings before an order is issued, including:
- "the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substances or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
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In essence, tobacco companies must provide robust evidence that the modified risk tobacco product reduces the harms associated with tobacco through

Further, the FDA is given ongoing oversight authority via postmarket surveillance data and studies, which are required in Section 911. After issuing a modified risk order, the applicant must

"conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health … and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product." These results "shall be submitted to the Secretary on an annual basis."

The FDA also has exclusive authority to withdraw the modified risk order marketing authorization at any time after the order has been issued. The FDA can remove the order for many reasons, including:

- "the applicant, based on new information, can no longer make the demonstrations required
- … the application failed to include material information or included any unture statement of material fact;
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- … any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;
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The TCA provides the FDA with a full range of authority to recognize and permit the marketing of tobacco products that have reduced harm. Not only must companies submit rigorous scientific evidence that proves the product is less harmful than current tobacco products, but it also must monitor those products.

Should youth use become an issue, or perhaps long-term evidence indicates that the product may in fact not be less harmful, the FDA can withdraw the modified risk order and the company must quit marketing the product as such.

To date, the FDA has only granted 14 modified risk orders for tobacco products. Eight of the modified risk orders were for smokeless tobacco products, and the remaining orders were for combustible and heated cigarette tobacco products. The agency has also refused to accept 10 other applications and has refused to file 11 applications.

There are a very limited number of modified risk tobacco products that are legally marketed in the United States, and only one product can be marketed in New Hampshire, as of January 2022.

Tobacco Harm Reduction

The evidence of harm associated with combustible cigarettes has been understood since the 1964 U.S. Surgeon General's Report that smoking causes cancer. Research overwhelmingly shows the smoke created by the burning of tobacco, rather than the nicotine, produces the harmful chemicals found in combustible cigarettes.[iii] There are an estimated 600 ingredients in each

tobacco cigarette, and "when burned, [they] create more than 7,000 chemicals."[iv] As a result of these chemicals, cigarette smoking is directly linked to cardiovascular and respiratory diseases, numerous types of cancer, and increases in other health risks among the smoking population.[v]

For decades, policymakers and public health officials looking to reduce smoking rates have relied on strategies such as emphasizing the possibility of death related to tobacco use and implementing tobacco-related restrictions and taxes to motivate smokers to quit using cigarettes. However, there are much more effective ways to reduce tobacco use than relying on government mandates and "quit or die" appeals.

During the past 30 years, the tobacco harm reduction (THR) approach has successfully helped millions of smokers transition to less-harmful alternatives. THRs include effective nicotine delivery systems, such as smokeless tobacco, snus, electronic cigarettes (e-cigarettes), and vaping.

Swedish Match's PMTA and MRTP Orders

In 2015, Swedish Match's portioned snus products (defined as smokeless tobacco products) were the first ever-tobacco products to be granted a marketing order through the premarket tobacco product application (PMTA). The FDA's PMTA process requires the manufacturer to demonstrate to the agency that its product is appropriate for the "appropriate for the protection of public health," or the APPH standard.

In issuing the first-ever PMTAs, the FDA announced that the decision "reflects evidence showing that these products, marketed as described in the manufacturers' application, would result in a low likelihood of new initiation, delayed cessation or relapses."[vi] Further, the FDA "also determined that [the new] products would likely provide less toxic options if current adult smokeless tobacco users used them exclusively."[vii]

As emphasized by the FDA, the PMTA did not permit the company to "market a product with claims of reduce exposure or reduced risk," including the FDA finding the products being less toxic. As such, Swedish Match first applied for a MRTP order in 2014.

According to the company, Swedish Match provided "an abundance of Swedish and international evidence on the health effects of snus – evidence that stretches over three decades and includes governmental cohort studies and clinical trial results."[viii] The company's MRTP application consisted of "more than 100,000 pages."[ix]

Youth Use of Snus & Other Smokeless Tobacco Products Is at Record Lows

The Monitoring the Future (MTF) Study is conducted annually by the University of Michigan, with support from the National Institute on Drug Abuse. The MTF is "an ongoing study that uses

annual surveys to track the behaviors, attitudes, and values of U.S. secondary school students, college students, and adults through age 60."[x]

The MTF has been tracking snus among youth in 8th, 10th, and 12th grades since 2012, while the study first asked 12th graders about use in 2011. That year, only 5.7 percent of youth in the MTF study reported past-year use of snus products. Since 2012, the percentage of youth reporting past-year use of snus products has only decreased. In 2023, only 1.1 percent of youth had used snus in the past year. This was a 30.6 percent decline from 1.6 percent of youth who had used snus in 2022, and a whopping 80.2 percent decline from 2012.

As youth use of such products is not an issue, FDA should continue to permit the reduced risk marketing of Swedish Match's snus products.

Women In Need of More Marketing of THR Products

In the United States, about 10 percent of women were smoking in 2021, compared to 13.1 percent of men.[xi] Yet, regarding smokeless tobacco product use, around 4.2 percent of men were using smokeless tobacco products in 2021, compared to 0.2 percent of women.[xii]

Given that smokeless tobacco products are significantly less harmful than combustible cigarettes, there is an urgent need to message females. While cigarette rates are comparable, the use of smokeless tobacco products among genders is very disparate.

Authorizing Swedish Match's MRTP order would help to increase the use of smokeless tobacco products among women who smoke and help to reduce the cost burden related to smoking.

Conclusion

The FDA should continue to authorize Swedish Match's MRTP orders, as well as reforming the TCA process to facilitate more THR products to come to market.

Lindsay Stroud
Senior Fellow
Taxpayers Protection Alliance
Visiting Fellow, IWF

Julie Gunlock
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Independent Women's Forum

[i] U.S. Food and Drug Administration, “Family Smoking Prevention and Tobacco Control Act - An Overview,” June 3, 2020, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview.

[ii] U.S. Food and Drug Administration, “Section 911 of the Federal Food, Drug, and Cosmetic Act - Modified Risk Tobacco Products,” January 7, 2018, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-911-federal-food-drug-and-cosmetic-act-modified-risk-tobacco-products.

[iii] Brad Rodu, For Smokers Only: How Smokeless Tobacco Can Save Your Life, Sumner Books, 1995, p. 103.

[iv] American Lung Foundation, “What’s In a Cigarette?,” February 20, 2019, https://www.lung.org/stop-smoking/smoking-facts/whats-in-a-cigarette.html.

[v] Centers for Disease Control and Prevention, “Health Effects of Cigarette Smoking,” January 17, 2018, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm.

[vi] U.S. Food and Drug Administration, “FDA issues first product marketing orders through premarket tobacco application pathway,” Nov. 10, 2015, https://wayback.archive-it.org/7993/20170111122117/http:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472026.htm/

[vii] *Ibid.*

[viii] Swedish Match, “Swedish Match submits a Modified Risk Tobacco Product (MRTP) application,” Jun. 11, 2014, https://www.swedishmatch.com/Media/Pressreleases-and-news/Press-releases/2014/Swedish-Match-submits-a-Modified-Risk-Tobacco-Product-MRTP-application/.

[ix] *Ibid*.

[x] U.S. Centers for Disease Control and Prevention, “Monitoring the Future (MTF) Study,” *National Center for Health Statistics*, Jun. 26, 2023, https://www.cdc.gov/nchs/hus/sources-definitions/mtf.htm.

[xi] U.S. Centers for Disease Control and Prevention, “Current Cigarette Smoking Among Adults in the United States,” *Smoking and Tobacco Use*, May 4, 2023, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

[xii] U.S. Centers for Disease Control and Prevention, “Smokeless Tobacco Product Use in the United States,” *Smoking and Tobacco Use,* May 15, 2024, https://www.cdc.gov/tobacco/other-tobacco-products/smokeless-product-use-in-the-us.html.

The Consumer Advocates for Smoke-free Alternatives Association

www.casaa.org PO Box 2991, Plattsburgh, NY 12901 202-241-9117

June 20, 2024

To: Serina Hunter-Thomas
Office of Science, Center for Tobacco Products
Food and Drug Administration
Document Control Center, Bldg. 71, Rm. G335
10903, New Hampshire Ave.
Silver Spring, MD 20993-0002.

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

RE: Renewal of modified risk orders submitted by Swedish Match USA, Inc. for eight loose and portioned snus products.

Members of the Tobacco Products Scientific Advisory Committee (TPSAC),

The Consumer Advocates for Smoke-free Alternatives Association (CASAA) is writing in support of Swedish Match's application for the renewal of modified risk orders (MROs) for eight General snus products. The renewal of these MROs does not introduce new questions or concerns related to public health.

Upon reviewing the post-market surveillance materials provided by Swedish Match, it is clear that the modified risk statements associated with General snus are effectively supporting consumers' understanding of the continuum of risk and that switching completely from cigarettes to a product like General snus can reduce the likelihood of developing disease attributed to smoking. While these results are encouraging, CASAA encourages PMI/Swedish match to expand the reach of their modified risk statements as part of a more concerted effort to reach people who smoke who are in greater need of understanding what low-risk options are available to them.

Authorized modified risk statements are a vital part of educating consumers about the reduced risks associated with using General snus compared to smoking combustible tobacco products. It is imperative that more smoke-free products are authorized to carry these messages, both in terms of promoting switching away from the deadliest tobacco products and as part of the overall effort to correct misperceptions of risk associated with nicotine.

While CASAA is writing in support of renewing the existing MROs for all General snus products, we are also expressing concerns that these statements are not reaching a broader audience of nicotine consumers. There is no communication at points of sale that contains the authorized modified risk statements and this information is easy to miss on the bottom of the General snus website. Although CASAA understands that changing the marketing plan for General products means undertaking an exhausting and expensive application process, we encourage PMI/Swedish Match to expand its communications about the relative risk of snus to more effectively reach populations who smoke at disproportionately higher rates.

Enhance Accessibility of the MRTPA Process

The Center for Tobacco Products (CTP) needs to take steps to make the Modified Risk Tobacco Product Application (MRTPA) process more accessible. Currently, applicants face significant challenges, including inadequate returns on the investment required to prepare and submit an MRTPA, coupled with tremendous uncertainty regarding the issuance of a MRO. This creates a deterrent, or barrier, preventing more companies from even attempting the process. As a result, consumers are not being adequately informed about the low-risk alternatives to smoking that are available to them.

CASAA lacks the experience of submitting a MRTPA as we are not a manufacturer and do not represent nicotine companies. Therefore our recommendations for solutions are without technical know-how. All of that aside, it has been our thinking for many years that the appropriate for the protection of public health standard (APPH) makes the MRTP process somewhat redundant and arguably unnecessary. If a product meets the APPH standard, implying that such products are less harmful than cigarettes, why should companies apply for MROs? It seems appropriate for modified risk statements that a company wishes to use in their marketing to undergo review concurrently with a PMTA. If a product is not “safer than a cigarette” then how can it meet the APPH standard?

Increase Public Awareness of MRTPs

The FDA must do more to inform the public about Modified Risk Tobacco Products (MRTPs). CASAA underscores our previous comments urging the FDA to promote awareness of the existence of modified risk products and urges the Center for Tobacco Products (CTP) to develop education campaigns directed at both adult nicotine consumers and the general public. While we acknowledge that the FDA will never endorse or promote any specific tobacco product, there are no statutory limitations on the agency's role in educating consumers about the continuum of risk.

Promoting awareness about MRTPs aligns with the FDA's recent commitment to correct misperceptions of risk associated with nicotine among healthcare providers and consumers. An informed public is essential for harm reduction and for enabling smokers to make choices that significantly reduce their health risks.

Youth Use of Oral Tobacco/Nicotine Remains Low

Youth use of oral tobacco or nicotine products is historically much lower than use of combustible or vapor products. But we would be wise to brace for change. This is not to suggest that regulations need to be stricter, but rather, we need a whole-of-society reevaluation of what we deem as acceptable in terms of substance use prevention, use prevalence, and education about any substance use. FDA has a role to play in this conversation by communicating patterns of use among all age groups more objectively rather than using the abstinence-only language and preferred outcomes of anti-tobacco campaigns.

While we agree that messaging about the tobacco risk continuum requires study and review, we urge the FDA and any researchers engaging on this matter to prioritize honest statements over coercive and hysterical claims intending to discourage use. It is clear that US regulators and health agencies have work to do in terms of rebuilding the public's trust. Honesty and transparency are the only way forward.

Conclusion

Renewing Swedish Match's modified risk orders for General snus products is a critical step in supporting public health by providing consumers with accurate information about lower-risk alternatives to smoking. Additionally, making the MRTPA process more accessible and increasing public awareness of MRTPs are essential actions that the FDA must undertake to fulfill its commitment to public health.

Thank you for considering our comments.

Sincerely,
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June 20, 2024

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ATTN: Serina Hunter-Thomas

Subject: Tobacco Products Scientific Advisory Committee Meeting, June 26, 2024

The American Latino Veterans Association (ALVA) writes in support of the modified risk tobacco product (MRTP) authorization renewal for General Snus smokeless tobacco products submitted by Swedish Match USA, Inc. In 2019, after the U.S. Food and Drug Administration (FDA) conducted rigorous, science-based reviews they gave MRTP authorization to eight General Snus products, which allowed them to be marketed as reduced risk relative to cigarettes.

According to the Center for Disease Control and Prevention more than 1 in 5 (21.6%) veterans in the US reported current cigarette smoking and about 1 in 13 (7.7%) Hispanic or Latino adults smoked in the US. Smoking is a major cause of cardiovascular disease. Decades of research and scientific data have proven that switching from combustible cigarettes to smokeless products, like General Snus, reduces adverse health outcomes. Swedish Match has also supplied the FDA with annual studies on the reduced risks associated with their products, all of which have verified that same conclusion.

Additionally, we believe efforts should also be made to improve the efficacy and transparency of the MRTP application review process by adopting recommendations provided by the Reagan Udall Foundation. In their 2022 Evaluation Report, five independent experts agreed that the FDA should take additional steps to simplify, standardize, and document its procedures to allow industry players to better prioritize and submit high-quality applications.

Our organization shares the FDA's desire to protect public health. We also understand that for many in the Latino/Hispanic community, switching from cigarettes can be challenging and often a multi-step journey. Adult tobacco consumers have the right to access information about the relative risks of tobacco products to inform their choices. They should feel confident that their adoption of less harmful tobacco products is backed by the most modern scientific assessments and studies.

Sincerely,

(b) (6)

Raul Danny Vargas
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NATIONAL TAXPAYERS UNION
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June 20, 2024

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Submitted via Email: *TPSAC@fda.hhs.gov*

Re: Written Comments to Accompany Oral Presentation the Center for Tobacco Products' (CTP) Tobacco Products Scientific Advisory Committee's June 26, 2024 Public Hearing on Docket No. FDA-2024-N-0008

On behalf of National Taxpayers Union (NTU), I write with comments regarding Docket No. FDA-2024-N-0008, a public hearing of the Tobacco Products Scientific Advisory Committee concerning a renewal request of a risk modification order from Swedish Match, along with "[a]dditional discussion about broader Modified Risk Tobacco Products (MRTP) program developments related to the conceptualization and measurement of consumer understanding." These comments are intended to accompany and provide additional background to NTU's oral presentation at the June 26th public hearing.

I. Introduction

NTU is the nation's oldest taxpayer advocacy organization, founded in 1969 to achieve favorable policy outcomes for taxpayers with Congress and the executive branch. Our experts and advocates engage federal policymakers on important matters affecting taxpayers in a variety of settings, including tax administration, trade, telecommunications and technology, transportation and infrastructure, financial services, health care, and product regulation. It is these latter two items which intersect and provide NTU with an opportunity to offer its views today.

We do not profess a specific expertise in the snus products that comprise the immediate topic of today's hearing; however, in the past NTU has provided perspectives on Pre-Market Tobacco Product Applications (PMTA), MRTP, as well as other initiatives under FDA's and the Center's purview that are of keen interest to taxpayers. Examples include:

- Late last year, we filed comments with the Office of Information and Regulatory Affairs urging consideration of the fiscal problems associated with FDA's Tobacco Product Standard for Menthol in Cigarettes. We noted that state-level experience in Massachusetts showed a menthol ban drove a rise in illicit sales and a loss in tax revenue.[1]

[1] See comments at https://www.ntu.org/publications/detail/ntu-submitted-comments-to-oira-on-ill-advised-menthol-ban.

- In mid-2023 NTU led a coalition letter in support of Sections 768 and 769 of the House's FY 2024 Agriculture, FDA and Related Agencies Appropriations bill to specify that none of the funds could be used to enact certain product bans or content levels tobacco products, so as to "prevent overreach by regulators that would have significant negative impacts on taxpayers, farmers, retailers, consumers, manufacturers, state and local governments, and supply chains across the country."[2]
- In 2022, we noted that despite creation of the PMTA process, at that time barely 20 product applications for e-cigarettes had been approved out of millions submitted. The result was a "gray market" in illicit products that could pressure states to raise taxes.[3]
- Throughout this time and into 2024, NTU has weighed in on numerous state-level tax and regulatory proposals affecting combustible tobacco and tobacco alternative products.[4]

The following comments will therefore focus on the "broader … developments" mentioned in the Federal Register notice for Docket No. FDA-2024-N-0008.

II. Comments

1) Taxpayer-funded Public Health Programs Could Fiscally Benefit over the Longer Term by More Products Entering the Market More Quickly; and the Overall Net Fiscal Picture, including Non-Health Care Programs, Can Become Clearer as a Result

In order to connect the matters before the Committee to the fiscal policy concerns of taxpayers, some rather lengthy explanation is in order.

Research on the *gross* fiscal impact of combustible tobacco use on programs such as Medicaid, Medicare, veterans care, and government employee health programs is reasonably conclusive, if not unanimous on the exact amount of impact. Smoking and its various health outcomes – such as cancers, cardiovascular and pulmonary disease, and Type 2 diabetes – can increase hospital stays, surgeries, and other costly treatments and therapies.[5]

The *net* fiscal impact to taxpayers, considering health and non-health related government programs, is a more interpretative matter. For instance, because habitual smokers tend on average to have shorter lifespans, they can improve the overall actuarial position of government retirement systems. Counterfactuals could include diminished productivity in federal, state, and local government workforces which taxpayers fund, higher life insurance premiums, as well as the potential for increased disability benefit claims.[6]

On the revenue side, anti-smoking interest groups point out that taxes on tobacco products remain too low, whether the aim is to discourage use of the products or to cover their societal costs. But this point is also highly contentious. Roughly 30 years ago, some researchers began to suggest that smokers were

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[2] See https://www.ntu.org/publications/detail/coalition-supports-efforts-to-stop-tobacco-prohibitions-in-ag-approps-bill.
[3] See https://www.ntu.org/publications/detail/fdas-lack-of-enforcement-continues-to-prop-up-gray-market-disposables.
[4] For just a few examples, see https://www.ntu.org/publications/detail/ntu-opposes-expansion-of-taxes-on-vapor-products-in-nebraska; and https://www.ntu.org/publications/detail/ntu-applauds-gov-scott-veto-of-flavor-ban.
[5] Gross estimates of smoking-related costs vary by definition, and types of government programs examined, but often run in the mid- to high- tens of billions annually. See, as a few examples, Xu, et al., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4603661/; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052927/; and testimony from Moody, https://olis.oregonlegislature.gov/liz/2016R1/Downloads/CommitteeMeetingDocument/84458.
[6] A representative examination of this phenomenon is Tiihonen, et al., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3533014/.

more than "paying their way" for their decision to consume combustible tobacco. This connection was posited well before subsequent tax and regulatorily induced price hikes on the products have made that margin even greater.[7]

Additionally, there are political factors at work in tobacco tax increases, as NTU's research arm (NTU Foundation) has well documented. As far back as 2013, our examination of budget and economic data determined that:

- States with low cigarette taxes have lower overall tax burdens;
- Tobacco tax increases are rarely used to offset other taxes;
- Tobacco taxes do not forestall other tax increases;
- Tobacco tax increases may encourage other subsequent tax increases; and
- Cigarette taxes do not spur economic growth.[8]

Other health innovations taking shape now will challenge the conventional "balance sheet" calculations of how smoking affects government-wide fiscal conditions and health care programs in particular. Newer prescription drugs to treat cardiovascular diseases (which can be exacerbated by smoking), have been estimated to significantly reduce per-capita Medicare expenditures. Recent trials with anti-obesity medications have likewise shown reductions in cardiovascular events. Other research has posited a longer-term contribution to program savings in Medicare and Medicaid by greater availability of AOMs, despite initially high costs of the medication.[9] How would the outcomes from these medications interact with smoking-related treatments for traditionally associated comorbidities?

Moreover, if these increasingly encouraging signs of long-term fiscal benefits to health programs materialize, what will the net government-wide impact be? How could longevity increases impact not only retirement system benefits, but also decisions to delay retirement and keep contributing to the tax base? How would predilections for contributing toward self-funded plans like Individual Retirement Accounts change? Would disability programs see a moderation in claims? While those questions are obviously beyond the purview of this hearing, both TPSAC and FDA have a role in decisions that could move the body of research closer to finding more answers.

A final element in this discussion is whether and how the tobacco alternative products under CTP's jurisdiction affect smoking uptake or cessation and subsequently, health.[10] Here again, however, taxes play a role in calculations of costs and benefits. As one of my former colleagues Nicole Kaeding recounted in 2020, the "delicate balance" between tax rates and smoking could actually work against public health aims if policymakers choose excessive taxes on certain products. She provided analysis of a National Bureau of Economic Research Working Paper that explored Minnesota's high taxes on vapor products and scaled those results to national policy options, concluding that as many as 2.75 million smokers could be deterred from quitting smoking.[11]

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[7] One of the more seminal examples, from Viscusi, appears here: https://www.cato.org/sites/cato.org/files/serials/files/regulation/2005/12/v25n4-13.pdf.

[8] See https://www.ntu.org/foundation/detail/tobacco-taxes-problems-not-solutions-for-taxpayers-and-budgets.

[9] For a comprehensive review of research on the value of prescription drug medication innovations in taxpayer-funded health settings, see https://www.ntu.org/publications/detail/how-much-is-medicine-worth-to-the-american-taxpayer-a-cost-benefit-analysis. See also Sepp, Pete, Comments to Centers for Medicare and Medicaid Services on 2025 Notice of Benefit and Payment Parameters (NBPP) Rule, January 8, 2024.

[10] A very thorough treatment of this question appears in testimony from Stroud, Taxpayers Protection Alliance, https://www.house.mn.gov/comm/docs/WzWBOPyugkCmn5l7v_AIog.pdf.

[11] See Tax Rates and Smoking: A Delicate Balance - Foundation - National Taxpayers Union (ntu.org).

But this otherwise compelling research may still insufficiently stress a crucial point, as far as taxpayers are concerned. Some researchers lament the fact that too little independent research exists to verify the efficacy of alternatives to combustible tobacco for uptake and cessation. Yet, even a modest change to uptake or cessation from any of these products is useful feedback. And, the change can be tracked not only through scientific studies, *but also market data reflecting actual consumer preferences and purchases*. With the other factors described above, such as new health innovations, taxpayers can have a clearer idea of how public policy can be modulated to exert a salutary fiscal impact on health and non-health programs across government. *None of this can be known if products are never given the time and space in the market to demonstrate whether they can control costs to the economy and the public fisc.*

NTU believes the Committee's role is to recognize the need for a stable policy climate that can add to the empirical collection of data. Denying, delaying, or deterring innovation in alternatives to traditional smoking -- whether through a poorly functioning approval process, excessive taxes, overly burdensome regulations, or other ill-advised market interventions -- will only thwart that goal.

2) The Application Process, in General, Needs Greater Certainty, Transparency, and Alacrity to Encourage the Development of and Investment in New Products. From PMTA to the Substantial Equivalence Pathway, to MRTP, both TPSAC and CTP can facilitate accumulation of better knowledge on the fiscal outcomes noted in 1).

CTP's challenges with issues such as balancing workloads, embracing proactive instead of reactive management, and building trust in the community it serves are not unique to the federal government. NTU has observed them in numerous contexts as diverse as the Internal Revenue Service, the Surface Transportation Board, and the Federal Housing Finance Agency.

However, CTP does have an advantage over many other federal agencies facing transition, in the form of a detailed management assessment report sanctioned by cabinet-level leadership and conducted by a respected *external* party in consultation with numerous stakeholders. In December 2022, the Reagan-Udall Foundation for the FDA published "Operational Evaluation of Certain Components of FDA's Tobacco Program," led by an independent expert panel that gathered views and input from numerous individuals and organizations – including two taxpayer organizations with whom NTU was partnered in the past.[12] The general recommendations were:

- "CTP must invest the time, now, with staff and public input, to create and implement a Strategic Plan that identifies the Center's strategic objectives and plots an operational roadmap of the steps CTP will take over the next five years to achieve those objectives." NTU has found that numerous government entities rise, or fall, based on the comprehensiveness of their strategic plans and the level of commitment that managers make toward their implementation. These two factors have, for example, proven remarkably predictive of the ebbs and flows that the IRS has experienced over the past 30 years.

- "CTP should increase its use of the Tobacco Products Scientific Advisory Committee (TPSAC) to obtain expert input on scientific issues and policy development, including regulations, guidance, and data needs for effective product regulation." Of direct importance to today's meeting of TPSAC, this recommendation is second in importance only to the development of the strategic plan itself. The most successful agency transformations are undertaken with the assistance of an advisory or oversight body that stands sufficiently *apart* from that agency to render *candid*

[12] See the report at https://reaganudall.org/operational-evaluation-fdas-tobacco-program.

guidance, yet stands sufficiently *close* to that agency to render *relevant* guidance. Again, using the IRS as just one illustration, NTU has traced the decline of the IRS Oversight Board into dormancy in the early 2010s as a major cause of the tax agency's persistent modernization problems.[13]

- Between hiring authorities under the 21st Century Cures Act and consultations with the Office of Personnel Management, TPC should pursue a workforce that can support the goals outlined above. Attracting new talent with fresh perspectives toward longstanding issues is often a catalyst for agency transformation.

- "The Agency should continue to pursue securing user fees from each sector regulated by the Center, including, for example, Electronic Nicotine Delivery Systems." This topic, of special import for taxpayers, is discussed in greater detail in Comment #3.

Overall, stakeholders consulted for Reagan-Udall report consistently voiced concern over lack of transparency, clarity, and consistency on the part of CTP's regulatory, guidance, and enforcement actions, especially in the PMTA and MRTP application submission and review stages. Certainly, the four recommendations elucidated above could help to address these shortfalls, but how could they be operationalized? In NTU's opinion, it all begins with early, robust collaboration with the constituencies CTP and TPSAC are intended to serve.

Our experience tells us that there are several methods CTP and TPSAC could embrace that carry a better promise of success:

- *Adapt the "Job Aid" concept for tax guidance to CTP guidance.* Although they can vary somewhat in their composition and operation, Job Aids are generally initiated by the IRS for either members of their own staff or the practitioner community as "how-to" guides for ensuring best practices in carrying out the intent of tax administration. As one expert we cited in testimony to the IRS put it, Job Aids "provide clarity and understanding of the Service's stance without creating significant disputes between taxpayers, their advisers, and the Service's agents, saving the Service time and taxpayer money in attempting to pass and then properly enforce its regulations."[14] This is precisely the kind of synergy that could benefit CTP and TPSAC.

- *Create an Ombudsman/Advocate for individuals and companies that must interact with CTP application, review, and approval processes.* The Reagan-Udall report noted the explosion in litigation that has resulted from the millions of product determinations that CTP faces, and the perception among some applicants with fewer resources of barriers to entry in the review and approval process. Aside from reducing the workload through judicious reorientation of the review process, "early intervention" could prevent costly and time-consuming compliance activity for applicants and the government. One way this has occurred at other agencies is to provide stakeholders with a genuine opportunity to resolve administrative problems through a dedicated intermediary – one housed within that agency but nonetheless focused outward on those who interact with processes that can sometimes prove difficult to understand or even frustrating. Another is to staff an entity that serves as a convenor and articulator of stakeholder concerns. Two standout models here are the National Taxpayer Advocate at the IRS, which is directly empowered to assist taxpayers who are unable to resolve tax administration issues through the conventional

[13] See testimony of Pete Sepp before the U.S. Senate Committee on Finance, May 16, 2023, at https://www.ntu.org/publications/detail/compliance-should-be-irs-goal-not-enforcement.
[14] See https://www.ntu.org/publications/detail/irs-considering-backdoor-death-tax-hike.

IRS chain of customer interaction. Another is the Small Business Administration Office of Advocacy, which was created to serve as "the independent voice for small business within the federal government, the watchdog of the Regulatory Flexibility Act, and a source of small business statistics and research."[15]

- *Utilize "Regulatory Sandboxes."* This concept, in widespread practice abroad, was originally proven in the tech policy sphere. As Ryan Nabil, the Director of Technology Policy and Senior Fellow for NTU's research arm (NTU Foundation) wrote prior to coming to our organization:

> '[R]regulatory sandbox' programs allow companies to test innovative products and services under a modified and frequently lightened regulatory framework for a limited period. These programs allow companies to test new financial products and enable regulators to become more familiar with technological innovation and its impact on businesses. By allowing regulators to evaluate how different rules impact businesses, sandbox programs can provide crucial information to help regulators craft business- and innovation-friendly rules.[16]

Recently NTU Foundation proposed this framework to the Internal Revenue Service for developing tax regulations governing cryptocurrency. As NTU Foundation Attorney Lindsey Carpenter explained in comments to the IRS:

> Under this sandbox method, the IRS would recruit cryptocurrency experts from outside the IRS. These experts should represent all areas of cryptocurrency: Regulatory, taxation, trading platforms, cybersecurity, investors, brokers, sellers, etc. Then, in a controlled environment, the IRS should foster allowing for the free flow of ideas about cryptocurrency and how to properly tax such.[17]

TPSAC would be an ideal candidate for adapting the regulatory sandbox method for entities interacting with CTP on a variety of highly technical aspects surrounding PMTAs and MRTPs.

3) Participants in the Process Deserve Value for the Considerable Regulatory Costs and Charges They Must Bear for Engaging in that Process.

The fourth recommendation in the Reagan-Udall report goes on at length to discuss expansion and revision of the regulatory user fee regime that CTP currently operates. NTU is quite familiar with the operation of government user charges in other contexts, and would recommend some additional principles for CTP, beyond Reagan-Udall's findings:

- *Fees should be proportionate to the cost and level of service provided.* The Internal Revenue Service recently lost litigation brought by practitioners who argued that the government was collecting excessive charges to administer the Preparer Tax Identification Number (PTIN) program. The government is now in discussions with plaintiffs to arrive at a settlement for

[15] For further introductory information on Office of Advocacy activities, see https://advocacy.sba.gov/category/regulation/agency-roundtables/, https://advocacy.sba.gov/regulatory-reform/, and https://advocacy.sba.gov/category/research/economic-reports/.
[16] See https://cei.org/studies/how-regulatory-sandbox-programs-can-promote-technological-innovation-and-consumer-welfare/ and NTUF Comments to OMB on AI Governance - Foundation - National Taxpayers Union.
[17] NTUF's Comments On IRS Cryptocurrency Regulations - Foundation - National Taxpayers Union.

repaying excessive charges.[18] Had the fees been properly calibrated in the first place, this costly and time-consuming process could have been avoided.

- *Fees should be carefully managed and safeguarded from attempts to divert them to other programmatic activities or causes.* The "Passenger Security Fee" levied by the Transportation Security Administration was statutorily increased so that the proceeds could be used to offset the deficit impact of spending increases in larger legislation, while multi-year extensions of customs user fees are often employed as an artifice to improve the budgetary "score" behind numerous bills.[19]

- *The fee system should be transparently managed and subject to regular oversight.* One of the best managerial success stories behind user fees is the model for air traffic control systems in ubiquitous practice for most U.S. trading partners. The typical structure is that ATC services are provided by a nonprofit entity governed and funded by users ranging from airlines to cargo carriers and overseen by a board of directors that carriers, labor organizations, and passenger advocates.[20] A counterexample is the Environmental Protection Agency's approval process for industry applications to bring new chemicals into commercial use, which has been plagued with delays and heavy additional regulatory costs for the private sector.[21]

Besides these positive -- and cautionary -- examples, CTP can also draw lessons from FDA's User Fee Agreements (UFAs) that help to provide a reasonable level of certainty and continuity for applicants seeking permission to market branded and generic prescription drugs, biologics, and medical devices. The UFA program does not function perfectly, as NTU has pointed out on previous occasions. Yet, it does possess virtues worth CTP's emulation, including early and frequent stakeholder engagement, and a proactive, businesslike approach to fee-setting that makes the process less susceptible to controversial interventions from elected officials.

III. Conclusion

NTU is grateful for your consideration, and I am hopeful that the fiscally based framing we have provided in these comments are useful to you. If you have any questions or concerns, please do not hesitate to contact us.

Sincerely,

Pete Sepp
President

[18] See https://www.forbes.com/sites/kellyphillipserb/2023/10/05/irs-lowers-ptin-fees-as-another-court-battle-brews-over-regulating-tax-preparers/.

[19] See https://www.ntu.org/publications/detail/bigger-government-burdens-on-air-travel-like-pfcs-wont-fly-with-taxpayers and https://www.ntu.org/foundation/detail/one-weird-trick-congress-uses-to-game-budget-numbers.

[20] For a thorough archive on this issue, see https://enotrans.org/faa-reform-reference-page/.

[21] See, for example, https://www.ntu.org/publications/detail/ntu-led-coalition-writes-to-house-energy-and-commerce-committee-on-epa-regulatory-powers.

FDA should consider the significant public health issues, especially for youth, created by Philip Morris International's co-marketing of its Swedish Match General Snus products with its Swedish Match ZYN oral nicotine products and deny Swedish Match's request to renew the MRTP order permitting it to market General Snus products with a modified risk claim

Docket Number FDA-2014-N-1051

Lauren K. Lempert, JD, MPH; Pamela M. Ling, MD, Stanton A. Glantz, PhD

University of California San Francisco TCORS

June 20, 2024

FDA granted Modified Risk Tobacco Product (MRTP) marketing authorization for eight Swedish Match General Snus smokeless tobacco products (including four mint-flavored products) on October 22, 2019, permitting Swedish Match to market these products with the following modified risk information:

> "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."[1]

Philip Morris International (PMI) purchased Swedish Match in 2022 for $16 billion because it recognized a consumer shift away from traditional tobacco products and towards alternatives such as nicotine pouches and snus.[2]

In deciding whether to renew the existing MRTP order for General Snus, FDA is required to make a determination that General Snus products will benefit the health of individuals and the population as a whole, taking into account:

(1) The increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to [General Snus];
(2) The increased or decreased likelihood that persons who do not use tobacco products will start using [General Snus]; and
(3) The risks and benefits to persons from the use [General Snus] as compared to the use of [FDA approved smoking cessation and nicotine dependence treatments].[3]

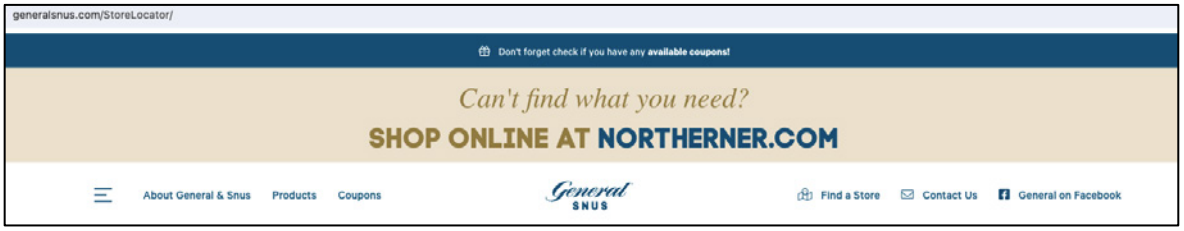
[1] US Food & Drug Administration, Modified Risk Granted Orders – Risk Modification for eight General Snus Smokeless Tobacco Products, October 22, 2019. Available: https://www.fda.gov/media/131922/download?attachment

[2] Ringstrom A, Philip Morris bets on cigarette alternatives with $16 bln Swedish Match bid, May 11, 2022. Available: https://www.reuters.com/business/philip-morris-launches-16-bln-cash-offer-swedish-match-2022-05-11/

[3] Family Smoking Prevention and Tobacco Control Act, section 911(g)(4), Public Law 111-31, 21 USC 387k (June 22, 2009).

Of particular concern is whether General Snus products are or will be used concurrently with Swedish Match's ZYN nicotine pouches, which are highly popular,[4] especially with adolescents and young adults.[5] Mint-flavored ZYN is one of the most popular flavors,[6, 7] and nicotine pouch product marketing features their flavors.[8,9] As detailed below, Swedish Match submitted a PMTA application for ZYN in 2020, but, as of June 20, 2024, FDA has not made a decision on it. ***This concurrent use is of particular concern because Swedish Match co-markets mint-flavored and other flavors of ZYN with mint- and tobacco-flavored General Snus.[10]***

Although PMI announced on June 17, 2024, that it would suspend online sales of Swedish Match's ZYN pouches on its ZYN.com website,[11] as of June 19, 2024, Swedish Match's General Snus website[12] directed consumers to shop online with a link to Northerner.com where they could purchase ZYN:



Source: https://generalsnus.com/StoreLocator/ (accessed June 19, 2024)[13]

The Northerner.com website offers smokeless tobacco and nicotine products "from top brands" including ZYN, General Snus, and Copenhagen.

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[4] Dowd AN, Thrul J, Czaplicki L, Kennedy RD, Moran MB, Spindle TR. A Cross-Sectional Survey on Oral Nicotine Pouches: Characterizing Use-Motives, Topography, Dependence Levels, and Adverse Events. Nicotine Tob Res. 2024 Jan 22;26(2):245-249. doi: 10.1093/ntr/ntad179. PMID: 37712111; PMCID: PMC10803111.

[5] Gaiha SM, Lin C, Lempert LK, Halpern-Felsher B. Use, marketing, and appeal of oral nicotine products among adolescents, young adults, and adults. Addict Behav. 2023 May;140:107632. doi: 10.1016/j.addbeh.2023.107632. Epub 2023 Jan 27. PMID: 36731224.

[6] Dowd AN, Thrul J, Czaplicki L, Kennedy RD, Moran MB, Spindle TR. A Cross-Sectional Survey on Oral Nicotine Pouches: Characterizing Use-Motives, Topography, Dependence Levels, and Adverse Events. Nicotine Tob Res. 2024 Jan 22;26(2):245-249. doi: 10.1093/ntr/ntad179. PMID: 37712111; PMCID: PMC10803111.

[7] Gaiha SM, Lin C, Lempert LK, Halpern-Felsher B. Use, marketing, and appeal of oral nicotine products among adolescents, young adults, and adults. Addict Behav. 2023 May;140:107632. doi: 10.1016/j.addbeh.2023.107632. Epub 2023 Jan 27. PMID: 36731224.

[8] Ling PM, Hrywna M, Talbot EM, Lewis MJ. Tobacco-Derived Nicotine Pouch Brands and Marketing Messages on Internet and Traditional Media: Content Analysis. JMIR Form Res. 2023 Feb 15;7:e39146. doi: 10.2196/39146. PMID: 36790840; PMCID: PMC9978966.

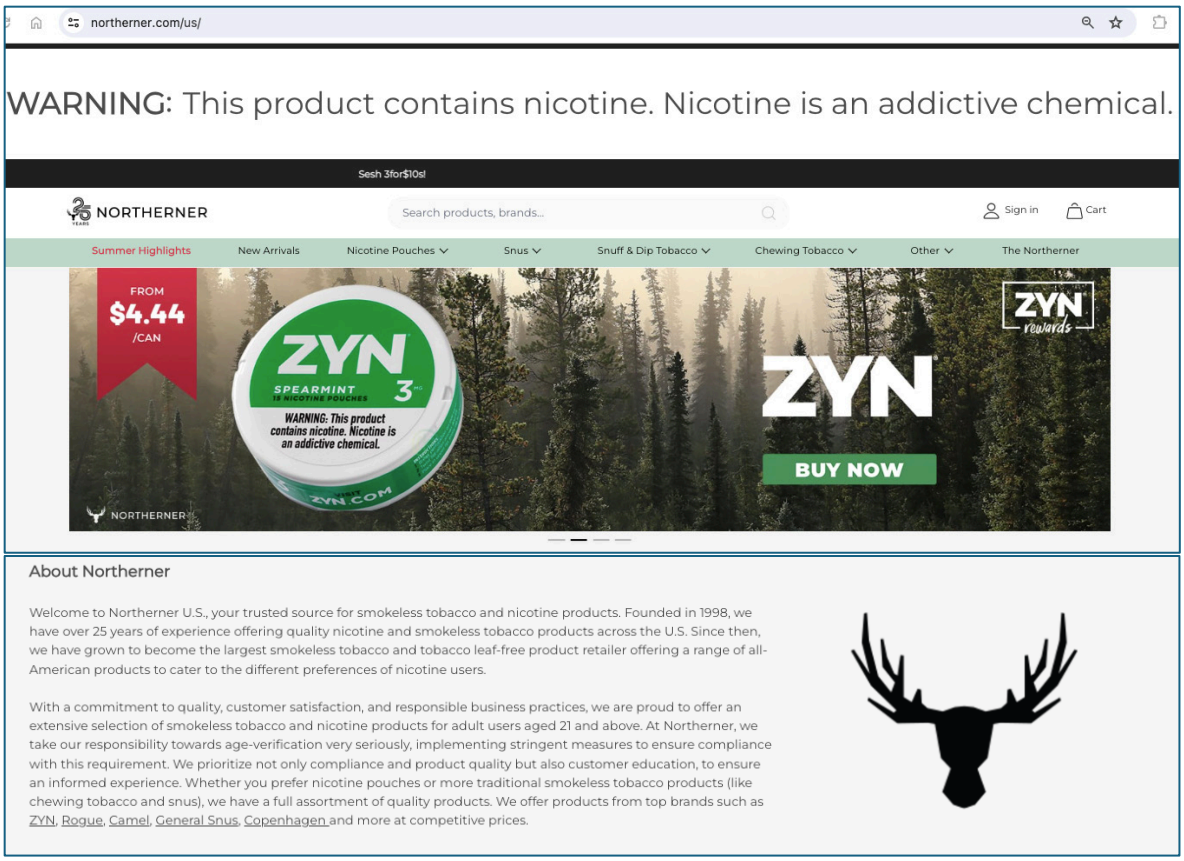
[9] Duan Z, Henriksen L, Vallone D*, et al*
Nicotine pouch marketing strategies in the USA: an analysis of Zyn, On! and Velo
Tobacco Control 2024;**33:**154-163.

[10] https://www.northerner.com/us/the-northerner/review/snus-vs-zyn (accessed June 19, 2024)

[11] Reuters, Philip Morris suspends nationwide sales on Zyn.com after D.C. subpoena, June 17, 2024. Available: https://www.reuters.com/business/retail-consumer/philip-morris-suspends-nationwide-sales-zyncom-after-dc-subpoena-2024-06-17/

[12] https://www.generalsnus.com/StoreLocator/

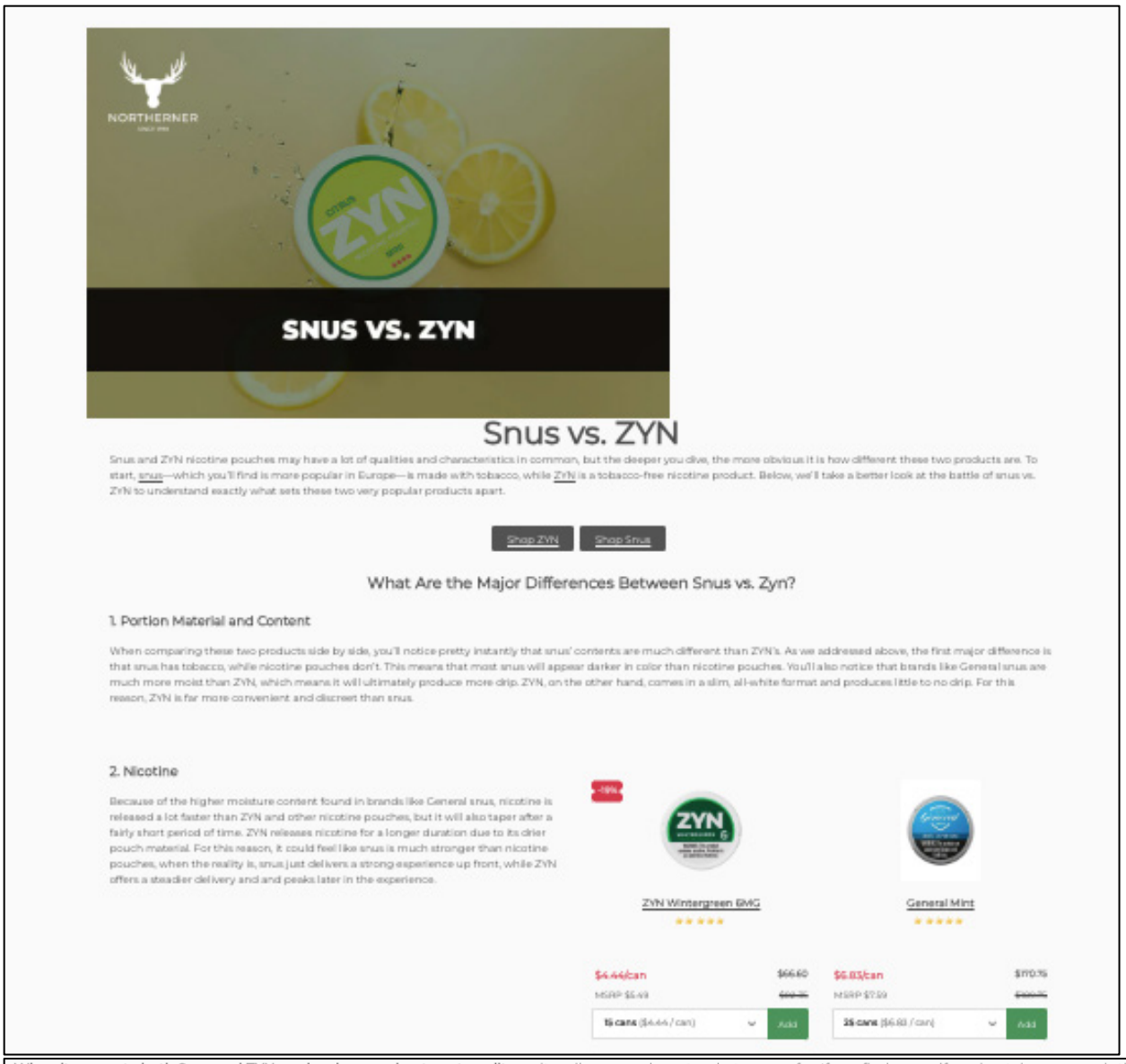
[13] generalsnus.com/StoreLocator/ (accessed June 19, 2024)



Source: https://www.northerner.com/us/ (accessed June 19, 2024)[14]

Importantly, Swedish Match's General Snus and ZYN nicotine pouches are co-marketed as companion products to use in different situations: "If you find yourself craving tobacco, snus is the product for you. If you're looking for a nicotine kick while you're in meetings at work, or in transit somewhere, then ZYN nicotine pouches are the better option." Both are sold on the same Northerner webpage with links to purchase both products.[15]

[14] https://www.northerner.com/us/ (accessed June 19, 2024)
[15] https://www.northerner.com/us/the-northerner/review/snus-vs-zyn



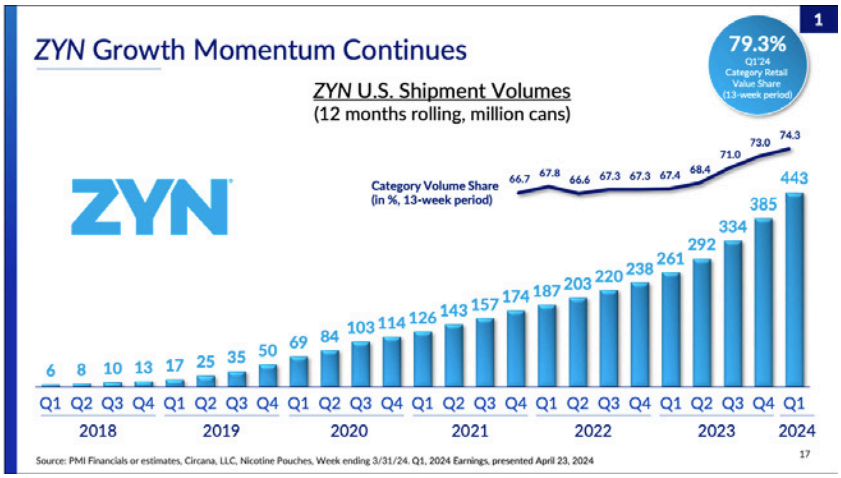
Source: https://www.northerner.com/us/the-northerner/review/snus-vs-zyn (accessed June 19, 2024)[16]

1. Co-marketing Swedish Match General Snus with Swedish Match ZYN oral nicotine products presents significant public health risks, especially for youth, that must be addressed in FDA's consideration of the General Snus MRTP renewal application.

[16] https://www.northerner.com/us/the-northerner/review/snus-vs-zyn (accessed June 19, 2024)

Swedish Match's ZYN oral nicotine products are the latest chapter in Philip Morris International's actions to addict adolescents and young adults to nicotine to maintain its market for nicotine products. ZYN's popularity and sales in the US have skyrocketed. In its investor report, PMI boasts that ZYN is the "#1 nicotine pouch brand" with approximately 4 million users, reaching a $2 billion retail value brand in the US within five years of national launch, and estimated that as of the first quarter of 2024, ZYN accounted for 74.3% of the oral nicotine pouch market share.[17] Like General Snus, ZYN is available in several mint flavors appealing to kids and ZYN is sold in cans designed to look like popular mint candies. Like General Snus, ZYN can be used discretely at times and places where using other tobacco products would not be allowed. And like General Snus, ZYN is being promoted as healthy and a nicotine-cessation device, despite the fact that these claims have not been substantiated or authorized by the FDA.

Source: PMI Investor Information, May 2024.[18]



Source: PMI Investor Information, May 2024.[19]

PMI's Swedish Match applied for PMTA marketing authorization of its ZYN oral nicotine products in March 2020.[20] As of June 20, 2024, FDA had not acted on this application.

[17] PMI Investor Information, May 2024. Available: https://www.pmi.com/investor-relations/overview

[18] PMI Investor Information, May 2024. Available: https://www.pmi.com/investor-relations/overview

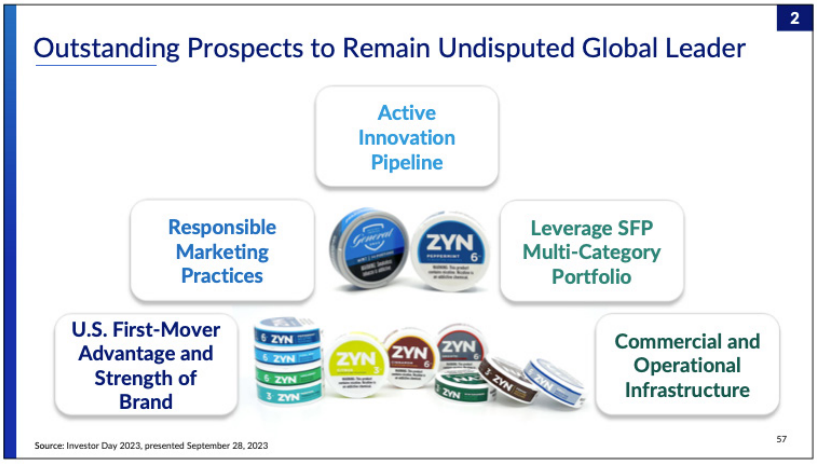
[19] Source: PMI Investor Information, May 2024. Available: https://www.pmi.com/investor-relations/overview

[20] https://www.pmiscience.com/en/smoke-free/tobacco-regulation/us-regulation-tobacco-nicotine-products/#:~:text=For%20example%2C%20PMTAs%20for%20Swedish,only%20one%20variant%20so%20far.

PMI's May 2024 investor presentation shows that the company is poised to market them as modified risk products if they obtain FDA marketing authorization:

> Continuous efforts to further increase consumer awareness of the dramatic difference in the relative risk between smokefree products and cigarettes will remain a focus going forward.
>
> …
>
> Swedish Match's 2020 PMTA applications for all its ZYN products presently on the US market show that almost all harmful and potentially harmful components commonly associated with tobacco products have been reduced below detection levels. Further, the consumer studies presented in the applications show that there is little interest in the ZYN products among consumers who are not tobacco consumers and that there is a large potential to attract existing tobacco users to the products. During 2022, Swedish Match has continued to work on new PMTA applications for products not presently on the US market.[21]

PMI's Swedish Match openly acknowledges that it intends to leverage the "SFP [Smoke-Free Products] Multi-Category Portfolio," concurrently marketing General Snus with ZYN.[22] PMI's marketing of both snus and ZYN raises public health concerns because ZYN is marketed aggressively on social media channels popular among youth,[23] and increasing numbers of youth report awareness of nicotine pouch products.[24] ***Because PMI/Swedish Match co-markets its General Snus products with ZYN, consumers are likely to be confused and believe that ZYN is authorized to be sold in the US, despite the fact that FDA has not granted ZYN PMTA marketing authorization.***



Source: PMI Investor Information, May 2024.[25]

[21] https://www.swedishmatch.com/Sustainability/focus-areas/improve-public-health/
[22] PMI Investor Information, May 2024. Available: https://www.pmi.com/investor-relations/overview
[23] Dobbs PD, Kong G, Berman ML, *et al.*'Cashing in' nicotine pouches for prizes *Tobacco Control* Published Online First: 15 June 2024. doi: 10.1136/tc-2024-058691
[24] Birdsey, J. (2023). Tobacco product use among US middle and high school students—National Youth Tobacco Survey, 2023. *MMWR. Morbidity and Mortality Weekly Report*, *72*.
[25] Source: PMI Investor Information, May 2024. Available: https://www.pmi.com/investor-relations/overview

ZYN is also being marketed with modified risk claims (as of June 19, 2024) despite the fact that FDA has not posted any MRTP applications for ZYN. A June 17, 2024, *Wall Street Journal* article includes a video that highlights how proponents of ZYN pouches are using their experience with Snus to justify ZYN's use and safety.[26] However, a recent systematic review found increased risk of cancer of the esophagus, pancreas, stomach and rectum as well as cancer-specific death associated with the use of Swedish snus.[27]

2. Conclusion:

- FDA must consider the joint marketing of ZYN nicotine pouches with Swedish Match General Snus as part of a determination that continued authorization of MRTP claims for Swedish Match is not "appropriate for the protection of public health" and deny Swedish Match's MRTP renewal application.

- Further, FDA must act to prevent illegal marketing of ZYN, including marketing ZYN with modified risk claims, because FDA is still considering the PMTA application and has not issued any marketing orders for ZYN.

[26] Ojea S, Zyn Nicotine Pouch Maker Halts Sales on Its Website, June 27, 2024. Available: https://www.wsj.com/business/retail/philip-morris-international-suspends-zyn-com-sales-amid-d-c-probe-over-banned-flavored-nicotine-pouches-8f61ae5e?st=pflf1hyroqj9kfa&reflink=desktopwebshare_permalink

[27] Valen H, Becher R, Vist GE, Holme JA, Mdala I, Elvsaas IØ, Alexander J, Underland V, Brinchmann BC, Grimsrud TK. A systematic review of cancer risk among users of smokeless tobacco (Swedish snus) exclusively, compared with no use of tobacco. Int J Cancer. 2023 Dec 15;153(12):1942-1953. doi: 10.1002/ijc.34643. Epub 2023 Jul 21. PMID: 37480210.

Swedish Match's claim that perceptions of health risks of snus are exaggerated is likely incorrect

Docket ID: FDA-2014-N-1051

Lucy Popova, PhD & Pamela M. Ling, MD, MPH
Center for Tobacco Control Research and Education
University of California San Francisco
November 24, 2014

The petitioners claim that "adults generally, and smokers in particular, had an exaggerated perception of the health risks related to snus use" (p. 688). In support of this claim, they cite five studies with adults and one with youth that measured perceptions of relative risk, all done in Scandinavia.

Leaving aside the issue whether the Scandinavian data on harm perceptions are applicable to the US case, there is another serious problem with this claim. This issue is detailed in our attached paper, "Perceptions of Relative Risk of Snus and Cigarettes Among US Smokers" (American Journal of Public Health 2013;103:e21–e23. doi:10.2105/AJPH.2013.301547).

This demonstrates that the proportion of people saying that smokeless tobacco is less harmful than cigarettes depends on the way relative harm is described in the question. One way is to measure the relative harm directly, by asking a single question, such as "Compared to cigarettes, is smokeless tobacco less harmful, as harmful as, or more harmful?" Another way is to ask about perceived harm of cigarettes and smokeless tobacco separately. In our study, only 22.1% of the nationally representative sample of smokers said smokeless tobacco was less harmful than cigarettes when we used a single question, but 51.6% gave lower ratings of harm to smokeless tobacco when two separate questions were asked. Thus, assessing perceived relative harm with a single question dramatically underestimates actual understanding of perceived risks.

Among the studies cited in the petition that measured relative risk to justify changing the warning label on snus, all but one used direct measurement of relative risk, asking the single question, and, so, likely underestimating the true proportion of participants who believe that smokeless tobacco or snus is less harmful than cigarettes.

The details of the studies are presented below:

Study	Measure of relative harm
Borland R, Li L, Cummings KM, O'Connor R, Mortimer K, Wikmans T, Ramstrom L, King B, and McNeill A. 2012. Effects of a Fact Sheet on beliefs about the harmfulness of alternative nicotine delivery systems compared with cigarettes. Harm Reduct J 9:19.	Single question
Lund I and Scheffels J. 2012. Perceptions of the relative	Single question

harmfulness of snus among Norwegian general practitioners and their effect on the tendency to recommend snus in smoking cessation. Nicotine Tob Res 14:169-175.	
Lund I and Scheffels J. 2013. Perceptions of Relative Risk of Disease and Addiction From Cigarettes and Snus. Psychol Addict Behav Epub	Single question
Lund KE. 2012. Association between willingness to use snus to quit smoking and perception of relative risk between snus and cigarettes. Nicotine Tob Res 14:1221-1228.	Single question
Wikmans T and Ramstrom L. 2010. Harm perception among Swedish daily smokers regarding nicotine, NRT-products and Swedish Snus. Tob Induc Dis 8:9.	Single question
Overland S, Hetland J, and Aaro LE. 2008. Relative harm of snus and cigarettes: what do Norwegian adolescents say? Tob Control 17:422-425.	Multiple questions

In determining what portion of the population believes that smokeless tobacco is less harmful than cigarettes, FDA should recognize that data from studies, including those cited by Swedish Match, that use a single question to measure comparative harm are likely to underestimate the proportion of people who consider smokeless tobacco to be less harmful than cigarettes.

Based on the combination of the lack of US data and the fact that the evidence submitted to justify the claim that the public does not appreciate the likelihood that snus is less dangerous than cigarettes the FDA should deny the requested petition to change the warning labels on snus.

Attached: Popova, L, Ling, PM. "Perceptions of Relative Risk of Snus and Cigarettes Among US Smokers." Am J Public Health. 2013;103:e21–e23. doi:10.2105/AJPH.2013.301547

"Swedish Experience" extolled in this MRTP application is not transferrable to the US because of the dual use with cigarettes and differences in the tobacco advertising environment

Docket ID: FDA-2014-N-1051
Stanton A. Glantz, PhD, Lucy Popova, PhD, & Lauren K. Lempert, JD MPH
Center for Tobacco Control Research and Education
University of California San Francisco
November 25, 2014

Note: This comment is identical to 1jy-8fot-818d except that the URL for the Trinkets and Trash website has been corrected.

Although snus presents lower health risks to individual users than cigarettes, the benefit of snus as a reduced harm product is only realized if smokers switch to snus completely rather than become dual users. Currently, we have little data on the trajectories of use of combustible and smokeless tobacco products in the US. We do know that in the US, the rates of smokeless tobacco use among cigarette smokers are lower than rates of smoking among smokeless tobacco users.[1] For example, in 2011, ever use of smokeless tobacco among smokers was 25.5% (of snus specifically it was 13.2%), past 30-day was 7.0% (snus 2.3%).[2] Yet rates of smoking among smokeless tobacco users are much higher (20% for daily SLT users and 40% for occasional SLT users in 1998).[3] This indicates that dual use might be a more common pattern of use and a bigger problem than argued in this application. In addition, a high quality longitudinal study of the relationship between snus use and cigarette smoking done in the United States found that smokeless tobacco users were more likely to smoke cigarettes than non-users after a period of tobacco abstinence.[4]

Any change to the warning label must reflect these realities, particularly the likelihood of dual use and the fact that to have a reasonable chance of affecting risk (at both the individual and population level) users would have to completely switch from cigarettes to snus, something that is rare in actual practice in the US.

The application argues for the transferability of the Swedish and Norwegian experience to the United States (Section 2.5.2.3.3); however, the differences in marketing environments are largely ignored. The application extolls the fact that "both the Swedish and Norwegian experiences occurred in the complete absence of a national coordinated advertising campaign" (p. 106), but fails to mention that the absence of the advertising campaign was due to bans on tobacco advertising in both Sweden[5] and Norway.[6] In the US, tobacco advertising for both cigarettes and smokeless tobacco is pervasive (see, for example www.trinketsandtrash.org), and any potential change in warning labels need to examine the effects in a context completely different from that of Sweden and Norway. For this reason, it is not reliable to make US regulatory policy based on the Swedish and Norwegian experience until there are comparable changes to the advertising environment in the US.

One way to evaluate potential effects in the absence of existing data on the effects of advertising is to model a variety of scenarios. This is exactly what we did in our 2011 paper[7] (copy

attached). We estimated the effects of aggressive promotion of snus in the United States. The analyses show that promoting snus as a harm reduction strategy is unlikely to result in substantial net health benefits on a population level, but might instead undermine other tobacco control strategies that are working.

For these reasons, the MRTP application should be denied.

References

1. Hatsukami DK, Lemmonds C, Tomar SL. Smokeless tobacco use: harm reduction or induction approach? Preventive Medicine. 2004;38(3):309-17.
2. Popova L, Ling, PM. Alternative tobacco product use and smoking cessation: A national study. American Journal of Public Health. 2013;103:923-30.
3. Tomar SL. Snuff use and smoking in U.S. men: Implications for harm reduction. National Institutes of Health State-of-the-Science Statement on Tobacco Use - Prevention, Cessation, and Control. 2002;23(3):143-9.
4. Klesges RC, Sherrill-Mittleman D, Ebbert JO, Talcott GW, Debon M. Tobacco use harm reduction, elimination, and escalation in a large military cohort. Am J Public Health. 2010;100(12):2487-92. Epub 2010/11/12. doi: 100/12/2487 [pii] 10.2105/AJPH.2009.175091.
5. Campaign for Tobacco-Free Kids. Tobacco Control Laws. Country Details for: Sweden. 2014. Available from: http://www.tobaccocontrollaws.org/legislation/country/sweden/summary
6. Campaign for Tobacco-Free Kids. Tobacco Control Laws. Country Details for: Norway. 2014. Available from: http://www.tobaccocontrollaws.org/legislation/country/norway/summary
7. Mejia AB, Ling PM, Glantz SA. Quantifying the effects of promoting smokeless tobacco as a harm reduction strategy in the USA. Tob Control. 2010;19(4):297-305. Epub 2010/06/29. doi: 10.1136/tc.2009.031427.

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

Docket ID: FDA-2014-N-1051

Lucy Popova, PhD & Stanton A. Glantz, PhD
Center for Tobacco Control Research and Education
University of California San Francisco

November 24, 2014

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.

FDA should require that all communications from tobacco manufacturers regarding MRTPs be done in a way that narrowly target smokers

Docket ID: FDA-2014-N-1051

Stanton A. Glantz, PhD
Center for Tobacco Control Research and Education
University of California San Francisco
November 25, 2014

The individual and population health goal of any MRTP is to reduce risks to smokers of higher risk products. At the same time, it is important to minimize risks of increasing initiation and relapse and reducing cessation or increasing dual use. Any MRTP application or possible MRTP order must minimize the risk of undesired impacts (e.g., increasing initiation, increasing relapse among non-using former users). Therefore, ***any reduced-risk claim that obtains an MRTP order should be permitted to be delivered only to the users of the higher-risk tobacco products (the only persons who could possibly benefit from using the reduced-risk product) and be required to be delivered in such a way as to minimize any exposure to the reduced risk claim among youth or adult non-tobacco-using populations (who might be prompted to start using) or even among current users of the reduced-risk product (who might be prompted to keep using instead of quitting) is minimized.***

This standard likely means that the MRTP claim obtaining an order should be delivered only through direct communications (e.g., email, regular mail) to pre-verified adult smokers.

In addition, any reduced risk claim permitted by an FDA order should be required to be delivered with accompanying government messages about the need to switch entirely and completely to possibly obtain any harm-reduction benefit, that quitting all tobacco use is the most effective and powerful way to reduce harms and risks.

In this case, Swedish Match is not even asking for an order allowing it to make a reduced-risk claim to any consumers but is asking FDA to change the government's warning labels that are required by law to be on the packages of the subject products.

Putting aside the fundamental question as to whether the MRTP process can be used to request changes to the use or content of government warning labels, the text changes to the warning label requested by Swedish Match would be only on the alleged reduced-risk products, meaning that the primary audience receiving the proposed reduce-risk text would be those already using the product (who would likely respond to the message by being less likely to try to quit or reduce consumption) and the claim would not be effectively delivered directly to smokers (those who would be the most likely to benefit from switching to the reduced-risk product). Moreover, if the warning label text change were featured in Swedish Match ads, it would be seen by youth, those at risk of relapse, and all the other sub-populations that would not benefit from seeing it.

For these reasons, the Swedish Match MRTP application should be denied.

In addition, to ensure that future MRTP applications do not suffer from this problem, FDA should issue a Guidance making these points. FDA has authority to place such restrictions and requirements on the delivery of MRTP claims through Sec. 911(h)(4).

The revised Swedish Match modified risk tobacco product application for General Snus fails to provide evidence that the claim is not misleading and will have a beneficial effect on the population as a whole

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January 16, 2019

BACKGROUND

Swedish Match originally submitted a Modified Risk Tobacco Product Application (MRTPA) in June 2014 to permit it to market eight sub-brands of General Snus with warning label statements different from those required by law for other commercially marketed smokeless tobacco products. In its MRTPA, Swedish match cited Swedish and international evidence to support its claim that Swedish smokers who switch completely to snus derive individual health benefits, and that the high prevalence of snus usage among men in Sweden has contributed to a lower frequency of tobacco-related disease and mortality than is found in comparable populations with higher cigarette smoking rates. The MRTPA was based on the proposition that if Swedish Match were permitted to make modified risk claims, it would lead smokers who would not otherwise quit smoking to switch completely to a Swedish match snus product, and would not lead to dual use or significant use among youth.

In December 2016, the FDA[1] denied Swedish Match's request to remove a currently required warning stating that the products can cause gum disease and tooth loss, and deferred final action on the company's other requests to remove or revise two additional currently required warnings (that the products can cause mouth cancer and that the products present "substantially lower risks to health than cigarettes"), and issued a response with advice on how the company may consider amending their applications to better align with existing evidence. FDA determined that the MRTPAs did not contain sufficient evidence to demonstrate that, as actually used by consumers, the snus products sold with modified risk claims would significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole. However, FDA stated it believed the MRTPAs could be amended to provide sufficient evidence to support issuance of MRTP orders.

In September 2018 Swedish Match submitted an amendment in response to the three deficiencies enumerated in FDA's December 2016 letter, and submitted a second amendment in November 2018[2] in response to FDA's October 2018 Advice and Information Request Letter. Regarding

[1] https://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM533236.pdf
[2] https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm533454.htm

the first two deficiencies, the company's September 2018 amendment accepted FDA's recommendations to retain the warnings stating that the product "can cause mouth cancer" and "is not a safe alternative to cigarettes." In response to the third deficiency, Swedish Match conducted a new consumer perception study entitled "Perceptions and Behavioral Intentions Study" to address the issues with its previous consumer perception study that the FDA identified. Based on the results of this study and other research, Swedish Match proposed the following modified risk claim for the General Snus:

> "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

Among other things, Swedish Match's November 2018 amendment provides copies of advertising, marketing, promotional, training, and educational materials the company plans to use to communicate modified risk information to consumers, as well as clarifications of the company's analyses of the data from the Perceptions and Behavioral Intensions Study.

REQUIREMENTS FOR AN MRTP ORDER

To be granted an MRTP order permitting Swedish Match to market its products with its proposed modified risk claim, the company must demonstrate that the product, *as actually used by consumers*, will both:

1) Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

2) 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.[3]

This two-pronged statutory requirement means that Swedish Match must submit evidence about the way consumers use the product, including whether consumers typically use snus together with cigarettes and/or other combustible tobacco products. Additionally, even if Swedish Match can meet the first prong of the statutory test and demonstrate that marketing snus with the proposed modified risk claim will significantly reduce the risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis to individual users, the MRTPA fails if marketing snus with the proposed modified risk claim will not benefit the health of the population as a whole, including youth and other people who currently do not use tobacco products.

COMMENTS ON SWEDISH MATCH AMENDMENTS TO MRTP APPLICATION

- **Adult consumers are likely to understand the claim "instead of cigarettes" as compatible with dual use.**

[3] Family Smoking Prevention and Tobacco Control Act, section 911(g)(1), Public Law 111-31, 21 USC 387k (June 22, 2009).

Tobacco Control Act section 911(h)(1) requires 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 scientific studies submitted by the MRTP 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."[4]

In particular, "the scientific studies submitted by the applicant should inform FDA's evaluation of the tobacco product's impact on tobacco use behavior, including:

- The likelihood that current tobacco product users will start using the product;
- The likelihood that tobacco users who adopt the product will switch to or switch back to other tobacco products that present higher levels of individual health risk;
- The likelihood that consumers will use the product in conjunction with other tobacco products;
- The likelihood that users who may have otherwise quit using tobacco products will instead use the product; and
- The likelihood that consumers will use the product as intended or designed."[5]

However, the application fails to demonstrate that adult consumers understand that the mode of use described in the claim ("instead of cigarettes") means a complete switch to General Snus, not a dual use with cigarettes or other tobacco products.

Swedish Match evaluated "comprehension" of the claim by asking:

> For General Snus to put you at a lower risk of disease, how many cigarettes can you smoke on a day when you also use General Snus?
>
> 1 Zero (0) cigarettes
> 2 Up to 5 cigarettes
> 3 Up to 20 cigarettes
> 4 As many as you want to smoke

[4] FDA, Guidance for Industry, Modified Risk Tobacco Product Applications, Draft Guidance, March 2012. Available at: https://www.fda.gov/downloads/TobaccoProducts/Labeling/UCM297751.pdf
[5] FDA, Guidance for Industry, Modified Risk Tobacco Product Applications, Draft Guidance, March 2012. Available at: https://www.fda.gov/downloads/TobaccoProducts/Labeling/UCM297751.pdf

5 None of the above
99 Don't know
999 Decline to answer[6]

The wording of this question is problematic because it implies that switching on some days while continuing to smoke on other days is compatible with complete switching. Furthermore, only between 37.4% and 56.2% of participants selected the correct number (zero cigarettes) (Table 1). (The detailed breakdown of proportions for other answer options has only been provided for current smokers after FDA requested it, but examining the raw data shows that across all groups, among other answers, the largest proportions were for "don't know" and "none of the above".)

Table 1. Proportion of participants who selected "zero cigarettes" in response to the question regarding the number of cigarettes one can smoke a day to lower risk of disease when using General Snus.

Participant category	Test (claim 1)	Control	p-value
Never tobacco users - legal age to 24 years	42.3%	37.2%	0.055
Never tobacco users – older than 24 years	37.4%	31.2%	0.020**
Former cigarette smokers - legal age and older	49.7%	37.0%	<0.001***
Current cigarette smokers - legal age to 24 years	56.2%	45.0%	<0.001***
Current cigarette smokers - older than 24 years of age	43.7%	33.9%	0.001*
Current smokeless tobacco users - legal age and older	53.9%	49.4%	0.160

Source: pp. 155-160, 04-study-smna-report-section-01-through-16_Redacted.pdf
P-values were reported from one-tailed independent two-sample proportion tests. Statistical significance was adjusted according to the Holm procedure, whereby p-values ordered from lowest to highest are compared (in that order) against target, adjusted p-values of *** - $p<0.017$, ** - $p<0.025$, and * - $p<0.050$, respectively. Testing ends with the first non-significant comparison.

In addition, consumer understanding of the phrase "instead of cigarettes" has been tested in Copenhagen Moist Snuff MRTP application.[7] It was found that: "some 21–34-year old adult smokers who do not reject MST [moist smokeless tobacco] disliked Prefix, 'Using this product instead of cigarettes…,' because it connoted ideas of switching to MST from cigarettes. A few participants in this group, however, thought 'instead of' was as open-ended as 'alternative to' and found the phrasing acceptable as a way of suggesting choice."[8] In the Copenhagen MRPT qualitative study, participants understood "alternative" to be compatible with continued smoking and not necessarily requiring complete switching from cigarettes to the smokeless tobacco product ("Across the board, the participants in this study tended to prefer a prefix that frames MST as an alternative to cigarettes rather than a replacement"[9]).

The quantitative findings from the Swedish Match study that users will not understand the message that they need to stop smoking all cigarettes are corroborated with results of a

[6] Kantar Health, General Snus MRTPA Study, p. 30, 04-study-smna-report-section-172_Release in Full.pdf
[7] Altria Client Services. (2018). *USSTC MRTP Application for Copenhagen Snuff Fine Cut: 6.2.: Effect of Marketing on Consumer Understanding and Perceptions*. Available at http://digitalmedia.hhs.gov/tobacco/static/mrtpa/Copenhagen/6-2-risk-perceptions_Release%20in%20Full.pdf
[8] Copenhagen MRTP application, 7.3.3-1: CS-01- Claims Qualitative Study; p. 17, app-7-3-3-1-cs-01-claims-qual-study_Redacted.pdf
[9] Copenhagen MRTP application, 7.3.3-1: CS-01- Claims Qualitative Study; p. 6, app-7-3-3-1-cs-01-claims-qual-study_Redacted.pdf

qualitative study from Copenhagen moist snuff MRTP application.[10] ***Together, they indicate that at least some adult consumers are likely to understand "instead of cigarettes" to mean using snus in addition to smoking cigarettes, a behavior that does not carry reduction in harm but likely increases harm to the users.***

- **Videos only showed mint and wintergreen products, not the other products for which the Swedish Match is seeking MRTP authorization.**

In Swedish Match's "Perceptions and Behavioral Intentions Study," "videos rotated evenly between mint and wintergreen flavors, which were chosen because they comprise roughly 70% of General Snus product sold in the US (internal sales data on file)".[11] However, it is unclear whether the effects of the claim will extend to other General Snus products (e.g., General Loose, General Portion Original Large, General Portion White Large).

Furthermore, the application did not address the appeal of flavors to youth. This is especially critical since youth are likely to use flavors. Adolescents' decisions to adopt use of any tobacco product are based on several considerations, including whether the product appeals to them, the product's flavors, smell and taste, the product's perceived harm reduction, and the ease and location of use.[12]

In order to attract young and new users, the tobacco industry adds characterizing flavors like mint, menthol, fruit, and candy to tobacco products,[13] including smokeless tobacco products.[14] These flavors appeal to new users by masking the harsh taste of tobacco. Additionally, tobacco products with a characterizing flavor including fruit-flavored e-cigarettes[15] and menthol cigarettes[16] are perceived to be less harmful than unflavored or tobacco-flavored products. In addition, there is some evidence that menthol cigarettes are harder to quit.[17] General Snus is no exception in how tobacco flavors and packaging elements affect youths' harm perceptions: Youth shown packages for smokeless tobacco with or without a flavor descriptor (primarily for snus and dissolvable tobacco) were more likely than older adults to associate the flavor descriptor

[10] Copenhagen MRTP application, 7.3.3-1: CS-01- Claims Qualitative Study; app-7-3-3-1-cs-01-claims-qual-study_Redacted.pdf
[11] MRTPA Response Amendment for MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029; p. 12, 02-response-document_Release in Full.pdf
[12] McKelvey, K., Ramos, M., Roditis, M., Ramamurthi, D., Halpern-Felsher, B. A Qualitative Analysis of Adolescents' Appeal of Various Tobacco Products. In preparation.
[13] Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. N Engl J Med. 2014;370(23):2250-2252.
[14] Kostygina G, Ling PM. Tobacco industry use of flavourings to promote smokeless tobacco products. Tob Control. 2016 Nov;25(Suppl 2):ii40-ii49.
[15] Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. Tob Control. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.
[16] Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. N Engl J Med. 2014;370(23):2250-2252.
[17] Pletcher MJ, Hulley BJ, Houston T, Kiefe CI, Benowitz N, Sidney S. Menthol cigarettes, smoking cessation, atherosclerosis, and pulmonary function. 2006;166.
Trinidad DR, Pérez-Stable EJ, Messer K, White MM, Pierce JP. Menthol cigarettes and smoking cessation among racial/ethnic groups in the United States. Addiction. 2010;105(SUPPL.1):84-94. doi:10.1111/j.1360-0443.2010.03187.x.

with better taste, more appeal, and lower health risks.[18] ***Swedish Match ignored this evidence and failed to address how youth will perceive the flavors in the Snus products, that youth will perceive lower risk associated with General Snus due to the flavors, and that such flavored Snus products will result in greater likelihood for initiation of General Snus among non-users.***

- **No effects on dual users were examined.**

In Swedish Match's "Perceptions and Behavioral Intentions Study," submitted as part of the amendment to the MRTP application, participants were either non-users, exclusive cigarette smokers, or exclusive smokeless users. Dual users were not included. However, it is important to include dual users in participants given that dual use of smokeless tobacco (ST) products (including snus) and other products is common. According to an analysis of the 2012-14 National Adult Tobacco Survey, 3.6% of U.S. adults aged 18+ were current ST users and 52.4% of these current ST users concurrently used one or more other tobacco products.[19] Dual use also increases the risk of myocardial infarction more than cigarette smoking alone.[20]

General Snus has been on the US market for several years, since Swedish Match North America (SMNA) received market authorization for General Snus in November 2015. ***Given that it has been over three years since General Snus has been authorized to be sold in the US, Swedish Match should present updated epidemiological data demonstrating real-world use of the product, particularly the rates of initiation, switching, dual use, and cessation.***

- **Post-market surveillance program needs to be evaluated before MRTP authorization.**

In the application, Swedish Match states: "If modified risk orders are issued for the eight General Snus products, Swedish Match looks forward to presenting a post-market surveillance program that will generate valid, real-life data on actual use behaviors and perceptions."[21] However, the plan for post-market surveillance program should be presented at the time of the application to allow the FDA and the research community to comment on its adequacy and to point out the issues needed to be monitored for.

- **Swedish Match presents no evidence that the proposed modified risk claim will make current smokers completely switch to General Snus.**

Swedish Match's "Perceptions and Behavioral Intentions Study" aimed to assess the impact of the proposed claim on behavioral intentions among non-users, former users, current smokers, and current smokeless tobacco users. ("Objective 1: Compare the likelihood of various usage

[18] Adkison SE, Bansal-Travers M, Smith DM, O'Connor RJ, Hyland AJ. Impact of smokeless tobacco packaging on perceptions and beliefs among youth, young adults, and adults in the U.S: findings from an internet-based cross-sectional survey. Harm Reduct J. 2014 Jan 17;11:2. doi: 10.1186/1477-7517-11-2.
[19] See Table 2, Sung HY, Wang Y, Yao T, Lightwood J, Max W. Polytobacco Use and Nicotine Dependence Symptoms Among US Adults, 2012-2014. Nicotine Tob Res. 2018;20(suppl_1):S88-S98. PMCID: PMC6093419.
[20] Teo KK, Ounpuu S, Hawken S, et al. Tobacco use and risk of myocardial infarction in 52 countries in the INTERHEART study: a case-control study. Lancet. 2006;368(9536):647–658.
[21] MRTPA Response Amendment for MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029; p. 16, 02-response-document_Release in Full.pdf

intentions and behaviors related to General Snus and cigarettes after having viewed a single General Snus video."[22]) A modified risk claim might have a population-level benefit if smokers otherwise not willing to quit switched to General Snus completely. However, the study does not assess the intentions to switch completely. Instead, it measures smokers' likelihood of buying General Snus for themselves ("How likely are you to buy General Snus® for yourself if sold in a store where you usually shop?" Responses were on 11-point Juster scale where 0= no chance, almost none [1 in 100] to 10= certain, practically certain [99+ in 100].) Even then, the study found only one significant difference (only smokers older than 24 had greater intentions to buy General Snus in the test condition (Mean=2.04) than in the control condition (Mean=1.49).

Furthermore, exposure to the modified risk claims did not change intentions to quit smoking, reduce the number of cigarettes, or seek smoking cessation aid.[23] ***Thus, the revised application provides no evidence that the proposed modified risk claim will affect current smokers' switching behavior in a way that would be protective of public health.***

- **Swedish Match presents no information on the effect of their proposed modified risk claims might have on youth**

The revised Swedish Match application does not provide any reliable information on whether adolescents would be interested in using General Snus, especially after viewing the claims, if adolescents would initiate nicotine use with General Snus, if adolescents would switch from another tobacco product to General Snus, or if adolescents would use it along with other tobacco products.

One way to obtain information on adolescents' interests and behavior is to conduct studies with adolescents. However, no tobacco company should be permitted to conduct research on youth below the legal age for tobacco use (21, to be conservative) because they could use such information to design marketing campaigns to attract youth to their products. A different way to get at adolescents' interest and behavior is relying on research on other, similar products, such as electronic cigarettes, conducted with no direct or indirect involvement of tobacco companies or their agents.[24]

Our recent research with California youth (Wave 6 of an ongoing prospective cohort study that began in 2014-2015 with 9th and 12th graders) showed that youth exposed to modified risk claims perceived the target tobacco product as lower in risk compared to the non-exposure controls and only 70% understood that "switching completely" is incompatible with continued smoking.[25] This study tested the claims proposed in the PMI's MRTP for IQOS: a) *"Scientific studies have shown that switching completely from conventional cigarettes to IQOS system can reduce the risks of tobacco related-diseases;"* (reduced risk claim), and b) *"Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's*

[22] Protocol SMNA 17-01GEN: Observational Study Report, p. 69, 04-study-smna-report-section-01-through-16_Redacted.pdf
[23] Protocol SMNA 17-01GEN: Observational Study Report, pp. 76-81, 04-study-smna-report-section-01-through-16_Redacted.pdf
[24] Institute of Medicine. 2012. *Scientific Standards for Studies on Modified Risk Tobacco Products*. Washington, DC: The National Academies Press. https://doi.org/10.17226/13294.
[25] Halpern-Felsher, B. and UCSF TCORS, unpublished data.

exposure to harmful or potentially harmful chemicals." Nonetheless, the findings might be applicable to other modified risk claims and indicate that such claims have significant effect in lowering youth's perceived risk of tobacco products. As extensive body of research has documented, lower perceived risks are associated with increased trial and use of tobacco products.[26] This indicates that the proposed claim will likely have negative impact on youth.

Because the application did not consider the impact of smokeless tobacco on adolescent use, it did not demonstrate that the product,* as actually used by consumers*, will benefit the health of the population as a whole, including current non-users; in particular, it did not provide any scientific evidence regarding the effect that this product and its marketing would have on increasing the likelihood that adolescents who are currently not tobacco users will start using smokeless.

Despite section 911(g)'s requirement, this application failed to provide adequate scientific evidence demonstrating that their Snus products would "benefit the health of the population as a whole," in particular non-users (including adolescents) as well as current users of other tobacco products.

- **Proposed modified risk claim misleads consumers about risks of General Snus**

The proposed modified risk claim is misleading because participants who saw the modified risk claim were more likely to say that General Snus is less harmful than never using any tobacco products compared to the control group, and were less likely to say that General Snus is equally or more harmful than never using any tobacco products compared to the control group. For example, among young never tobacco users (legal age to 24 years), in the control group, 10.1% believed that using General Snus daily has "a much lower chance" or "a lower chance" of "serious health problems" compared to never having used any tobacco products while 89.9% believed that using General Snus daily has "the same chance", "a higher chance", or "a much higher chance" of "serious health problems" compared to never having used any tobacco products. In the test group (claim 1, the proposed modified risk claim), the corresponding proportions were 18.7% and 81.3%, respectively.[27] Among older cigarette smokers (over 24 years old), in the control group, 24.6% believed that using General Snus daily has "a much lower chance" or "a lower chance" of stroke compared to never having used any tobacco products while 75.4% believed that using General Snus daily has "the same chance", "a higher chance", or "a much higher chance" of "serious health problems" compared to never having used any tobacco products. In the test group (claim 1), the corresponding proportions were 39.0% and 61.0%, respectively.[28]

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[26] Halpern-Felsher, BL, Biehl, M, Kropp, RY, & Rubinstein, ML. Perceived risks and benefits of smoking: Differences between adolescents with different smoking experiences and intentions. Preventive Medicine. 2004 Sep; 39(3): 559-567. PMID: 15313096. Roditis, M., Delucchi, K., Cash, D., & Halpern-Felsher, BL. Adolescents' Perceptions of Health Risks, Social Risks, and Benefits Differ across Tobacco Products. Journal of Adolescent Health. 2016 May, 58(5):5558-66. PMID: 27107909. Chaffee BW, Couch ET, Urata J, Gansky SA, Essex G, Cheng J. Predictors of Smokeless Tobacco Susceptibility, Initiation, and Progression Over Time Among Adolescents in a Rural Cohort. Substance Use and Misuse. 2019 (In Press).

[27] Protocol SMNA 17-01GEN: Observational Study Report, p. 128, 04-study-smna-report-section-01-through-16_Redacted.pdf

[28] Protocol SMNA 17-01GEN: Observational Study Report, p. 137, 04-study-smna-report-section-01-through-16_Redacted.pdf

This pattern of findings in terms of direction and statistical significance is consistent across all 8 diseases examined (chronic bronchitis, emphysema, lung cancer, serious health problems, gum disease, heart disease, mouth cancer, and stroke) for both young and older never tobacco users, former smokers, and older cigarette smokers; and across 6 (emphysema, serious health problems, gum disease, heart disease, mouth cancer, and stroke) of the 8 diseases examined for younger cigarette smokers. The findings are in the same direction for current smokeless tobacco users, but are not significant due to the small sample size. The findings are generally the same when comparing daily use of General Snus to quitting all tobacco products[29] and when comparing daily use of General Snus to daily use of aids that help stop smoking.[30] These findings indicate that seeing the ***proposed modified risk claim makes some participants more likely to believe that General Snus has protective qualities***, since its use is less risky than never using any tobacco products or quitting tobacco products. This clearly exacerbates the misperception that some participants already have (including a large proportion of current smokers and smokeless tobacco users) that use of General Snus is less harmful than not using any tobacco products. This indicates that ***the proposed modified risk claim is misleading***.

Swedish Match glosses over this problem by stating that: "The test groups in the cohorts of non-TNP [tobacco/nicotine products] users and current smokers did not perceive that the relative risks of each health condition (respiratory and non-respiratory) were equal or higher than the control group in most of the comparisons, when comparing daily use of General Snus vs. never having used any TNP. However, all respondents across test and control groups perceived the daily use of General Snus to pose higher risk for each health condition than never having used any TNP."[31] There are two flaws in this statement. First, instead of saying "The test groups ….did not perceive …," the correct statement should be "The test groups ….**were less likely to** perceive …" Second, it is incorrect to say "all respondents … perceived the daily use of General Snus to pose higher risk for each health condition than never having used any TNP." The correct statement should be "**the proportion of** respondents … who perceived the daily use of General Snus to pose **equal or** higher risk for each health condition than never having used any TNP **is greater than the proportion of respondents who perceived the daily use of General Snus to pose lower risk for each health condition than never having used any TNP**."

The exposure to the proposed claim led to another misperception. The claim explicitly lists 6 diseases ("mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis"), but does not list "gum disease." However, the exposure to the modified risk claim significantly reduced the perceived risk of gum disease. This indicates that seeing this claim might make people erroneously believe that the risk of other diseases, not listed on the claim, is reduced as well. It might stem from the fact that so many diseases were listed in the claim ("mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis") that people reading this claim generalized the risk reduction to all diseases.

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[29] Protocol SMNA 17-01GEN: Observational Study Report, pp. 140-152, 04-study-smna-report-section-01-through-16_Redacted.pdf

[30] Protocol SMNA 17-01GEN: Observational Study Report, pp. 168, 196-209, 04-study-smna-report-section-01-through-16_Redacted.pdf

[31] Protocol SMNA 17-01GEN: Observational Study Report, p. 222, 04-study-smna-report-section-01-through-16_Redacted.pdf

- **Problems with the way hypotheses are worded and tested**

There are multiple problems with how hypotheses are worded and tested (using one-tailed instead of two-tailed tests).

Here is how Hypothesis 3.3 is presented in the application:

> **Hypothesis 3.3:** The test groups will perceive the relative risk of each health condition as equal or higher than the control group when comparing daily use of General Gnus vs. never having used any TNPS.

Problem 1: Incorrect wording.

The way H3.3 is worded makes it sound like the measure of relative risk is continuous; however, it is measured as:

- a much lower chance
- a lower chance
- the same chance
- a higher chance
- a much higher chance.

It is then dichotomized into "a much lower/a lower chance" and "the same chance/a higher chance/a much higher chance." Therefore, the hypothesis should be stated in terms of proportions:

> **Reworded Hypothesis 3.3:** Greater or same proportion of participants in the test group than in the control group will perceive the relative risk of each health condition as equal or higher when comparing daily use of General Gnus vs. never having used any TNPS.

We are including "or same proportion" here because that is how these hypotheses are tested in the study. For example, in a grid on p. 99 (below), the Hypothesis 3.3 is listed as "Supported" (green X) for chronic bronchitis for "current smokers Legal – 24". The results on p. 134 (next panel below) show non-significant result (p=0.032). (Note that the result is non-significant due to the Holm correction for multiple testing.) Thus, they are holding lack of significant difference as evidence of equivalence and present is as support for their hypothesis 3.3. This leads us to the second problem.

Objective 3 Hypotheses	Never TNP Legal-24			Never TNP >24			Former Smokers			Current Smokers Legal-24			Current Smokers >24			Current Smokeless Tobacco		
	T1 vs. C	T2 vs. C	T3 vs. C	T1 vs. C	T2 vs. C	T3 vs. C	T1 vs. C	T2 vs. C	T3 vs. C	T1 vs. C	T2 vs. C	T3 vs. C	T1 vs. C	T2 vs. C	T3 vs. C	T1 vs. C	T2 vs. C	T3 vs. C
3.3 T≥C	Test groups will perceive the relative risks of each health condition (respiratory and non-respiratory) as equal or higher than the control group, when comparing daily use of *General* Snus vs. never having used any TNP. Specifically, the health conditions are:																	
Chronic bronchitis	O	O	X	O	O	O	O	O	O	X	X	X	O	O	O	X	X	X
Emphysema	O	O	X	O	O	O	O	O	X	O	O	O	O	X	X	X	X	X
Lung cancer	O	X	X	O	O	O	O	O	O	X	X	X	O	O	O	X	X	X
Serious health problems	O	O	X	O	O	O	O	O	O	O	O	O	O	O	O	X	X	X
Gum disease	O	O	X	O	O	O	O	O	X	O	X	X	O	O	O	O	X	X
Heart disease	O	O	X	O	O	O	O	O	O	O	O	O	O	O	O	O	X	X

d. Current cigarette smokers - legal age to 24 years

		Control Vs. Claims (1/2/3)								p-value (C1 vs. control)
		Claim 1 (N= 454)		Claim 2 (N= 457)		Claim 3 (N=455)		Control (N=462)		
		%	n	%	n	%	n	%	n	
Relative risk of chronic bronchitis	A much lower chance/A lower chance	28.1%	121	25.8%	111	25.3%	110	22.6%	99	0.032
	The same chance/A higher chance/A much higher chance	71.9%	310	74.2%	320	74.7%	325	77.4%	339	
	Don't Know	-	23	-	23	-	19	-	22	-
	Decline to Answer	-	0	-	3	-	1	-	2	-

Problem 2: Stating hypothesis of equivalence but testing it with nil-null hypothesis testing.

Hypothesis 3.3 is essentially a hypothesis of equivalence, which is aimed at finding evidence of no difference.[32] However, it is tested using null hypothesis of no effect (nil-null hypothesis); the test procedure is known as nil-null hypothesis significance testing (nil-NHST).[33] As typically used, the familiar independent samples t-test is an example of a nil-NHST. To test H3.3, the Swedish Match used "one-tailed independent two sample proportion tests," which are also an example of nil-NHST. As a result, they used non-significant finding (as in the example above with chronic bronchitis and current cigarette smokers between legal age and 24) as evidence of support for their hypothesis. This is wrong. An equivalence test should have been used instead. However, as we argue below, a much simpler solution should have been used.

Problem 3: Using one-tailed tests of significance is inappropriate and two-tailed tests should have been used instead.

[32] Levine, T. R., Weber, R., Park, H. S., & Hullett, C. R. (2008). A communication researchers' guide to null hypothesis significance testing and alternatives. Human Communication Research, 34, 188–209..
[33] Weber, R., & Popova, L. (2012). Testing Equivalence in Communication Research: Theory and Application. *Communication Methods and Measures, 6*(3), 190-213.

In testing the proposed hypotheses about effects of the modified risk claim on perceptions and behavioral intentions, one-tailed tests of significance were used. Instead, two-tailed tests should have been used. One-tailed tests make it easier to reach statistical significance. They are appropriate when researchers are interested only in studying one direction of differences. However, FDA is interested in significant changes in both directions – for example, not only in whether the modified risk claim increases intentions to quit smoking but also if they decrease intentions to quit smoking. The two-tailed hypotheses are the ones that matter for the protection of public health.

Overall, instead of coming up with these complicated and unnecessarily convoluted hypotheses, the study should have used simple two-tailed tests to answer the question: What effect does exposure to modified risk claim have on various populations?

- **The Dynamic Population Model used by Swedish Match is inappropriate to assess the population health impact of the proposed modified risk claim for a product which is already in the U.S. market.**

Although FDA encourages the development and application of computational models to forecast the harm to public health from the use of an MRTP applicant's product, FDA recommends that studies and analyses conducted to support an MRTP application have the following characteristics:

- Clearly articulated objectives and hypotheses;
- Protocols that employ standardized and validated methods of analysis;
- Sample sizes that permit for robust statistical analyses;
- Designs that permit valid comparisons with appropriate controls for the testing of study hypotheses (selection of the control group(s) should be based on the endpoint or effect to be evaluated);
- Procedures to minimize bias on the part of observers and analysts of the data and prevent undue influences on the results and interpretation of the study data, such as blinding, masking, random assignment to condition, etc.;
- Procedures for the selection of human subjects to allow for generalizability of study results to the U.S. population;
- Methods for assigning subjects to different comparator groups that are appropriate for making comparisons between groups with respect to pertinent variables;
- Oversampling of populations that are particularly likely to be affected, positively or negatively, by the marketing of the product;
- Protocols that allow for conditions of use of the product that are reflective of how the product will actually be used by consumers when it is marketed;
- A study duration to allow for adequate assessment of selected endpoint(s) and/or effects;[34] and

[34] Fn 17 from FDA guidance on MRTP:
[17] For example, a study of the product's effect on cessation from tobacco use would likely require greater duration than a study to assess the topography of product use or consumer perception of the product.

- Analyses that adequately address the effects of the product on the study measures, endpoints or outcomes.[35]

The Dynamic Population Model (DPM) estimates the difference in population-level survival between a counterfactual scenario that allows the use of a higher risk product and/or a lower risk product, and a ***base case scenario that only allows the use of the higher risk product***.[36] [37] For the purposes of the General Snus MRPTA, a variant of the model was used in which only cigarettes are available for use in the base case and one new product (General Snus) is added in the counterfactual scenario.[38] However, General Snus has been sold in the U.S. for several years. In this amendment, Swedish Match is seeking an authorization to market General Snus with a modified risk claim. In order to be granted this authorization, the FDA must determine whether marketing General Snus as MRTP will have a net benefit or harm for the health of the population as a whole compared to marketing General Snus without the MRTP claim. For this purpose, ***Swedish Match should construct a statistical model which compares the difference in population health between a base case that includes two products (cigarettes, and General Snus without the MRTP claim) and a counterfactual scenario that is the same as the base case except allowing for marketing General Snus as MRTP.*** The current DPM does not permit two products to be included in the base case, and hence is inappropriate to assess the impact of the proposed claim on U.S. population health.

- **The impact of the proposed claim on tobacco use behaviors should be used as the input parameters of the statistical model to forecast the resulting impact on population health.**

Although the FDA application guidelines recommend that the potential impact on mortality and morbidity be assessed for seven population groups and exposure patterns,[39] the Swedish Match used the DPM model to assess the impact of the proposed claim on mortality only for the following three groups/patterns: 1) cigarette smokers who switch to the MRTP completely instead of continuing to smoke, 2) cigarette smokers who opt to use the MRTP rather than quitting smoking, 3) never tobacco users who initiate the MRTP instead of remaining as never tobacco users. The model also examined never tobacco users who initiate the MRTP instead of initiating cigarette smoking. The model left out: 1) tobacco users and non-users who, after adopting the proposed product, switch to or switch back to other tobacco products that may present higher levels of individual health risk; 2) tobacco users who opt to use the proposed product rather than an FDA-approved tobacco cessation medication; 3) tobacco users who use the product in conjunction with other tobacco products; and 4) non-users who experience health

[35] FDA, Guidance for Industry, Modified Risk Tobacco Product Applications, Draft Guidance, March 2012. Available at: https://www.fda.gov/downloads/TobaccoProducts/Labeling/UCM297751.pdf

[36] Bachand AM, Sulsky SI. A dynamic population model for estimating all-cause mortality due to lifetime exposure history. Regulatory Toxicology and Pharmacology 2013;67(2):246-51.

[37] Bachand AM, Sulsky SI, Curtin GM. Assessing the likelihood and magnitude of a population health benefit following the market introduction of a modified-risk tobacco product:
enhancements to the Dynamic Population Modeler, DPM(+1). Risk Analysis 2018;38(1):151-62.

[38] MRTPA Response Amendment for MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029, p. 17, 02-response-document_Release in Full.pdf

[39] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. Guidance for industry. modified risk tobacco product applications. Draft Guidance, 2012, p. 22.

risks from the product ***Therefore, their assessment does not fully satisfy FDA guidelines for MRTP applications.***

Furthermore, even for the four population groups and tobacco use patterns considered, Swedish Match fails to incorporate the findings from their "Perceptions and Behavioral Intentions Study" as input parameters of the statistical model to make a comprehensive assessment of how the changes in tobacco use behaviors that may result from the proposed claim would affect the population health.

- **Swedish Match provides no explanation to ascertain the direction and magnitude of the net effect on U.S. population health that may result from the proposed modified risk claim.**

Swedish Match did not revise their estimation of the DPM model. The results[40] shown in Appendix 1 "Dynamic Population Model" were redacted from their original MRTP application in 2014,[41] and all the tables presented in Appendix 1 were copied from the original MRTP applications.[42] As in the original application, Appendix 1 in this amendment does not provide clear description about the net effect (including direction and magnitude) of the proposed modified risk claim on population health after considering all the potential harmful and beneficial effects simulated under various hypothetical scenarios of switching rates (such as 1%, 5%, and 10%) for the four population groups and tobacco use patterns. ***Therefore, the results of this model cannot be used to support that allowing a modified risk claim would benefit the public health.***

- **Some of the messaging infringes on FDA's anti-tobacco efforts**

One of the Facebook posts that Swedish Match posted for General Snus used the tagline "Stay Fresh"[43] that is very similar to "Keep It Fresh", the slogan that FDA's anti-tobacco campaign Fresh Empire is using[44] (see Figure 1 below). Fresh Empire is the FDA's campaign to prevent and reduce tobacco use among multicultural youth. Using a similar tagline in advertisements that promote tobacco use undermines the anti-tobacco brand of the Fresh Empire campaign. ***The FDA should prohibit Swedish Match from using the "Stay Fresh" as a tagline in advertisements for tobacco products to avoid confusion with the FDA campaign and avoid the possibility that readers would misunderstand this as a health message.***

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[40] MRTPA Response Amendment for MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029, pp. 20-26, 02-response-document_Release in Full.pdf

[41] pp. 17-35, "Consequences of Marketing Modified Risk Tobacco Product: Population Effects Estimated with the Dynamic Population Modeler", See: 24 appendix-6g-environ-tipping-point-analysis-2014.pdf

[42] pp. 740-743, "Information about Swedish Match North America's Modified Risk Tobacco Product Applications, See: 01 application narrative summary_Redacted.pdf.

[43] FDA Registration Brand Consumer Communications, p. 49, air-response-03-appendix-1_Release in Full.pdf.

[44] Fresh Empire Campaign, https://www.fda.gov/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/FreshEmpireCampaign/default.htm

Figure 1. A Facebook post for General Snus (left) and the logo for Fresh Empire, the FDA's anti-tobacco campaign (right). Both use similar taglines: "STAY FRESH" and "KEEP IT FRESH."

Conclusion

FDA acted appropriately in December 2016, when FDA[45] denied Swedish Match's request to remove a currently required warning stating that the products can cause gum disease and tooth loss. FDA also determined that the MRTP application did not contain sufficient evidence to demonstrate that, as actually used by consumers, the snus products sold with modified risk claims would significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole. However, FDA issued a response with advice on how the company may consider amending their applications to provide sufficient evidence to support issuance of MRTP orders.

Swedish Match's September 2018 and a second amendment in November 2018[46] accepted FDA's recommendations to retain the warnings stating that the product "can cause mouth cancer" and "is not a safe alternative to cigarettes." As discussed earlier in this comment, Swedish Match's new consumer perception study "Perceptions and Behavioral Intentions Study" does not support the FDA permitting Swedish Match to market General Snus with its proposed modified risk claim "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis." ***FDA should not issue a marketing order approving this modified risk claim because doing so would not improve public health and might harm public health by promoting more use (including more dual use with cigarettes).***

[45] https://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM533236.pdf
[46] https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm533454.htm

FDA should not renew the Modified Risk Granted Order for eight Swedish Match General Snus modified risk tobacco product application for General Snus products because as actually used by consumers, these products will not benefit the health of the population as a whole

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University of California San Francisco TCORS

Docket Number FDA-2014-N-1051

June 20, 2024

BACKGROUND

FDA granted Modified Risk Tobacco Product (MRTP) marketing authorization for eight Swedish Match General Snus smokeless tobacco products (including four mint-flavored products) on October 22, 2019, permitting Swedish Match (which is wholly owned by Philip Morris International (PMI)) to market these products with the following modified risk information:

> "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."[1]

The MRTP marketing order included requirements related to conditions of marketing and postmarket surveillance and studies. The order expires 5 years from the issue date (i.e., October 22, 2024), with an opportunity for renewal. On July 17, 2023, Swedish Match submitted an application requesting renewal of the MRTP order.[2] On May 6, 2024, FDA announced it would convene a meeting of the Tobacco Products Scientific Advisory Committee (TPSAC) on June 26, 2024, to discuss Swedish Match's application for renewal of the General Snus MRTP order and to also discuss "broader Modified Risk Tobacco Products program developments related to the conceptualization and measurement of consumer understanding."[3]

[1] US Food & Drug Administration, Modified Risk Granted Orders – Risk Modification for eight General Snus Smokeless Tobacco Products, October 22, 2019. Available: https://www.fda.gov/media/131922/download?attachment

[2] Swedish Match USA, Inc. MRTP Renewal Request, July 17, 2023. Available https://digitalmedia.hhs.gov/tobacco/hosted/mrtpa/swedish/1%20MR%20Renewal%20July%2017%2C%202023.zip

[3] Food and Drug Administration, The Tobacco Products Scientific Advisory Committee; Notice of Meeting, May 6, 2024. 89 FR 37231. Available: https://www.federalregister.gov/documents/2024/05/06/2024-09786/the-tobacco-products-scientific-advisory-committee-notice-of-meeting

To be granted a renewal of its MRTP order permitting Swedish Match to market its products with its modified risk claim, the company must demonstrate that the product, *as actually used by consumers*, will continue to both:

1) Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

2) 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.[4]

In particular, Swedish Match must demonstrate with scientific evidence that consumers, including youth and nonusers, continue to understand what is meant by the MRTP claim, are not misled by it, and that marketing these products with MRTP claims do not lead to initiation by youth or other nonusers.

It is especially important that the evidence demonstrates reduction of harms and addition of benefits to the whole population based on how the products are *actually used by consumers*. This means Swedish Match must address whether consumers, including youth, understand that to obtain the purported benefits, General Snus *must be used exclusively, not with cigarettes* or other tobacco products. Additionally, Swedish Match must not only demonstrate *understanding* but also that MRTP claims will affect behavior, leading to exclusive use of General Snus in place of cigarettes. In particular, Swedish Match must address the likelihood of dual- and poly-use of smokeless tobacco products with cigarettes, nicotine pouches, e-cigarettes, and other tobacco products. Further, it is essential that Swedish Match consider the impact, especially on youth, of marketing mint-flavored tobacco products and of co-marketing these products with the PMI ZYN nicotine pouches that are popular with youth (which we discuss more fully in a separate comment).

As we discuss in detail below, ***Swedish Match did not meet these statutory burdens. Therefore, FDA should allow the current marketing order to lapse and not renew the MRTP authorization for its General Snus products.***[5]

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[4] Family Smoking Prevention and Tobacco Control Act, section 911(g)(1), Public Law 111-31, 21 USC 387k (June 22, 2009).

[5] UCSF TCORS submitted comments opposing Swedish Match's original 2014 MRTP application and its amended 2018 MRTP application. Those comments continue to be relevant and are incorporated by reference and attached to this comment. Popova L, Sung H-Y, Chaffee B, et al. The revised Swedish Match modified risk tobacco product application for General Snus fails to provide evidence that the claim is not misleading and will have a beneficial effect on the population as a whole, January 16, 2019. Available: https://www.regulations.gov/comment/FDA-2014-N-1051-0931; Four UCSF comments to FDA on Swedish Match's original 2014 MRTP application, including: Popova L, Glantz S, Swedish Match's Consumer Perception Study Provides No Evidence for the Population-Level Effects of Modified Snus Labels, November 24, 2014; Popova L, Ling P, Swedish Match's claim that perceptions of health risks of snus are exaggerated
is likely incorrect, November 24, 2014; Glantz S, Popova L, Lempert L, "Swedish Experience" extolled in this MRTP application is not transferrable to the US because of the dual use with cigarettes and differences in the tobacco advertising environment, November 25, 2014; Glantz S, FDA should require that all communications from tobacco manufacturers regarding MRTPs be done in a way that narrowly target smokers, November 25, 2014. All available at: https://tobacco.ucsf.edu/summary-ucsf-public-comments-fda-swedish-match-mrtp-application

Swedish Match's July 2023 MRTP Renewal Request[6] states, "The scientific evidence in our initial application demonstrated consumer comprehension of the claim (i.e., fully switching to these products from combustible products would provide risk reduction), as well as a correct consumer perception of risk associated with the MRTP products (i.e., relative to cigarettes)." However, as we explained in our January 16, 2019, comment to FDA and TPSAC[7] asking FDA to deny Swedish Match's request for its initial MRTP order, Swedish Match did not provide sufficient evidence to support issuance of such an order.

FDA's authorization of Swedish Match's proposed MRTP claim would not benefit public health because:

- Consumers are likely not to understand that the language "instead of cigarettes" in the then-proposed advertising and labeling means a ***complete switch*** to General Snus and may instead interpret this statement as saying General Snus is compatible with dual use with cigarettes or other tobacco products.

- Swedish Match presented no evidence that the modified risk claim would result in current smokers completely switching to General Snus.

- Swedish Match only tested a limited number of their products seeking MRTP orders, not all eight sub-brands.

- Swedish Match's studies failed to test the effects of the modified risk claim on dual users.

- Swedish Match failed to present information on the impact of their proposed modified risk claim on youth.

- The modified risk claim misleads consumers about the health risks of General Snus.

- Because the studies presented in the original MRTP application, the postmarket surveillance, and studies submitted in support of the MRTP renewal application use hypotheses with flawed wording and flawed testing procedures, FDA should not rely on conclusions reached in these studies.

- The results of Swedish Match's studies submitted with its original MRTP application suggest that their proposed modified risk claims can be misunderstood to indicate "no risk" or reduced risk of various health conditions that were not included in the claim, such as gum disease.

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[6] Swedish Match USA, Inc., MRTP Renewal Request for MR0000020 - MR0000022, MR0000024- MR0000025, MR0000027- MR0000029, July 17, 2023, pp 9-10. Available: https://digitalmedia.hhs.gov/tobacco/hosted/mrtpa/swedish/1%20MR%20Renewal%20July%2017%2C%202023.zip

[7] Popova L, Sung H-Y, Chaffee B, et al. The revised Swedish Match modified risk tobacco product application for General Snus fails to provide evidence that the claim is not misleading and will have a beneficial effect on the population as a whole, January 16, 2019. Available: https://www.regulations.gov/comment/FDA-2014-N-1051-0931

• The Dynamic Population Model used by Swedish Match in its original MRTP application is inappropriate to assess the population health impact of the proposed modified risk claim for a product which is already marketed in the U.S.

• Swedish Match failed to provide details about its post-market surveillance plan.

Therefore, FDA should *not* have issued an order in 2019 permitting Swedish Match to market its General Snus products with the proposed MRTP claim because marketing General Snus with the then-proposed modified risk claim might actually harm public health by promoting more use of this tobacco product, including more dual use with cigarettes and other tobacco products.

Further, as we describe in more detail below, the "General Snus Patterns of Use Study, Baseline Study Report, SMU 19-01GENS"[8] which Swedish Match submitted on December 13, 2023 as part of its required postmarket surveillance and studies (PMSS) reporting failed to provide the evidence that is necessary to support a determination that the marketing of General Snus products with modified risk claims is appropriate for the protection of the public health. ***As of June 19, 2024, FDA has not posted any additional evidence from or reporting by Swedish Match to support this claim. Therefore, FDA should not renew the MRTP order now.***

1. Consumers are likely not to understand that the language "instead of cigarettes" in the MRTP claim means a *complete switch* to General Snus and may instead interpret this statement as compatible with dual use of General Snus with cigarettes or other tobacco products.

As we stated in our January 2019 comment,[9] Tobacco Control Act section 911(h)(1) requires 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 scientific studies submitted by the MRTP 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

[8] December 13, 2023, Amendment: Response to FDA Request for Clarification, General Snus Patters of Use Study, Baseline Study Report, SMU 19-01GENS Available: https://digitalmedia.hhs.gov/tobacco/hosted/mrtpa/swedish/2022%20Periodic%20Reports/MR000258%2012-13-2023%20NEW.zip

[9] Popova L, Sung H-Y, Chaffee B, et al. The revised Swedish Match modified risk tobacco product application for General Snus fails to provide evidence that the claim is not misleading and will have a beneficial effect on the population as a whole, January 16, 2019. Available: https://www.regulations.gov/comment/FDA-2014-N-1051-0931

- Consumer beliefs about the risks of using the product relative to quitting all tobacco use."[10]

In particular, "the scientific studies submitted by the applicant should inform FDA's evaluation of the tobacco product's impact on tobacco use behavior, including:

- The likelihood that current tobacco product users will start using the product;
- The likelihood that tobacco users who adopt the product will switch to or switch back to other tobacco products that present higher levels of individual health risk;
- The likelihood that consumers will use the product in conjunction with other tobacco products;
- The likelihood that users who may have otherwise quit using tobacco products will instead use the product; and
- The likelihood that consumers will use the product as intended or designed."[11]

If the modified risk claim is not communicated properly, it could lead to misperception about the safety of the product.

There is a well-developed literature addressing relative risk perceptions of smokeless tobacco and cigarettes. A systematic review demonstrated misperceptions of the risks of smokeless tobacco were common in the scientific literature, and can be sensitive to measurement methods.[12] Furthermore, studies have shown that exposure to reduced-risk claims can decrease harm perception of smokeless tobacco among adolescents and increase their willingness to try these products, as well as among current tobacco users.[13] Data from the Population Assessment of Tobacco and Health (PATH) study indicate that lower risk perceptions were associated with subsequent use of multiple non-cigarette tobacco products, including smokeless tobacco.[14] Furthermore, evidence shows that FDA authorization claims can lead both adults and youth to perceive tobacco products as safe, potentially increasing their use.[15]

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[10] FDA, Guidance for Industry, Modified Risk Tobacco Product Applications, Draft Guidance, March 2012. Available at: https://www.fda.gov/downloads/TobaccoProducts/Labeling/UCM297751.pdf

[11] FDA, Guidance for Industry, Modified Risk Tobacco Product Applications, Draft Guidance, March 2012. Available at: https://www.fda.gov/downloads/TobaccoProducts/Labeling/UCM297751.pdf

[12] Czoli CD, Fong GT, Mays D*, et al.* How do consumers perceive differences in risk across nicotine products? A review of relative risk perceptions across smokeless tobacco, e-cigarettes, nicotine replacement therapy and combustible cigarettes. *Tobacco Control* 2017;**26:**e49-e58.

[13] Chaffee BW, Couch ET, Popova L, Halpern-Felsher B. Effects of a Reduced Risk Claim on Adolescents' Smokeless Tobacco Perceptions and Willingness to Use. J Adolesc Health. 2023 Sep;73(3):445-451. doi: 10.1016/j.jadohealth.2023.04.025. Epub 2023 Jun 9. PMID: 37294249; PMCID: PMC10527275.

[14] Elton-Marshall T, Driezen P, Fong GT, Cummings KM, Persoskie A, Wackowski O, Choi K, Kaufman A, Strong D, Gravely S, Taylor K. Adult perceptions of the relative harm of tobacco products and subsequent tobacco product use: Longitudinal findings from waves 1 and 2 of the population assessment of tobacco and health (PATH) study. Addictive behaviors. 2020 Jul 1;106:106337.

[15] Olivia A Wackowski, Michelle Jeong, Stefanie K Gratale, Caitlin Weiger, Julia Chen-Sankey, Andrew A Strasser, Cristine D Delnevo, The impact of exposure to FDA e-cigarette authorization messages on product perceptions and interest – an experiment with adults who smoke and youth, *Nicotine & Tobacco Research*, 2024;, ntae141, https://doi.org/10.1093/ntr/ntae141

Therefore, it is essential that the General Snus modified risk claim is properly communicated, that consumers understand that they must completely switch to General Snus and not dual use these products with cigarettes or other tobacco products, and that Swedish Match demonstrate that consumers do not have misperceptions about the safety of the product. Swedish Match failed to meet these burdens, so FDA should deny reauthorization of its MRTP order.

Our January 2019 comment[16] explained that Swedish Match evaluated "comprehension" of the claim by asking:

> For General Snus to put you at a lower risk of disease, how many cigarettes can you smoke on a day when you also use General Snus?
>
> 1 Zero (0) cigarettes
> 2 Up to 5 cigarettes
> 3 Up to 20 cigarettes
> 4 As many as you want to smoke
> 5 None of the above
> 99 Don't know
> 999 Decline to answer[17]

The wording of this question is problematic because it implies that switching on some days while continuing to smoke on other days is compatible with complete switching.

As we explain in our earlier comment, only between 37.4% and 56.2% of participants selected the correct number (zero cigarettes) (Table 1 from the Kantar Health study Swedish Match submitted to support its original MRTP application[18]). The detailed breakdown of proportions for other answer options has only been provided for current smokers after FDA requested it, but examining the raw data shows that across all groups, among other answers, the largest proportions were for "don't know" and "none of the above". The current renewal application fails to correct the problems with the question and wording from 2019, and FDA should not renew the MRTP order. While the renewal application does report a higher percentage of survey respondents identifying that smoking zero cigarettes would lower their risk of disease, this finding was based on a highly selective population that does not represent cigarette smokers in general, as we discuss below.

Table 1. Proportion of participants who selected "zero cigarettes" in response to the question regarding the number of cigarettes one can smoke a day to lower risk of disease when using General Snus.

Participant category	Test (claim 1)	Control	p-value

[16] Popova L, Sung H-Y, Chaffee B, et al. The revised Swedish Match modified risk tobacco product application for General Snus fails to provide evidence that the claim is not misleading and will have a beneficial effect on the population as a whole, January 16, 2019. Available: https://www.regulations.gov/comment/FDA-2014-N-1051-0931
[17] Kantar Health, General Snus MRTPA Study, p. 30, 04-study-smna-report-section-172_Release in Full.pdf
[18] Kantar Health, General Snus MRTPA Study, pp. 155-160, 04-study-smna-report-section-01-through 16_Redacted.pdf

Never tobacco users - legal age to 24 years	42.3%	37.2%	0.055
Never tobacco users – older than 24 years	37.4%	31.2%	0.020**
Former cigarette smokers - legal age and older	49.7%	37.0%	<0.001***
Current cigarette smokers - legal age to 24 years	56.2%	45.0%	<0.001***
Current cigarette smokers - older than 24 years of age	43.7%	33.9%	0.001*
Current smokeless tobacco users - legal age and older	53.9%	49.4%	0.160

Source: pp. 155-160, 04-study-smna-report-section-01-through-16_Redacted.pdf
P-values were reported from one-tailed independent two-sample proportion tests.
Statistical significance was adjusted according to the Holm procedure, whereby p-values ordered from lowest to highest are compared (in that order) against target, adjusted p-values of ***-p<0.017, ** -p<0.025, and * -p<0.050, respectively. Testing ends with the first non-significant comparison.

In addition, Altria tested consumer understanding of the phrase "instead of cigarettes" has been tested in Altria's 2018 Copenhagen Moist Snuff MRTP application.[19] Altria found that: "some 21–34-year-old adult smokers who do not reject MST [moist smokeless tobacco] disliked Prefix, [wording of the question] 'Using this product instead of cigarettes…,' because it connoted ideas of switching to MST from cigarettes. A few participants in this group, however, thought 'instead of' was as open-ended as 'alternative to' and found the phrasing acceptable as a way of suggesting choice."[20] In particular, ***Altria found in its Copenhagen MRPT qualitative study, that participants understood "alternative" to be compatible with continued smoking and not necessarily requiring complete switching from cigarettes to the smokeless tobacco product: "Across the board, the participants in this study tended to prefer a prefix that frames MST as an alternative to cigarettes rather than a replacement"[21].***

PMI's current General Snus application does not appear to take note of this study, which is publicly available, or present any evidence that the proposed MRTP statement would yield any different results.

To support their current MRTP renewal application for four mint flavors and four tobacco flavors of General Snus, PMI/Swedish Match cites the FDA's March 2023 MRTPA authorization of tobacco-flavored Copenhagen Classic Snuff[22] which permits Altria's U.S. Smokeless Tobacco Company to market its loose moist snuff product Copenhagen Classic Snuff

[19] Altria Client Services. (2018). *USSTC MRTP Application for Copenhagen Snuff Fine Cut: 6.2.: Effect of Marketing on Consumer Understanding and Perceptions*. Available at http://digitalmedia.hhs.gov/tobacco/static/mrtpa/Copenhagen/6-2-risk-perceptions_Release%20in%20Full.pdf
[20] Copenhagen MRTP application, 7.3.3-1: CS-01- Claims Qualitative Study; p. 17, app-7-3-3-1-cs-01-claims-qual-study_Redacted.pdf
[21] Copenhagen MRTP application, 7.3.3-1: CS-01- Claims Qualitative Study; p. 6, app-7-3-3-1-cs-01-claims-qual-study_Redacted.pdf
[22] US Food and Drug Administration, Modified Risk Granted Order – Risk Modification for US Smokeless Tobacco Company's Copenhagen Classic Snuff, March 16, 2023. Available: https://www.fda.gov/media/166254/download?attachment

with the claim, "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."

As we noted in an earlier public comment,[23] the "Claim Comprehension and Intentions" study[24] (CCI) originally submitted by Altria Client Services LLC, on behalf of US Smokeless Tobacco Company LLC (a subsidiary of Altria Group, Inc.) to support the MRTPA authorization of Copenhagen Classic found few statistically significant changes in harm perceptions among study participants shown the proposed reduced risk statement. Notably, the only subset of the CCI study population for which the test group reported a statistically significant decrease in the perception that smokeless tobacco "negatively impacts health" was young adult tobacco non-users.

More importantly, compared to viewing a control image, viewing an advertisement with the reduced risk claim (MRTP image) did not increase intentions to try Copenhagen snuff among any of the tobacco user or nonuser subgroups included in the analysis.

This finding is important because it shows that while consumers may <u>understand</u> the MRTP claim, there is no evidence supporting the assumption that viewing the MRTP claim encourages cigarette smokers to switch to the purportedly less harmful product.

Swedish Match provides no additional evidence that the MRTP claim for General Snus will encourage cigarette smokers to switch to snus use.

Our own research independently supports this conclusion. Specifically, we conducted a study[25] of California adolescents in which participants were randomized to view a Copenhagen snuff image with or without the MRTP reduced risk claim. Adolescents exposed to the MRTP claim were less likely to perceive smokeless tobacco to cause "a lot" of harm. In addition, among adolescents who were past 30-day users of at least one nicotine product (predominantly consisting of e-cigarette users), viewing the MRTP claim increased willingness to try moist snuff. ***These findings suggest that smokeless tobacco MRTP claims increase interest in using smokeless tobacco among youth.***

Because youth, as a whole, have a low prevalence of cigarette smoking and smokeless tobacco use, increased susceptibility to smokeless tobacco in this population is likely to harm public health.

The lack of evidence that MRTP claims increase interest in switching to smokeless tobacco among adult cigarette smokers means that there is no evidence for an offsetting adult benefit

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[23] Chaffee B, Popova L, Lempert L, et al. FDA should not permit the U.S. Smokeless Tobacco Company to market Copenhagen Snuff with modified risk claims, January 16, 2019, Docket Number FDA-2018-N-3261, available: https://www.regulations.gov/comment/FDA-2018-N-3261-0014

[24] Copenhagen MRTP application, 7.3.3-1: CS-01- Claims Qualitative Study; app-7-3-3-1-cs-01-claims-qual-study_Redacted.pdf

[25] Chaffee BW, Couch ET, Popova L, Halpern-Felsher B. Effects of a Reduced Risk Claim on Adolescents' Smokeless Tobacco Perceptions and Willingness to Use. J Adolesc Health. 2023 Sep;73(3):445-451. doi: 10.1016/j.jadohealth.2023.04.025. Epub 2023 Jun 9. PMID: 37294249; PMCID: PMC10527275.

to overcome the increased risk to youth that could result from authorizing the proposed MRTP statement.

The quantitative findings from the Swedish Match study that not all users understand the message that they need to stop smoking all cigarettes are corroborated with results of a qualitative study from Copenhagen moist snuff MRTP application.[26] ***Together, they indicate that at least some adult consumers are likely to understand "instead of cigarettes" to mean using snus in addition to smoking cigarettes, a behavior that is likely to increase harm to the users.***

As of 2024, Swedish Match was continuing to promote its General Snus products using the MRTP claim, including specific reference to the FDA order permitting Swedish Match to make this claim.[27] It is likely that consumers interpret FDA's MRTP authorization as approval or endorsement of this product. As mentioned above, evidence shows that FDA authorization claims can lead both adults and youth to perceive tobacco products as safe, potentially increasing their use.[28] Importantly, ***Swedish Match did not submit evidence that consumers understand that FDA's authorization does not mean that these products are safe or "approved" by FDA.***

In sum, Swedish Match is required to demonstrate in its renewal MRTP application that marketing its products with modified risk claims will continue to benefit the population as a whole, considering both users and non-users of the proposed MRTP product. ***Swedish Match failed to meet its burden of demonstrating population benefit, so FDA must not issue a renewal of the MRTP order for General Snus.***

2. The Postmarket Surveillance and Studies (PMSS) submitted by Swedish Match are flawed and cannot be used to support renewal of its MRTP order.

Postmarket Surveillance and Studies (PMSS) are required under Tobacco Control Act section 911(i)(1) and under the October 2019 MRTP order are a condition for marketing Swedish Match's General Snus products with the MRTP claim. On June 5, 2024, FDA posted the PMSS report Swedish Match submitted on December 13, 2023[29] which includes the General Snus Patterns of Use Study, Baseline Study Report, SMU 19-01GENS. Although this report is heavily redacted, there is enough information to demonstrate that the PMSS lacks key information necessary to support FDA concluding that authorizing renewal of the MRTP application is warranted.

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[26] Copenhagen MRTP application, 7.3.3-1: CS-01- Claims Qualitative Study; app-7-3-3-1-cs-01-claims-qual-study_Redacted.pdf

[27] https://www.generalsnus.com/ModifiedRisk/

[28] Olivia A Wackowski, Michelle Jeong, Stefanie K Gratale, Caitlin Weiger, Julia Chen-Sankey, Andrew A Strasser, Cristine D Delnevo, The impact of exposure to FDA e-cigarette authorization messages on product perceptions and interest – an experiment with adults who smoke and youth, *Nicotine & Tobacco Research*, 2024;, ntae141, https://doi.org/10.1093/ntr/ntae141

[29] December 13, 2023, Amendment: Response to FDA Request for Clarification, General Snus Patters of Use Study, Baseline Study Report, SMU 19-01GENS Available: https://digitalmedia.hhs.gov/tobacco/hosted/mrtpa/swedish/2022%20Periodic%20Reports/MR000258%2012-13-2023%20NEW.zip

The PMSS report provides a description of the frequency of snus use and other tobacco product use among a convenience sample of General Snus users. ***As a result, the PMSS report cannot be considered to represent the patterns in the use of snus and other tobacco and nicotine products in the general population or the overall public health impact of MRTP authorization, or even whether and how the existing MRTP General Snus authorization has affected these patterns.***

In particular, the PMSS report cannot answer whether:

- MRTP authorization has encouraged cigarette smokers to switch completely to snus use;
- Tobacco non-users (youth or adults) have initiated snus use because of MRTP authorization;
- Any cigarette smokers switched to snus who would have otherwise quit all tobacco use;
- Any snus users continued to use snus who would have otherwise quit all tobacco use.

Specifically, the PMSS report (study SMU 19-01GENS) analyzed a convenience sample of 1655 individuals who purchased General Snus from one of approximately 10,600 retail locations and completed an online survey.

This is not a representative sample. Respondents joined the study by answering a study invitation on stickers placed on snus packages at those retail locations. The number of stickers per location is not reported. The response percentage is not reported but is likely to be very small. If we assume that 20 consumers per location received the sticker, the participation percentage would be <0.8% (i.e., 1655 out of 10,600 x 20); if 100 consumers per location received the sticker, the participation percentage would be <0.2% (i.e., 1655 out of 10,600 x 100). As Swedish Match acknowledged, that meant the study sample was a convenience sample that included those "who were more interested in research, or perhaps healthy enough to participate, may be over-represented, hence the possibility of selection bias." In addition, it is unclear how the data were processed before analysis, which may lead to selection bias during the data processing and analysis phase.

There is self-selection bias inherent in this study design. As stated in the Amendment, this sample is likely healthier and more interested in research than the general population. Not stated, but important, this sample is likely more interested in snus and committed to the General Snus brand to self-select into consumer research about it. Similarly, consumers who made multiple General Snus purchases would have more opportunities to view the study invitation. It is not stated in the Amendment whether there were any mechanisms to protect against the same individual submitting multiple responses to the survey. In total, this sample likely overestimates snus use frequency, familiarity with snus, and favorable perceptions of snus compared to the general population. Indeed, in this survey sample, 82% of snus users reported using General Snus every day. In nationally representative surveys of adult men from a mature snus market (Norway), pooled from 2005-2010, only ~60% of current snus users reported using snus every day.[30]

[30] Lund KE, McNeill A. Patterns of dual use of snus and cigarettes in a mature snus market. Nicotine Tob Res. 2013 Mar;15(3):678-84. doi: 10.1093/ntr/nts185. Epub 2012 Sep 18. PMID: 22990221; PMCID: PMC3572872.

At each wave of the survey, a substantial portion of potential respondents was excluded for reasons not presented in the public (unredacted) application materials. At baseline, nearly as many participants were terminated (N=1048) as were retained in the analytic sample (N=1655). Quotas were used, presumably to control the demographic distribution of the survey sample, but it is not clear what variables were used to set the quotas. It is unclear why quotas were then used in follow-up waves of the survey. For example, another N=159 potential respondents were terminated from the 6-month follow-up survey "based inclusion/exclusion criteria/quota filled/Intellectual Property blocker." It is not stated why these participants, who were deemed eligible for the baseline survey, were deemed to no longer be eligible at follow-up. At the least, removing these responses decreased the sample size and contributed to losses to follow-up. The specific reasons that these potential participants were excluded and how their exclusion affected the reported findings are unclear.

There were extremely large losses to follow-up at each wave of the survey, making the survey population less representative in each subsequent wave. After 6 months, less than half of the baseline sample was retain for analysis (695 out of 1655; 42%). By the final wave of the survey, only 27% of the initial analytic sample was included in the data (451 out of 1655).

The application notes that the prevalence of cigarette smoking is lower in the survey follow-up waves than at baseline, but due to losses to follow-up, this does not necessarily mean that individual consumers changed their smoking behaviors over time. Alternatively, it is plausible that cigarette smokers were less likely to complete a follow-up survey about snus than were dedicated snus users. With such high percentages of losses to follow-up, differences between who does and does not respond can have a major impact on the characteristics of the retained sample. This could have easily been examined in the data but was not presented in the renewal application.

In the application, assessments of change in cigarette smoking behavior are made among non-representative sub-sets of the data. For example, consider General Snus® POU Study Report; Section 7.3.5; Primary Objective. In this analysis, changes in cigarette smoking behaviors are assessed but only among respondents who maintained the same frequency of General Snus use. Excluded are any participants who increased or maintained their cigarette smoking frequency while decreasing (or increasing) their frequency of snus use. Examining only this narrow subset of the sample precludes broad conclusions about the impact of MRTP authorization.

Completely ignored is the key question of whether the MRTP claim authorized for General Snus has caused any cigarette smokers to switch completely to a less harmful product and whether that switching has been counterbalanced by dual use, less total cessation, and snus uptake among non-smokers.

It was stated that "current General Snus® users include a significant number of former cigarette smokers (67.2%) suggesting that use of General Snus® may support a reduction in smoking." However, the use of smoking cessation methods, particularly evidence-based ones, was not clearly addressed. It is not valid to claim General Snus® as an effective smoking cessation aid without clarifying these influencing factors. In fact, it is possible that some of these former

cigarette smokers had quit smoking long ago and only initiated use of General Snus more recently.

Table 7. Outcomes Table for Secondary Objective 1 – Perceptions of absolute risk.

Measurement Domain	Subcategory	Measurement Details	Metric
Absolute risk attributed to using *General* Snus® and to smoking cigarettes daily but using no other TNPs (Baseline, Month 6, Year 1, Year 2)	Mouth cancer	One item for each health condition (3 health conditions total) will assess the perception of the absolute risk from: a) daily use of only *General* Snus® and no other TNP; b) daily use of only cigarettes and no other TNP.	Absolute risk perception of a person suffering from each health condition will be assessed with "Very low chance," "Low chance," "Moderate chance," "High chance" and "Very high chance." "Don't know" is also available as a response option.
	Heart disease		
	Lung cancer		

Source: December 13, 2023, Amendment: Response to FDA Request for Clarification

Table 7 from the "Amendment - Postmarket Surveillance Studies Wave Reports" submitted by Swedish Match supporting its MRTP renewal MR0000256 *on* December 13, 2023,[31] reproduced above, shows the statements used to assess the absolute risk perception of using General Snus® and of smoking cigarettes daily. The actual results were redacted, but Swedish Match claimed that "results demonstrated that respondents perceived that cigarettes presented the greatest risk of health conditions which include mouth cancer, heart disease and lung cancer. Moreover, usage of General Snus® products alone was associated with some risk of health conditions, although at a lower rate than smoking." It is important to note that these measures leave out the important behavior of dual use of both General Snus and cigarettes, and the risk perceptions of dual use.

Since the postmarket surveillance studies fail to address risk perceptions of dual use, there is insufficient evidence to support renewal of the MRTP order.

3. Swedish Match did not address dual- or poly- use of General Snus with cigarettes and/or other tobacco products.

As we noted in our January 2019 comment,[32] in Swedish Match's "Perceptions and Behavioral Intentions Study," submitted as part of an amendment to the 2019 MRTP application, participants were either non-users, exclusive cigarette smokers, or exclusive smokeless users. Dual users were not included. However, it is important to include dual users as study participants because dual use of smokeless tobacco products (including snus) and other products is common. The 2012-14 National Adult Tobacco Survey showed that 3.6% of U.S. adults aged 18+ were current smokeless tobacco users and 52.4% of these current smokeless tobacco users were dual users, i.e., concurrently used one or more other tobacco products.[33] A detailed study of tobacco

[31] December 13, 2023, Amendment: Response to FDA Request for Clarification, General Snus Patters of Use Study, Baseline Study Report, SMU 19-01GENS, PDF p. 32. Available: https://digitalmedia.hhs.gov/tobacco/hosted/mrtpa/swedish/2022%20Periodic%20Reports/MR000258%2012-13-2023%20NEW.zip

[32] Popova L, Sung H-Y, Chaffee B, et al. The revised Swedish Match modified risk tobacco product application for General Snus fails to provide evidence that the claim is not misleading and will have a beneficial effect on the population as a whole, January 16, 2019. Available: https://www.regulations.gov/comment/FDA-2014-N-1051-0931

[33] See Table 2, Sung HY, Wang Y, Yao T, Lightwood J, Max W. Polytobacco Use and Nicotine Dependence Symptoms Among US Adults, 2012-2014. Nicotine Tob Res. 2018;20(suppl_1):S88-S98. PMCID: PMC6093419.

use patterns among dual users of cigarettes and smokeless tobacco among adult dual users in West Virginia conducted in 2015-2017 found the average number of cigarettes smoked per day and cotinine levels were higher on days when cigarettes were used concurrently with smokeless tobacco, suggesting that product replacement was not occurring.[34] Another study of dual tobacco users in the military found that dual users had earlier age at smoking initiation, longer duration of smoking and heavier smoking, all higher risk behavior patterns.[35]

FDA cannot ignore this substantial group of tobacco users, particularly since dual use is riskier than smoking or snus use alone.

For example, dual use increases the risk of myocardial infarction more than cigarette smoking alone.[36]

National Youth Tobacco Survey data from 2014-2020 also found that dual and polytobacco use of e-cigarette with other tobacco products including smokeless tobacco is increasing.[37]

General Snus has been marketed in the US since Swedish Match North America (SMNA) received market authorization for General Snus in November 2015, and has been marketed with the MRTP claim since October 2019. ***Given this lengthy marketing period, there is no reason that Swedish Match could not present updated epidemiological data demonstrating real-world use of the product, particularly the rates of initiation, switching, dual use, and cessation.***

The lack of such data is another reason that FDA should deny the MRTP renewal.

The December 13, 2023 amendment[38] purported to present co-use rates across four waves of the postmarket surveillance and studies (PMSS). Based on the data presented in the PMSS, at the baseline (Wave 1), the percentage of co-use was 14.5% (sum of everyday and some-day cigarette smokers who also use General Snus). At Wave 2, there was a slight reduction to 12.3%. At Wave 3 the co-use rate was 14.1%, and Wave 4 was 13.5%. Overall, while there were fluctuations, the percentage of dual users remained relatively stable around 12-14% over the course of the study. These percentages are lower than presented in studies of the general population, largely because the PMSS was conducted among a non-representative convenience sample of individuals who purchased General Snus and self-selected to be in a study about it. Despite this self-selection, a substantial portion of responds used General Snus in combination with cigarette smoking.

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[34] Felicione NJ, Ozga-Hess JE, Ferguson SG*, et al.* Cigarette smokers' concurrent use of smokeless tobacco: dual use patterns and nicotine exposure. *Tobacco Control* 2021;**30:**24-29.

[35] Lin, J., Zhu, K., Soliván-Ortiz, A. M., Larsen, S. L., Irwin, S. P., Schneid, T. R., ... & Lee, S. (2022). Dual use of cigarettes and smokeless tobacco among active duty service members in the US military. *Military Psychology*, *34*(4), 432-444.

[36] Teo KK, Ounpuu S, Hawken S, et al. Tobacco use and risk of myocardial infarction in 52 countries in the INTERHEART study: a case-control study. Lancet. 2006;368(9536):647–658.

[37] Cook, S., Ortiz Chavez, S., Zavala-Arciniega, L., Hirschtick, J. L., & Fleischer, N. L. (2023). Trends of single, dual, and polytobacco use among school-based students in the United States: an analysis of the national youth tobacco survey. *American Journal of Health Promotion*, *37*(8), 1078-1090

[38] December 13, 2023, Amendment: Response to FDA Request for Clarification, General Snus Patters of Use Study, Baseline Study Report, SMU 19-01GENS Available: https://digitalmedia.hhs.gov/tobacco/hosted/mrtpa/swedish/2022%20Periodic%20Reports/MR000258%2012-13-2023%20NEW.zip

Additionally, in its Summary of Wave 4 Results, Swedish Match reported that of those respondents who endorsed that use of General Snus presented less risk to health than cigarette smoking, 79.8% understood that no cigarettes can be smoked while using General Snus to benefit from it being lower risk. Again, despite this being a convenience sample likely to be more dedicated to and interested in General Snus than the general population of tobacco users and non-users, ***approximately one-fifth (20.2%) of these General Snus users do not understand that they must completely switch from cigarettes to General Snus to obtain the lower risk of some adverse health effects described in the authorized MRTP claim.***[39]

As noted above, postmarket surveillance and studies (PMSS) are required under Tobacco Control Act section 911(i)(1) and under the October 2019 MRTP order for continued marketing Swedish Match's General Snus products with the MRTP claim. In its MRTP Renewal Request, Swedish Match states that "Seven years of post-market tracking and annual reporting continue to support the conclusion that consumers of General Snus, even while reducing the amount of the product they use longitudinally, remain committed to a reduction of combustible products."[40] However, FDA redacted the Swedish Match data PMI submitted to substantiate this claim. In any case, ***Swedish Match's contention in the PMSS that it remains "committed to a reduction of combustible products" does not indicate complete switching from cigarettes to General Snus, but instead strongly suggests that consumers continue to use General Snus concurrently with cigarettes and/or other tobacco products (i.e., dual- or poly- use).***

4. **Marketing Swedish Match General Snus products does not benefit the health of the population as a whole.**

The law is clear. To renew the existing MRTP order permitting Swedish Match to market its products with its modified risk claim, FDA must make a determination that General Snus products will benefit the health of individuals and the population as a whole, taking into account:

> (1) The increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to [General Snus];
> (2) The increased or decreased likelihood that person who do not use tobacco products will start using [General Snus]; and
> (3) The risks and benefits to persons from the use [General Snus] as compared to the use of [FDA approved smoking cessation and nicotine dependence treatments].[41]

There is no support for the claim that, among the general population, existing adult users of tobacco products will switch completely to General Snus. As discussed in more detail above, the

[39] General Snus Patterns of Use Study, Wave 4 Technical Report – Final, at PDF p. 186. Available: https://digitalmedia.hhs.gov/tobacco/hosted/mrtpa/swedish/2022%20Periodic%20Reports/MR000258%2012-13-2023%20NEW.zip

[40] Popova L, Sung H-Y, Chaffee B, et al. The revised Swedish Match modified risk tobacco product application for General Snus fails to provide evidence that the claim is not misleading and will have a beneficial effect on the population as a whole, January 16, 2019, p. 10. Available: https://www.regulations.gov/comment/FDA-2014-N-1051-0931

[41] Family Smoking Prevention and Tobacco Control Act, section 911(g)(4), Public Law 111-31, 21 USC 387k (June 22, 2009).

PMSS report submitted in support of ***Swedish Match's MRTP renewal application was not based on a representative sample and did not provide sufficient evidence that the MRTP claim increased switching to smokeless tobacco among adults.***

Additionally, as discussed above, independent research[42] suggests that ***smokeless tobacco MRTP claims increase interest in using smokeless tobacco among youth. As a result, marketing Swedish Match with the MRTP claim may increase the likelihood that youth non-users of tobacco products will start using General Snus and/or other tobacco products.***

Of particular concern, Swedish Match General Snus is available in four mint flavors which include flavor ingredients that have potential adverse effects. Sucralose, a high intensity sweetener, is included in high levels in many snus products which makes the otherwise aversive flavors of tobacco ingredients more attractive to adolescents and other users and can lead to higher rates of initiation and continued use.[43, 44]

Further, the applicant does not present any evidence that using General Snus would present greater benefits to current users of tobacco products than completely ending all tobacco use or as compared to using FDA-approved nicotine replacement therapies.

5. Conclusion

FDA should not renew the Modified Risk Granted Order for eight Swedish Match General Snus products because Swedish Match failed to demonstrate that, as actually used by consumers, these products will benefit the health of the population as a whole.

In particular:

1. Consumers are likely not to understand that the language "instead of cigarettes" in the MRTP claim means a *complete switch* to General Snus, and may instead interpret this statement as compatible with dual use of General Snus with cigarettes or other tobacco products.
2. The postmarket surveillance and studies Swedish Match relied on to support its renewal application are flawed and cannot be considered to represent the patterns in the use of snus and other tobacco and nicotine products in the general population.
3. Swedish Match did not address dual- or poly- use of General Snus with cigarettes and/or other tobacco products.

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[42] Chaffee BW, Couch ET, Popova L, Halpern-Felsher B. Effects of a Reduced Risk Claim on Adolescents' Smokeless Tobacco Perceptions and Willingness to Use. J Adolesc Health. 2023 Sep;73(3):445-451. doi: 10.1016/j.jadohealth.2023.04.025. Epub 2023 Jun 9. PMID: 37294249; PMCID: PMC10527275.

[43] Miao S, Beach ES, Sommer TJ, Zimmerman JB, Jordt SE. High-intensity sweeteners in alternative tobacco products. *Nicotine Tob Res*. 2016;18(11):2169–73.

[44] Rezk-Hanna M, Talhout R, Jordt SE. Sugars and Sweeteners in Tobacco and Nicotine Products: Food and Drug Administration's Regulatory Implications. Nicotine Tob Res. 2023 Mar 22;25(4):838-840. doi: 10.1093/ntr/ntac222. PMID: 36148496; PMCID: PMC10032193.

4. Marketing Swedish Match General Snus products does not benefit the health of the population as a whole.

In addition, FDA's October 22, 2019, MRTP orders[45] state unequivocally: "These orders expire 5 years from the issue date of this letter [October 22, 2024]." Because Swedish Match did not offer sufficient evidence to support renewal of those orders, FDA should simply allow the current marketing order to lapse and enforce against Swedish Match/PMI if it continues marketing General Snus with unauthorized MRTP claims.

[45] US Food & Drug Administration, Modified Risk Granted Orders – Risk Modification for eight General Snus Smokeless Tobacco Products, October 22, 2019. Available: https://www.fda.gov/media/131922/download?attachment

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June 20, 2024

VIA ELECTRONIC SUBMISSION

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Re: Docket No. FDA-2024-N-0008-0007: The Tobacco Products Scientific Advisory Committee; Notice of Meeting

Following the May 6, 2024 Notice in the Federal Register announcing the public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC),[1] PMI Global Services Inc. (PMIGS) hereby submits these comments on behalf of Philip Morris International (PMI) and its affiliates[2] to Docket No. FDA-2024-N-0008-0007 and appreciates TPSAC's and the U.S. Food & Drug Administration's (FDA's or Agency's) consideration.

PMI and our affiliate Swedish Match USA, Inc. share a commitment to a workable modified risk tobacco product (MRTP) process. Notably, our smoke-free products represent thirteen of the sixteen modified risk granted orders,[3] including the Agency's first-ever modified risk granted order for *General Snus* and the only modified risk granted order for a novel tobacco product, the *IQOS* heating system.

We also unequivocally agree that complete cessation is the best choice for adults who smoke cigarettes and no one under 21 should use any tobacco products. At the same time, an exclusive focus on cessation and prevention efforts fails to fully address the millions of adults who continue smoking. Activating the harm reduction components that exist in the Family Smoking

[1] FDA, The Tobacco Products Scientific Advisory Committee; Notice of Meeting (May 6, 2024), https://tinyurl.com/3eade3y5 (TPSAC meeting to discuss the renewal of a risk modification order submitted by Swedish Match USA, Inc., for several loose and portioned snus products, and to discuss broader Modified Risk Tobacco Products (MRTP) program developments).

[2] PMI's affiliates include PMIGS, Philip Morris Products, S.A., Triaga, Inc., and Swedish Match USA, Inc., among other entities.

[3] FDA, Modified Risk Granted Orders, https://tinyurl.com/yp8n8nxz (last updated March 16, 2023).

Prevention and Tobacco Control Act (TCA),[4] including through the timely review and authorization of scientifically substantiated modified risk tobacco products and increasing public awareness about the relative risk of tobacco products, can dramatically increase the impact on smoking-related morbidity and mortality.

In enacting the TCA, Congress recognized the importance of harm reduction as a necessary and complementary pillar to prevention and cessation.[5] To effectively protect and promote the public health, Congress established the MRTP pathway to empower FDA to "require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified."[6]

Despite historical low smoking rates, the potential for harm reduction envisioned by Congress through the TCA does not reflect the regulated market. Combustible cigarettes continue to dominate shelves and sales at retail.[7] Illicit disposable vapor products are increasingly present as the primary "alternative" to traditional tobacco products; and, as available data shows, many of these disposables are the primary source of concern for underage use.[8] As premarket tobacco product applications remain under the Agency's review well-beyond the TCA's 180-day deadline, FDA-authorized smoke-free products represent a small percentage of the total market. Products with a modified risk granted order are even fewer.

In the face of persistent misunderstanding about the relative risk of tobacco products (as well as nicotine), getting the MRTP process right is critical for public health. FDA should prioritize lowering tobacco-related disease and death for the millions of adult smokers who do not otherwise quit through FDA-authorized claims for modified risk tobacco products (by applying a workable process with an achievable standard), in tandem with accurate communications from FDA and other government agencies to adult smokers and healthcare providers.

I. In the anticipated proposed rule for Modified Risk Tobacco Product Applications (MRTPAs), FDA should transparently and specifically communicate the Agency's expectations and how they are informed by FDA's experience, available science, and feedback received since issuing the 2012 MRTPA Draft Guidance.

With an NPRM expected November 2024, FDA has announced its intention to publish a proposed rule that "would establish content and format requirements to ensure that modified risk tobacco product applications contain sufficient information for FDA to determine whether it should permit the marketing of a modified risk tobacco product. Additionally, the proposed rule would set forth the basic procedures for modified risk tobacco product application review and require

[4] Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009).

[5] *See, e.g.*, *id.*, §§ 2(36), 2(44), 904(b)(2), 911(b)(1), 918(b)(1)(C).

[6] *Id.* § 2(43).

[7] *See* Euromonitor International, Passport: Tobacco in the US, at 11 (June 2023) (Table 3 showing cigarettes comprising over 80% of sales of tobacco products in 2022).

[8] *See* FDA, Results from the Annual National Youth Tobacco Survey, https://tinyurl.com/pk4mkxe6 (Nov. 2, 2023) ("The most popular brands include disposable and cartridge-based products, and the most commonly reported products were: Elf Bar (56.7%), Esco Bars (21.6%) . . .").

applicants receiving authorization to market a modified risk tobacco product to establish and maintain records, conduct postmarket surveillance and studies, and submit reports to FDA."[9]

The proposed rule would be the first time FDA publicly communicates its expectations for MRTPAs since the Agency's 2012 guidance.[10] In the proposed rule, FDA should be specific and transparent about how FDA's experience over the past twelve years has informed the Agency's expectations for MRTPAs, including: FDA's review of submitted MRTPAs to date; the 2013 Joint Meeting of FDA's Tobacco Products Scientific Advisory Committee and FDA's Risk Communication Advisory Committee;[11] the resulting FDA-funded additional research on how FDA can disclose HPHC information to the public in a manner that is "understandable and not misleading" and also useful to consumers;[12] the comments to FDA's 2012 MRTP Guidance,[13] including after FDA specifically requested comments in 2018;[14] and the ongoing FDA-funded effort: "Public Health Communication Messaging about the Continuum of Risk for Tobacco Products."[15]

In the proposed rule, FDA should also be specific and transparent about how the Agency's public messaging about the relative risks of tobacco products and cigarette smoking informs FDA's expectations for MRTPAs and for manufacturers providing accurate and non-misleading information about tobacco products through FDA-authorized product claims, including:

- "No tobacco product is safe. However, the health risks for different tobacco products exist on a spectrum, which is sometimes referred to as a 'continuum of risk.'"[16]
- "Combusted, or smoked, tobacco products - such as cigarettes - are the most harmful type of tobacco product. Non-combusted products - such as e-cigarettes and other smokeless tobacco products - generally have lower health risks than cigarettes and other combustible tobacco products."[17]
- "For adults who currently smoke cigarettes, fully quitting the use of all forms of tobacco products would most benefit their health."[18]

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[9] U.S. Exec. Ofc. of the President, Ofc. of Info. & Reg. Affairs, Ofc. of Mgmt. & Budget, View Rule: Modified Risk Tobacco Product Applications, https://tinyurl.com/2zewjkcx (last accessed June 11, 2024).

[10] FDA, (Draft) Guidance for Industry: Modified Risk Tobacco Product Applications (March 2012), https://tinyurl.com/2x3y8erc.

[11] FDA, Joint Meeting of the Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee; Notice of Joint Meeting, 78 Fed. Reg. 37,821 (June 24, 2013).

[12] Nat'l Inst. of Health, Administrative Supplements for Tobacco Regulatory Research on the Public Display of Harmful and Potentially Harmful Constituents (HPHC) Information, https://tinyurl.com/2nsfwbs3 (last accessed June 14, 2024).

[13] *See* FDA, Modified Risk Tobacco Product Applications, Dkt. No. FDA-2012-D-0071, https://tinyurl.com/3bxarz3m (last accessed June 20, 2024) (showing 3,539 comments received).

[14] FDA, Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance for Industry: Modified Risk Tobacco Product Applications 83 Fed. Reg. 3,158 (Jan. 23, 2018).

[15] Nat'l Inst. of Health, Administrative Supplements for Tobacco Regulatory Research on Public Health Communication Messaging about the Continuum of Risk for Tobacco Products, https://tinyurl.com/yc8cny3d (last accessed June 14, 2024).

[16] FDA, The Relative Risks of Tobacco Products, https://tinyurl.com/4x7dw89w (last updated Apr. 16, 2024).

[17] *Id.*

[18] *Id.*

- "For adults who smoke, switching completely from cigarettes to e-cigarettes may reduce exposure to many harmful chemicals present in cigarettes. However, it is important that they switch completely from cigarettes to e-cigarettes to get the full health benefit."[19]
- "Many people who use tobacco products have misperceptions about nicotine and the risks of various tobacco products. Despite science that shows that e-cigarettes generally have lower levels of harmful ingredients than cigarettes, many adults believe that e-cigarettes are just as harmful or more harmful than cigarettes."[20]
- "Tobacco and tobacco smoke contain thousands of chemicals. This mix of chemicals—not nicotine—is what causes serious disease and death."[21]

Through the anticipated proposed rule, FDA has the opportunity to ensure a workable MRTP process. We strongly encourage FDA to directly and transparently explain the Agency's expectations for MRTPAs and how they are informed by FDA's experience, available science, and feedback the Agency has already received since 2012.

II. By encouraging more adult smokers to stop smoking, FDA can maximize the public health benefits of the MRTP pathway through a more practical scientific approach.

As FDA has explained, "[s]ignificant progress has been made in reducing cigarette smoking in the United States through comprehensive, population-level strategies. However, more than 30 million U.S. adults still smoke cigarettes, and smoking remains the leading cause of premature disease and death nationwide."[22] Because cigarettes "are still the most commonly used tobacco product in the United States,"[23] and are also "responsible for the vast majority of all tobacco-related disease and death in the U.S.,"[24] FDA should ensure that the Agency's decisions do not negate the benefits for adult smokers and public health that the TCA intends the MRTP pathway to provide.

One in ten U.S. adult smokers will quit smoking each year, which also means that roughly nine in ten usually continue smoking.[25] Without a doubt, smoking cessation products are reserved for the jurisdiction of other centers in FDA.[26] Because cigarettes are currently the most commonly

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[19] *Id.* (citing Nat'l Acads. Sci. Eng'g & Med., Public Health Consequences of E-Cigarettes (2018), https://tinyurl.com/mrxp2sxf).

[20] *Id.* (citing Bandi, et al., Relative Harm Perceptions of E-Cigarettes Versus Cigarettes, U.S. Adults, 2018-2020, 63(2) Am. J. Prev. Med. 186-194 (Aug. 2022), https://pubmed.ncbi.nlm.nih.gov/35868816/).

[21] FDA, Cigarettes, https://tinyurl.com/dnhhzfzr (last updated May 31, 2024).

[22] FDA, The Relative Risks of Tobacco Products, https://tinyurl.com/4x7dw89w (last updated Apr. 16, 2024).

[23] FDA, Cigarettes, https://tinyurl.com/dnhhzfzr (last updated May 31, 2024).

[24] *Id.*

[25] *See* U.S. Ctrs. for Disease Cntrl. & Prevention, Smoking Cessation Data, https://tinyurl.com/33wcajrn (last reviewed Mar. 21, 2022) (citing U.S. Dep't of Health & Human Servs., "Smoking Cessation: A Report of the Surgeon General" (2020), https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf).

[26] *See* TCA § 911(c) ("A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Food and Drug Administration and is subject to the requirements of chapter V."). *See also* FDA, Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products: Amendments to Regulations

used, and responsible for the vast majority of all tobacco-related disease and death in the U.S., the MRTP process should focus on products that adult smokers can use "to reduce harm or the risk of tobacco-related disease."[27]

To provide a risk modification order, the TCA provides FDA with considerable discretion to determine the scientific evidence necessary for an applicant to "demonstrate[] that such product, 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 users of tobacco products and persons who do not currently use tobacco products."[28] The TCA does not require, for example, decades-long epidemiological studies in order to provide the Agency with sufficient certainty to permit a product to be marketed with a claim that, for adult smokers, exclusive use of a modified risk tobacco product is an improvement from combustible cigarette use.[29]

The TCA is clear: "[t]he dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product."[30] Over the last fifteen years, FDA has developed the experience of reviewing PMTAs and MRTPAs for novel tobacco products, as well as the understanding to deliver public communications about the relative risks of tobacco products to the public. Armed with this experience and understanding, FDA has the tools to review and authorize additional modified risk tobacco products under a more flexible scientific standard while also upholding the TCA's command to mitigate the risk of products sold as modified risk tobacco products that do not in fact reduce risk. Without showing that it is possible to demonstrate reduced risk, even in the absence of decades-long epidemiological research, there is very little incentive for companies to invest the time and money required to file an MRTP application, market the product in an overly prescriptive way, and spend additional time and resources complying with post-market requirements and research.

Modified risk products are not perfect solutions. They contain nicotine, which is addictive, and they are not risk-free. As FDA has made clear, "[f]or adults who currently smoke cigarettes, fully quitting the use of all forms of tobacco products would most benefit their health."[31] But convincing adult smokers who would otherwise continue smoking to switch completely to less harmful products is definitely a positive step for public health. To maximize the potential for adult smokers to make these positive steps, adult smokers deserve access to additional FDA-authorized modified risk tobacco products, as well as complete, accurate and non-misleading information as they make product choices. As misperceptions about the relative risk of tobacco products, and

Regarding "Intended Uses," 82 Fed. Reg. 2,193, 2,203 (Jan. 9, 2017).

[27] FDA, Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products: Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2,193, 2,199 (Jan. 9, 2017) (citing TCA § 911(b)(1).

[28] TCA, § 911(g)(1).

[29] *See id.*

[30] *Id.* § 2(40).

[31] FDA, The Relative Risks of Tobacco Products, https://tinyurl.com/4x7dw89w (last updated Apr. 16, 2024).

about nicotine, persist, the millions of adult smokers who do not otherwise quit can benefit from access to additional modified risk tobacco products, along with accurate communications from FDA and other government agencies to adult smokers and healthcare providers.

III. FDA should improve communication with the public about the MRTP process and modified risk tobacco products.

As the lead Agency designated by Congress to regulate tobacco and nicotine products, FDA has a responsibility to ensure the public receives complete and accurate information about tobacco and nicotine products, including the evidentiary rigor required to issue a modified risk granted order.[32] Also, FDA should undertake more efforts to educate the public on the MRTP pathway, the regulatory review process for modified risk products, and the availability of modified risk tobacco products.

Misperceptions about the relative risk of tobacco products, and about nicotine, persist. One Center for Tobacco Products (CTP or Center) study found that nearly 75% of U.S. adults surveyed incorrectly believed that nicotine causes cancer or were unsure about the relationship between nicotine and cancer.[33,34] Other studies have shown similar results: "A national representative survey of smokers and a focus group study of ethnically diverse smokers found that over half of respondents were unaware that nicotine does not cause tobacco-related cancer. Additionally, a study of adult smokers found that most participants believed nicotine caused numerous other smoking-related ailments, including stroke, asthma, diabetes, gum disease, and emphysema."[35] Misperceptions about tobacco products also extend to a staggering number of U.S. healthcare providers, on whom adult smokers rely to provide accurate medical information.[36]

Misperceptions about nicotine can contribute to beliefs among adult smokers—and healthcare professionals—that modified risk tobacco products are equally or more harmful than traditional combustible cigarettes. As CTP has recognized, "incorrectly believing that nicotine

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[32] *See* TCA, §§ 2(44) ("promote understanding of the impact of the product on health."), 3(6) ("ensure that consumers are better informed").

[33] See FDA, Nicotine Is Why Products Are Addictive, https://tinyurl.com/2rsj64k6 (last updated June 29, 2022) ("Nicotine is what keeps people using tobacco products. However, it's the thousands of chemicals contained in tobacco and tobacco smoke that make tobacco use so deadly. Some of these chemicals, known to cause lung damage, are also found in some e-cigarette aerosols. This toxic mix of chemicals—not nicotine—cause the serious health effects among those who use tobacco products, including fatal lung diseases, like chronic obstructive pulmonary disease (COPD) and cancer.") (citing HHS, The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General; 2014).

[34] O'Brien EK, et al., U.S. adults' addiction and harm beliefs about nicotine and low nicotine cigarettes. FDA, U.S. Center for Tobacco Products (2017), https://tinyurl.com/ywu54mya ("Although most people (83%) believed that nicotine is the main substance in cigarettes that makes people want to smoke, about half (49%) incorrectly believed that nicotine is the main substance in cigarettes that causes cancer, and another 24% were unsure.").

[35] *See id.* (citing Carpenter *et al.*, Misperceptions of nicotine replacement therapy within racially and ethnically diverse smokers. J. Natl. Med. Assoc. 2011;103(9–10):885–894; Bansa, *et al.*, Smokers' beliefs about nicotine and the safety/efficacy of nicotine medications. Nicotine & Tobacco Research. 2004b; 6:1–8. Carpenter, *et al*., Misperceptions of nicotine replacement therapy within racially and ethnically diverse smokers. J. Natl. Med. Assoc. 2011;103(9–10):885–894; Mooney, *et al*., Attitudes and knowledge about nicotine and nicotine replacement therapy. Nicotine Tob. Res. 2006;8(3):435–446).

[36] *See, e.g.*, B. Toll, T. Smith and B. King, Nicotine e-cigarettes: considerations for healthcare providers, 30 Nature Medicine 1513-1514 (June 2024), https://tinyurl.com/4rvdehv7 ("Similarly, many physicians also believe that all tobacco products are equally harmful.").

causes cancer could discourage smokers from switching to safer nicotine-containing alternatives."[37]

Following its review of CTP's operations in 2023, the Reagan-Udall Foundation urged the Center to consider how to address calls for communication about the relative risks of tobacco products and improve the overall transparency of the tobacco program, particularly with respect to the regulatory process and its scientific underpinnings.[38] The Reagan-Udall Foundation also urged CTP to enhance the use of available communication tools to better communicate with the public about its decision-making and scientific views.[39]

While CTP has taken the first steps to educate adults about the risk continuum as outlined above, FDA has narrowly focused risk continuum content on e-cigarettes, rather than discussing all smoke-free products. FDA has noted that while e-cigarettes "can generally be a lower-risk alternative" to cigarettes, "further high-quality research on both short- and long-term health outcomes is needed."[40] These qualities—lower-risk, high-quality research on short- and long-term health outcomes, and evidence-based research on communicating the relative risk of a specific product—are precisely the information that has been presented to FDA and substantiated through the MRTP pathway, resulting in modified risk granted orders for several new tobacco products, including *General Snus* and the *IQOS* heating system.

In the limited content on the MRTP process and products, FDA simply states that an MRTP application "generally" must show that a product will reduce the harm and risk of tobacco-related disease,[41] a characterization that is not only at odds with the TCA,[42] but also is inadequate to inform adult consumers about the high evidentiary and scientific standards these products must meet. Notably absent is an explanation to the public of the various modified risk granted orders available under the TCA, the specific standards that must be met to receive the orders, the scientific burden to be met, or the restrictions FDA may place on how such products may be marketed to adult consumers.

FDA's omission of clear and transparent information regarding the MRTP pathway and products in receipt of a modified risk granted order as a critical element of the risk continuum leaves the public uninformed and confused about the importance and availability of modified risk tobacco products.

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[37] King, et al., Commentary on Wackowski et al.: Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products among Adult Smokers, Addiction 2023; 1-3 (June 23, 2023), https://tinyurl.com/yaz36w7h.

[38] Reagan-Udall Foundation, Operational Evaluation of Certain Components of FDA's Tobacco Program, at 27 (Dec. 2022) https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf.

[39] *Id.*

[40] FDA, The Relative Risks of Tobacco Products, https://tinyurl.com/4x7dw89w (last updated Apr. 16, 2024).

[41] FDA, Modified Risk Tobacco Products, https://tinyurl.com/3zeyxxcx (May 31, 2024) ("An MRTP application generally must demonstrate that the product 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.").

[42] *See* 21 U.S.C. 387(k)(g)(1) (providing that a product may be marketed as a modified risk product when "the Secretary determines that that applicant has demonstrated that such product, as it is actually used by consumers, *will* (A) significantly reduce harm and the risk of tobacco-related disease of individual users; and (B) benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products") (emphasis added).

FDA should take additional steps to educate and inform adults about the MRTP process and available MRTP products to further the public health potential of modified risk granted orders and the harm reduction goals of the TCA. Without proper adult consumer awareness and understanding of these key pillars, the MRTP pathway cannot be fully utilized to protect and promote the public health as Congress intended.

IV. CTP should increase transparency, predictability, and efficiency of the MRTP process.

In the past, FDA has recognized "[a]n important way FDA can promote and encourage the development of 'innovative products and treatments' to achieve abstinence, reductions in consumption, and reductions in harm is by providing open and working pathways for products to come to market."[43] The MRTP pathway has the potential to provide "valuable tools in the effort to promote public health by reducing the morbidity and mortality associated with tobacco use, particularly if companies take advantage of these provisions by making bold, innovative product changes that substantially reduce, or even eliminate altogether, either the toxicity or addictiveness of tobacco products, or both."[44]

In 2017, FDA leadership reiterated this call to support innovation "where innovation could truly make a public health difference, and making sure we have the foundational regulations we need in place to make the entire program transparent, predictable, and sustainable for the long run."[45] A critical component of this transparency and predictability included advancing a rule to clarify the needs for modified risk tobacco product applications.[46] In spite of CTP's repeated recognition of the importance of a clear, efficient process, CTP has yet to finalize guidance for industry or publish final rules to address the need for transparency and predictability in the MRTP process. Recognizing this, the Reagan-Udall Foundation urged that FDA "should develop a more clear and predictable framework for high-quality MRTP application and submission reviews"[47] and made two recommendations: (1) CTP should prioritize timely development and completion of policies and scientific standards necessary for high-quality submissions, and (2) CTP should simplify, standardize, document, and publicly disseminate its MRTP review procedures.[48]

As it currently exists, the MRTP pathway is wholly underutilized. To improve and incentivize the use of the MRTP pathway, we recommend that CTP create and prioritize a dual

[43] FDA, Report to Congress: Innovative Products and Treatments to Achieve Abstinence from Tobacco Use, Reductions in Consumption of Tobacco, and Reductions in the Harm Associated with Continued Tobacco Use, at 2, https://tinyurl.com/ymyhu8fn (Apr. 22, 2013).

[44] FDA, Draft Guidance for Industry: Modified Risk Tobacco Product Applications, https://tinyurl.com/f5mncafz (March 2012).

[45] FDA, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco, https://tinyurl.com/4x4hynna (last updated Mar. 28, 2018).

[46] *Id.*

[47] Reagan-Udall Foundation, Operational Evaluation of Certain Components of FDA's Tobacco Program, at 19 (Dec. 2022) https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf.

[48] *Id.*

PMTA and MRTP pathway, as envisioned by the TCA.[49] A combined PMTA and MRTP application pathway presents key potential to benefit public health through the streamlined proliferation of scientifically substantiated products that are a better alternative to continued smoking along with increased public understanding. Prioritization of combined PMTA and MRTP applications through a single review team could further incentivize its use by leveraging the resources and expertise that already exist within the Office of Science.

CTP should also implement accelerated authorizations and fast-track review provisions for MRTP renewals and applicants seeking minor product improvements to existing modified risk granted orders. Directing resources to expedite the review of products with an existing modified risk granted order further incentivizes applicants to seek to improve existing modified risk products. Establishing fast-track provisions and prioritization for these products ensures adult smokers will continually have access to authorized modified risk products.

Building on the successes of other FDA Centers, CTP should promote innovation in and utilization of the MRTP pathway through enhanced communication with applicants throughout the review process. CTP should hold meetings with the applicant and review team throughout the application review process, provide timely advice to the applicant, and encourage collaboration with experienced review staff. As recognized by other FDA Centers, earlier and more frequent communication assures questions and issues are resolved quickly, which can facilitate a more efficient, effective, and thorough review of MRTP applications.

Improving the efficiency of the MRTP process will incentivize product innovation, improve Agency communication with applicants, and result in additional modified risk granted orders to unlock the potential of postmarket data for near-, mid-, and long-term study and evaluation.

* * * * *

We greatly appreciate the opportunity to submit these comments as part of the June 26, 2024 Tobacco Products Scientific Advisory Committee meeting and look forward to further constructive dialogue with the Committee and FDA regarding MRTP program developments. We offer these suggestions as ways to improve the MRTP process and the public's understanding of this important product pathway, both of which are important harm reduction measures to disrupt the current trajectory of smoking. Thank you for your consideration.

[49] *See* TCA, § 911(l)(4).

June 19, 2024

Office of Science, Center for Tobacco Products,
Food and Drug Administration Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
ATTN: Serina Hunter-Thomas

RE: June 26 Meeting of the Tobacco Products Scientific Advisory Committee for General Snus

On behalf of the Hispanic Leadership Fund (HLF), I'm writing in support of the modified risk tobacco product (MRTP) authorization renewal for General Snus smokeless tobacco products, as submitted by Swedish Match USA, Inc. HLF is a national non-partisan advocacy organization that promotes common-sense public policy solutions that foster liberty, opportunity, and prosperity for all Americans.

The Food and Drug Administration (FDA) began reviewing General Snus product applications in 2015, and in 2019 the FDA authorized eight General Snus smokeless tobacco products. After these comprehensive, rigorous reviews, the FDA concluded that two particularly dangerous carcinogens in smokeless tobacco products are lower in General Snus, and that if used as an alternative to other smokeless tobacco products, it presents a diminished cancer risk.[1] This authorized General Snus to market these products with an emphasis on their safety, relative to the risks associated with cigarettes and other smokeless tobacco products. The 2019 authorization requires a review every five years.[2]

The FDA's review confirmed the accuracy of the scientific evidence General Snus advanced to support its claims that consumer use of modified risk products will significantly reduce harm, and the risk of tobacco-related disease, for both individual tobacco users and the broader population. Since your last review, the science in support of less harmful alternatives to cigarettes has not changed.

[1] FDA grants first-ever modified risk orders to eight smokeless tobacco products | FDA
[2] US regulatory landscape

Among all Americans, 30% of all cancer deaths are related to smoking tobacco.[3] Cigarette smoking is also economically detrimental: $240 billion in healthcare spending and $372 billion in lost productivity are a result of cigarette smoking related complications.

These effects are notable in underserved communities. For example, according to the Center for Disease Control and Prevention (CDC), about one in 13 (7.7%) Hispanic or Latino adults in the US smokes cigarettes.[4] Cigarette smoking increases the risk of heart disease and cancer, the leading causes of death (24.9% and 20.3%, respectively) for Hispanics in the United States.[5] This has led to an adverse, cross-generational health impact on the Hispanic community.

In addition, HLF would like to emphasize the importance of the MRTP process, and the need for reforms to ensure consumers have access to innovative, harm-reducing alternatives to cigarettes.

The Reagan Udall Foundation recommends that the Center for Tobacco Products (CTP) "develop a clearer and more predictable framework for high-quality MRTP application and submission reviews." Since 2009, the CPT has approved less than half out of more than 26 million premarket tobacco product applications (PMTAs). The CTP has only authorized a total of 16 modified risk tobacco products from four individual manufacturers.[6]

Sustainment and expansion of modified risk tobacco product alternatives in the market cultivates the development and innovation of products that decrease the risk of death and serious disease associated with smoking and tobacco use. The development of these products benefits America's general population, and especially those in underserved communities.

(b) (6)

Mario H. Lopez
President

[3] Health Risks of Smoking Tobacco
[4] Hispanic and Latino People | For Specific Groups | Tips From Former Smokers | CDC
[5] Tobacco use among Hispanic and Latin Americans
[6] Tobacco Induced Diseases

World Vapers' Alliance testimony to the Food and Drug Administration (FDA) Tobacco Product Scientific Advisory Committee (TPSAC) Public Meeting

About the World Vapers' Alliance

The World Vapers' Alliance (WVA) amplifies the voices of vapers worldwide and empowers them to make a difference in their communities. Our members are vapers associations and individual vapers from all over the world. More information can be found at www.worldvapersalliance.com

About this consultation and why the World Vapers' Alliance is responding to it

The World Vapers' Alliance is committed to advocating for safer alternative nicotine products that have already helped millions of smokers quit worldwide. This is the case with snus, a smokeless, moist powder tobacco pouch which originated in Sweden, and is used by placing it under the top lip.

Sweden is on the way to becoming the first country to reach the smoke-free goal, with a current smoking rate of 5.6%, thanks to the massive adoption of snus by smokers looking to quit combustible cigarettes. As a consequence, Sweden has the lowest smoking-related mortality and cancer rates across the European Union, despite similar nicotine consumption levels.

The FDA TPSAC Public Meeting on the Modified Risk Tobacco Product (MRTP) renewal for snus products represents an opportunity for the United States to follow the harm reduction path endorsed by Sweden by allowing the use of snus as a tool for smoking cessation and safer nicotine consumption. Since MRTP applications aim to demonstrate that the product will significantly reduce the risk of tobacco-related illnesses to users and improve public health, we at the World Vapers' Alliance seek to provide information supporting the life-saving potential of snus and its capacity to improve public health.

The Swedish experience

The World Health Organization recently highlighted that Sweden is on track to become the first smoke-free country in the world. This achievement is largely due to Sweden's proactive approach to tobacco harm reduction, which encourages citizens to switch from traditional cigarettes to less harmful alternatives like vaping, nicotine pouches, and snus.

Snus, offering a smokeless experience and containing lower levels of harmful chemicals, stands out as a less harmful alternative to traditional cigarettes. It is unique among smoke-free products in having decades of data supporting its safety profile in Sweden, showing that individuals who use snus instead of combustible tobacco are at reduced risk of developing smoking-related illnesses. Furthermore, because snus does not generate smoke, it completely eliminates the risk of secondhand smoke exposure, addressing a major concern associated with traditional tobacco products.

In Sweden, the use of snus has surpassed the smoking of combustible cigarettes, mainly due to smokers switching to it. Similarly, nicotine pouches, introduced in Sweden in 2018, have contributed to a significant reduction in smoking rates, which have fallen by over 20% since their introduction. Snus has been primarily adopted by men as a means to quit smoking, while nicotine pouches have become the preferred choice among women.

Thanks to the replacement of tobacco by this safer alternative, Sweden's smoking rates have decreased at double the pace of any other European Union country, dropping by 55% over the past decade and putting Sweden on the way to becoming the first country to reach the smoke-free goal, with a smoking rate of 5.6% as of 2023.

Even though total nicotine consumption in Sweden is similar to that of other European nations, smoking-related mortality and cancer rates are much lower due to it being consumed via safer alternative nicotine products. The Scandinavian nation has a 22% lower rate of smoking-related deaths compared to the EU average. The incidence of cancer is 41% lower than in the rest of Europe, with overall cancer-related deaths being 38% lower. These results prove snus is a much less harmful product with great potential to improve public health. In fact, Sweden is now looking to accelerate this process by reducing its tax on snus by 20%.

The rising popularity of nicotine pouches and snus provides consumers with more options to transition away from combustible tobacco. One-fits-all solutions do not work when it comes to smokers trying to quit, so it is crucial for the FDA to give smokers as many choices as possible to use what fits them best. If the United States follows the Swedish example, it could quickly reduce smoking rates and smoking-related deaths and diseases and become a leader in tobacco harm reduction

Consideration of other smokeless nicotine products

While snus is the focus of this TPSAC meeting, it’s crucial to also consider and promote other smokeless tobacco products as less harmful options than combustible tobacco.

E-cigarettes or vapes have become popular and effective technologies for helping consumers move away from smoking traditional cigarettes. However, there are

additional alternatives, such as nicotine pouches, gums, and lozenges, that also deserve attention.

In Canada, vaping is promoted as a less harmful nicotine alternative to assist individuals in quitting smoking. Evidence from Canada indicates that those who switch completely from combustible tobacco to vaping can immediately reduce their exposure to the harmful chemicals found in cigarette smoke. They often experience general health improvements in the short term, face no serious unwanted effects while using vaping products to quit, and are more likely to quit smoking compared to those who use nicotine replacement therapy (NRT) or counseling. Although the initial cost of vaping might be higher, it tends to save money in the long run due to the lower cost per equivalent puff.

The United Kingdom serves as another leading example, having embraced vaping as a harm-reduction tool. In 2015, Public Health England announced studies showing vaping to be 95% less harmful than smoking. The UK government continues to research the impact of vaping on public health, with the latest 2022 report indicating that flavored vaping products, particularly fruit and menthol/mint flavors, are the most commonly used aids for quitting smoking. In recent initiatives, the UK government encouraged one million smokers to swap cigarettes for free vape starter kits and offered financial incentives to pregnant women to quit smoking.

MRTPs should be granted to any nicotine alternative that scientific evidence shows to be less harmful than combustible cigarettes. The approval and renewal of reduced-risk products have the potential to benefit millions of Americans and public health overall. By supporting a broader range of nicotine alternatives through the MRTP program, the FDA can provide consumers with more choices to help them quit smoking and reduce the harm associated with tobacco use.

Concluding remarks

For any questions or comments, please contact the submitter of the response.

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June 19, 2024

To: Tobacco Products Scientific Advisory Committee (TPSAC)
From: Americans for Tax Reform

Dear Members,

On behalf of Americans for Tax Reform (ATR), a non-profit organization which advocates for the interests of taxpayers and consumers throughout the United States, we thank the Tobacco Products Scientific Advisory Committee for the opportunity to provide testimony with respect to Swedish Match USA's application to renew Modified Risk Tobacco Product (MRTP) authorization for General Snus. It is submitted that the evidence overwhelmingly demonstrates that it is in the interest of public health to renew MRTP authorization, and that the products under consideration 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.

Allowing General Snus products to be accurately marketed as a reduced risk product is consistent with the principles of harm reduction and best practices across all public health disciplines. This approach is designed to mitigate the negative health impacts of tobacco use by encouraging smokers to switch to less harmful alternatives. The primary health risks associated with smoking stem from the combustion process, which releases harmful chemicals found in tobacco smoke. By offering smokers safer alternatives to combustible cigarettes, their exposure to these toxic substances is significantly reduced, thereby lowering the risks of cancer, heart disease, and lung disease. This strategy has been demonstrated to improve health outcomes for smokers by addressing the dangers of tobacco combustion, in similar manners to how it has improved health outcomes in other fields.

It is submitted that all available academic and scientific evidence clearly demonstrates that switching to snus would improve the health prospects of smokers who are unable or unwilling to quit using nicotine, as the absence of combustion allows users to consume nicotine without the thousands of toxic chemicals that make traditional cigarettes harmful, and the relatively low risk of snus compared to cigarettes is not in dispute. However, significant misinformation persists in the community, as recognized by FDA, of the risk spectrum, and MRTPs are a powerful way to address consumer knowledge. Allowing Swedish Match USA, Inc. to continue marketing their products with such authorization will grant them the ability to accurately present factual data and provide the public the knowledge that these products are a safer alternative to combustible cigarettes and path toward cessation.

A 2021 study showed that about 2.1% of U.S. adults, or approximately 5.2 million individuals, reported using smokeless tobacco. The Federal Drug Administration (FDA) has noted that General snus products contain lower levels of carcinogens N-Nitrosonornicotine (NNN) and Nicotine-derived nitrosamine ketone (NNK) compared to most other smokeless tobacco products on the market. This lower carcinogen level suggests a reduced risk of cancer, heart disease, and lung disease for snus users. A 2019 study revealed that interest in snus was highest among current smokers, who could benefit significantly from switching to snus, as highlighted in the modified-risk advertisements. As a result, snus has the potential to improve health outcomes for a significant portion of tobacco users in the U.S.

It is also worth noting that according to the 2023 National Youth Tobacco Survey, only 1.6% of high school students use any form of smokeless tobacco (a category which, in addition to snus, includes chewing tobacco, snuff, and dip). While obviously zero use is ideal, 1.6% is so low as to indicate that no youth usage problem exists that might negatively impact on any MRTP application.

We also attached to this submission, as APPENDIX A, a white paper released by the Tholos Foundation entitled *Safer Nicotine Works* which examined various data sources regarding how snus products in Sweden are helping to lower the smoking rate in the country. Sweden demonstrates a significant success in the campaign to eliminate smoking, where the use of Snus has been embraced as a key component of public health planning, and as a result, the country is set to become the world's first smoke-free society. The Tholos Foundation's white paper looked at data from the Public Health Agency of Sweden which revealed that over the past ten years, the smoking rate in Sweden has more than halved, dropping from 11.4% in 2012 to just 5.6% in 2022. Sweden's low smoking rates have led to significant public health benefits, including a notably reduced incidence of tobacco-related cancers compared to European averages. The White Paper also referenced data by the Institute for Tobacco Studies, which found that "more than eight out of ten smokers who started using snus had quit daily smoking and that almost one-third no longer used any form of tobacco on a daily basis." In addition, the Institute also suggests that due to the use of snus products, each year in the 2010s, Sweden has saved more than 4,000 lives compared to other EU countries, with similar Human Development Indexes (HDI). This is possible because snus products are estimated to only cause 5% of the harm cigarettes do. It is also important to note that according to a comprehensive analysis published in the International Journal of Environmental Research and Public Health, data from Sweden shows that people who start using snus are less likely to start smoking compared to those who don't use snus. Not only does switching from smoking to snus help people quit smoking, but it also stops them from picking up smoking in the first place.

In 2019, FDA accepted Swedish Match's USA, Inc.'s original MRTP claim, and since then, nothing has fundamentally changed. FDA stated that their original claim was "supported by scientific evidence" and that "consumers understand the claim and appropriately perceive the relative risk of these products compared to cigarettes." In connection with tobacco use behavior, the presence of an MRTP claim continues to transition intended users who are already "down that continuum of risk", and according to the National Youth Tobacco Survey, young adults have not demonstrated significant use of snus. No new evidence has emerged since 2019 to cause any reason therefore to think that the MRTP ought be withdrawn.

As such, the evidence clearly shows that Snus products are playing a significant role in Sweden's progress towards a smokeless society. Allowing these products to be accurately marketed in the U.S. will provide reassurance that they not only reduce smoking rates but also help people quit tobacco entirely. This cessation effort is saving lives and emphasizes the potential benefits of promoting such alternatives.

For the reasons outlined above, in the interests of public health, we call upon you to renew Swedish Match USA, Inc.'s ability to market their snus products as an MRTP, thereby reducing harm and tobacco related diseases across the United States.

Sincerely,

Tim Andrews
Director of Consumer Issues
Americans for Tax Reform

06/18/2024

Office of Science, Center for Tobacco Products,
Food and Drug Administration Document Control Center
Bldg. 71, Rm. G335, 10903, New Hampshire Ave.
Silver Spring, MD
20993-0002

ATTN: Serina Hunter-Thomas
Comments re: Tobacco Products Scientific Advisory Committee Meeting, June 26, 2024
The Latino Coalition (TLC) is writing in support of the modified risk tobacco product (MRTP) authorization renewal of eight General Snus products.
The MRTP pathway, authorized by Congress and established by the U.S. Food and Drug Administration (FDA), plays a pivotal role in evaluating and regulating tobacco products that reduce health risks compared to conventional cigarettes. This pathway is crucial in promoting public health by providing consumers with less harmful alternatives to traditional tobacco products.
On October 22, 2019, the FDA gave the first-ever MRTP authorization to eight General Snus smokeless tobacco products submitted by Swedish Match. In their 2019 report, the FDA commented that "the available scientific evidence demonstrates that exclusive use of the eight General Snus products will significantly reduce harm and the risk of tobacco‐related disease to individual tobacco users." Since then, over a decade of epidemiological data continues to show that switching from cigarettes to General Snus will significantly reduce harm and the risk of tobacco-related disease to the individual consumer.
The 2019 report also noted evidence that other countries that have been early adopters of General Snus products saw public health benefits. As seen in public health data, tobacco-related illness and mortality are lower in Sweden than in any other European country. At the same time, the use of smoke-free products, such as snus, has drastically increased. The evidence supporting these products' receiving MRTP authorization is only stronger than it was in 2019. Therefore, the FDA should move forward with reauthorization.
Additionally, we advocate for improvements to the MRTP process, which can currently be cumbersome and lacking clarity. Congress established the MRTP pathway as the primary avenue for tobacco manufacturers to inform users about reduced-risk options. In 2022, the Reagan-Udall Foundation recommended that the Center for Tobacco Products (CTP) create a more transparent and predictable framework for reviewing MRTP applications and submissions3. The report went on to recommend CTP prioritizing timely development and completion of policies and scientific standards necessary for high-quality submissions.
TLC strongly supports renewing MRTP authorization for the eight General Snus products. This pathway, overseen by the FDA, evaluates tobacco products with reduced health risks compared to cigarettes. The FDA's 2019 decision highlighted the benefits of General Snus, and we advocate for reforming the MRTP process. Let's prioritize public health by ensuring access to safer alternatives while maintaining rigorous standards.

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Serina Hunter-Thomas
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Re: Tobacco Products Scientific Advisory Committee (TPSAC) Meeting on June 26, 2024

Founded in 1989, the Progressive Policy Institute (PPI) started as the intellectual home of the New Democrats. We are a catalyst for policy innovation and political reform based in Washington, D.C. with a mission to create radically pragmatic ideas to move America beyond ideological and partisan deadlock. Our focus is on working Americans and policy that impacts them.

Tobacco harm reduction is a core of our current health policy focus on how policymakers and regulators can improve the outcomes for working Americans.

With that, we are submitting this statement in support of the Modified Risk Tobacco Product authorization (MRTPA) renewal for the General Snus smokeless tobacco products as submitted by Swedish Match USA, Inc. We encourage the FDA to renew this MRTPA and continue to give working Americans the less harmful nicotine alternative that Swedish match offers.

In 2019, the Food and Drug Administration (FDA) authorized the first-ever modified risk orders to these eight General Snus smokeless tobacco products. FDA's own review determined that the claim proposed by Swedish Match USA, Inc. in its application is supported by scientific evidence, that the relative risk of these products compared to cigarettes, 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.[1]

In particular, the evidence submitted in the application also demonstrated that the levels of two potent carcinogens in smokeless tobacco products called NNN and NNK are lower in these General Snus products than the vast majority of smokeless tobacco products on the U.S. market.[2] In addition, the evidence showed when used exclusively instead of other smokeless tobacco products, General Snus products offer the potential for reductions in oral cancer risk.[3]

The science behind General Snus products has not changed since then and, in fact, all evidence supports continued authorization and meets the same appropriate for public health (APPH) standards. The FDA made the correct decision in 2019 and should embrace this success by quickly reauthorizing the application.

ppi radically pragmatic

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Failure to renew the modified risk order for General Snus would imply that the FDA's own robust review process is not working and would deny adult consumers information and access to FDA-authorized reduced-risk products.

More broadly on the MRTP program, we urge the FDA and CTP to function as an effective regulator and drive toward a workable, regulated market for the benefit of adult consumers. The MRTP pathway is an opportunity to encourage the development and innovation of products that can make a major difference in death and disease from smoking and combustible tobacco use. The current process is unclear and burdensome to the point that it disincentivizes the use of the MRTP pathway. The reality is that approximately 30 million adult men and women continue to smoke cigarettes each year[4] and today, these adults have very few available FDA-authorized alternatives available.

The FDA has a pivotal role to play in promoting innovation and improving public health. We therefore urge the Agency to focus on science-based regulatory policy, no matter where the evidence leads us. This means tackling tough problems with an open and pragmatic mind to achieve the best possible outcomes.

Sincerely,

Mr. Lindsay Mark Lewis
Executive Director
PPI

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[1] FDA grants first-ever modified risk orders to eight smokeless tobacco products | FDA

[2] *Ibid*.

[3] *Ibid*.

[4] Current Cigarette Smoking Among Adults in the United States | CDC

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Memorandum

Date: June 18, 2024

To: Members of the CTP Tobacco Products Scientific Advisory Committee

From: Adam Hoffer, PhD, Director of Excise Taxation, Tax Foundation

Subject: Comments on Modified Risk Renewal for General Snus

In the five years since the Food and Drug Administration (FDA) granted the first modified risk order for Swedish Match snus, the scientific consensus is unchanged that snus products are less harmful to consumers than combustible cigarettes. The United States snus market is still in its infancy, but the lack of problematic snus consumption suggests that snus products continue to fit the criteria for modified risk tobacco products (MRTP).

Tax and pricing studies reveal that price matters to consumers. Snus consumption is highly price-elastic in local markets and closer to unit-elastic at the national level.[1] Several states and local governments use MRTP status to determine tax rates and whether products can be sold in their jurisdictions.[2] MRTP status, therefore, plays a key role in establishing price differentials between combustible cigarettes and snus products, a key factor in encouraging smokers to switch to less harmful products.

The nicotine market in the United States is transforming. The innovation and development of alternative nicotine consumption products represent a massive change from a market historically dominated by cigarettes. Alternative tobacco products like snus allow users to consume nicotine with only a fraction of the risk present in combustible cigarettes. With appropriate tax and regulatory policy, these products have the potential to save millions of lives each year.

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[1] Jidong Huang, Cezary Gwarnicki, Xin Xu, Ralph S. Caraballo, Roy Wada, and Frank J. Chaloupka, "A comprehensive examination of own- and cross-price elasticities of tobacco and nicotine replacement products in the U.S.," *Preventative Medicine* 117 (December 2018): 107–114, https://www.sciencedirect.com/science/article/abs/pii/S009174351830135X?via%3Dihub.
[2] Adam Hoffer, "How Should Alternative Tobacco Products Be Taxed?," Tax Foundation, Aug. 24, 2023, https://taxfoundation.org/research/all/federal/taxing-alternative-tobacco-products.

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June 20, 2024

Ms. Serina Hunter-Thomas
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration
Document Control Center, Bldg. 71, Rm. G335
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Sent by e-mail

Dear Ms. Hunter-Thomas:

Please accept this letter, and the attached October 19, 2020 letter signed by six public health groups, as the written comments of the Campaign for Tobacco-Free Kids in Docket No. FDA-2024-N-0008, Tobacco Products Scientific Advisory Committee; Notice of Meeting called to discuss the renewal of a risk modification order submitted by Swedish Match USA, Inc. for several snus products. The attached letter concerns the role of TPSAC in Modified Risk Tobacco Product Proceedings.

Thank you for this opportunity to share our views.

Sincerely,

/s/ Dennis A. Henigan

Dennis A. Henigan
Vice President, Legal and Regulatory Affairs
Campaign for Tobacco-Free Kids

October 19, 2020

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Role of the Tobacco Products Scientific Advisory Committee in Modified Risk Tobacco Product Proceedings

Dear Director Zeller:

In the Family Smoking Prevention and Tobacco Control Act (TCA) Congress mandated the creation of the Tobacco Products Scientific Advisory Committee (TPSAC or the Committee) and gave it several specified roles, including in the evaluation of Modified Risk Tobacco Product (MRTP) applications. Specifically, it required that MRTP applications be submitted to TPSAC and that TPSAC provide FDA with its recommendations on the applications before FDA issues or denies MRTP orders. For TPSAC to carry out its mandated function, and for the FDA and the public to have the benefit of TPSAC's assessment of the scientific evidence necessary for it to make the recommendations that are required for a decision on each application, TPSAC must be given the opportunity to evaluate the scientific issues and articulate its individual and collective views as to whether an application has met the required scientific standard.

We are writing because the role TPSAC has been playing in modified risk proceedings has not been consistent with the letter or spirit of the TCA. The Committee's role has been increasingly marginalized; it has not been asked, or provided an opportunity, to indicate whether applications meet the required scientific standards, and more recently, it has not been provided with an opportunity to vote on the most important scientific issues necessary for it to make recommendations concerning such a determination.

FDA's marginalization of TPSAC's role has been compounded by FDA's failure to give due deference to TPSAC's conclusions regarding Philip Morris' application for IQOS. On the IQOS application, TPSAC provided clear, consistent, scientifically-based guidance on key population health questions establishing that the product did not meet the scientific threshold required for MRTP authorization.[1] Nevertheless, FDA recently issued exposure modification orders for the IQOS system.

[1] A majority—and at times, overwhelming majority—of TPSAC members did not believe (a) the applicant demonstrated that reductions in exposure were reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality (5 of 8 votes), (b) it was likely that U.S. smokers would switch completely to IQOS (7 votes of low likelihood, 2 for medium, and 0 for high), or (c) that consumers would accurately understand the risks of IQOS as conveyed in the proposed modified risk labeling and advertising (9 of 9 votes). In addition, eight of nine voting members found a medium-high likelihood that U.S. smokers would become long-term dual users of IQOS and conventional cigarettes, and three found a medium-high likelihood that U.S. never

In short, the diminished role FDA has given to TPSAC, combined with the manner in which it appeared to disregard TPSAC's conclusions regarding the IQOS application, is inconsistent with the TCA and the traditionally important role of FDA scientific advisory committees to enhance public trust in FDA decisions regarding industry applications. FDA must reverse course and enable TPSAC to provide objective, credible public scrutiny to MRTP applications and recommendations as to whether such applications meet the required scientific standard.

I. STATUTORY AND REGULATORY BACKGROUND

Section 911(f)(1) of the Food, Drug, and Cosmetic Act (FDCA) requires FDA to refer every MRTP application to TPSAC. In turn, "[n]ot later than 60 days after the date an application is referred" to TPSAC, it "*shall* report its recommendations on the application" to FDA.[2] The final decision to issue or deny a modified risk order rests with FDA, but the statute makes receipt and consideration of TPSAC's recommendations an essential component of FDA's review of every MRTP application. In other words, no modified risk application may be acted upon without TPSAC making recommendations on whether to grant or deny an application and on the scientific issues necessary to make such a determination.

The unique importance of TPSAC's role in the MRTP application review and authorization process is illustrated by the contrast between its mandatory MRTP role and the discretionary role of other scientific advisory committees respecting review of new products under other sections of the FDCA. For example, when reviewing a drug or biologic with a novel active ingredient, FDA need not seek advisory committee input as long as it explains its decision for not making a referral in its action letter.[3] FDA has similar discretion to seek advisory committee input on premarket approval applications for a novel medical device.[4] The TCA's MRTP provisions do not afford such discretion to FDA. Rather, Congress left no doubt that TPSAC is a critical part of the process by requiring it to make substantive recommendations on FDA's review and authorization of MRTP applications.

FDA has provided little guidance as to how it views TPSAC's role in light of the statutory language. The process FDA uses to refer individual MRTP applications to the Committee was first discussed at the April 30, 2013 TPSAC meeting.[5] In the fiscal year (FY) 2013 TPSAC Report, FDA indicated that "[t]he [MRTP

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smokers would become established IQOS users. January 25, 2018 TPSAC Meeting Transcript, at 559, 583, 594, 607, available at https://www.fda.gov/media/111450/download (last accessed Oct. 2, 2020).

[2] 21 U.S.C. § 387k(f)(2) (emphasis added).

[3] *See* 21 U.S.C. § 355(s) (requiring referral of only some new drug and biologic license applications to an advisory committee for "review," unless FDA states its reasons for not referring the application in the action letter on the application).

[4] 21 U.S.C. § 360e(c)(3) (requiring referral of a device premarket approval application to an advisory committee panel for "study and for submission … of a report and recommendation respecting approval of the application" only upon request of an applicant, unless FDA determines there would be substantial duplication of information already reviewed by a panel).

[5] The Campaign for Tobacco-Free Kids submitted comments discussing the rigorous standards for scientific proof required by Section 911 of the TCA, including the historical basis for Congress mandating a demanding scientific review, and outlined the statutory role of TPSAC in FDA's assessment of whether an applicant has met its burden to provide such proof, noting that the TCA requires TPSAC involvement in FDA's evaluation of MRTP applications and TPSAC recommendations on each application. Comments of Campaign for Tobacco-Free Kids (CTFK) in Docket No. FDA-2013-N-0001, April 30, 2013 TPSAC meeting re process for TPSAC consideration of modified risk tobacco product applications (April 23, 2013), available at https://bit.ly/2GqskKS (last accessed Oct. 2, 2020). Public health

application] recommendation would likely be a compilation of TPSAC meeting materials (e.g., transcript, slides, etc.) and may include a brief written report."[6] The FY 2013 TPSAC Report also stated, "Further scientific, administrative and legal review will be needed for FDA to determine the precise processes to be used for MRPT [sic] application review, referral to the TPSAC, and the TPSAC's recommendation regarding the application." To our knowledge, no further clarification of TPSAC's role has been provided.[7]

The 2008 FDA guidance document on voting procedures for advisory committee meetings (Voting Procedures Guidance) identifies two ways that advisory committees typically communicate advice or recommendations to the Agency:

> First, FDA learns from the discussion and exchange that occurs among advisory committee members, and from individual recommendations and suggestions made during the discussion of any advisory committee meeting. Second, advisory committees often vote on a question or series of questions posed to the committee during a committee meeting. As the agency makes its final decision, FDA seriously considers the recommendations made by advisory committees, including the advisory committee deliberations and voting.[8]

The Voting Procedures Guidance, however, is not legally binding and concerns only uniform voting procedures for when votes *are* taken, not when votes *should be* taken.[9] It was also developed before the enactment of the TCA and thus does not address TPSAC's mandatory role in FDA's review of MRTP applications and its requirement that TPSAC provide FDA with "recommendations" on each application.

Nevertheless, the Voting Procedures Guidance is instructive for understanding FDA's thinking as to when advisory committee votes generally are taken to provide committee recommendations to FDA. The guidance states that votes are not taken at some advisory committee meetings, such as "meetings to discuss the development of a clinical trial design or the development of a guidance document," but "[a]t other advisory committee meetings, members cast a formal vote on issues related to the approvability of a product submission."[10] As discussed more fully below, in TPSAC's review of MRTP applications during the period 2015-18, FDA asked the Committee to vote on a number of issues related to the authorization criteria for the subject MRTPs. However, more recently that practice has been

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groups have filed multiple comments with FDA on this topic in recent years and incorporate those comments by reference: Comments by CTFK, et al., in Docket No. FDA-2014-N-0001, April 18, 2014 TPSAC meeting re modified risk tobacco products (April 2, 2014), available at https://bit.ly/2HLvfON (last accessed Oct. 2, 2020); Comments of CTFK in Docket No. FDA-2017-N-0001, April 6, 2017 TPSAC meeting re review of modified risk applications (March 22, 2017).

[6] Available at https://www.facadatabase.gov/FACA/FACAPublicCommittee?id=a10t0000001h1L3 (last accessed Oct. 2, 2020).

[7] The Technical Project Lead (TPL) reports for MRTP orders both granted and denied thus far simply recite the statutory language that TPSAC reported its recommendations on the applications during an open public committee meeting held on the relevant date(s). The TPL reports provide no further clarification of what constitutes TPSAC's "recommendations." *E.g.* FDA, IQOS TPL Report, available at https://www.fda.gov/media/139796/download (last accessed Oct. 2, 2020).

[8] FDA, Voting Procedures Guidance at 4, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/voting-procedures-advisory-committee-meetings (last accessed Oct. 2, 2020).

[9] *Id.* at 3.

[10] *Id.* at 4.

discontinued, and at no point has TPSAC reported recommendations as to its overall disposition of the applications themselves.

II. TPSAC'S ROLE IN EVALUATING MRTP APPLICATIONS HAS BEEN INAPPROPRIATELY MARGINALIZED OVER TIME AND TPSAC IS NOT PERFORMING THE ROLE GIVEN IT BY THE TCA

Five different sets of MRTP applications have been referred to TPSAC to date.[11] FDA sets the agenda for each TPSAC meeting, including identifying questions for the Committee to guide the Committee's deliberations. A review of TPSAC meetings on MRTP applications supports the following observations, indicating that the Agency has set the agenda so that TPSAC has served merely as a discussion forum, rather than a body that provides recommendations to the Agency:

- Without explanation, in the last two years, FDA has reduced its voting questions for TPSAC to zero.[12] This is demonstrated by the table below.

TPSAC Meeting Date	MRTP Application Under Consideration	Number of Voting Questions
April 2015	Swedish Match's general snus products	10
January 2018	Philip Morris Products' IQOS system and Heatsticks	9
September 2018	RJ Reynolds' Camel snus products	8
February 2019	1. Swedish Match's general snus products[13] 2. Altria's Copenhagen snuff	0 1
February 2020	22nd Century Group's very-low-nicotine cigarettes	0

- In its first three meetings to consider MRTP applications, FDA asked TPSAC to ***vote*** on important scientific issues regarding relative-risk determinations, the likelihood of changes in patterns of use among tobacco users and non-users, the likely potential users of the proposed MRTP, and consumer comprehension of modified risk information.[14] More recently, FDA has asked TPSAC only to ***discuss*** these same issues without voting on them and without asking for any recommendations on the applications.

[11] The applications for Swedish Match's general snus products have been referred to TPSAC twice, but we count them as one set. The original submission was referred to TPSAC in April 2015, and an amendment to the original submission was referred to TPSAC in February 2019.

[12] During one TPSAC meeting, Dr. Brian King from the Center for Disease Control and Prevention asked why there wasn't any type of vote on the Swedish Match amendment, and Dr. Benjamin Apelberg from FDA responded that the Agency "felt what would be most useful was to really just have the qualitative discussion [because] it's the richness of the discussion that's really the most useful and informative." February 6-7, 2019 TPSAC Meeting, Transcript from Day 1 at 139-40.

[13] Amended application.

[14] All questions to the Committee for all MRTP applications referred to TPSAC to date are provided in the Appendix.

- For four of the five products, FDA asked TPSAC to vote on one of the required authorization criteria in Section 911(g)—whether evidence substantiates the scientific accuracy of proposed modified risk claims[15]—but the Agency has stopped asking TPSAC to vote on other critical questions material to application of the public health standard for authorizing MTRPs, such as the likelihood of changes in patterns of use or consumer comprehension of modified risk information. FDA has not posed such questions to TPSAC since the second TPSAC meeting on an MRTP application in January 2018 when Philip Morris' IQOS was the product under review.

- At no point has FDA asked TPSAC for its recommendations on the most important of all questions regarding the applications: whether to grant or deny MRTP orders based on the scientific evidence before the Agency.

In short, FDA has curtailed TPSAC's ability to use its scientific expertise to provide FDA with a clear opinion on issues directly related to whether an application should be granted in the MRTP evaluation process. This is wholly inconsistent with Congress' intent that FDA's evaluation of MRTP applications include independent and transparent recommendations by TPSAC.

For TPSAC to fulfill its statutory role, it must go beyond general discussion where no conclusions or recommendations are reached and where the Committee is deprived of the ability to voice its views on the issues that determine the outcome of an MRTP application. Congress required TPSAC to be given the opportunity, indeed the obligation, to issue ***recommendations*** on critical aspects of each application, and that requires that FDA provide TPSAC the opportunity to vote on each scientific question necessary to be resolved for FDA to reach a decision on applications. Most importantly, by failing to vote on key scientific questions, TPSAC cannot establish a foundation from which to make recommendations on the application itself, as required by law.[16]

A comparison of the TPSAC meetings reviewing Philip Morris' IQOS and 22nd Century's very-low-nicotine (VLN) cigarettes illustrates the stark contrast between clear, specific, and actionable votes on important scientific questions, and general discussion of similar concepts. The voting questions posed to TPSAC about IQOS provided FDA, and the public, with the Committee's assessment of the available scientific evidence on specific material issues. For example, TPSAC members overwhelmingly found it unlikely that consumers would completely switch to IQOS from conventional cigarettes and that there was a medium-high probability consumers would be converted into dual users.[17] Committee members were

[15] The four products include: (1) Swedish Match's general snus at the April 2015 TPSAC meeting, (2) Philip Morris' IQOS system and Heatsticks at the January 2018 TPSAC meeting, (3) RJ Reynolds' Camel snus at the September 2018 TPSAC meeting, and (4) Altria's Copenhagen snuff at the February 2019 TPSAC meeting. In the most recent February 2020 TPSAC meeting discussing 22nd Century Group's very-low-nicotine cigarettes, FDA's briefing document stated that its preliminary scientific review found the three proposed claims substantiated and that it was not seeking committee input on the seven additional, but similar-in-content, claims. Similarly, TPSAC was not asked to vote on Swedish Match's amended application discussed at the February 2019 meeting.

[16] Applications may also be amended or supplemented after TPSAC meetings, depriving TPSAC of the opportunity to consider all relevant data and undermining the Committee's ability to fulfill its statutory duty to report its recommendations on the application.

[17] *Supra* note 1, at 594.

also asked to concisely summarize the reasoning for their votes,[18] providing FDA with a clear indication of TPSAC's views on each of the topics about which it was asked to vote. For example, following the first voting question on whether "scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases, Dr. O'Connor stated that he "had a problem with the linkage between scientific studies and human disease," Dr. Beirut said she did not "believe that the scientific evidence in humans exists at this point," and Dr. Huang concluded "the evidence [was] lacking" in terms of impact on human disease.[19] The Technical Project Lead report accurately reflects these assessments, concluding that "most members stated that the lack of long-term human studies led them to conclude that a reduction in risk of tobacco-related disease had not been demonstrated."[20]

Yet, at the latest TPSAC meeting where the VLN cigarettes applications were discussed, TPSAC was not asked to vote on any specific questions and no similarly clear conclusions emerged. The Committee was not asked—either as individual voting members or as a body—to provide any summary of its views or even state a position on the particular issues discussed. While some voting members took it upon themselves to make such remarks,[21] these rare instances do not fulfill TPSAC's statutory obligation to report its recommendations on each application.

Finally, in defiance of Section 911(f)(2) of the FDCA, TPSAC was not asked, at either the IQOS meeting where votes were taken, or the VLN cigarettes meeting where the Committee served as merely a discussion forum, to provide its recommendation as to whether FDA should grant or deny the applications based on its scientific evaluation.

III. FDA SHOULD FULLY ENABLE TPSAC TO FULFILL ITS STATUTORY DUTY TO TIMELY REPORT ITS RECOMMENDATIONS ON MRTP APPLICATIONS

The modified risk proceedings of TPSAC are critical for gaining public and expert input and for transparency to enable the public to understand and evaluate the scientific merit of MRTP applications. The TCA also makes TPSAC more than a discussion forum. It gives it a legal mandate to evaluate the scientific evidence and offer its scientific assessments and recommendations to the FDA on the issues that the statute requires FDA to consider in making its decision. To enable the Committee to provide such recommendations, FDA must provide TPSAC with the opportunity to vote on each of the scientific issues that must be resolved to determine whether MRTP applications meet the statutory public health standard. In addition, TPSAC voting members should be instructed to vote on whether an application meets the scientific standards for granting the MRTP applications.

[18] Immediately prior to calling the first vote in January 2018, TPSAC Chair, Dr. Huang, explained that, after every vote, "each member will state his or her name and vote into the record and reason you voted as you did." *Id.* at 524.

[19] *Id.* at 526-27.

[20] *Supra* note 8. However, as noted supra at n.1, TPSAC's assessments apparently were disregarded by FDA in authorizing the reduced exposure claims for IQOS.

[21] For example, Dr. Warner and Ms. Herndon expressed concern about the subject products' name change to Moonlight, and TPSAC Chair, Dr. Mermelstein, summarized the Committee sentiment that the name "VLN" is less concerning than Moonlight. February 14, 2020 TPSAC Meeting Transcript, at 16, https://www.fda.gov/media/136252/download (last accessed Oct. 2, 2020).

Respectfully,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

Appendix

Date	MRTPA	FDA's Questions to the Committee
April 2015	Swedish Match's general snus products	**With respect to the relative health risks to individual users of these snus products (i.e., the Swedish Match North America, Inc. snus tobacco products that are the subject of these applications):**[1] 1. Discuss the evidence regarding the association between the ten snus products and gum disease or tooth loss. Please address the following issues in your discussion. • Biological plausibility that gum disease or tooth loss in snus users would differ from those in users of other smokeless tobacco products; • Confidence in the information from studies that only include young adults under the age of 25, given that the prevalence of periodontal disease increases with age; • Confidence in the information on tooth loss from the use of snus, where the studies presented in the application evaluated the number of teeth between snus users and non-users in cross-sectional studies; • Sufficiency of information from studies where the number of snus users in many of the cross-sectional surveys was fewer than 50. a. Does the evidence support that these snus products *do not* pose risks of gum disease to individual users of these products? (vote) b. Does the evidence support that these snus products do not pose risks of tooth loss to individual users of these products? (vote) 2. Discuss the evidence regarding the association between these ten snus products and oral cancer. a. Does the evidence support that these snus products *do not* pose risks of oral cancer to individual users of these products? (vote) 3. Discuss the evidence regarding the association between the ten snus products and overall risks to health as compared to cigarettes. a. Should the comparison focus on the major smoking-related diseases according to population burden or assess all relevant health outcomes? (vote) b. Does the evidence support the statement that health risks to individual users from using these snus products *exclusively,* are "substantially lower" than the health risks from smoking cigarettes? (vote)

[1] Note: revisions made by the TPSAC appear in italics.

		c. Does the *evidence support that* the proposed warning statement adequately communicates the potential health risks to individual users of these snus products? (vote) 4. Assuming that the behavior of U.S. population does mimic those in Sweden with respect to the use of snus, what information would the Committee need to know about the snus products that are used in Sweden and the snus products that are the subject of these applications in order to have confidence that the health outcomes observed in Sweden would also be observed in the U.S.? For example, would it be sufficient to know that the exposures to individual users of the Swedish products are comparable to the exposures to individual users of these snus products, or would knowledge about other characteristics of the tobacco product be needed to determine that the health outcomes would likely be comparable? **With respect to the likelihood that existing users of tobacco products who would otherwise stop using those products will instead switch to these snus tobacco products, and the likelihood that persons who do not use tobacco products will start using these snus tobacco products:** 5. Discuss the evidence regarding the likely impact of these ten snus products on tobacco use behaviors among tobacco users and non-users. a. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the: i. The likelihood that current tobacco users in the U.S. will switch to the use of these snus products? (vote) ii. The likelihood that non-users of tobacco in the U.S. will initiate the use of these snus products?(vote) b. The applications did not include several types of studies that could be useful in order to assess impacts on behavior, such as actual use studies, self-selection studies, or other behavioral studies. Does the Committee believe that the applications include sufficient information on the behavioral aspects of the use of these snus products among the U.S. population? (vote) **With respect to enabling consumers to comprehend the modified risk information and understand its relative significance in the context of total health: (time permitting)** 6. The applicant proposes to include modified risk information within a warning label. FDA has potential concerns that inclusion of information about relative benefits of product use within a warning label may raise additional questions regarding consumer comprehension of the modified risk information and perceptions of the product.

		a. From the perspective of enabling consumers to understand the modified risk information in the context of total health, does the Committee believe it is appropriate to include modified risk information within the context of the required warning label as opposed to in a statement separate from, and in addition to, the warning label? (vote) **With respect to postmarket surveillance and studies to be conducted by Swedish Match North America, Inc.: (time permitting)** 7. If FDA were to issue an order allowing the marketing of these snus products as modified risk tobacco products, what recommendations does the Committee have for postmarket surveillance and studies? a. What elements should Swedish Match North America, Inc. include in a postmarket surveillance and studies program in order to monitor product use transitions for these snus products, which may have a low prevalence of use? b. What methods does the Committee recommend that Swedish Match North America, Inc. employ for assessing the impact of a specific modified risk tobacco product marketing on perceptions and behavior in a postmarket setting, particularly among youth? c. What sources of data does the Committee recommend that Swedish Match North America, Inc. use for providing information on impacts resulting from the marketing of the products as modified risk tobacco products? d. What additional information does the Committee recommend that FDA request from the applicant regarding plans to conduct postmarket surveillance and studies?
January 2018	Philip Morris Products' IQOS system and heatsticks	1. Discuss evidence related to the health risks of the IQOS system and the appropriateness of the proposed modified risk information. a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Scientific studies have shown that switching completely from cigarettes to the IQOSsystem can reduce the risks of tobacco-related diseases."? (Vote) b. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes."? (Vote) 2. Discuss evidence related to human exposure to harmful or potentially harmful chemicals when combusted cigarette smokers completely switch to the IQOS system, including the implications of changes in exposure for long-term disease risk and the appropriateness of the proposed modified risk information.

		a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Scientific studies have shown that switching completely from cigarettes to the IQOSsystem significantly reduces your body's exposure to harmful or potentially harmful chemicals."? (Vote) b. If the answer to question 2a is "yes", has the applicant demonstrated that the reductions in exposure are reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality? (Vote) *[To be answered by Committee members who voted "yes" to 2a.]* 3. Discuss evidence regarding the likelihood that existing combusted cigarette smokers will initiate use of the IQOS system, completely switch to IQOS, and/or become long-term dual users of IQOS and combusted cigarettes. a. What is the likelihood that that U.S. smokers would completely switch to use of the IQOS system? (High/Medium/Low) b. What is the likelihood that U.S. smokers would become long-term dual users of IQOS and combusted cigarettes? (High/Medium/Low) 4. Discuss evidence regarding the likelihood that persons who do not use tobacco products will start using the IQOS system. a. What is the likelihood that U.S. never smokers, particularly youth, will become established users of the IQOS system? (High/Medium/Low) b. What is the likelihood that former smokers will re-initiate tobacco use with the IQOS system? (High/Medium/Low) 5. Discuss evidence regarding consumer comprehension and perceptions of the proposed modified risk labeling and advertising. a. Has the applicant demonstrated that, after viewing the proposed modified risk labeling and advertising, consumers accurately understand the risks of IQOS use as conveyed in the modified risk information? (Vote) b. What additional information, if any, needs to be communicated, other than what has been proposed by the applicant, for consumers to understand the health risks of the IQOS system?
September 2018	RJ Reynolds' Camel snus products	1. The proposed modified risk claims that the applicant identifies as its "key" claims describe the reduction in risk for specific diseases as a result of completely switching to the six Camel Snus products from cigarettes. DISCUSS the available scientific evidence and VOTE on the extent to which the available scientific evidence substantiates the following modified risk information in the applicant's advertising: "Smokers who switch completely from cigarettes to Camel SNUS can significantly reduce their risk of…" a. lung cancer? (yes/no/abstain)

		b. oral cancer? (yes/no/abstain) c. respiratory disease? (yes/no/abstain) d. heart disease? (yes/no/abstain) 2. The applicant's advertising also contains modified risk statements that describe a reduction in harmful chemicals in Camel Snus vs. cigarettes, or that are not as specific as those presented in Question 1 (e.g., do not reference reduction in specific diseases or the need for complete switching). All of these statements are being evaluated as part of the MRTPAs. DISCUSS the available scientific evidence and VOTE on the extent to which the available scientific evidence substantiates the following modified risk information in the advertising: a. "…Camel SNUS contains less of the harmful chemicals than cigarette smoke"? (yes/no/abstain) b. "Smokers who use Camel SNUS instead of cigarettes can significantly reduce their health risks from smoking." (yes/no/abstain) c. "Switching to snus means less risk for you." (yes/no/abstain) d. "NO SMOKE = LESS RISK" (yes/no/abstain) 3. In addition to evaluating the proposed modified risk for scientific accuracy, FDA is also evaluating consumer understanding and perception of the modified risk information in the advertising. The applicant plans to communicate all of the modified risk information together, i.e., the first page has less specific modified risk information, while the second and third pages have more specific modified risk information and additional information the applicant refers to as "balancing information" (e.g., that Camel Snus and other tobacco products contain nicotine and are addictive; the recommendation that smokers concerned about the health risks of smoking should quit and talk to a healthcare provider). DISCUSS potential implications of the proposed modified risk information, including the non-specific modified risk language, as described in Question 2, on consumer understanding and perceptions and tobacco use behavior: a. Can the non-specific modified risk information be misinterpreted? b. Is there sufficient evidence that consumers would understand the non-specific modified risk information? c. Is there sufficient evidence about the impact of the non-specific modified risk information on the likelihood of use? d. Is there sufficient evidence about the impact of the non-specific modified risk information on poly tobacco use or partial switching?

		4. DISCUSS the potential users of the proposed MRTPs. a. What is the likelihood that cigarette smokers will switch completely to the six Camel Snus products? b. Are there other groups of potential users, particularly unintended users (e.g., youth, former cigarette smokers), of concern?
February 2019	1. Swedish Match's general snus products[2] 2. Altria's Copenhagen snuff	**1. Swedish Match's general snus products** FDA's preliminary assessment of the amendment finds that the applicant has addressed previous concerns by proposing a modified risk claim that is (a) more specific and (b) independent of the warning label; and by conducting a new consumer perception study that does not suffer from the methodological flaws of their original study. Q1: DISCUSS FDA's preliminary assessment, including whether the revised modified risk claim raises new or additional concerns regarding the potential impact on: a. consumer understanding; and b. population health. **2. Altria's Copenhagen snuff** Q1: The applicant proposed the following modified risk claim: "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer." DISCUSS the available scientific evidence and VOTE on the extent to which the proposed modified risk claim is scientifically accurate. (yes/no/abstain) Q2: In addition to evaluating the proposed modified risk claim for scientific accuracy, FDA also evaluates consumer understanding and perception of the modified risk information in the advertising. DISCUSS the potential implications of the proposed modified risk information on consumer understanding and perceptions. Q3: DISCUSS the potential users of the proposed MRTP. a. What is the likelihood that cigarette smokers will switch completely to Copenhagen Snuff Fine Cut? b. Considering the health risks from the use of Copenhagen Snuff Fine Cut and those who may be likely to use the product, what are the groups of potential concern (e.g., users of smokeless tobacco products with lower HPHC levels, youth)?
February 2020	22nd Century Group's	1. Morbidity & Mortality. Discuss the likelihood that reductions in dependence translate into substantial reductions in morbidities and mortality among individual tobacco users.

[2] Amended application

	very-low-nicotine cigarettes	2. Effect on Nonsmokers. Discuss the extent to which the following groups are likely to try and progress to regularly using the proposed MRTPs: Never smokers, Former smokers. 3. Effect on Smokers. Discuss the extent to which the following groups will dual use the proposed MRTPs with their usual brand of cigarettes or exclusively use the proposed MRTPs: Cigarette smokers who want to quit smoking, Cigarette smokers who do not want to quit smoking. 4. Understanding. Discuss whether the labeling enables consumers to accurately understand the following effects of using the products: Addiction risk, Disease risks.

June 18, 2024

ATTN: Serina Hunter-Thomas

Office of Science, Center for Tobacco Products,
Food and Drug Administration Document Control Center
Bldg. 71, Rm. G335, 10903, New Hampshire Ave.
Silver Spring, MD
20993-0002

Re: June 26 Meeting of the Tobacco Products Scientific Advisory Committee for General Snus

The Pelican Institute for Public Policy is a non-profit, non-partisan organization that researches and develops policy solutions to address the most significant barriers to opportunity in Louisiana and across the United States. We educate the public about the benefits of individual liberty and free enterprise, turning great ideas into powerful policy solutions that make a meaningful difference in people's lives. We also routinely address cases of significant government overreach that present barriers to opportunity. With those goals in mind, we offer this letter in support of the Modified Risk Tobacco Product authorization (MRTPA) renewal for the General Snus smokeless tobacco products as submitted by Swedish Match USA, Inc., which will be discussed at the June 26 TPSAC Meeting.

In 2019, FDA's independent, rigorous, science-based reviews determined the first-ever MRTP claim for General Snus, which allowed the product to be marketed as reduced risk relative to cigarettes.[1] FDA's own review determined that the claim proposed is supported by scientific evidence, that consumers understand the claim and appropriately perceive the relative risk of these products compared to cigarettes, and that the modified risk products, as 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.[2] This was further supported by the required post-market surveillance and studies where no new issues or concerns have arisen. All evidence supports continued authorization and meets the same appropriate for public health (APPH) standards. Failure to renew the modified risk order for General Snus would suggest that the FDA's own rigorous review process is not working and would deny adult

[1] FDA grants first-ever modified risk orders to eight smokeless tobacco products | FDA
[2] *Ibid.*

consumers truthful information they could use to make better and informed decisions on reduced risk products.

On the broader MRTP program, we urge the FDA to meet its harm reduction goals – and for that to happen, it must have a functioning authorization process. According to the Centers for Disease Control and Prevention (CDC),[3] cigarette smoking is the leading cause of preventable disease and death in the United States, where nearly 31 million Americans smoke cigarettes. Combustible cigarette smoking is on the decline due in part to the availability of harm reduction alternatives. Congress recognized the importance of harm reduction when it passed the bipartisan Family Smoking Prevention and Tobacco Control Act of 2009, which charged the FDA with establishing one of the most comprehensive approaches to tobacco harm reduction globally. The Tobacco Control Act requires the FDA's Center for Tobacco Products (CTP) to make application determinations within 180 days, yet the Agency routinely fails to meet this requirement.

Since 2009, more than 26 million premarket tobacco product applications (PMTAs) have been submitted for new tobacco products in the U.S. Of those 26 million applications, the CTP has authorized fewer than 50 for consumers. The CTP has authorized a total of only 16 Modified Risk Tobacco Products (MRTPs) for only four unique products and their accessories.[4] This authorization rate is not in keeping with the CTP policy acknowledging that tobacco products fall on a continuum of risk – especially since FDA has significant resources, among others, the FDA has the authority to assess and collect user fees from tobacco manufacturers and importers, with those fees being $712 million annually since 2019.[5] The availability of scientifically substantiated, authorized PMTAs or MRTPs could potentially improve health outcomes for smokers currently using riskier products.

We urge the FDA and CTP to meet its harm reduction goals and enhance the availability of safer consumer options by developing clearer and predictable framework for high-quality PMTA and MRTP application submission and reviews - as also recommended in the independent Reagan-Udall Foundation evaluation report.[6]

Sincerely,

(b) (6)

Daniel J. Erspamer
Chief Executive Officer
Pelican Institute for Public Policy

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[3] https://www.cdc.gov/media/releases/2022/p0318-US-tobacco-use.html
[4] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-granted-orders
[5] https://www.fda.gov/media/155617/download. Footnote 1 from FDA's Report to the House and Senate Committees on Appropriations dated November 2, 2021, stated that CTP's budget became flat at $712 million per year beginning in FY 2019
[6] https://reaganudall.org/operational-evaluation-fdas-tobacco-program

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Free Markets. Real Solutions.
www.rstreet.org

June 18, 2024

Dr. Brian King
Director, Center for Tobacco Products
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

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[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,

Jeffrey S. Smith, Ph.D.
Resident Senior Fellow
R Street Institute
(b) (6)
(b) (6)

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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 Ekbom, 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

June 26, 2024

FDA Tobacco Product Scientific Advisory Committee Public Meeting
Consumer Choice Center Testimony

As a consumer advocacy group that fights for lifestyle freedom, innovative technologies, and smart policy, we appreciate the Food and Drug Administration's Tobacco Product Scientific Advisory Committee's open call for public comment on the Modified Risk Tobacco Products (MRTP) program and current products seeking MRTP renewal.

According to the FDA, an MRTP application generally must demonstrate that the product 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. In order to reach a decision to authorize marketing of a proposed MRTP, FDA must consider a variety of factors under section 911(g)(4).

As staunch advocates for consumer choice, we outline and expand on key points we think are crucial to consider for this issue:

1. **An appropriate and scientifically minded reduced-risk protocol for tobacco products is both necessary and vital if we want to protect the next generation.**

Due to the smokeless experience and lower level of chemicals, snus is a less harmful nicotine alternative to combustible tobacco. It is the only smoke-free product that has decades worth of data showing that consumers who use snus instead of combustible tobacco are at lower risks of developing smoking-related diseases. Additionally, due to the fact that the product does not produce smoke, any concerns of secondhand smoke affecting other individuals is null and void.

In October 2019, the FDA granted eight Swedish Match snus products with the first-ever modified risk orders, with 8 additional products from various companies also being granted modified risk orders since then. This greatly benefits consumers as more of those who smoke will be made aware of the fact that smokeless nicotine products are less harmful than consuming combustible tobacco and could prompt them to switch.

FDA's website states:

> "The available scientific evidence shows that exclusive use of these specific General Snus smokeless tobacco products poses lower risks than cigarette smoking for many of the major causes of tobacco-related disease. In addition, FDA previously determined that the levels of N-nitrosonornicotine (NNN) and nicotine-derived nitrosamine ketone (NNK), two potent cancer-causing chemicals, in these General Snus products are lower than those in most smokeless tobacco products sold in the U.S., and when used exclusively instead of other smokeless tobacco products, the General Snus products may pose lower risk of oral cancer. Significant amounts of data shows that switching from cigarettes to products like snus reduces the risk of known smoking-related cardiovascular diseases, respiratory diseases, and cancers."

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Since the original MRTP authorization, there has not been any evidence contradicting the science presented in 2019. With that in mind, we hope that the current products up for renewal are granted reauthorization, in addition to the FDA looking at additional smokeless tobacco or nicotine products which deserve a modified risk authorization as well to provide further options for consumers to choose from within the regulated market. Reducing the barriers of receiving MRTP authorization will help more smokeless tobacco and nicotine products achieve this status and allow consumers to use the pertinent information to make more informed decisions about their health, potentially encouraging consumers to switch to a less harmful choice when consuming nicotine.

2. **We must spread awareness of other less harmful nicotine alternatives to combustible tobacco such as nicotine pouches, snus, gums, and lozenges, and our national health regulator should be empowered to do so.**

While snus is the smokeless tobacco product being focused on for this specific TPSAC matter, it's crucial that other smokeless tobacco and nicotine products are also being considered and promoted as less harmful options than combustible tobacco for consumers.

E-cigarettes or nicotine vapes are the most popular and effective technology to move consumers away from combustible tobacco, but other nicotine alternative products exist including nicotine pouches, nicotine gums and lozenges, and more.

Canada announced that they are promoting vaping as a less harmful nicotine alternative that can help individuals stop smoking combustible tobacco. They note that evidence indicates those who switch completely from combustible tobacco to vaping:

1. Immediately reduce their exposure to the harmful chemicals found in cigarette smoke
2. See general health improvements in the short term as a result of no longer smoking cigarettes
3. Are more likely to quit smoking than those who use nicotine replacement therapy (NRT) or counseling to quit
4. Do not currently report serious unwanted effects while using vaping products to quit
5. May have a higher startup cost but save money in the long run (cost per equivalent puff)

The United Kingdom was one of the first countries to embrace vaping as a harm reduction tool when Public Health England announced in 2015 that studies showed it to be 95% less harmful than smoking. Since 2015, the UK government continues to study the effects that vaping has had on public health and produces their findings annually. The latest report from 2022 shows that flavored vaping products, specifically fruit and menthol/mint flavors, remain the most common aid used by people to help them stop smoking combustible tobacco. When analyzing the stop smoking service data from 2020 to 2021, it was noted that vaping devices produced the highest success rates for attempts at quitting.

More recently, the UK government doubled down on its harm reduction strategy through vaping by encouraging one million smokers to swap their cigarettes for a free vape starter kit, providing financial incentives to pregnant women to quit smoking, as well as introducing mandatory information sheet inserts about vaping into packages of cigarettes.

It is our belief that MRTPs should be granted to any nicotine alternative that has scientific evidence indicating it is less harmful than combustible cigarettes to ensure consumers are aware of as many less harmful alternatives to combustible tobacco as possible.

3. **Approval of additional reduced-risk products, and renewal of risk modification orders, would be beneficial for millions of Americans and public health.**

Modified Risk Tobacco Product classification should encourage innovation of nicotine alternatives to combustible tobacco that have the potential to drastically reduce smoking-related death and disease. In its current form, the MRTP process lacks clarity and discourages innovators from pursuing it to begin with. This unclear and burdensome process harms consumers as it prevents less harmful nicotine products from being effectively marketed, meaning the consumers who are ready to move away from combustible tobacco products but aren't sure what to switch to could miss the opportunity to understand what the less harmful products available to them are.

As the Reagan-Udall Evaluation Report noted, FDA's Center for Tobacco Products has an opportunity to develop a more concise and understandable framework for MRTP applications to follow. Some of these recommendations include prioritizing timely development and completion of policies and scientific standards necessary for high-quality MRTP applications and simplifying, standardizing, documenting, and publicly sharing review procedures.

In general, more transparency from the FDA's Center for Tobacco Products in regard to the regulatory process and scientific foundation from which they are operating off of would be prudent. Ideally, CTP would openly support the importance of MRTP authorized products and create an effective communication strategy to educate adult consumers of combustible tobacco products as to what other options they have for FDA-approved less harmful nicotine alternatives.

Although not the focus of this TPSAC meeting, we would be remiss not to mention the importance of also reforming the PMTA process in addition to the MRTP pathway. While over 26 million applications were submitted to the FDA's Center for Tobacco Products seeking approval to sell their products on the legal market, to date only 23 products have been approved, including 8 separate devices (only 5 currently available on market today), and only in tobacco flavors. All PMTAs for flavored nicotine products were rejected, and of the estimated remaining 560,000 pending applications, the CTP has a June 30, 2024 deadline to make a decision. Implementing a de facto ban on any flavored nicotine alternative products is an enormous missed opportunity to help consumers as studies show that those who use flavored nicotine alternative products are 2.3x more likely to stop smoking combustible tobacco.

It's clear that these regulatory pathways for product authorization were created with the intention of ensuring that any products reaching the marketplace meet the required standards for consumer use. However, it is also clear that these FDA regulatory pathways are broken and have created an extremely complex illicit market that meets consumer demand in a way that the current pathway does not allow the regulated marketplace to compete with. The illicit market presents dangerous conditions for consumers, considering the products are unregulated, age verifications are not performed, and points of sale could present additional safety concerns.

4. **Low-risk nicotine alternatives have the potential to completely supplant combustible tobacco use in the United States, which would continue to save lives, empower consumers, and strengthen our public health.**

The FDA can look to global public health counterparts and follow in their successful footsteps, like Sweden. The World Health Organization recently announced that Sweden will likely become the first smoke-free country. Sweden has embraced the concept of tobacco harm reduction and supports its citizens to switch from combustible cigarettes to less harmful alternatives including vaping, nicotine pouches, and snus.

Consequently, Sweden has reduced its smoking rates two times faster than any other country in the European Union and smoking rates have declined by 55% in the last decade. Additionally, smoking-related deaths are 22% lower in Sweden than the European Union average and cancer incidence is 41% lower than in the rest of Europe, with total deaths from cancer being 38% lower.

Nicotine pouches became available in Sweden in 2018 and the smoking rates dropped by more than 20% since then. Interestingly, snus has been used mostly by men in Sweden as means to stop smoking combustible tobacco and nicotine pouches have become the preferred option for female smokers.

Nicotine pouches and snus are gaining popularity and provide consumers with additional options and choices to move away from combustible tobacco. While gums and lozenges are less popular among consumers, they still pose a versatile contribution to ending smoking.

In conclusion, MRTP authorizations play a crucial role in educating consumers on the less harmful nicotine alternatives available on the regulated market. Products with existing MRTP authorizations should keep their clearance due to the scientific evidence showing they are less harmful than combustible tobacco. Additionally, the MRTP application and authorization process should be reformed and streamlined to ensure that even less harmful nicotine alternatives are promoted to the consumers who need them most and public health can drastically improve as a result.

Thank you for your time and consideration on this matter.

CONSUMER CHOICE CENTER

June 26, 2024

Respectfully,

Elizabeth Hicks
US Affairs Analyst

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CITIZENS AGAINST GOVERNMENT WASTE

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June 17, 2024

Serina Hunter-Thomas
Office of Science
Center for Tobacco Products
Food and Drug Administration
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Re: Tobacco Products Scientific Advisory Committee (TPSAC) Open Session to discuss the renewal of a risk modification order submitted by Swedish Match USA, Inc. for eight snus smokeless tobacco products.

Dear Advisory Committee Members,

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit organization representing more than one million members and supporters nationwide. CAGW's mission is to eliminate waste, mismanagement, and inefficiency in government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CAGW was created to follow up on the report of the President's Private Sector Survey on Cost Control, also known as the Grace Commission. CAGW appreciates the opportunity to provide comments regarding the renewal of a risk modification order submitted by Swedish Match USA, Inc. for eight snus smokeless tobacco products to be submitted to the meeting record for your June 26, 2024, meeting.

Efforts to reduce burn tobacco product use include less harmful alternatives to cigarettes. Snus, an oral tobacco product that is placed in the mouth between the lip and gums, but not spitted out, is among the products that help transition smokers to less harmful products.

Although the product still contains nicotine, and may still be addictive, a November 27, 2019, study in the *Harm Reduction Journal* found that, "The most recent Eurobarometer data from 2017 reported that Sweden had the lowest prevalence of daily cigarette use in the European Union at 5% whilst daily 'oral tobacco' use was reported to be 20%. European data published by the World Health Organization in 2018 indicated that Sweden had the lowest rate of tobacco-related mortality and the lowest incidence of male lung cancer. Overall, prevalence statistics and epidemiological data indicate that the use of snus confers a significant harm reduction benefit which is reflected in the comparatively low levels of tobacco-related disease in Sweden when compared with the rest of Europe." The report also noted a decline in daily cigarette smokers in both Sweden and Norway, as adoption of snus among men in particular increased.

The Food and Drug Administration (FDA) first granted authorization for Swedish Match's eight premarket tobacco applications for snus smokeless tobacco products on November 10, 2015. On October 22, 2019, the FDA issued a modified risk tobacco authorization to Swedish Match for the eight products currently under consideration for renewal, allowing these products to be advertised as lower risk for certain health effects compared to smoking cigarettes. Since that time, no reported issues relating to the

use of these products has come up, and youth use of the products remain consistently low according to post-market surveillance by the FDA and the Centers for Disease Control, which found that smokeless tobacco products, including chewing tobacco, snuff, dip, or snus, were used by only 1.5 percent of teen tobacco users.

CAGW has long been engaged in promoting the benefits of tobacco harm reduction products. We ask that the advisory committee members review the scientific evidence that shows these products to be of lower risk than combustible tobacco products like cigarettes and cigars and approve the renewal of the risk modification order for the eight products offered by Swedish Match. Again, I appreciate the opportunity to offer the views of CAGW.

Sincerely,

(b) (6)

The American Consumer Institute
Center for Citizen Research

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]

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[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 quittng, 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%2Breduction2013.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.

Comments of Scott D. Ballin, JD

Health Policy Consultant

Before the Tobacco Products Scientific Advisory Committee
Center for Tobacco Products, US Food and Drug Administration

Concerning MRTP Applications Related to Camel Snus Products

Unabridged Written Version

September 13-14, 2018

"Carpe Diem"

I Background

My name is Scott Ballin. I have spent much of my professional life working on issues pertaining to tobacco and health with a particular interest in FDA. As the Vice President for Public Policy and Legislative Counsel of the American Heart Association and as Chairman of the Coalition on Smoking OR Health (AHA,,ACS, ALA), I authored petitions to the FDA seeking to bring tobacco products under FDA authorities back in the 1990's, an effort that would find its way all the way to the Supreme Court. I conceived of the idea that we needed to bring the tobacco Executives before Congress, have them sworn in, and ask them tough questions, including about whether 'nicotine was addictive'. I have been working in the area ever since and have written a number of white papers on the changing tobacco and nicotine environment (see www.tobaccoatacrossroads.com) , and made a keynote presentation to the Center for Tobacco Products in 2011 on the need to bring FDA regulatory authorities into the 21st Century. For a number of years my focus has also been to encourage stakeholders to engage in civil dialogues including here at the FDA. I have also worked with the University of Virginia on what are commonly referred to as the 'Morven' dialogues (see www.morvencoreprinciples.net) as well as serving as a consultant to the Food and Drug Law Institute (FDLI) for several of their tobacco conferences. I am also a member of a small group of highly respected former tobacco control experts

(National Tobacco Reform Initiative (NTRI) - see http://www.tobaccoreform.org) who believe that one of our primary public health goals should be to significantly reduce the use of the deadly **combustible** cigarette. We believe that science-based significantly lower risk, cleaner tobacco and nicotine products have an important role to play. In July of this year the NTRI sent Commissioner Gottlieb and Director Zeller a letter commending them for their new 'visionary' efforts but raising concerns that the CTP needed to be diligent in the implementation of that vision and not find itself being pulled into bureaucratic 'quicksand' (see the NTRI website). I say all this because the views and positions I and others have been advocating for some years seem to be getting the attention they need in terms of debate, discussion, traction and implementation. For me the 'tobacco wars' of the 1980's and 90's are in many ways over. This does not mean that there aren't many battles to be fought nor that we should trust what has been called the 'tobacco industry', which for many, now includes e-cigarette manufacturers. We have many challenges before us but more importantly, opportunities.

Last July 2017, FDA Commissioner Scott Gottlieb and CTP Director Mitch Zeller, recognizing that the tobacco and nicotine world has changed dramatically and is at a major 'crossroads', announced a new 'vision' about where the agency should be headed- one that includes consideration of new overlapping and complimenting strategies. It focuses on ensuring that children and adolescents do not use any tobacco or nicotine product but equally important ***ensuring that adult smokers have access to lower risk consumer acceptable forms of nicotine including products like snus.*** I believe both of these goals and objectives can be achieved in tandem.

I am also of the opinion that collectively, as governmental agencies, researchers, NGO's, innovators, manufacturers and consumers, we need to **'modernize'** our thinking about what should be a more rational and flexible regulatory framework that can serve our public health needs not only for today but for the future as well. TPSAC along with other stakeholders has an important role to play. My comments today are more about what the regulatory framework should look like rather than focusing just on the snus applications before you.

II Regulating Tobacco, Nicotine and Alternative Products Based on the 'Continuum of Risk'

In spite of progress since the release the first Surgeon General's report in 1964, tobacco products in the form of the deadly combustible cigarette kill 480,000 Americans each year and cost this country an estimated $ 300 billion in health care costs and lost productivity. There are approximately 30 million smokers in the US. For me and many others this is not acceptable and we need to step up our efforts to help smokers quit their deadly cigarette habit. As has been said, **"people smoke for the nicotine but they die from tar"** (Michael Russell, 1976).

For some time now, there have been significantly lower risk, 'cleaner' products on the market and more in the pipeline. Yet and unfortunately many in the tobacco control community and in government continue to talk about all tobacco products as being equally harmful. Such antiquated, inaccurate, unscientific statements are misleading at the very best. Technology and innovation have had a major impact over the years in product development that have allowed for a growing spectrum of products that could have a significant result in reducing disease and death from the deadly cigarette.

Commissioner Gottlieb has stated that 'innovation' is something that should be **encouraged** rather than stifled. He and Director Zeller have also talked about the need for *streamlining* the approval processes for science- based lower risk products.

I have often commented and reminded people that it's not the 'tobacco' (an agricultural plant) that causes the disease and death but rather how it is grown, cured, processed, manufactured and most importantly ***used*** that determines the most harm. While 'tobacco' is often referred to as this nation's single most preventable cause of death, if one segments out combustible products versus noncombustible products the equation drastically changes. Smokeless products, NRT and e-cigarettes fall much lower down the scale. We need to begin to evaluate products based on their risks, relative risks and intended uses, to develop regulations that more appropriately fit those categories, and to assign 'risk profiles' to these various categories. It is also important to point out as a side note that 'tobacco' is considered the 'white rat' of the plant world and is being used in the development of pharmaceutical products as well as industrial enzymes. Such properties and research could also be applied in the development of lower risk tobacco, nicotine, and alternative products, including the reduction and removal of toxins and being able to lower or adjust nicotine levels.

Regulating based on the 'continuum of risk 'was a major focal point in last July 2017's FDA announcement and I think its time to start having constructive dialogues about how to ***expeditiously*** *implement this approach.* Fair but effective, *workable* regulations can be achieved by establishing 'product standards' for differing categories of products such as snus. Working closely with those manufacturing lower risk smokeless tobacco products, FDA can monitor how these products are being used and by whom, and can curtail any unforeseen abuses and concerns that might occur and which will allow for a better assessment of the impacts on both the individual as well as the broader population.

No matter who does the scientific research, 'good science' is going to be essential in order to help shape the framework for regulating all tobacco and nicotine products based on the 'continuum of risk'. Like it or not there will have to be continued/increased engagement and collaboration in the scientific arena between the FDA, manufacturers, the scientific and public communities and other experts, something that I know does not sit well with some in the tobacco control community. But here we are today with an opportunity for the TPSAC to have such an engagement with a spectrum of stakeholders. If indeed we wish to hold the 'industry' accountable for the products they may wish to develop and get approval for from the FDA, then we need to have transparent policies and processes in place that allow for interested parties to have access to their research. There must be avenues for engagement.

Side note: While at the American Heart Association some years ago, I also worked on food and nutrition policy issues, including FDA's efforts to 'modernize' food labeling laws and regulations. Our foods were loaded with undisclosed unhealthy components including fats, cholesterol, salt, and sugar. These components were/are and remain serious risk factors for obesity, heart disease and stroke, diabetes, and cancer. We took the position that we needed to 'educate' consumers and the public about the risks of these products and to encourage manufacturers in a regulated environment to develop and make available products that could reduce health risks. Truthful, more complete labeling on packages was an essential tool as part of a more comprehensive educational effort. The allowance of *informational* claims or *health* claims was to be determined based on the amount of scientific evidence available. I think that the time is long overdue for us to start applying these types of approaches to the broad spectrum of tobacco and nicotine products not only on the market today but for the future as

well. Sweden has chosen to regulate its 'snus' products using their food authorities and there may be some merit in the CTP looking at and gaining expertise and insights from the Agency's Center for Food Safety and Applied Nutrition on how to create a more workable regulatory system for the entire *noncombustible* category.

III Providing Truthful, Accurate, and Non-misleading Information to Consumers and the Public

As part of regulating tobacco and nicotine products based on the 'continuum of risk', it is critical that we better educate the public and users of tobacco and nicotine products about the risks and relative risks of such products. It is tragic as I noted above that most of the public and users of products continue to think that all tobacco products carry the same risks. They also continue to think nicotine causes cancer. Confusion reigns and the time has come in my view for the agency, the tobacco control community and manufacturers to initiate new actions to correct the long existing *informational deficiencies**. We have known for almost twenty (20) years that noncombustible low TSNA smokeless products are 90% plus lower in risk than the deadly cigarette. Yet little information has reached the very people that could benefit from such information -- the addicted cigarette smoker.***

When we think of deceptive labeling, advertising and marketing we often think of inaccurate statements that appear in the labeling and in the marketing of a product. However, the **omission** of critical information can be legally deceptive as well. If those omissions are part of regulatory mandated constraints, one has to ask the question as to whether this might be a restraint on truthful speech under the First Amendment? The labeling of a product such as in the case of snus, is one way of correcting the misinformation being provided and providing more truthful information to the public. But I believe that the CTP must do a better job in developing comprehensive educational campaigns that should involve and be coordinated with the public health community, consumers and even the manufacturers of these products so that there is a consistent and uniform message that the public and consumers can easily comprehend.

IV A Word About Flavors

The flavor issue has become a 'flash point' of debate in the tobacco and nicotine world—highly emotional, almost toxic. I believe that a rational approach to the use of flavors can be achieved if stakeholders are willing to step back from what is the excessive rhetoric being used and look for balanced workable solutions. Seven years ago, I pointed out that NRT products 'come in all sorts of enticing flavors such as fruit chill, lime, mocha etc. But that if a tobacco-based product has a flavor in it, it is a 'candy' targeted to kids'. Yes, there are certain flavors that probably do appeal to kids but let's be careful not to throw the baby out with the bath water. In 2011 I further noted that a press release for what was then a new product stated that the product was flavored with ***'fresh tasting mint , a product that is handy and discreet so you can relieve your nicotine cravings whenever and wherever they strike".*** The product was a new Nicorette 'mouth spray'. If the product had been developed by a tobacco company there would have been national and international outrage that the product was

targeted at kids to get them hooked. No one in the public health community said a word or raised a concern if I recall. Much of the problem in my opinion lies in **how** the product is the labeled, marketed and promoted. I and others have suggested that the use of flavors should be based on regulating along the 'continuum of risk'. For the deadliest of products, such as cigarettes, we need stringent regulations or the complete prohibiting of flavors- including menthol. For products that are significantly lower in risk as in the case of smokeless products like snus, NRT, and e-cigarettes, consideration should be given to the allowance of flavors (and for their disclosure) absent efforts to market such markets in a way that might appeal to kids. Adult users of tobacco and nicotine products should be able to obtain products that are *consumer acceptable* and which will aid them in finding a suitable lower risk alternative to the deadly cigarette.

V The Critical Need for Stakeholder Engagement and Dialogue

Commissioner Gottlieb and Director Zeller have both spoken about the importance of stakeholder engagement and dialogue both at the FDA as well as in the private sector. This is an area where I think much progress can and has been made. Engagement is taking place at the FDA, at meetings like the Society for Research on Nicotine and Tobacco (SRNT), the Food and Drug Law Institute (FDLI), the University of Virginia's 'Morven Dialogues', the Global Nicotine Forum (GNF), the Global Tobacco Nicotine Forum (GTNF) and others. These dialogues serve as forums for allowing a spectrum of stakeholders to come together and talk about important and often controversial issues relating to science and policy. They should be encouraged. A failure to embrace and support such efforts merely continues the 'tobacco wars' of the 1980's and 90's, and creates polarization that prevents the exchange of ideas and views… negatively impacting on public health.

VI Conclusion

Almost 20 years ago, the Institute of Medicine (IoM) issued its land mark report entitled '**Clearing the Smoke'.** Much of the report's findings and recommendations remain very relevant to today. The Center for Tobacco Products (CTP) has been in existence for nine (9) years and I recognized that much of the early years were devoted to getting the Center up and running and having to implement numerous often burdensome Congressionally mandated requirements. But we are at a unique and critical 'crossroads', as Commissioner Gottlieb has said, for developing and implementing more workable and rational tobacco and nicotine policies. We should not have to wait another 5,10, or 15 years to do what we know should be done. Allowing noncombustible smokeless tobacco product to be labeled with truthful and accurate information would be a major step forward.

Thank you.

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Comments Submitted by Scott D. Ballin, JD, Health Policy Consultant *

to the Tobacco Products Scientific Advisory Committee (TPSAC) Concerning the

"Renewal of a Risk Modification Order Submitted by Swedish Match USA, Inc."

I appreciate the opportunity to provide these written comments for consideration by the Tobacco Products Scientific Advisory Committee (TPSAC) concerning Swedish Match's request for the renewal of a risk modification order relative to a number of its 'snus' products.

My comments will be focused on two areas. One being my views about the need to **approve** the risk modification order and two, on the 'broader Modified Risk Tobacco Products program developments related to the conceptualization and measurement of consumer understanding".

It is important to continuously remind ourselves that tobacco use and in particular use of the **deadly combustible cigarette** remains this nation's single most **preventable** cause of disease and death, accounting for the deaths of approximately 480,000 Americans each year. There are some 30 million Americans who still smoke, many of whom will die tragically. The health care costs and lost productivity costs associated with smoking runs into the billions of dollars. I wish to echo my support for the words of former FDA Commissioner Scott Gottlieb who along with CTP Director Mitch Zeller some seven years ago, provided a 'visionary' approach as to how the agency's tobacco and nicotine policies could should adapt to a rapidly changing environment.

> **"Envisioning a world where cigarettes would no longer create or sustain addiction and where adults who need or want nicotine could get it from less harmful alternative sources, needs to be the cornerstone of our efforts and we believe it is vital that we pursue common ground." (Comments of FDA Commissioner Scott Gottlieb, July 2017)**

Those words are as relevant today as they were seven years ago and I encourage the TPSAC to be thinking in terms of how best to look to the future in making not only the 'snus' products being considered here, but other science-based lower risk alternative products, available to smokers as expeditiously as possible.

1.Swedish Match's request for Renewal of a Risk Modification Order should be approved.

It has been some four (4) years since the Center for Tobacco Products, with the advice of the TPSAC, authorized that these products be allowed to be marketed. The Center considered substantial scientific evidence about the risks, relative risks and benefits that these products (especially in comparison to the combustible cigarette) could provide to the millions of adult smokers. In addition to the science, TPSAC should, as it did in the past, also draw on the dramatic impact and actual successes that have occurred in Sweden, in what has been referred to as the 'Swedish Experience". To my knowledge the post-marketing monitoring and evaluation of these products, since initially approved, has found no concerns that would suggest that the renewal order of these products should be denied.

In addition to the visionary statement expressed by FDA Commission Scott Gottlieb in July of 2017(see above), the current FDA Commissioner, Robert Califf has made the issue of **'misinformation'** a major priority that I am told should apply to **all** of the agency's 'Centers' including the Center for Tobacco Products (CTP). I therefore strongly encourage the TPSAC to consider looking at ways that truthful, accurate, and non- misleading information be provided to not only the users of tobacco products (especially smokers) but to medical professionals, the general public, the media and others.

2. FDA/CTP's Modified Risk Tobacco Products program should be 'modernized', 'incentivized' and 'streamlined' to meet new opportunities to reduce the disease and death caused by the deadly combustible cigarette.

The experience that has occurred in terms of allowing these 'snus' products into the market place, coupled with the Swedish success story should serve as a 'green light' for the CTP to move forward in expanding and implementing product approvals and programs which can move the July 2017 visionary comprehensive plan forward-- not only with providing smokers with significantly lower risk products but also ensuring that the sale, marketing, advertising and promotion of these and other products do not encourage adolescents to use these products. I believe that these two objectives can go hand in hand.

The idea and concept of 'harm reduction' is something we apply to many other areas in our day to day lives. We see harm reduction principles being applied to our foods, legal and illicit drugs, alcohol, automobile safety, environmental pollution and also in the area of marijuana use, just to name a few.

Again, I think that Commissioner Gottlieb's advice from July of 2017 is extremely relevant to today's environment.

> **"To succeed, FDA must be strategic about how to use its tobacco and drug authorities. To succeed, participants from all sectors in the ongoing harm reduction debate need to take a step back and work together to reach greater common ground."** (Comments of FDA

Commissioner Scott Gottlieb concerning the FDA's visionary comprehensive tobacco and nicotine plan- July 2017)

Having fought 'Big Tobacco' for many years I am very well aware of the deep mistrust that many of my mainstream public health colleagues have about tobacco companies and about the idea of harm reduction. Yet with the proper oversight of the FDA/CTP and leadership needed to bring stakeholders together, we can I believe expediate the eventual demise of the deadly cigarette. I have provided comments to TPSAC on many other occasions and am pleased to offer my views and suggestions now.

I have also had the privilege of participating and later serving as an advisor to the University of Virgina's Institute for Engagement and Negotiation (IEN) which for over 20 years, has provided a forum that has allowed stakeholders, with seemingly differing views, to engage in 'safe-haven' civil discussions on tobacco and nicotine harm reduction. I am attaching a copy of a report (Morven VII) that was released in 2019 and which may be of interest to TPSAC members and CTP staff. Entitled **Civil Dialogue on Tobacco, Nicotine and Alternative Products Harm Reduction- Addressing a National and Global Smoking Epidemic**, the report's ten core principles are intended to educate and provide guidance to a broad spectrum of stakeholders on issues surrounding tobacco harm reduction. A new, up- dated report titled **"Time to Clear the Smoke"** is expected to be released by the Institute later in June.

I also plan to include in my email submission, comments that I provided to the TPSAC in September 2018 concerning MRTP applications related to Camel 'snus' products.

This is not the 20th century so although we have many challenges ahead, there are also many opportunities to be considered and taken. The Tobacco Products Scientific Advisory (TPSA) along with the Center for Tobacco Products (CTP) has a vital **leadership** role to play.

Respectfully Submitted,

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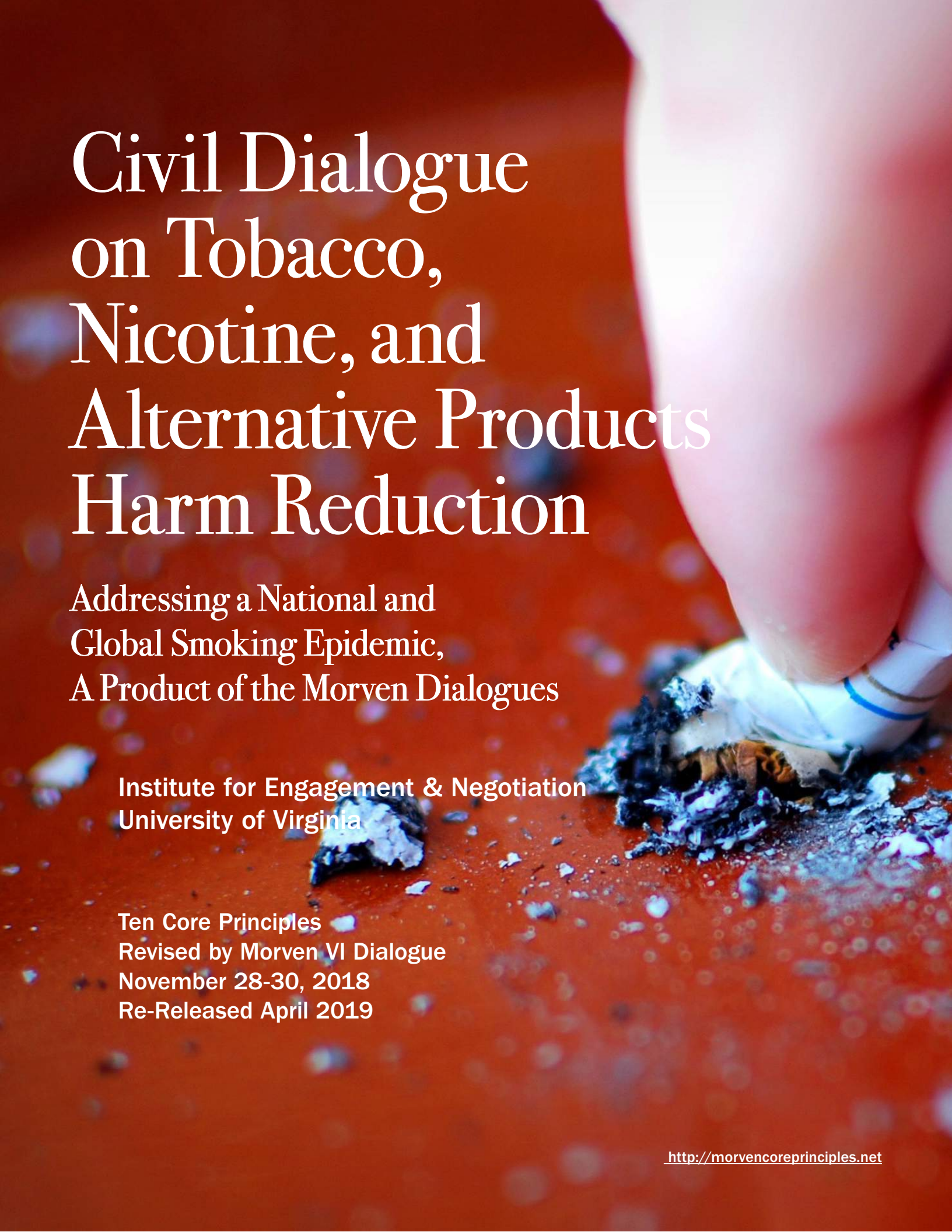
Scott Ballin has spent five (decades) working on issues related to tobacco and nicotine. He served as the American Heart Association's Vice President and Legislative Counsel as well a two-time Chairman of the Coalition on Smoking OR Health (ACS, AHA,ALA). He was instrumental in pushing for FDA oversight of tobacco, petitioning the agency to regulate tobacco. After leaving the AHA he provided consulting services to the Campaign for Tobacco Free Kids and the American Lung Association. In more recent years he has also served as an advisor to the Food and Drug Law Institute (FDLI) as well as to the University of Virginia's Institute for Engagement and Negotiation (IEN), both of which have been strong advocates for stakeholder engagement.



Civil Dialogue on Tobacco, Nicotine, and Alternative Products Harm Reduction

Addressing a National and Global Smoking Epidemic, A Product of the Morven Dialogues

Institute for Engagement & Negotiation
University of Virginia

Ten Core Principles
Revised by Morven VI Dialogue
November 28-30, 2018
Re-Released April 2019

http://morvencoreprinciples.net

Report prepared by the
Institute for Engagement & Negotiation
University of Virginia
February 2019

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The Morven VI Dialogue

The purpose of the forum for **Civil Dialogue on Tobacco, Nicotine and Alternative Product Harm Reduction** and its series of dialogues is to bring stakeholders together in a safe haven to discuss a spectrum of issues pertaining to tobacco, nicotine, and alternative products harm reduction strategies. The dialogues were convened and facilitated by the UVA Institute for Engagement & Negotiation (IEN).[1] The first dialogue was held in March 2011 at Morven Farm, a historic retreat venue located outside of Charlottesville, Virginia. The second and third dialogues were also held at Morven, hence the name "Morven Dialogues." The forum and its dialogues recognize that some forms of harm reduction will be part of a viable strategy for reducing disease and death caused by tobacco use. Its focus is therefore less on whether harm reduction should be considered a viable strategy and more on how – and with what protections – it may be effectively implemented, not only in the United States but globally as well.

The fourth and fifth dialogues were held in 2014 and 2015 at the National 4-H Center in Bethesda, Maryland, and built on the earlier dialogues which resulted in a revised set of Core Principles released in January 2016. Because of what has been a dynamically changing environment, both in the US and globally, it was decided that a sixth dialogue should be held, this time again at Morven in November 2018, to review the Core Principles and to modify and amend them appropriately. As with all previous dialogues, the sixth Morven Dialogue focused on updating the Core Principles in a way that can be used by all stakeholders to help guide ongoing and future important discussions to develop and implement effective and workable policies and objectives.

The IEN has appreciated the input of many individuals who have participated in the Morven Dialogues over the years and who came to the table prepared to engage in civil discussions.

**Prior to the Morven Dialogues, IEN sponsored a series of dialogues in the 1990's between the public health community and tobacco growing communities called the "Southern Tobacco Communities Project" that facilitated the eventual passage of the FDA tobacco legislation as well as a tobacco "buyout."*

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[1] The IEN was formerly the Institute for Environmental Negotiation. Its new name, given in 2019, better reflects its evolving mission.

“It is important to see the one across from you—who may be your enemy—and see him as a friend waiting to be made.”

— ARCHBISHOP DESMOND TUTU

Contents

Executive Summary

There are an estimated one billion smokers worldwide, with the overwhelming majority living in low and middle-income countries. A staggering seven million of these smokers will die prematurely this year. If not confronted aggressively and with innovative policies, an estimated one billion people will die of smoking related causes during the 21st century. Today, there are a growing number of science-based significantly lower risk tobacco, nicotine, and alternative products being developed and put on the market that could have a notable impact in reducing the devastating disease and death caused by cigarette smoking. These include but are not limited to a growing range of products such as snus, gums, lozenges, and a variety of electronic delivery systems. The Core Principles were originally produced and published in October 2013, amended in January 2016, and now in February 2019.

April 2019

The Ten Core Principles that have been Identified by the Morven VI Dialogue Participants

1. Definitions and Terminologies: Develop Clear and Useful Definitions and Terminologies to Adapt to a Changing Environment

There is an urgent need to better define and understand the growing number of tobacco, nicotine, and alternative products on the market (and being developed) and to communicate truthful and accurate information about these products to all stakeholders in a more consistent manner – including their risks, relative risks, and intended uses.

2. Smoking Replacement Products (SRP's): Recognize, Understand, and Act on the Significant Differences Between Combustible and Non-Combustible Products

A growing spectrum of tobacco and nicotine products being introduced into the global market place need to be more appropriately defined (see Core Principle #1). Although these products have differing characteristics, they all can be considered lower risk non-combustible products. This Core Principle further suggests that non-combustible products be collectively classified as Smoking Replacement Products (SRP's) to further distinguish them from the more traditional forms of harmful combustible smoked products such as cigarettes.

3. Regulatory Oversight: Develop Consistent, Science- Based, Consumer Friendly, and Incentive-Based Regulatory Framework

All tobacco, nicotine, and alternative products should be regulated based on the risks, relative risks, and intended uses of the products (continuum of risk). This should include such areas as labeling, marketing, sales and distribution, and product standards and taxation. Consideration should be given to regulating products under a single regulatory authority (or at a minimum with close collaboration between authorities). Legislative and regulatory policies should be consumer-friendly and based on sound science.

4. Research and Science: Encourage Transparent, Collaborative Research of the Highest Integrity to Reduce Risks

Scientific research will be increasingly essential to the development and implementation of effective and workable regulatory policies for overseeing all tobacco, nicotine and alternative products. Greater collaborations between the broader research community that includes academic research institutions, public health authorities, product manufacturers, and governmental agencies should be promoted. Research should be made available and disseminated, including publication in scientific journals, using the highest standards of research, transparency, and peer review.

5. Innovation and Technology: Encourage and Incentivize Lower Risk Products

New technology and innovation should be encouraged in both the public and private sectors. This should include a commitment from governmental bodies and manufacturers to devote a greater amount of financial resources to developing science-based lower risk products. It should also include providing concrete incentives (such as tax credits, patent extensions, and flexible regulatory policies) to tobacco growers, tobacco, nicotine, and alternative products manufacturers, entrepreneurs, and research institutions.

6. Monitoring, Evaluation, and Accountability: Balance Regulatory Incentives and Fast-Tracking for Lower Risk Products with Rigorous Oversight

Regulatory oversight of all tobacco, nicotine, and alternative products should require that the sale, distribution, and marketing of these products be monitored and evaluated to assess the health and behavioral effects of using such products on both the individual and the broader population. This is particularly important to preventing the initiation and use of tobacco and nicotine products by underage populations. Science-based lower risk products should be allowed on the market if there is a reasonable expectation that the product will reduce exposure to tobacco toxicants and/or reduce the risk of tobacco related disease. Rigorous monitoring, surveillance, and enforcement can provide an effective bridge to address concerns with the potential fast-tracking of reduced-risk products.

7. Consumers and the General Public: Involve Those Impacted by Decisions in Developing Communication and Regulatory Framework

Consumers and the general public should be provided with accurate, science-based, and understandable information to better understand the risks, relative risks, and intended uses of the various spectrum of products on the market. Consumers who are at risk of disease and death need alternatives that are affordable, accessible, and acceptable. Consumers should also be actively consulted and involved in the development of policy and regulations.

8. Nicotine: Communicate Truthful and Accurate Information About the Risks, Relative Risks, and Possible Benefits About the Use of Nicotine

As part of any effort to communicate truthful information about the risks and relative risks of tobacco and nicotine products, special attention should be given to include the communication of truthful information with respect to nicotine. While nicotine is highly addictive and not benign, and no child or adolescent should use any nicotine product, a large portion of the both the public and of smokers continues to believe that all tobacco and nicotine products are equally harmful, and that nicotine is the major cause of cancer. Adult smokers are entitled to know more about the availability of “cleaner” and safer forms of nicotine products to help break their addiction to cigarettes.

9. Tobacco Agriculture: Involve Agriculture Stakeholders in Developing Communication and Regulatory Framework

Tobacco producers should be actively involved in working with public health authorities, agriculture authorities, and other policy makers in both the public and private sectors. This includes the development of science-based quality controls and health and safety standards to produce tobacco. A more concerted and cooperative effort should be undertaken to help growers transition out of the production of tobacco and/or assist growers in transitioning to a new system of production that makes risk-reduction a priority.

10. Engagement and Dialogue: Encourage Civil Dialogues with Broad Stakeholder Involvement

There is a need for greater civil engagement between a growing number of stakeholders and experts that includes governmental agencies, public health organizations, tobacco, nicotine and alternative product manufacturers, researchers, consumers, health care professionals, laboratory testing facilities, retailers and wholesalers, and agricultural interests. Engagement should be encouraged in both public and private sector venues.

A full copy can be found online at: www.virginia.edu/ien/tobacco

Preamble

According to the World Health Organization, there are more than one billion smokers in the world, with an increasing number (80%) of these smokers living in low and middle-income countries. This year alone, a staggering seven million of those people will die prematurely from cigarette smoking, making cigarette smoking the single most preventable cause of disease and death globally. The United Nations and other domestic and international bodies have made prevention of non-communicable diseases (NCD's), including cancer, heart disease, and diabetes, a major global health priority. The growing use of combustible tobacco, a major risk factor in all these conditions, requires urgent attention at national and global levels.

The global epidemic in smoking is alarming in both its magnitude and its escalating prevalence. Despite considerable public health effort, the reduction in disease and death has been slow, and rates of cessation success, even with nicotine replacement therapy (NRT) assistance, tend to be disappointingly low. If not confronted aggressively and with innovative policies, an estimated one billion people will die of smoking-related causes during the 21st century. It is particularly critical to address youth and combustible tobacco products.

Recognizing that nicotine,[2] though addictive and habit-forming for some, is not itself a significant factor in the causation of disease, addicted smokers urgently need access to significantly lower risk tobacco, nicotine, and alternative products. In order to achieve this goal, it is necessary to inform the general public, consumers, policy makers, healthcare providers, and other stakeholders about the benefits that can be obtained by switching from a combustible/smoked tobacco product to a significantly lower risk noncombustible product.

Today's products include not only the more traditional tobacco and nicotine products, but newer innovations including gums, lozenges, vaping products often referred to as e-cigarettes, heat-not-burn products, and inhalers. This expansion presents new challenges, but it also creates new opportunities for reducing the devastating disease and death caused by using tobacco on both a national and global scale. Applying harm reduction principles can have an impact at many points along the tobacco and nicotine chain – from the growing, curing and processing of the leaf; to the complex manufacturing processes; to the use of new technologies and innovation; and to how the products are labeled, sold, marketed, and used.

The development and implementation of consistent, effective global public health policies that significantly reduce disease and death from tobacco use is going to require the involvement of numerous stakeholders, interests, and disciplines, working both independently and together, as well as transparently. This includes government agencies and regulators; public health officials; researchers and scientists; manufacturers of tobacco, nicotine, and alternative products; consumers of these products; farmers and entrepreneurs. Everyone has a critical role to play.

[2] See "The Health Consequences of Smoking- 50 Years of Progress: A Report of the Surgeon General", 2014 at http://www.surgeongeneral.gov/library/reports/50-years-of-progress/

Research over the last twenty years continues to shape and reshape the public health community's understanding of the core problem. While there are differing opinions about what should be done based on this understanding, there is an emerging recognition of the following key findings:

- The overwhelming harm from tobacco use comes from tobacco products that are combustible/smoked.
- Nicotine, although addictive, is not carcinogenic and at relevant exposures presents reduced health risks.
- The spectrum of harm is not a continuous curve, but rather a "cliff," reflecting the high level of toxicity of specific combustible smoking products at the "top of the cliff" with noncombustible products at the "bottom of the cliff."
- Existing efforts to reduce the toll of tobacco are failing to meaningfully change the projections of expected early death.
- With the advent of long-sought more visionary regulatory frameworks, there is a new opportunity to reduce the incidence of disease and death from tobacco products.
- The new regulatory approaches should coincide with the development of new nicotine-delivery products and other alternative products such as gums, lozenges, e-cigarettes, and other devices.
- All tobacco, nicotine, and alternative products should be evaluated based on both individual risk and relative risk.
- Preventing access by children and adolescents under legal age – the purchase, sale, initiation, use and possession of all tobacco, nicotine and alternative products – should be a high priority harm reduction strategy.
- Public policy should promote the development, use, and continuing evaluation of reduced-risk products.
- Measures need to be taken to inform, educate, incentivize, and drive consumers to lower risk products to reduce the use of cigarettes and other dangerous combustible tobacco products.
- Whatever strategies are used to achieve this goal, they must serve both the individual and the population as a whole.
- The engagement of stakeholders in civil dialogues and in the development of new visionary policies is essential.

To provide focus for what a successful effort to reduce the global burden of disease and premature death from tobacco products might encompass, these Core Principles have been developed.

Harm reduction is something that is common to many activities in our society and is not unique to the area of tobacco and nicotine. We see harm reduction/minimization being applied to our foods, drugs, automobile safety, and environmental pollution, and increasingly being considered in the area of marijuana production and use. Although the support for harm reduction policies continues to grow there is also a growing concern by some who fear that new products, such as the e-cigarette, may have unintended consequences.

These Core Principles are an effort to address some of these fears and also to provide guidance for the creation and implementation of harm reduction policies that will significantly reduce the devastating disease and death, caused nationally and globally by combustible products, and in particular cigarettes.

These Interrelated Core Principles are owned by none, yet belong to and can be embraced by everyone.

They serve as guiding principles for on-going efforts to reduce the harm associated with smoking. They represent a framework for moving forward and should be seen as complementary to other existing tobacco control efforts and, most importantly, should prevent all youth access, initiation, and use of any tobacco and nicotine products.

Individuals or representatives of organizations and businesses, consumers, academic institutions and other entities who believe that they can conceptually embrace these Core Principles are encouraged to conceptually support them.

Further, individuals and organizations are encouraged to use and disseminate these Core Principles to help move the Tobacco, Nicotine, and Alternative Products Harm Reduction Dialogue agenda forward.

Therefore, Be It Resolved: That in order to address the global burden of disease and death caused using cigarettes and other dangerous combustible tobacco products, and in the furtherance of promoting public health through product modification and the development and availability of significantly lower risk tobacco, nicotine, and alternative products, the following interrelated principles be embraced and implemented. These interrelated Core Principles fall within ten (10) categories:

1. Definitions and Terminologies
2. Smoking replacement Products (SRP's)
3. Regulatory Oversight
4. Research and Science
5. Innovation and Technology
6. Monitoring and Surveillance
7. Consumers and the General Public
8. Nicotine
9. Tobacco Agriculture
10. Engagement and Dialogue

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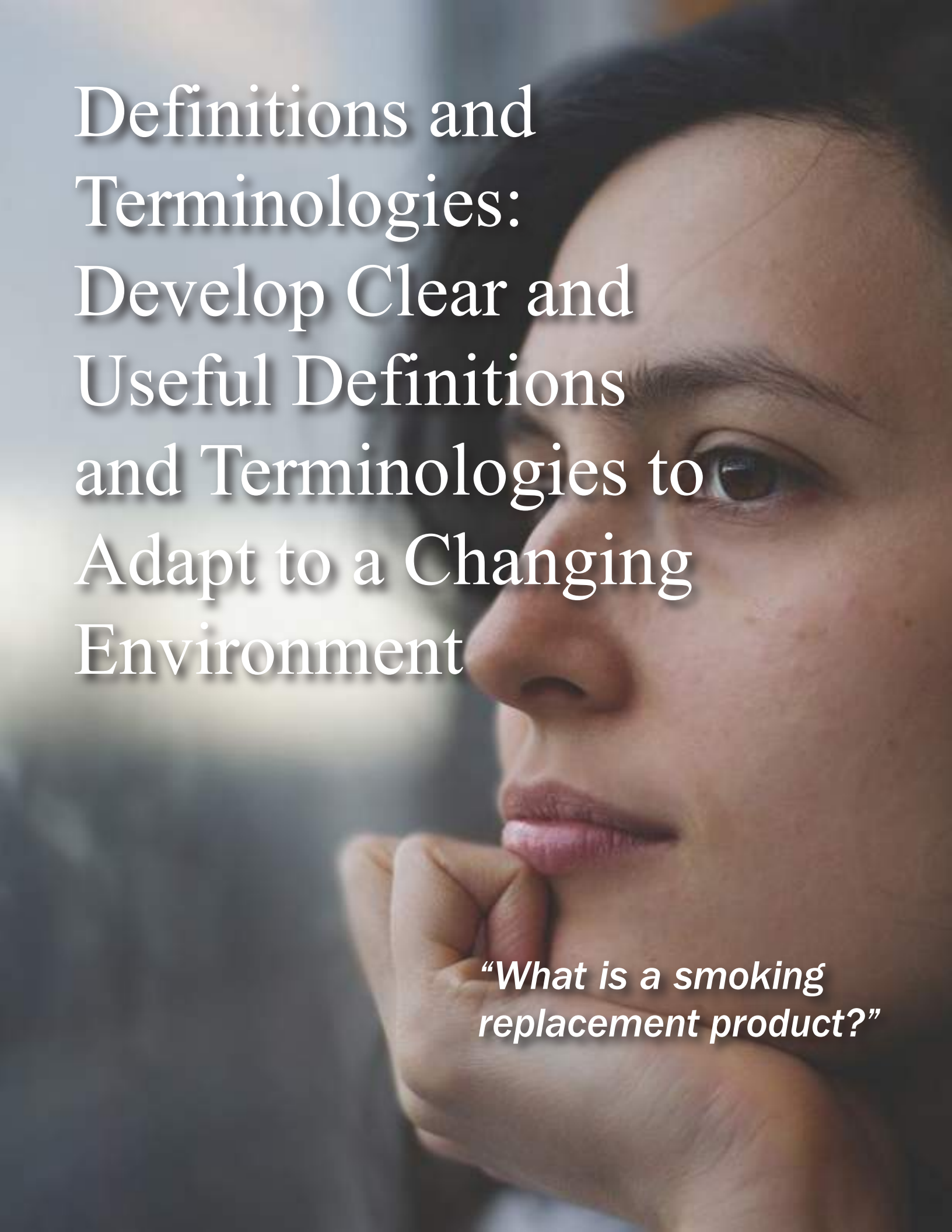
Definitions and Terminologies: Develop Clear and Useful Definitions and Terminologies to Adapt to a Changing Environment



"What is a smoking replacement product?"

Core Principle 1

Definitions and Terminologies: Develop Clear and Useful Definitions and Terminologies to Adapt to a Changing Environment

Today's global marketplace continues to have a rapidly growing number of products and manufacturers. It is no longer a marketplace where new products are or can be evaluated only in terms of black and white, but instead the evaluation yields multiple shades of gray. In an evolving and confusing marketplace like this, with so many lives hanging in the balance, the goal of achieving harm reduction requires that clear and truthful communication about the risks and benefits be disseminated. Additionally, a complete understanding of supply chain sources needs to be transparent and communicated to the general public and consumers. This should include that:

- All tobacco, nicotine, and alternative products including cigarettes, smokeless tobacco, nicotine replacement products (NRT), noncombustible products, vaping products (e-cigarettes), gums, lozenges, snus, inhalers, and heat-not-burn products are more clearly defined for purposes of public understanding, statutory definition, regulatory consistency, and relevance;
- Terms such as cessation, innovative products, tobacco industry, combustible and non-combustible industry, therapeutic products, alternative products, smoking/vaping, harm reduction, addiction, smoking replacement products, modified risk tobacco products, current user, experimentation, and others are more clearly defined for purposes of public and user understanding, statutory definition, and regulatory consistency and relevance;
- Governmental agencies, policy makers, non-governmental organizations, health care providers, manufacturers, and consumer organizations need to work cooperatively and transparently to develop more useful definitions and terminologies, as well as to transmit and communicate that information in a more consistent manner to consumers, the general public, patients, and other stakeholders;
- To accomplish these goals and objectives, consideration should be given to the establishment of a process to develop a glossary and set of recommendations for defining and clarifying terms that could serve all stakeholders including the general public.

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Smoking Replacement Products (SRP's): Recognize, Understand and Act on the Significant Differences Between Combustible and Non-Combustible Products[3]

Core Principle 2

Smoking Replacement Products (SRP's):[3] Recognize, Understand and Act on the Significant Differences Between Combustible and Non-Combustible Products

A growing spectrum of tobacco, nicotine, and alternative products being introduced into the market place need to be more appropriately defined (See Core Principle #1). These products have differing characteristic as well as differing "risk profiles," but all of them can be considered non-combustible products that are significantly lower in risk when compared to combustible/smoked products. (Combustible products include cigarettes, cigars, pipes, hookah, roll your own, etc.) These non-combustible products should be collectively classified as Smoking Replacement Products (SRP's) to more clearly differentiate the non-combustible from combustible/smoked classifications. SRP's need to be considered a part of comprehensive public health strategies to discourage and prevent the use of combustible products, especially cigarettes, which are by far, in the US and globally, the leading cause of disease and death. This Core Principle articulates some general principles for how SRP's should be manufactured, sold, labeled, and marketed. (More specifics can be found throughout this document). This should include that:

- All tobacco, nicotine, and alternative products should be proportionately regulated based on their risks and relative risks. The differences in risks between combustible/smoked and non-combustible products (SRP's) are significant;
- The public, consumers, and all stakeholders are entitled to truthful, accurate, and non-misleading information about the risks, relative risks, and intended uses of SRP's, and should be provided such information by governmental agencies, public health organizations, researchers, manufacturers, and the media;
- It should be unlawful for all tobacco and nicotine products (including SRP's) to be sold, made available to, or used by anyone under the age of 18/21. Advertising and marketing of these products must not be targeted to those under the age of 18/21;
- SRP's should be consumer acceptable and readily available to adults over the age of 18/21. Consumer acceptability of SRP's should allow the use of flavors. Flavors are not inherently bad, but they can cause appeal. Therefore, companies should specifically avoid using flavor descriptors or target-marketing that may significantly impact youth;

• Monitoring and surveillance of who is using a product, and how it is used, must be given a high priority by all stakeholders (See Core Principle #5);

• The cooperative development of fair, workable, flexible, and enforceable product standards should be given a high priority by regulators. SRP innovation should be encouraged, not stifled (See Core Principles #3 & 4);

• The scientific/regulatory standards for allowing SRP's on the market should be made with the view that there is a reasonable expectation that the product is lower in risk based on the current availability of scientific evidence. A more collaborative transparent approach to the scientific review of SRP's should be undertaken involving academic research institutions, public health authorities, regulatory authorities, and manufacturers. (See Core Principle #3);

• SRP's should not be actively marketed or promoted to recruit new users of nicotine;

• There must be a coordinated effort to educate the public and consumers, health care professionals, policy makers, regulators, and the media about SRP's and the potential role they can play in reducing disease and death caused by combustible tobacco products.

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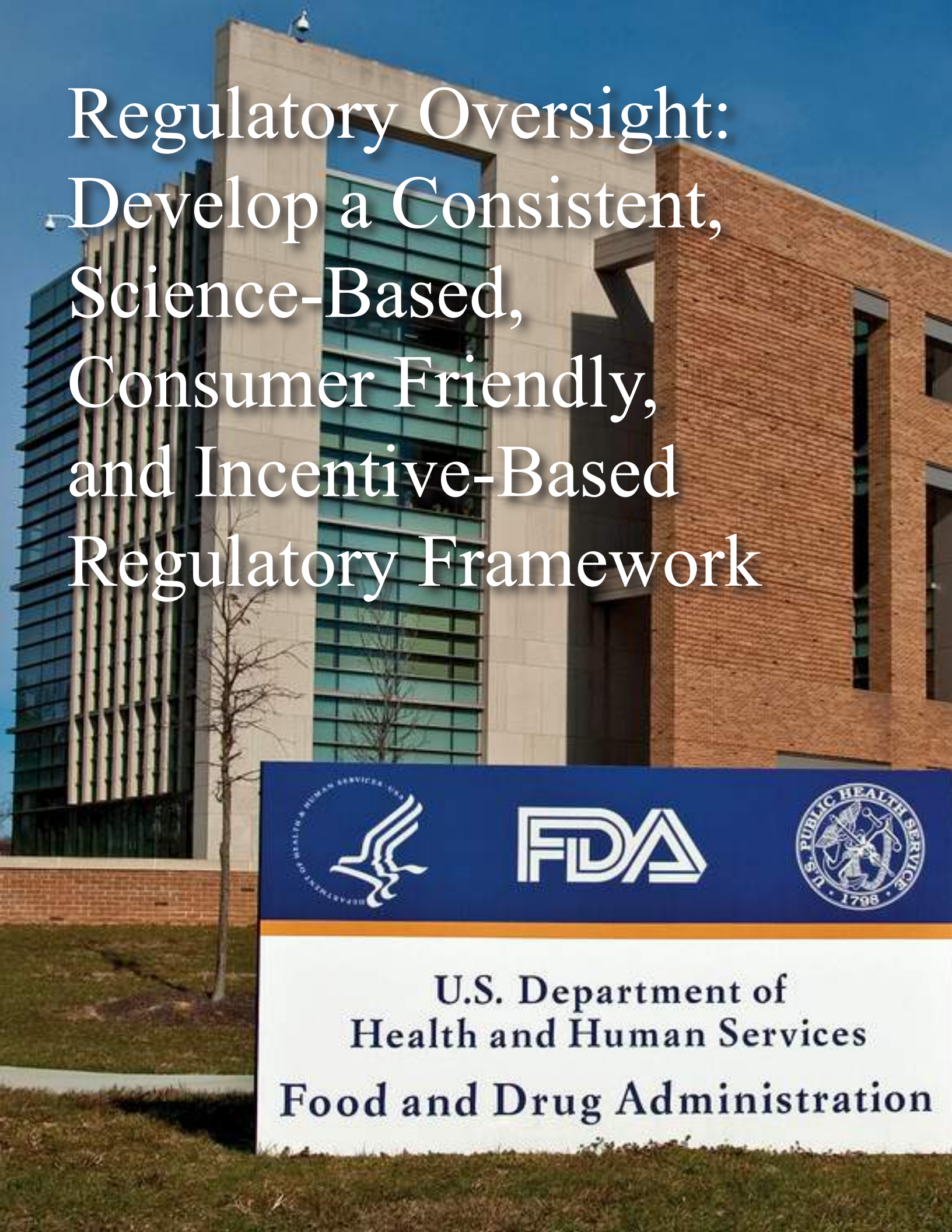
[3] This new Core Principle was added by the Morven VI Dialogue.


USE

Regulatory Oversight: Develop a Consistent, Science-Based, Consumer Friendly, and Incentive-Based Regulatory Framework



Core Principle 3

Regulatory Oversight: Develop a Consistent, Science-Based, Consumer Friendly, and Incentive-Based Regulatory Framework

A critical aspect for implementing successful tobacco, nicotine, and alternative products risk reduction policies, domestically and globally, is to regulate these products in a more comprehensive, inclusive, coherent, proportional, and consistent manner. This should include that:

- Governmental regulatory bodies should regulate the manufacturing, labeling, distribution, sale, and marketing of all tobacco, nicotine, and alternative products based on risks, relative risks (continuum of risk), and intended uses with a key goal of benefiting public health;
- Sound science, transparently developed and communicated, has global implications and should provide the basis for regulations and standards, including the regulations and standards governing harm reduction and alternative products;
- Those regulations and standards should take into consideration the interests and needs of the consumer and users of products, including environmental regulatory measures for agriculture, child labor laws, and sustainability principles;
- Consideration should be given to regulating all tobacco, nicotine, and alternative products under a single regulatory authority, or ensuring that there is close coordination, cooperation, and alignment between one or more regulatory bodies within government;
- The combustible cigarette should be used as the "reference product" for evaluating the risks and relative risks of other tobacco, nicotine, and alternative products;
- Legislative and regulatory bodies should develop consumer/user-friendly policies and regulations for all tobacco, nicotine, and alternative products that ensure that the public, consumers, and users can fully understand the risks and relative risks of products, and that deceptive labeling and advertising practices are prohibited;
- Tobacco, nicotine, and alternative products that are significantly lower in risk than the combustible cigarette, based on sound science, should be given a high priority for approval as viable, non-combustible alternatives/SRP's to combustible/smoking cigarettes. This could include the fast-tracking approval of harm reduction products as well as pricing and taxing lower risk products at lower levels;
- Statutory and regulatory policies should stimulate and encourage the development of significantly lower risk tobacco, nicotine, and alternative products to reduce the incidence of smoking;
- The broad scientific community in the US and globally, including the combustible and non-combustible industry, should be invited and encouraged to participate in the development of policies and regulations for all tobacco, nicotine, and alternative products.

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Research and Science: Encourage Transparent, Collaborative Research of the Highest Integrity to Reduce Consumer Health Risks

Image © https://commons.wikimedia.org/wiki/File:Scientists are working in the lab.9.jpg

Core Principle 4

Research and Science: Encourage Transparent, Collaborative Research of the Highest Integrity to Reduce Consumer Health Risks

Scientific research will be increasingly essential to the development and implementation of effective and workable regulatory policies for overseeing all tobacco, nicotine, and alternative products and the development of lower risk products. This should include that:

- Research into the development of significantly lower risk, science-based tobacco, nicotine, and alternative products should be given a high priority in both the public and private sectors;
- Manufacturers of tobacco, nicotine, and alternative products should make non-proprietary research readily available to regulators, academia, and the public by engaging in transparent dialogues and communication instruments, such as scientific journals and press releases;
- Manufacturers of tobacco, nicotine, and alternative products have an obligation and responsibility to conduct and use world-class science, and to follow the appropriate scientific protocols used by other industries;
- There should be greater interaction, including data sharing and collaborations (consortia) and a commitment to open science, between all researchers and scientists, regardless of institutional affiliation;
- Research, and the validation of the research by a third party, should be a shared responsibility of governmental oversight agencies, tobacco, nicotine, and alternative product manufacturers, academic research institutions, public health authorities, and others;
- Publication originating from any source should be encouraged, so long as the highest standards of research, transparency, and peer review are applied;
- In the case of funding to researchers, scientists, and academic institutions (including but not limited to corporate research funding), there should be appropriate and necessary safeguards in place to ensure that the research and the results of such research are held to and conducted with the utmost independence and integrity, including transparency in the financing, researching, and reporting process.

For more information, please refer to the 2011 “Core Principles Concerning Corporate Funding for Tobacco, Nicotine, and Alternative Product Harm Reduction Research”, available at: www.virginia.edu/ien/tobacco

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Innovation and Technology: Encourage and Incentivize Lower Risk Products

Image by Master Sgt. Kimberly Yearyean Siers

Core Principle 5

Innovation and Technology: Encourage and Incentivize Lower Risk Products

As is happening in other manufacturing sectors, the development of lower risk products, new technology, and innovation should be encouraged and supported in both the private and public health sectors. Historically, established industries have been transformed or eliminated when innovation flourishes. Innovation, in the form of novel nicotine delivery devices, smoking replacement products (SRP's) and in the application of technology to mitigate the problem of combustible/smoked tobacco use and nicotine dependence, must be actively encouraged in both the private and public health sectors. This should include that:

- Governmental research bodies, manufacturers of tobacco, nicotine, and alternative risk-reduction products should be encouraged to commit increasing amounts of financial resources to developing innovative lower risk products. Those manufacturing combustible products, such as cigarettes, should be incentivized to reprioritize their corporate goals and objectives away from combustible cigarettes;
- Concrete incentives (e.g., tax credits, patent extensions, regulatory prioritization) should be provided to nicotine product manufacturers, alternative product manufacturers, entrepreneurs, research institutions, and tobacco growers to develop non-combustible smoking replacement products (through advances in technology and innovation) that are significantly lower in risk than combustible products;
- New investment capital should be acquired to develop new technologies and innovations to reduce the devastating toll caused by combustible tobacco products;
- Regulations should be flexible and adaptable to allow new science-based, lower risk products into the marketplace in a more expeditious manner.

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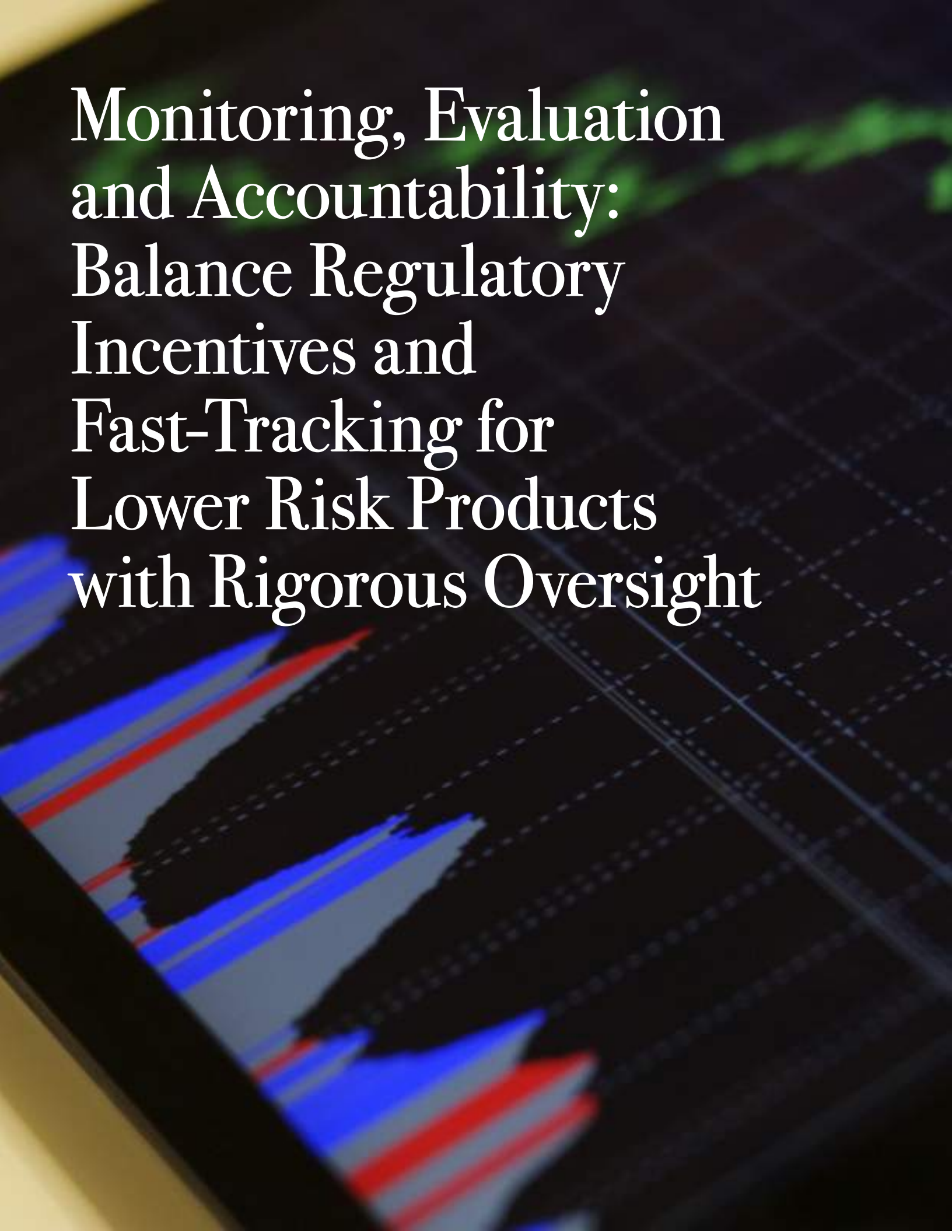

Monitoring, Evaluation and Accountability: Balance Regulatory Incentives and Fast-Tracking for Lower Risk Products with Rigorous Oversight

Core Principle 6

Monitoring, Evaluation and Accountability: Balance Regulatory Incentives and Fast-Tracking for Lower Risk Products with Rigorous Oversight

Regulatory oversight of all tobacco, nicotine, and alternative products will require that the sale, distribution, and marketing of these products be consistently monitored and evaluated, with results providing assurance of efficacy and reduced risk. Rigorous monitoring, evaluation, and enforcement can provide an effective mechanism to address concerns with fast-tracking reduced-risk products. This oversight process should include that:

- All tobacco, nicotine, and alternative products must be monitored in order to assess the health and behavioral effects of using such products, including the effects on the individual and the broader population;
- Regulatory bodies should provide leadership for developing a rigorous monitoring and surveillance system, conducted with governmental regulatory oversight, and including cooperation and collaboration with various stakeholders including tobacco, nicotine, and alternative products manufacturers, labeling and marketing experts, non-governmental organizations, and others;
- Coordinated and cooperative efforts to monitor the use of all tobacco and nicotine products by those under the age of 18/21 is given a high priority;
- Science-based, lower risk products should be allowed on the market (under the purview of regulatory oversight) if there is a reasonable expectation based on the available science that the product will reduce exposure to tobacco toxicants and/or reduce the risk of tobacco-related disease;
- Where scientific evidence, such as well-designed and analyzed survey data, demonstrates that the sale and marketing of a product is having unintended consequences leading to increased harm, appropriate steps should be taken to expeditiously correct such unintended consequences, including the removal of the product from the marketplace;
- Where it is determined that a manufacturer has intentionally not met its obligations under a statute or regulation, enforcement measures must be quickly implemented, and appropriate penalties must be assessed.

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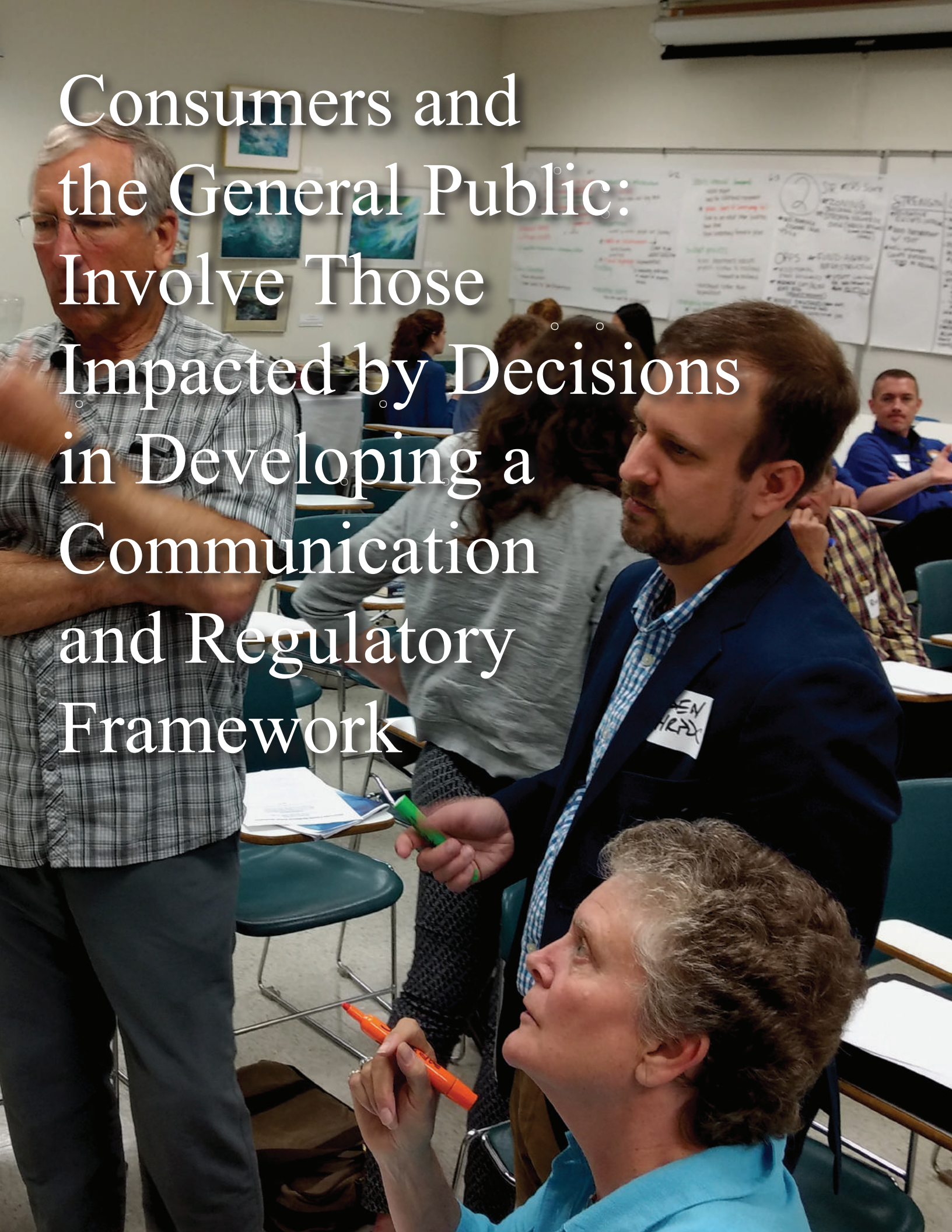


Consumers and the General Public: Involve Those Impacted by Decisions in Developing a Communication and Regulatory Framework

Core Principle 7

Consumers and the General Public: Involve Those Impacted by Decisions in Developing a Communication and Regulatory Framework

Consumers and users of tobacco, nicotine, and alternative products and the general public must always be provided with the science-based information necessary to understand the risks, relative risks, and intended uses of the various products currently on the market. Despite substantial efforts to promote cessation, many users of combustible/smoked tobacco products continue to smoke. Many consumers (and the general public) continue to believe that all forms of tobacco and/or nicotine are equally hazardous. Those consumers who are at the greatest risk for disease and death need non-combustible smoking replacement alternatives that are affordable, accessible, acceptable, and scientifically demonstrated to be significantly lower in risk. Closing this gap in understanding is important, and should include that:

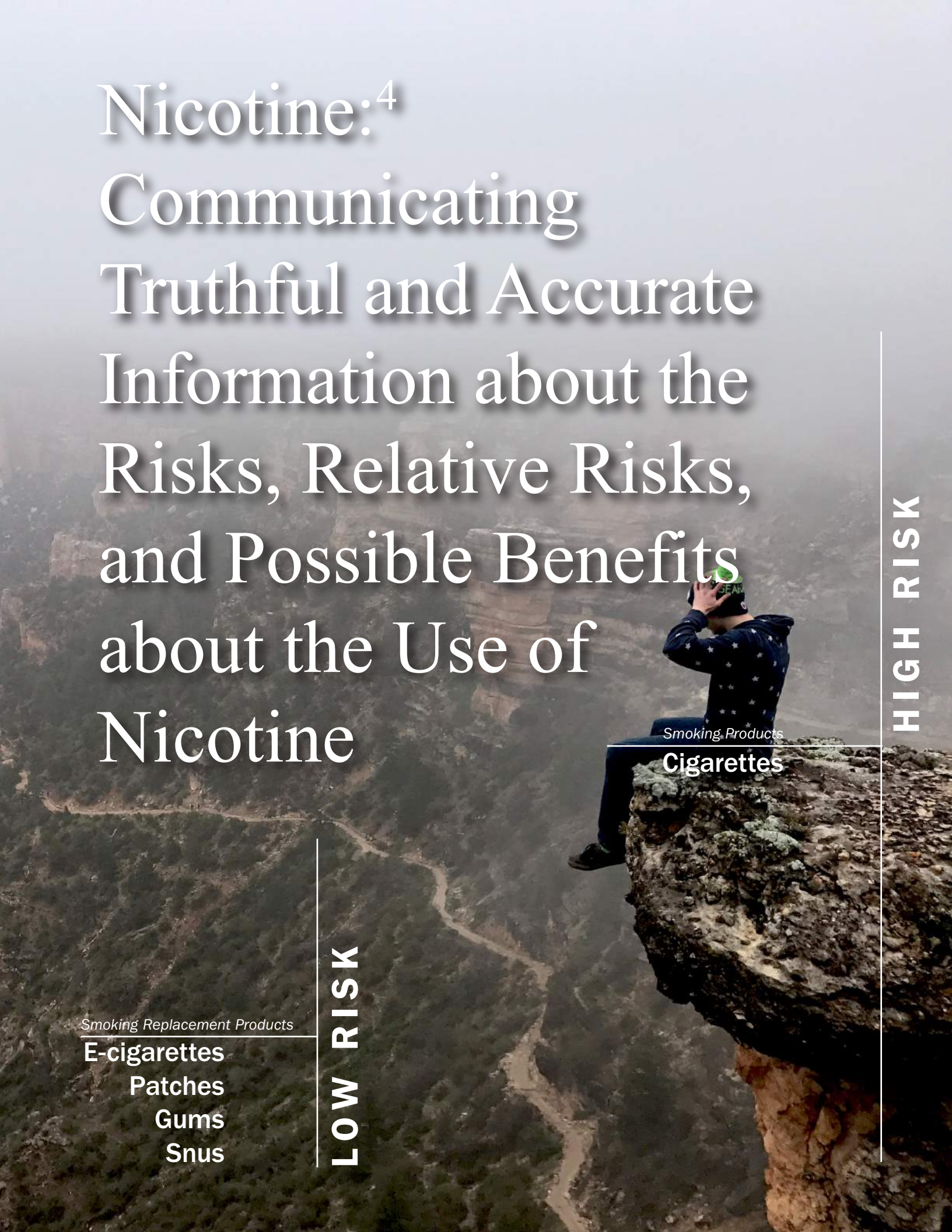
- The general public, health care providers, and consumers and users of tobacco, nicotine, and alternative products should be provided with accurate, science-based, and understandable information about the risks, relative risks, intended uses and effectiveness of all tobacco, nicotine, and alternative products. This information should be made available through consumer-oriented outlets such as social media, industry publications, governmental publications and sources, public health NGO's, university information distribution systems, and traditional advertising mechanisms, etc.;

- Users and potential users of tobacco, nicotine, and alternative products should be actively consulted and involved in the development of policies, in the setting of regulations, in the implementation of policies and regulations, and in identifying what kinds of information are most useful for them. In addition, consumers must be instructed on how these products should be used to achieve a measure of effectiveness. Efforts to reach consumers must include enabling and actively facilitating their participation to ensure their perspectives are heard;

- Governmental agencies at the global, national, state, and local level (as well as other public and private stakeholders) should have an active role in ensuring that the information provided to the consumer, health care providers, the general public, and other stakeholders is scientifically accurate, science-based, and is provided in a manner appropriate to the target audience.

To add your individual or organizational name of conceptual support, please go to: https://virginia.az1.qualtrics.com/jfe/form/SV_2c11xduiaMjUaQl

Nicotine:[4] Communicating Truthful and Accurate Information about the Risks, Relative Risks, and Possible Benefits about the Use of Nicotine



Core Principle 8

Nicotine:[4] Communicating Truthful and Accurate Information about the Risks, Relative Risks, and Possible Benefits About the Use of Nicotine

As part of any effort to provide the public, consumers, health care professionals, and others with truthful information about the risks and relative risks of tobacco, nicotine, and alternative products, special attention should be given to include the communication of truthful information with the respect to nicotine. While nicotine is highly addictive and not benign, and no child or adolescent should use any nicotine product, a large portion of consumers and the general public continues to believe that all tobacco and nicotine products are equally harmful, and that nicotine is the major cause of cancer. Adult smokers are entitled to know more about the availability of "cleaner" and safer forms of nicotine to help break their addiction to cigarettes.[5] As US Federal Drug Administration (FDA) Commissioner Scott Gottlieb has noted in articulating the FDA's new visionary nicotine policy announced in July 2017, "*While it's the addiction to nicotine that keeps people smoking, it is primarily the combustion, which releases thousands of harmful chemicals into the body at dangerous levels, that kills people.*" A more useful educational framework related to nicotine should include that:

- Nicotine, naturally occurring in the tobacco leaf, is a highly addictive substance and in high doses can cause significant harm. However, in doses that are currently used by consumers, evidence indicates that nicotine is not a cause of cancer nor a significant factor for other diseases;
- Because of concerns about the effects on nicotine on children and adolescents, no one under the age of 18/21 should use nicotine in any form. This includes ensuring that laws and regulations governing the sales and distribution of these products are strictly enforced and that marketing of these products is not targeted at adolescents;
- It is the method of nicotine delivery that causes the overwhelming disease and death from tobacco use. Combustible/smoked products are accountable for the overwhelming disease burden both nationally and globally. Cigarettes are the most appealing, most addictive, and most toxic of all nicotine containing products. "Cleaner" forms of nicotine delivery in noncombustible forms have been developed, and should be made available to adult smokers as both cessation therapies and as non-combustible smoking replacement products. If such consumer-acceptable products are made readily available, a complementary strategy for reducing the levels of nicotine in combustible products should be considered and pursued;

• Nicotine derived from tobacco has long been used in patches, gums, lozenges, inhalers, and other "Nicotine Replacement Therapy" (NRT) products, as a means of helping cigarette smokers quit the use of cigarettes. The evidence related to the safety of nicotine use in these products is significant;

• The public, users of tobacco and nicotine products, and other stakeholders are entitled to truthful and accurate information about the risks, relative risks, and intended uses of nicotine products. This information should be provided to all users in a consistent and truthful manner, by all stakeholders including governmental agencies (such as Federal Drug Administration, Centers for Disease Control, and World Health Organization), manufacturers, policy makers, public health organizations, academic institutions, health care professionals, the media, and others;

• Educational efforts on the risks and relative risks of alternative nicotine products should include the enhanced truthful labeling of products (including package inserts) and public educational/media campaigns, such as the responsible use of social media and various websites and publication in scientific journals;

• No nicotine product should be used during pregnancy except under advice of a health care practitioner;

• For some users, nicotine may have a positive effect on cognitive processes, motor coordination, concentration, and memory;

• Governmental agencies, both nationally and globally, should be encouraged to establish more flexible, visionary regulatory frameworks like the one articulated by the US Food and Drug Administration in July 2017.[6]

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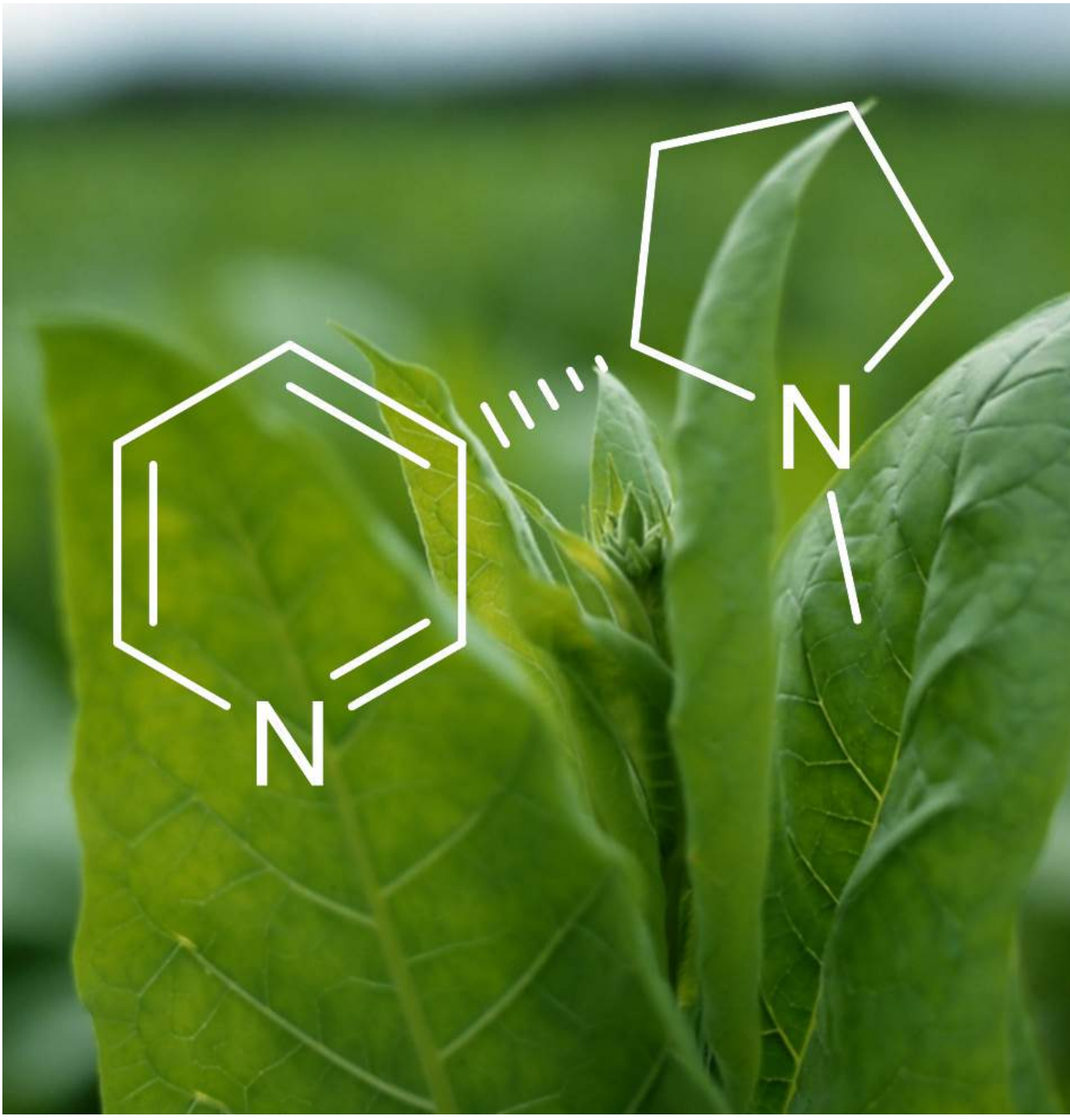
[4] This new Core Principle was added by the Morven VI Dialogue.

[5] For a more detailed review about nicotine and its pragmatic use in reducing disease and death from cigarette smoking, see *"Re-Thinking Nicotine and its Effects"* – by Raymond Niaura, PhD, formerly Director of Science and Training at The Steven Schroeder National Institute. https://truthinitiative.org/sites/default/files/ReThinking -Nicotine.pdf

[6] https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm

https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm629412.htm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Tobacco Agriculture: Involve Agriculture Stakeholders in Developing a Communication and Regulatory Framework

Core Principle 9

Tobacco Agriculture: Involve Agriculture Stakeholders in Developing a Communication and Regulatory Framework

Agriculture is often left out of consideration at both the global and national level when discussing harm reduction efforts, but it has an important role to play in how low-risk products are developed and manufactured. The growing and production of tobacco plays a critical role in the tobacco harm reduction movement. This should include that:

- Public health agencies and authorities in both the public and private sectors, as well as manufacturers, should work cooperatively with agricultural agencies and authorities in developing fair but effective science-based quality controls and health and safety standards to produce tobacco (growing, curing, and processing);
- Grower organizations, producers, agronomists, academic research institutions, and agricultural extension services, both nationally and globally, need to be actively involved in working with governmental organizations in efforts to establish fair but effective standards that reduce the harm caused by tobacco leaf and produce lower risk products;
- Concerted and organized efforts must be undertaken to assist growers in transitioning out of the production of tobacco and/or in assisting growers into transitioning to a new system of production that makes risk-reduction a priority;
- Tobacco grown for harm reduction products should be grown using Good Agricultural Practices 2 (GAP2),[7] which are designed to ensure environmentally sustainable growing and labor practices. These practices must be consistent with national and international laws governing the use of child labor.

To add your individual or organizational name of conceptual support, please go to: https://virginia.az1.qualtrics.com/jfe/form/SV_2c11xduiaMjUaQI

[7] The U.S Tobacco GAP program is an industry-wide program that aims at ensuring sustainable, economically viable production of useable tobacco and can be defined as: agricultural practices which produce a quality crop while protecting, sustaining or enhancing the environment regarding soil, water, air, animal and plant life as well as protecting and ensuring the rights of farm laborers.

http://www.gapconnections.com/Pages/US-Tobacco-GAP.aspx

Engagement and Dialogue: Encourage Ongoing Civil Dialogue with Broad Stakeholder Involvement

TOBACCO, NICOTINE, AND ALTERNATIVE PRODUCTS HARM REDUCTION STAKEHOLDERS

Core Principle 10

Engagement and Dialogue: Encourage Ongoing Civil Dialogue with Broad Stakeholder Involvement

Reducing disease and death from the use of tobacco, and most importantly the use of combustible forms of tobacco, on a global basis will depend on a willingness of stakeholders to maintain, expand, and develop new relationships. Words and subsequent actions do matter. If understanding and possible collaborations are to be fostered and solutions found, then it is important that stakeholders avoid portraying difficult issues in an overly simplistic "us versus them" manner. In this dynamically changing environment at both national and global levels, there will continue to be a need to engage in more frequent dialogues with a broader representation of stakeholders, at multiple levels and in multiple venues, both in the public and private sectors. This should include that:

- All stakeholders and other experts (including but not limited to governmental agencies; public health organizations; tobacco, nicotine, and alternative product manufacturers; researchers; consumers; tobacco agricultural interests) should be encouraged to engage in civil dialogues on a spectrum of tobacco, nicotine, and alternative products harm reduction topics;
- It will require a willingness on the part of participants to not only provide their views but to also be willing to listen and learn from the views of others;
- Where adversarial situations exist, such engagements should be held in venues that are considered "safe havens" for discussion, and where transparency and civil dialogue can be applied with the assistance of unbiased facilitation;
- Dialogues can take place in many differing venues and at many different levels in both the public and private sectors. Such venues include governmental agencies such as the Food and Drug Administration; academic institutions; public health and scientific conferences such as the Society for Research on Nicotine and Tobacco (SRNT), and CORESTA; trade association meetings such as the Global, Tobacco and Nicotine Forum (GNTF), Global Forum on Nicotine (GFN), and E-Cigarettes Summits in London and Washington D.C.; organizations like the Food and Drug Law Institute (FDLI), and World Health Organization; and "safe haven" venues like the University of Virginia IEN Morven Dialogues. Opportunities for the promotion of engagement and dialogue abound;

These 10 Core Principles are intended to provide some guidance for those willing to initiate and or participate in civil dialogues related to tobacco and nicotine harm reduction. They are owned by no one but can be embraced and used by all.

To add your individual or organizational name of conceptual support, please go to: https://virginia.az1.qualtrics.com/jfe/form/SV_2c11xduiaMjUaQl

“Never doubt that a small group of thoughtful, committed, citizens can change the world. Indeed, it is the only thing that ever has.”

— MARGARET MEAD

UNIVERSITY of VIRGINIA

INSTITUTE *for* ENGAGEMENT & NEGOTIATION

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Health, Food, and Social Equity
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US DOI, Collaborative Action and Dispute Resolution Practitioner Roster
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Institute for Engagement & Negotiation
Shaping our world together.

IEN is a nationally recognized leader in fostering **collaborative change** across a broad range of environmental, social, and economic issues. IEN is a public service organization of the University of Virginia, with a team of facilitators and mediators that assists organizations, agencies, industry, and communities in making bold, sustainable decisions. Our work spans health, food and social equity; sustainable environment; resilient communities; and building capacity.

Team members are known for expertise in designing and facilitating collaborative problem-solving processes, consensus building, conflict resolution, and strategic planning; programmatic evaluation; mediation; training in leadership, conflict management and negotiation skills; and working to foster equity and justice in community processes and outcomes.

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IEN adheres to the Ethical Guidelines for Environment and Public Policy Members published by the Association for Conflict Resolution which include:

1. **Self-determination** of participants to make their own informed decisions.
2. **Impartiality** of the facilitator regarding ideas, content and recommendations.
3. **Conflicts of Interest** potentially held by the facilitator will be disclosed.
4. **Competence** of the facilitator to successfully complete the scope of work and support the overall effort.
5. **Confidentiality** of discussions outside of meetings (and per Virginia Code sections 3705.1(11) and 2.2-4119).
6. **Quality of the Process** to support participants and encourage mutual respect.
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8. **Fees and Other Professional Charges** will be clearly stated to funders and transparency provided on who is funding an effort.
9. **Advancement of the Practice** by supporting diversity, education and mentoring.
10. **Maintaining the Integrity of the Profession** by placing the integrity of the process above personal interests.

For more information IEN's history, staff, and projects, please visit our website: www.ien.virginia.edu

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From: Lempert, Lauren (b) (6) >
Sent: Wednesday, June 5, 2024 3:53 PM
To: TPSAC <TPSAC@fda.hhs.gov>
Cc: Ling, Pamela (b) (6) >
Subject: [EXTERNAL] Swedish Match MRTP Renewal Application
Importance: High

Post-Market Surveillance Studies (PMSS) of Swedish Match General Snus products were a condition of continued MRTP authorization and are central to the question of whether FDA should renew the MRTP authorization. In particular, Appendix B of the Swedish Match Modified Risk Granter Order for eight General Snus products dated October 22, 2019 states:

> **Appendix B**
> **Required Postmarket Surveillance and Studies (PMSS)**
>
> Under Section 911(i)(1) of the FD&C Act, FDA must require postmarket surveillance and studies for any product for which an applicant received an order under 911(g)(1) in order to: "…determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product."
>
> I. PMSS Content
>
> MRTP Use Behavior and Consumer Understanding and Perception
>
> After receiving authorization, the determination of whether the eight General Snus products that are the subject of these applications, as actually used by consumers, continue to benefit the health of the population as a whole is likely to be driven by use

behavior. Therefore, monitoring use of the eight General Snus products that are the subject of these applications in terms of uptake, dual use, and complete switching is required. In particular, your PMSS must assess the extent to which new MRTP users were non-users, smokers, or other tobacco product users before initiating the MRTPs and the extent to which new users of the MRTPs become exclusive users or dual users with cigarettes or other tobacco products over time. Relatedly, such surveillance must include an assessment of consumers' understanding of the claim and perceptions of the products. In particular, PMSS must assess the extent
to which users of these products understand that, to reduce their risk of disease relative to smoking as described in the modified risk information, they must use General Snus exclusively. To adequately assess these impacts, you must conduct PMSS that include assessing users' behavior and consumer understanding at multiple time points.

The Swedish Match MRTP Renewal Application materials that FDA posted includes a redacted letter and an Excel spreadsheet, both of which refer to General Snus Patterns of Use Studies and other studies, presumably including data and information on how consumers actually use the tobacco products, that were attachments to the renewal application. However, none of these studies have been posted or otherwise made publicly available.

The Family Smoking Prevention and Tobacco Control Act Section 911(e) requires FDA to make all of these application materials publicly available. Data and information on how consumers actually use General Snus products are especially relevant to this MRTP renewal application and essential for the TPSAC meeting; the Notice of the TPSAC meeting published in the Federal Register on May 6, 2024 states: "Additional discussion about broader Modified Risk Tobacco Products program developments related to the conceptualization and measurement of consumer understanding will also occur." (89 FR 37231 at 37232)

Because these materials were not made publicly available, interested persons such as myself are unable to adequately examine and assess the application materials and unable to provide informed comments to TPSAC and/or FDA. This failure, in turn, prevents TPSAC to make recommendations to FDA informed by public comments as required by law.

Please post all of the PMSS reports on the MRTP application in sufficient time to allow the public to review them and comment. Since the deadline for comments for the TPSAC meeting is June 20, 2024 and the deadline for public comments for the FDA docket is July 5, 2024, it likely will be necessary to postpone these deadlines and postpone the TPSAC meeting.

Thank you for your prompt response.

Lauren Kass Lempert, JD, MPH
Law and Policy Specialist
Center for Tobacco Control Research & Education
University of California, San Francisco
530 Parnassus Ave., Suite 366, San Francisco, CA 94143-1390
Phone: (b) (6)

NATO

June 5, 2024

Via email

Ms. Serina Hunter-Thomas
Office of Science
Center for Tobacco Products, Food and Drug Administration
Document Control Center
Bldg. 71, Rm. G335
10903 New Hampshire Ave.
Silver Spring, MD 20993–0002

RE: Support of Renewal of a Risk Modification Order Submitted by Swedish Match USA, Inc. (Docket No. FDA-2024-N-0008)

Dear Ms. Hunter-Thomas:

As the Executive Director of the National Association of Tobacco Outlets (NATO), a national retail trade association that represents more than 66,000 tobacco retailers throughout the country, I write in support of the application of Swedish Match USA, Inc., for renewal of a risk modification order for eight General Snus products. Please consider this submission with respect to the Tobacco Products Scientific Advisory Committee (TPSAC) meeting on this subject scheduled for June 26, 2024.

NATO is the preeminent representative of the interests of tobacco retailers, including convenience stores, gas stations, grocers, and many other tobacco outlets selling the entire range of tobacco products, from traditional to modern oral to electronic nicotine delivery systems, including snus products. NATO and its members support responsible retailing to ensure youth do not access tobacco products.

NATO has also been supportive of the FDA's recognition of tobacco harm reduction and the continuum of risk for tobacco and nicotine products. Based both on their historic use in other countries and their relatively recent introduction in the United States, snus products have been recognized as a means for adults to choose a product lower on that continuum. At the same time, we know of no data suggesting that snus contribute to tobacco or nicotine uptake by underage youth. The rigorous scientific basis that supported the original marketing authorization orders in 2015 and the modified risk orders in 2019 has not changed. No reason exists to deny the renewal of the risk modification order.

Thank you for your consideration. Please let me know if you need any further information.

Sincerely,

David Spross

NATO Executive Director
(b) (6)