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Re: Docket No. FDA-2014-N-1051, Tobacco Products Scientific Advisory Committee meeting on amendments to Modified Risk Tobacco Product Applications for Snus Products Submitted by Swedish Match North America Inc.

The Campaign for Tobacco-Free Kids (Tobacco-Free Kids) submits these comments in connection with the upcoming meeting of the Tobacco Products Scientific Advisory Committee (TPSAC) to consider the amendments submitted by Swedish Match North America, Inc. (Swedish Match) to its modified risk tobacco product applications (MRTPs) of specific General snus products, 83 Fed. Reg. 5436 (October 29, 2018). The amendments propose to make the following modified risk claim with respect to the General snus products: "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

These are preliminary comments meant to inform the discussion before TPSAC, but because the formal comment period is open and will not close until an as yet undetermined date after the TPSAC meeting, and because the record that has been made available to the public is not complete, Tobacco-Free Kids reserves the right to submit more extensive comments on these amendments prior to the close of the comment period.

These comments will address:

(1) The statutory standards by which every Modified Risk Tobacco Application (MRTP) must be evaluated and the importance to public health of rigorous application of those standards; and

(2) The core empirical considerations that should govern TPSAC's consideration of whether the subject MRTP amendments meet the statutory standards for modified risk tobacco products.

I. THE STATUTORY STANDARDS THAT SHOULD GOVERN TPSAC'S CONSIDERATION OF THE GENERAL SNUS MODIFIED RISK TOBACCO APPLICATIONS

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act or TCA) assigns TPSAC a unique and central role in FDA's assessment of modified risk applications. The involvement of TPSAC in evaluating modified risk products is mandatory under the TCA.[1] In providing its evaluation, it is essential that TPSAC have a full understanding of the tobacco industry's conduct that should inform FDA's application of the statutory standards.[2]

The Swedish Match modified risk application amendments (General snus amendments) are governed by the standards set out in Section 911 of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (Section 911). Section 911 was enacted as a response to the tragic history of false and misleading tobacco industry claims that certain tobacco products were less dangerous than other products that persuaded health-conscious consumers to switch to the "reduced risk" products instead of quitting altogether.

In enacting the Tobacco Control Act, Congress made specific findings about the potential harm to public health from modified risk claims that should guide FDA in its consideration of any modified risk product application. Congress found that "unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health. . . ." Sec. 2(37). Congress also found that "the 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 products are complete, accurate, and relate to the overall disease risk of the product." Sec. 2(40). Congress determined that it is "essential that manufacturers, prior to marketing such

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[1] *See* Section 911(f)(1) of the Food, Drug and Cosmetic Act, as amended by the Tobacco Control Act, provides that FDA "shall refer" to TPSAC "any application" for a modified risk order.

[2] Tobacco-Free Kids has addressed TPSAC's role in evaluating modified risk tobacco applications in multiple comments filed with FDA in recent years and incorporates those comments by reference. *See* Comments of Tobacco-Free Kids in Docket No. FDA-2017-N-0001, April 6, 2017 TPSAC meeting re review of modified risk applications (March 22, 2017); Comments of Tobacco-Free Kids, et al., in Docket No. FDA-2014-N-0001, April 18, 2014 TPSAC meeting re modified risk tobacco products (April 2, 2014; Comments of Tobacco-Free Kids, et al., Docket No. FDA-2013-N-0001-0056 re evaluation of risk and benefits of proposed modified risk tobacco products to population as whole (August 1, 2013); Comments of Tobacco-Free Kids 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).

products, be required to demonstrate that such products will meet a series of rigorous criteria, and will 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." Sec. 2(36).

Under the Tobacco Control Act, a "modified risk tobacco product" is defined as a 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. A product is "sold or distributed" for such a use if, in relevant part,

> (1) [its] label, labeling, or advertising, either implicitly or explicitly [represents] that
>
> > (i) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
> >
> > (ii) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
> >
> > (iii) the tobacco product or its smoke does not contain or is free of a substance, or…
>
> (3) the tobacco product manufacturer has taken any action directed to consumers through the media or otherwise, other than by means of the label, labeling, or advertising…that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or its free of, a substance or substances.

Thus, a modified risk product is defined in terms of the manufacturer's claims of reduced risk or reduced exposure in marketing the product, as well as its actions that may suggest to consumers that a product reduces risk or exposure to hazardous substances.

In evaluating an application under section 911, FDA must consider both the product itself and the modified risk claims sought to be made by the manufacturers. Even though a product may meet the standard for the grant of a marketing application, the manufacturer may not make reduced risk or reduced exposure claims unless FDA has granted a separate application under Section 911 authorizing the making of such claims pursuant to the standards set forth in that section. With respect to the General snus products that are the subject of the General snus amendments, for example, FDA granted an application to market a number of new tobacco

products,[3] but denied the manufacturer's applications under section 911 to make the modified risk claims the company originally proposed in connection with the products.[4]

Under §911(g)(1), the burden is on the applicant seeking an order allowing the marketing of the product with a modified risk claim to demonstrate that the 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 population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." (emphasis added).

Sec. 911(g)(4) further requires FDA to take into account the following specific empirical factors in determining whether the (g)(1) standard has been met:

> (A) The relative health risks to individuals of the tobacco product that is the subject of the application;
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> (B) The increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;
>
> (C) The increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;
>
> (D) The risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence.

Thus, FDA must consider not only the effects of the asserted modified risk product on those who use it, but also its population-wide impact on tobacco use initiation, cessation and relapse, including an assessment of the likelihood that smokers would actually switch to the modified risk product, given the claims made. It is necessary but not enough for an applicant to show that the product is less hazardous to users than other tobacco products; in order for a modified risk application to be granted, the applicant is required to show that the benefits of risk reduction to the individual (considering the likelihood of smokers switching to the modified risk product) outweigh the risks of increased initiation or diminished cessation. In short, the statute requires FDA to make scientific judgments not only about the physical effect of the product's use, but also about the likely responses of potential consumers (both smokers and non-smokers) to the product's marketing as a modified risk product.

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[3] U.S. Food and Drug Administration, Premarket Tobacco Application (PMTA) Technical Project Lead (TPL) Review, Swedish Match North America, Inc. (Nov. 11, 2015).

[4] U.S. Food and Drug Administration, response letter from Benjamin J. Apelberg, CTP Office of Science to Swedish Match North America (Dec. 14, 2016).

II. CONSIDERATIONS RELATED TO TPSAC'S EVALUATION OF THE APPLICATION'S IMPACT ON THE INDIVIDUAL USER AND THE POPULATION AS A WHOLE

In the discussion that follows, we seek to inform TPSAC's consideration of the amendments to these applications in light of the statutory standards, based on the current science on the impact of using smokeless tobacco – particularly snus – at the individual and population level in the United States, as it affects switching from cigarette smoking to smokeless tobacco use, dual use of cigarettes and smokeless tobacco, and initiation of tobacco use.

A. Relevance of Scandinavian Epidemiological Evidence

The original modified risk applications filed by Swedish Match and the General snus amendments rely heavily on the experience with snus in Scandinavian countries, particularly Sweden, in assessing the likely behavioral impact in the U.S. of marketing General snus as modified risk products. The relevance of the Swedish experience is discussed extensively in previous submissions by the Campaign for Tobacco-Free Kids in this Docket, and in the Docket established in connection with the R.J. Reynolds modified risk application for Camel snus, which are incorporated by reference.[5] As those submissions argue, there are substantial reasons to be skeptical of the Swedish experience as a predictive guide to the likely population-wide impact of marketing General snus in the U.S. as modified risk tobacco products.

It should also be noted that TPSAC already has considered the relevance of the Swedish experience to the assessment of the impact of Swedish snus as modified risk products in the U.S. Thus, in its April, 2015 meeting on the Swedish Match modified risk applications, TPSAC voted on two issues relating to the relevance of the Swedish data. The key votes on these issues were as follows:

1. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the likelihood that current tobacco users in the U.S. will switch to the use of these snus products? **TPSAC voted 6 votes "no,", 1 vote "yes" and 1 abstention.**

2. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the likelihood that non-users of

[5] See e.g. Comments of Campaign for Tobacco-Free Kids and Tobacco Control Legal Consortium in Docket No. FDA-2014-N-1951, Modified Risk Applications for 10 Products Submitted by Swedish Match North America, Inc. (November 25, 2014), at 20-33; Comments of Campaign for Tobacco-Free Kids and Tobacco Control Legal Consortium in Docket No. FDA-2014-N-1051, Reopening of Comments Period for Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North America, Inc. (August 25, 2015); Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2018-N-2066, TPSAC Notice of Meeting re R.J. Reynolds Modified Risk Application for Camel Snus (August 29, 2018), at 6-9.

tobacco in the U.S. will initiate the use of these snus products? **TPSAC answered "no" by of vote of 5 votes "no" with 3 abstentions.**

Therefore, TPSAC should evaluate the appropriateness of a modified risk designation for these General snus products based on the available evidence on consumer behavior patterns with smokeless tobacco products in the U.S., not on the Swedish experience with snus, which is unlikely to be replicated in the U.S.

B. Importance of Determining if a Modified Risk Marketing Order for the Products Will Benefit the Population as a Whole.

In order to obtain a modified risk marketing order, the applicant must demonstrate that the issuance of such an order would "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." Demonstrating such a benefit requires a prediction of the effect of the proposed claim on consumer behavior. Assuming that an individual who smokes cigarettes or uses another smokeless tobacco product and switches to General snus as a result of the modified risk claim receives a significant health benefit, such benefits could be offset by (1) individuals who have never used tobacco products initiating with smokeless tobacco as a result of the claims; (2) individuals who might otherwise have quit smoking switching to smokeless tobacco for the long term instead of quitting as a result of the claims; (3) individuals engaging in dual use as a result of the claims; and (4) individuals who have quit using tobacco products re-initiating with smokeless as a result of the claims. Thus, it becomes necessary to predict the effect of such claims on each potential group.

It is important that the public and consumers receive accurate information about the relative risks of different tobacco products, but it is equally essential that evidence be provided that those messages are not misunderstood or create unintended consequences. Considering data showing that youth smokeless tobacco users already view the health risks from smokeless tobacco use as less severe compared to non-users,[6] statements needed to be evaluated as to whether providing this information encourages smokers to switch completely and to insure that it does not portray the information in such a way that non-users, particularly youth, believe that using smokeless tobacco is worth the health risk or that it discourages smokers from quitting altogether. This entails not only pre-review of messages, but also post-market evaluations.

If a cigarette smoker who would not otherwise quit altogether switched to snus completely, it is likely that the individual would reduce his/her risk of disease. One other potential effect should also be considered: in addition to considering the benefits from smokers who otherwise would not have quit switching completely to General snus, there would also likely be a population-wide benefit from users of other smokeless tobacco products switching to

[6] Couch, ET, et al., "Smokeless Tobacco Decision-Making Among Rural Adolescent Males in California," *Journal of Community Health* 42(3):544-550, 2017.

General snus. This is because snus exposes users to fewer harmful substances than other smokeless tobacco products. While this population is much smaller than that of smokers, given evidence that users of traditional smokeless tobacco products are more aware of snus than non-users,[7] the prospect of a complete switch to General snus might be higher. On the other hand, FDA must also evaluate the potential that consumers may attribute the relative risk of snus to other smokeless tobacco products that present a higher risk

For all these reasons, a determination of the effect of the proposed modified risk claim in the General snus amendments must depend principally on studies of consumer perception and consumer behavior in the United States. In evaluating these amendments, several issues should be considered as they pertain to consumer perception and behavior.

1. Claims should be considered in light of the population they are designed to target. The population as to which a modified risk claim should be addressed is existing users of cigarettes or other combusted tobacco products. The effectiveness with which such a claim is targeted to this population may affect the appropriateness of granting the application. Thus, *to truly benefit the population, the applicant must adequately show that the message is targeted exclusively to current adult smokers, and exposure to youth and non-tobacco users is limited.* In any event, consideration of any modified risk claim should take into account the population actually most likely to encounter the claim, as opposed to the population intended to encounter the claim. For instance, there is certainly a risk that the print advertisement proposed by Swedish Match,[8] which would be seen by tobacco users and non-tobacco users alike, could induce non-tobacco users to try snus because it is less hazardous than cigarettes.

As noted above, Swedish Match's proposed modified risk claim is as follows: "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis." By its terms, this claim is not directed exclusively at smokers. Moreover, nothing in the General snus amendments indicates that only adult smokers will be exposed to the claim.

2. Any claim should include sufficient information to avoid misleading or confusing consumers. Because the benefits of switching from cigarettes or other smokeless tobacco products to General snus accrue only to the extent that consumers who otherwise would not quit switch to this product exclusively, adequate testing must be done to ensure that any modified risk claim clearly and explicitly communicates this message in a way that is fully understood by the public.

As currently proposed, the language in Swedish Match's claim does not indicate to consumers that the benefit is derived from complete switching. The use of the term

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7 Biener L, et al., "Snus Use and Rejection in the United States," *Tobacco Control* 25(4):386-392, 2016.

8 Swedish Match, MRTPA Response to Advice/Information Request October 24, 2018, at 13.

"instead" could imply substituting General snus for some cigarette smoking, but not switching entirely from cigarettes to General snus.

3. The dissemination plan for the proposed marketing should be targeted exclusively to current smokers and users of tobacco products, with minimal exposure to youth and non-tobacco users. For instance, Swedish Match indicates its intention to include the proposed modified risk claim in messages to its list of recipients for General snus emails and direct mail.[9] These recipients are presumably existing General snus users, not necessarily smokers who could benefit from an effective modified risk message.

4. General snus presents a very different health risk to an individual than that presented by other smokeless tobacco products, particularly the traditional moist snuff products that are much more popular in the U.S. compared to any snus products. The potential exists for the specific modified risk claim proposed by Swedish Match to be interpreted by consumers as conveying a message about other, more hazardous, smokeless products, thus leading to a greater risk of initiation of those other products. Thus, TPSAC should make sure that Swedish Match has properly evaluated whether or not the use of modified risk message in General snus marketing would affect the use of other smokeless tobacco products, particularly among youth and other vulnerable populations.

5. Although general education about the relative risk of smokeless tobacco compared to cigarettes is important, comprehension of the statement still needs to be considered for nonsmokers, particularly youth. Given the history of tobacco companies misleading the public on "light" and "low-tar" cigarettes, and marketing to youth to increase product sales, the worst-case, and perhaps more likely, scenario would be if youth and nonsmokers misunderstand the message and believe that General snus and other smokeless tobacco products are "safe" to start using, but then become addicted to nicotine and switch to smoking cigarettes or other combustible products.

C. How Likely Would Youth Exposed to Modified Risk Messages Initiate Smokeless Tobacco Use or Transition from Smokeless Tobacco Use to Smoking?

Given that smokeless tobacco rates among youth have not declined as rapidly as cigarette smoking, [10] it is important that TPSAC carefully review any data on the impact of marketing General snus with a modified risk message on youth initiation, including a possible gateway effect to smoking and dual use. Because the consumer perception studies and the consumer behavior

[9] Swedish Match, MRTPA Response to Advice/Information Request October 24, 2018, at 15-17.

[10] CDC, "Tobacco Use Among Middle and High School Students—United States, 2011-2017," *Morbidity and Mortality Weekly Report (MMWR)* 67(22):629-633, June 7, 2018.

studies submitted by Swedish Match as part of its application did not include youth, a complete assessment of the impact of the modified risk statement cannot be made by TPSAC or FDA.

FDA's assessment of Swedish Match's amendments must consider the population-wide impact of the products on both users and non-users of tobacco products, which includes its impact on tobacco use initiation. Both FDA's Guidance for the preparation of Modified Risk Tobacco Product Applications and Institute of Medicine's (IOM) 2012 report, *Scientific Standards for Studies on Modified Risk Tobacco* recommend or even require the inclusion of youth in consumer perceptions studies of promotional material to determine the effect of such modified risk claims on adolescent risk perception or interest in using the product.[11] Given that adolescence is a period of heightened vulnerability for the initiation of tobacco use, it is important to evaluate whether adolescents accurately understand the purported benefits of an MRTP. Of particular importance are adolescents' perceptions of the risks and benefits of using the product, and whether they intend to initiate tobacco use with the MRTP rather than a traditional tobacco product because they believe the former is a "safe" alternative."[12] Swedish Match's failure to provide any evidence of the effect of these messages on adolescent risk perception is an inexplicable omission, against FDA's express instructions. The need to consider the effects of promotional statements on youth is vitally important in light of the industry's documented history of marketing tobacco products in ways that attract adolescents and the role that youth initiation has played—and continues to play—in the recruitment of long-term adult smokers.[13]

FDA's guidance on MRTP applications and IOM's report describe how such research should be done. Recognizing that research among non-smokers, and non-smoking youth in particular, requires care, FDA offered applicants an opportunity to work with the agency to determine the best way to conduct studies involving youth. [14] IOM suggested that such research could be appropriately done under the supervision of an independent third party.[15]

TPSAC should evaluate whether amendments that present no evidence on the effect of modified risk claims on youth initiation or perception of risk can possibly meet the public health standard.

Available U.S. prevalence surveys do not provide a lot of detail on snus use among youth, but even data on general smokeless tobacco use among youth indicate that overall use of snus is low. The most popular smokeless tobacco brands identified by youth (12-17 years old)

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11 FDA Draft Guidance, Modified Risk Tobacco Applications, March 2012, at 20.

12 Institute of Medicine, *Scientific Standards for Studies on Modified Risk Tobacco Products*, December 2011, ("IOM report") at 165.

13 U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012, at 530-41, 603-27 and sources cited therein; *U.S. v. Philip Morris*, 449 F. Supp. 2d at 561-691.

14 FDA 2012 Draft Guidance, at 26. IOM report at 7, 14, 50.

15 IOM report at 57.

smokeless tobacco users continue to be the traditional moist snuff brands,[16] some of which make pouch products, but those are vastly different from snus products.

Preliminary data indicate that smokeless tobacco use could be associated with future smoking for youth and young adults. One small study found an association between snus use among non-smoking youth and young adults and increased likelihood of cigarette smoking initiation, current cigarette smoking, and more intense cigarette smoking two years later.[17] Though the proportions from the study are small, those findings are supported by older studies linking smokeless tobacco use to later cigarette smoking.[18] More recently, a study using data from the Population Assessment of Tobacco and Health (PATH) study found that non-smoking youth (12-17 years old) using smokeless tobacco (including snus) at baseline had higher odds of cigarette smoking initiation and two times the odds of past 30-day cigarette smoking at follow-up a year later compared to non-users.[19] This pattern is not isolated to the U.S.: a study from Norway found that age may be a factor in transitioning from snus to cigarettes. It found that people who started using snus before 16 years old were much more likely to become adult smokers compared to those who started snus later.[20] Moreover, initial smokeless tobacco use is also associated with later multiple tobacco product use. A survey of adolescents and young adults who had ever used tobacco found that those who initiated any tobacco use with smokeless tobacco (or any other non-combustible product) had higher odds of using multiple tobacco products than those who initiated with a combustible product.[21]

Because most of the studies linking initial smokeless tobacco use to later smoking are older, TPSAC needs to determine how relevant these older findings are for General snus,

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[16] U.S. Department of Health and Human Services (HHS), SAMHSA Center for Behavioral Health Statistics and Quality, *National Survey on Drug Use and Health*, 2014. ICPSR36361-v1, Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor], 2016-03-22, http://doi.org/10.3886/ICPSR36361.v1.

[17] Soneji, S, et al., "Associations Between Initial Water Pipe Tobacco Smoking and Snus Use and Subsequent Cigarette Smoking Results from a Longitudinal Study of US Adolescents and Young Adults," *JAMA Pediatrics* 169(2):129-136, 2015.

[18] Tomar, SL, et al., "Is Smokeless Tobacco Use an Appropriate Public Health Strategy for Reducing Societal Harm?," *International Journal of Environmental Research and Public Health* 6:10-24, 2009, at 16. Severson, H, et al., "Use of smokeless tobacco is a risk factor for cigarette smoking," *Nicotine and Tobacco Research* 9(12):1331-1337, December 2007. Haddock, CK, et al., "Evidence that smokeless tobacco use is a gateway for smoking initiation in young adult males," *Preventive Medicine* 32:262-267, 2001. Tomar, S, "Snuff Use and Smoking in U.S. Men: Implications for Harm Reduction," *American Journal of Preventive Medicine* 23(3):143-149, October 2002. Tomar, S, "Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience," *Nicotine & Tobacco Research* 5(4):561-569, August 2003, http://www.ncbi.nlm.nih.gov/pubmed/12959794. See also, Tomar, SL, "Smokeless tobacco use is a significant predictor of smoking when appropriately modeled," *Nicotine & Tobacco Research* 5(4):571-573, August 2003, http://www.ncbi.nlm.nih.gov/pubmed/12959795.

[19] Watkins, SL, Glantz, SA, Chaffee, BW, "Association of Noncigarette Tobacco Product Use With Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015," *JAMA Pediatrics* 172(2):181-187, 2018.

[20] Lund, I & Scheffels, J, "Smoking and Snus Use Onset: Exploring the Influence of Snus Debut Age on the Risk for Smoking Uptake With Cross-Sectional Survey Data," *Nicotine & Tobacco Research* 16(6):815-819, 2014.

[21] Soneji, S, Sargent, J, & Tanski, S, "Multiple tobacco product use among US adolescents and young adults," *Tobacco Control*, 2014, [Epub ahead of print], http://www.ncbi.nlm.nih.gov/pubmed/25361744.

especially in the context of a tobacco product marketplace including e-cigarettes, which is currently more popular than even cigarettes.

D. Would a Modified Risk Claim Result in Increased Smoking Cessation or in Increased Dual Use?

General snus currently has relatively low use rates in the U.S. compared to traditional smokeless tobacco products. Swedish Match has not provided sufficient evidence that a modified risk designation will increase its use by smokers who plan to switch completely, or if those smokers will use General snus in addition to smoking cigarettes. In fact, a study of U.S. smokers who were interested in quitting smoking with oral tobacco products showed that smokers did not like General snus and did not choose to use it during the study period.[22] As discussed in our comments to Swedish Match's General snus modified risk docket[23] and those filed before TPSAC for the Camel snus modified risk docket,[24] data generally do not show that smokers will use smokeless tobacco products, including snus, to quit smoking, and that the opposite trend (smokeless tobacco to cigarette smoking) is more likely. The 2008 Update of the U.S. Public Health Service Clinical Practice Guidelines regarding tobacco cessation concluded, "the use of smokeless tobacco products is not a safe alternative to smoking, nor is there evidence to suggest that it is effective in helping smokers quit."[25] Thus, there is considerable reason to doubt, based on available U.S. data, experiences, alternative products on the market, and current regulatory structures, that U.S. smokers will actually switch completely to General snus, even with the proposed modified risk claim.

An alternative to switching completely is using both products concurrently (dual use), and that has extremely important health consequences. Dual use may prolong duration of smoking, which plays a major role in increasing risks of developing smoking-related diseases.[26]

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[22] Hatsukami, DK, et al., "Oral tobacco products: preference and effects among smokers," *Drug and Alcohol Dependence* 118(2-3):230–236, 2011.

[23] See e.g. Comments of Campaign for Tobacco-Free Kids and Tobacco Control Legal Consortium in Docket No. FDA-2014-N-1951, Modified Risk Applications for 10 Products Submitted by Swedish Match North America, Inc. (November 25, 2014), at 27-29; Comments of Campaign for Tobacco-Free Kids and Tobacco Control Legal Consortium in Docket No. FDA-2014-N-1051, Reopening of Comments Period for Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North America, Inc. (August 25, 2015)

[24] Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2018-N-2066, TPSAC Notice of Meeting re R.J. Reynolds Modified Risk Application for Camel Snus (August 29, 2018), at 17-19.

[25] Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update*, U.S. Public Health Service Clinical Practice Guideline, May 2008, http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

[26] U.S. Department of Health and Human Services (HHS), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*, U.S. Centers for Disease Control and Prevention (CDC), Office of Smoking and Health (OSH), 2010, at 9. HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, CDC, OSH, 2012, at 22, http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html. Schane, RE, Ling, PM, & Glantz, SA, "Health Effects of Light and Intermittent Smoking: A Review," *Circulation* 121(3):1518-1522, 2010. Tverdal, A & Bjartveit, K, "Health Consequences of Smoking 1-4 Cigarettes per Day," *Tobacco Control* 14(5), 2005. Hackshaw, A, et al., "Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports," *BMJ* 360:j5855, http://doi.org/10.1136/bmj.j5855, 2018.

Thus, TPSAC must assess whether smokers who take up a smokeless tobacco product will actually use that product (i.e., whether they would use it exclusively while abstaining from smoking or whether they would use both products concurrently) to determine if there is any potential benefit to health that might result from approval of a modified risk application.

Smokers may try snus for various reasons, including to reduce their smoking, but they more often end up using both products rather than switching completely.[27] Several studies have found that dual users have similar or lower likelihood of quitting or attempting to quit smoking compared to exclusive cigarette smokers.[28] One study has found that, while dual users were more likely to make a quit attempt compared to exclusive smokers, they tended to relapse more quickly compared to exclusive smokers, and had comparable 30-day abstinence levels to exclusive smokers.[29] U.S. smokers perceive snus as a temporary replacement, not a complete substitution for cigarettes,[30] and dual users of smokeless tobacco and cigarettes use smokeless tobacco to maintain their cigarette addiction, not to quit smoking,[31] and do not believe that smokeless products can help them quit smoking.[32] One study found that smokeless users who used these products to cut down on smoking were no more likely to stop using cigarettes compared to those smokers who did not use smokeless tobacco,[33] and another study found that smokers saw these products as temporary, rather than complete substitutes.[34]

Studies from the years before e-cigarettes became popular show an increase dual use of smokeless tobacco and cigarettes,[35] and Minnesota Adult Tobacco survey data show that the

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[27] Biener L, et al., "Snus Use and Rejection in the United States," *Tobacco Control* 25(4):386-392, 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4519419/pdf/nihms707341.pdf.

[28] Schauer, GL, Pederson, LL, & Malarcher, AM, "Past Year Quit Attempts and Use of Cessation Resources Among Cigarette-Only Smokers and Cigarette Smokers Who Use Other Tobacco Products," *Nicotine & Tobacco Research* 18(10):41-47, 2016. Klesges, RC, et al., "Tobacco Use Harm Reduction, Elimination, and Escalation in a Large Military Cohort," *American Journal of Public Health* 100(12):2487-2492, December 2010, at 2490 ("Importantly, dual users were less likely to become tobacco abstinent than were smokers or smokeless tobacco users . . . ."); Wetter, D, et al., "Concomitant Use of Cigarettes and Smokeless Tobacco: Prevalence, Correlates, and Predictors of Tobacco Cessation," *Preventive Medicine* 34:638-648,2002, ("Concomitant users were significantly less likely to quit using tobacco over the course of 4 years than were users of cigarettes or ST.").

[29] Messer, K, et al., "Cigarette smoking cessation attempts among current US smokers who also use smokeless tobacco," *Addictive Behaviors* 51:113-119, 2015.

[30] Bahreinifar, S, Sheon, NM, & Ling, PM, "Is snus the same as dip? Smokers' perceptions of new smokeless tobacco advertising," *Tobacco Control* 22:84-90, 2013, http://tobaccocontrol.bmj.com/content/22/2/84.

[31] McClave-Regan, AK & Berkowitz, J, "Smokers who are also using smokeless tobacco products in the US: a national assessment of characteristics, behaviours and beliefs of 'dual users'," *Tobacco Control* 20:239-242, 2011, http://www.ncbi.nlm.nih.gov/pubmed/21172853.

[32] McClave-Regan, AK & Berkowitz, J, "Smokers who are also using smokeless tobacco products in the US: a national assessment of characteristics, behaviours and beliefs of 'dual users'," *Tobacco Control* 20:239-242, 2011.

[33] Kasza, KA, et al., "Cigarette Smokers' Use of Unconventional Tobacco Products and Associations With Quitting Activity: Findings From the ITC-4 U.S. Cohort," *Nicotine & Tobacco Research* 16(6):672-681, June 2014, http://www.ncbi.nlm.nih.gov/pubmed/24376276.

[34] O'Connor, RJ, et al., "US smokers' reactions to a brief trial of oral nicotine products," *Harm Reduction Journal* 8:1-10, 2011, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3032705/pdf/1477-7517-8-1.pdf.

[35] Rath, JM, et al., "Patterns of Tobacco Use and Dual Use in US Young Adults: The Missing Link between Youth Prevention and Adult Cessation," *Journal of Environmental and Public Health* 2012(679134):1-9, 2012,

increase in smokeless tobacco use was largely due to current smokers using smokeless tobacco concurrently, not to smokers switching to smokeless tobacco.[36] Survey data show that multiple tobacco product use is common among youth and adult tobacco users,[37] and before e-cigarettes, dual use of smokeless tobacco and cigarettes was popular.[38] Data from the NIH and FDA-funded Population Assessment of Tobacco and Health (PATH) study from 2013-2014 survey found that there were more current snus users also using other tobacco products than exclusive snus users.[39] Moreover, snus users were "more likely to report…polytobacco use than users of other SLT [smokeless tobacco] products."[40]

In the U.S., many new smokeless tobacco products have been marketed as a way to get a nicotine fix when smokers cannot smoke. In Swedish Match's magazine promoting General snus, *Elevation*, an ad states, "With General snus, there's no smoke, no spit and no limit to where you can go. So no matter where you're off to next, pack the tobacco that helps you embrace any adventure, anywhere."[41] Such marketing discourages smokers from taking the one step that is sure to protect their health, which is to quit smoking entirely. Because this messaging could undermine any modified risk statement about "switching completely," TPSAC must evaluate the proposed statements in the context of other smokeless tobacco marketing.

CONCLUSION

In considering the General snus amendments under the statutory standards for modified risk products, TPSAC should consider the following issues:

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http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3361253/pdf/JEPH2012-679134.pdf. Boyle, R, et al., "Concurrent Use of Cigarettes and Smokeless Tobacco in Minnesota," *Journal of Environmental and Public Health*, 2012.

[36] Boyle, R, et al., "Concurrent Use of Cigarettes and Smokeless Tobacco in Minnesota," *Journal of Environmental and Public Health*, (2012).

[37] Kasza, KA, et al., "Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014," *New England Journal of Medicine* 376(4):342-353, 2017.

[38] Substance Abuse and Mental Health Services Administration (SAMHSA), *The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007*, Rockville, MD: Office of Applied Studies, March 5, 2009, at 5. Tomar, SL, "Patterns of Dual Use of Cigarettes and Smokeless Tobacco among U.S. Males: Findings from National Surveys," *Tobacco Control* 19:104-109, 2010, at 105. Rath, JM, et al., "Patterns of Tobacco Use and Dual Use in US Young Adults: The Missing Link between Youth Prevention and Adult Cessation," *Journal of Environmental and Public Health* 2012(679134):1-9, 2012, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3361253/pdf/JEPH2012-679134.pdf.

[39] Cheng, Y, et al., "Patterns of Use of Smokeless Tobacco in US Adults, 2013–2014," *American Journal of Public Health* 107(9):1508-1514, 2017.

[40] Cheng, Y, et al., "Patterns of Use of Smokeless Tobacco in US Adults, 2013–2014," *American Journal of Public Health* 107(9):1508-1514, 2017.

[41] General snus ad in *Elevation* magazine, 2017, available at http://www.trinketsandtrash.org/detail.php?artifactid=12362.

1. Is the Scandinavian experience with Swedish snus is a reliable predictive guide to the likely population-wide impact of General snus, with the modified risk claim proposed in the amendments, in the United States?

2. Is the text of the modified risk claim in the amendments, with its dissemination, sufficiently directed exclusively to adult smokers?

3. Does the text of the modified risk claim in the amendments sufficiently communicate to consumers that they realize health benefits only by completely switching from smoking to General snus? As currently proposed, the language in Swedish Match's claim does not indicate to consumers that the benefit is derived from complete switching. The use of the term "instead" could imply substituting General snus for some cigarette smoking, but not switching entirely from cigarettes to General snus.

4. Is there sufficient data in the amended applications to determine whether exposing youth to General snus with the proposed modified risk claim would lead to increased initiation of smokeless tobacco use and/or transition from smokeless tobacco use to smoking?

5. Would the marketing of General snus, with the proposed modified risk claim, result in increased smoking cessation or, rather, increased dual use with cigarettes?

Respectfully submitted,

Campaign for Tobacco-Free Kids