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Re: Docket No. FDA-2018-N-3261, Tobacco Products Scientific Advisory Committee; Notice of Meeting re Altria/U.S. Smokeless Tobacco Company's Modified Risk Application for Copenhagen Snuff Fine Cut

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 above-referenced modified risk tobacco product application for Copenhagen snuff fine cut, 83 Fed. Reg. 47925 (September 21, 2018). 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 unspecified 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 applications prior to the close of the comment period.

These comments will address three central issues:

(1) The relationship between the modified risk application that will be the subject of the TPSAC meeting and the pending FDA proposed rule that would establish a tobacco product standard for N-nitrosonornicotine (NNN) in finished smokeless tobacco products, including Copenhagen snuff fine cut;

(2) 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

(3) The core empirical considerations that should govern TPSAC's consideration of the subject MRTP.

I. THE POTENTIAL IMPACT OF FDA'S PROPOSED NNN PRODUCT STANDARD FOR SMOKELESS TOBACCO ON THE PENDING COPENHAGEN SNUFF FINE CUT MODIFIED RISK APPLICATION

In the pending application, Altria Client Services LLC (Altria), on behalf of its subsidiary, the U.S. Smokeless Tobacco Co. LLC (U.S. Smokeless Tobacco), seeks authorization to market Copenhagen snuff fine cut (Copenhagen) as a modified risk tobacco product. Altria seeks to market this product with the following claim: "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."

On January 23, 2017, FDA published a proposed rule that would establish a limit of 1.0 microgram per gram of tobacco (on a dry weight basis) of N-nitrosonornicotine (NNN), a potent carcinogen, in all finished smokeless tobacco products, which would include Copenhagen.[1] The pending application makes it clear that, at 3.622 micrograms per gram of tobacco[2], the level of NNN in Copenhagen snuff fine cut significantly exceeds the maximum level proposed as a product standard by FDA. Thus, in this application, Altria/U.S. Smokeless Tobacco seeks authorization to make a modified risk claim for a product that FDA has proposed to prohibit from the market because such a prohibition would be "appropriate for the protection of the public health."

Should the proposed rule become final prior to FDA's disposition of the pending MRTP application for Copenhagen, the application would become moot because this Copenhagen product would not conform to the new product standard. Should the proposed rule become final after an MRTP decision, the product would need to be withdrawn. Given the pendency of FDA's proposal of an NNN product standard for all smokeless tobacco, it makes little sense for the agency to consider the modified risk application for Copenhagen before it makes a final decision on the proposed product standard.

FDA should issue a final rule establishing the NNN product standard without further delay. The proposed rule is amply supported by scientific evidence establishing that (1) NNN in smokeless tobacco is carcinogenic, (2) reducing the level of NNN in smokeless tobacco products marketed in the United States would substantially reduce the risk of oral cancers for users, and (3) conformance of smokeless tobacco to the proposed product standard is technically feasible as demonstrated by the presence on the U.S. market of Swedish snus products sold by Swedish

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[1] Proposed Rule for Tobacco Product Standard for NNN level in Finished Smokeless Tobacco Products, 82 Fed. Reg. 8004 (January 23, 2017) (Proposed NNN rule).

[2] Altria/U.S. Smokeless Tobacco, 7.1: Product Analysis – HPHC, at 15.

Match that already meet the proposed standard.[3] Indeed, FDA estimates that in the 20 years following implementation of the proposed product standard, approximately 12,700 new cases of oral cancer and approximately 2,200 oral cancer deaths would be prevented in the United States. During that 20-year period, approximately 15,200 life years would be gained were the standard to be put into effect.[4]

In light of the substantial benefit to public health FDA anticipates from adoption of its proposed NNN standard, the proposed rule should be made final, and the standard implemented as soon as possible. The proposed rule was issued two years ago and the public comment period has been closed for almost eighteen months. There is simply no reason for FDA to further delay making the rule final. Once it does so, the pending MRTP application for Copenhagen snuff fine cut will become moot. It makes little sense for FDA to consume its resources, including TPSAC's resources, in further consideration of the pending MRTP application when it concerns a product that, according to FDA's own scientific conclusions, should no longer be permitted on the market.[5]

II. THE STATUTORY STANDARDS THAT SHOULD GOVERN TPSAC'S CONSIDERATION OF THE MODIFIED RISK TOBACCO APPLICATION FOR COPENHAGEN

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.[6] 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.[7]

The Altria/U.S. Smokeless Tobacco application is 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

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[3] *See generally*, Proposed NNN Rule, 82 Fed. Reg. at 8010-8026.

[4] Proposed NNN Rule, 82 Fed Reg. at 8026.

[5] Of course, once the proposed NNN rule becomes final and is implemented, Altria will be free to pursue a new MRTP for any of its products that conform to the new NNN standard.

[6] *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.

[7] 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).

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 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
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> > (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…
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> (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.

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 Swedish snus products marketed by Swedish Match North America, for example, FDA granted an application to market a number of new tobacco products,[8] but denied the manufacturer's application under section 911 to make the modified risk claims the company proposed in connection with the products.[9]

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 tobacco 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

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

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

also about the likely responses of potential consumers (both smokers and non-smokers) to the product's marketing as a modified risk product.

III. 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 this application in light of the statutory standards, based on the current science on the impact of using smokeless tobacco at the individual and population level in the United States, as it affects initiation of tobacco use, switching from cigarette smoking to smokeless tobacco use, and dual use of cigarettes and smokeless tobacco.

A. Importance of Determining How the Product Will Actually Be Used by Consumers.

TPSAC must consider how the changes in how Copenhagen snuff fine cut product is "actually used by consumers" after the introduction of the proposed modified risk messages will impact both the risk to the individual and the risk to the population as a whole. Whether the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" will depend on the way the product is "actually used by consumers" in the U.S., including whether they engage in dual use of cigarettes and Copenhagen, move from cigarettes to smokeless tobacco, or from smokeless tobacco to cigarettes. In this connection, Altria/U.S. Smokeless Tobacco's references to trends in Swedish snus use in Scandinavian countries have little relevance to this application, considering Copenhagen snuff fine cut is a different product and U.S. consumers "actually use" Copenhagen snuff fine cut differently than Swedish consumers use snus products.[10]

A substantial body of evidence supports the proposition that the significant health benefits to an individual from quitting smoking occur only if the individual completely quits smoking. Merely reducing the number of cigarettes smoked or engaging in dual use of cigarettes and other tobacco products does not substantially reduce the health risk, as several U.S. Surgeon General's Reports and other studies have indicated that the risk of cardiovascular disease and other smoking-related diseases depends largely on the length of time a person smokes, not the

[10] The relevance of the Scandinavian experience with snus to FDA's consideration of modified risk applications for smokeless products in the U.S. has been extensively discussed in previous Tobacco-Free Kids filings with TPSAC and FDA, which we incorporate by reference. *See* 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.

number of cigarettes smoked.[11] According to the CDC, "If you only cut down the number of cigarettes you smoke by adding another tobacco product…you still face serious health risks. Smokers must quit smoking completely to fully protect their health – even a few cigarettes a day are dangerous."[12]

While *complete switching* to Copenhagen snuff fine cut might "significantly" or "greatly" reduce smokers' risk of certain smoking-related diseases, as Altria/U.S. Smokeless Tobacco asserts in its application, incomplete switching (dual use or merely cutting down smoking) keeps smokers' risks of disease elevated. One study concluded, "Because the health risks associated with cigarettes and ST [smokeless tobacco] are different in some respects, and because their effects may be additive if not synergistic, the concomitant use of cigarettes and ST may increase the risk of tobacco-attributable death and disease relative to use of either product alone."[13] Another, more recent study determined that reporting health issues was more likely among people who used both smokeless tobacco and cigarettes compared to those who used only one product.[14]

This question of individual risks from dual use also has population-level implications. As we show in Section D below, dual or multiple product use is not a trivial concern in the U.S. According to Altria/U.S. Smokeless Tobacco's application, more than one-third of adult smokeless tobacco users is a dual user with cigarettes.[15]

Thus, TPSAC and FDA must carefully consider the way consumers will "actually use" the product when exposed to the proposed modified risk claim, including whether consumers actually switch completely rather than dual or multiple use with other tobacco products, particularly combustible products.

B. Evaluating Population-Level Risks of Copenhagen Snuff Fine Cut

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

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[11] 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.

[12] CDC, "Powerful new Tips from Former Smokers" ads focus on living with vision loss and colorectal cancer," CDC Press Release, March 26, 2015, http://www.cdc.gov/media/releases/2015/p0326-tips.html. See also: CDC, "Dual Use of Tobacco Products," http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html.

[13] Wetter, D, et al., "Concomitant Use of Cigarettes and Smokeless Tobacco: Prevalence, Correlates, and Predictors of Tobacco Cessation," *Preventive Medicine* 34:638-648, 2002.

[14] Hernandez, SL, et al., "Relationships Among Chewing Tobacco, Cigarette Smoking, and Chronic Health Conditions in Males 18–44 Years of Age," *Journal of Primary Prevention* 38(5):505-514, 2017.

[15] Altria/U.S. Smokeless Tobacco, Executive Summary, at 7.

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 Copenhagen snuff fine cut 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 will not be 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,[16] there needs to be a balance between providing this information to encourage smokers to switch completely and portraying the information in such a way that non-users, particularly youth, understand that using smokeless tobacco still carries health risks. This entails not only pre-review of messages, but also post-market evaluations.

For all these reasons, a determination of the effect of Altria/U.S. Smokeless Tobacco proposed claims must depend principally on studies of consumer perception and consumer behavior in the United States. In evaluating this application, 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 and design of its marketing materials, as well as its dissemination plan, 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.

While Altria/U.S. Smokeless Tobacco references "adult tobacco consumers" in its marketing plan, if the company is serious about having adult smokers switch completely,

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

then the marketing should focus primarily on those individuals. For instance, in announcing its purchase of 35 percent stake in Juul Labs, Inc., Altria's press statement included, "Altria will enable JUUL to reach adult smokers with direct communications through cigarette pack inserts."[17] However, in this modified risk application, Altria/U.S. Smokeless Tobacco does not propose any such insert or onsert connected to its cigarette packs, but instead mentions only labels added to the bottom of cans of Copenhagen.[18] Thus, its modified risk message is calculated to reach primarily current users of Copenhagen or consumers interested in using the product (whether youth or adult), not adult smokers.

2. Any claim should include sufficient information to avoid misleading or confusing consumers. Because the benefits of switching from cigarettes to Copenhagen snuff fine cut accrue only to the extent that consumers who otherwise would not quit smoking 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.

3. As noted above in terms of higher NNN content, Copenhagen snuff fine cut presents a greater health risk to an individual than other smokeless tobacco products in the U.S. TPSAC should evaluate whether the use of the modified risk message in Copenhagen snuff fine cut marketing would cause current users of other less hazardous smokeless tobacco products to switch to Copenhagen, with special attention to the impact on youth and other vulnerable populations. Given the current use of Copenhagen in the U.S., the risk is greater for Copenhagen than for General snus that a statement could lead to non-smokers taking up the use of the product or that current users of snus might switch.

4. Though Altria/U.S. Smokeless Tobacco's proposed modified risk message refers to "this product," none of the proposed marketing pieces identify the specific product to which the message applies. Unlike images of other Copenhagen products advertised in Altria/U.S. Smokeless Tobacco's other marketing materials, which show cans that indicate the specific variety of Copenhagen (i.e., "long cut" or "pouches"),[19] the image of the Copenhagen snuff can used in all of the proposed advertisements look generic, and the advertising pieces do not mention "fine cut" anywhere.[20] In addition, the coupon offer in the proposed direct mail piece is for "any style of Copenhagen." Viewers may misinterpret the modified risk message to apply to any and all Copenhagen snuff products, not just the fine cut product for which Altria/U.S. Smokeless Tobacco has submitted its

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[17] Altria, "Altria Makes $12.8 Billion Minority Investment in JUUL to Accelerate Harm Reduction and Drive Growth," Press Statement, December 20, 2018, http://investor.altria.com/file/Index?KeyFile=396169695.

[18] Altria/U.S. Smokeless Tobacco, 4.1: Labels, Labeling, and Advertising, at 6.

[19] See, for instance, Copenhagen email from September 14, 2018, courtesy of Trinkets and Trash at http://www.trinketsandtrash.org/detail.php?artifactid=13755.

[20] Altria/U.S. Smokeless Tobacco, 4.1: Labels, Labeling, and Advertising, at Appendices 4.1-1, 4.1-2, 4.1-4, 4.1-5, 4.1-7, 4.1-9.

application. While data on the differences in health outcomes from using fine cut vs. long cut (or any other variety of moist snuff) are not provided in the application, because Altria/U.S. Smokeless Tobacco has submitted this application specifically for the fine cut variety and not for all of its Copenhagen products, the company should show that its proposed modified risk message will be applied, and understood to apply, only to this specific product. Further, TPSAC should evaluate whether the messages could be interpreted as applying to any of the Copenhagen products.

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 Copenhagen snuff fine cut 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?

Copenhagen has been one of the top three most popular snuff brands reported by current smokeless tobacco users aged 12-17 since at least 1999[21] and has been promoted using images and messages that appeal to youth. It is essential, then, that TPSAC carefully consider the likely impact on youth initiation of marketing Copenhagen snuff fine cut with a modified risk message, including a possible gateway effect to smoking and dual use. Because the consumer perception and consumer behavior studies submitted by Altria/U.S. Smokeless Tobacco as part of its application do not address the impact on youth, a complete assessment of the impact of the modified risk statement cannot be made by TPSAC or FDA, based on the data in the pending application. These types of evaluations must be done before modified risk products are authorized by FDA, not only in post-marketing surveys and evaluations.

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.[22] 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

[21] Analysis of data from the National Household Survey on Drug Abuse and National Survey on Drug Use and Health, SAMHSA, HHS, Center for Behavioral Health Statistics and Quality.

[22] FDA Draft Guidance, Modified Risk Tobacco Applications, March 2012, at 20.

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."[23] Altria/U.S. Smokeless Tobacco'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.[24]

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. [25] IOM suggested that such research could be appropriately done under the supervision of an independent third party.[26]

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

Data indicate that smokeless tobacco use could be associated with future smoking for youth and young adults.[27] 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 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.[28] Moreover, initial smokeless tobacco use is also associated with later multiple tobacco product use. A survey of

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

[24] 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.

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

[26] IOM report at 57.

[27] 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.

[28] 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.

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.[29]

These studies underscore the importance of determining the likely impact of the proposed modified risk message on youth prior to FDA authorization.

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

As discussed in our comments to Swedish Match's General snus modified risk docket[30] and those filed before TPSAC for the Camel snus modified risk docket,[31] data generally do not show that U.S. smokers will use smokeless tobacco products to quit smoking, and that the opposite trend (transitioning from 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."[32] Even based on its own research, Altria/U.S. Smokeless Tobacco acknowledges the proposed modified risk message will not have a significant impact on intentions to try, use, or switch to Copenhagen snuff fine cut.[33] TPSAC should determine, based on available U.S. data, experiences, alternative products on the market, and current regulatory structures, if smokers will actually switch completely to Copenhagen snuff fine cut, 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

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[29] 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.

[30] 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)

[31] 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.

[32] 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.

[33] "Based on our assessment of the likelihood of use of the candidate product among various subgroups of current tobacco users after viewing the proposed modified risk claim, we demonstrate that:
• there is some increase in likelihood of use of the candidate product, although modest, with greatest use potential among the adult male smoker subgroup;
• there is no statistically significant increase or decrease in trial or switching behaviors;
• there is no statistically significant increase or decrease in the likelihood of candidate product use in conjunction with other products; and
• there is no statistically significant increase or decrease in the likelihood that users who may have otherwise quit using tobacco products will instead use the candidate product."
Altria/U.S. Smokeless Tobacco, Executive Summary, at 35-36.

smoking, which plays a major role in increasing risks of developing smoking-related diseases.[34] Thus, TPSAC must assess how smokers who initiate use of 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.

Though Altria/U.S. Smokeless Tobacco briefly references the Scandinavian smokeless (snus) experience, suggesting that snus users in Sweden transition from dual use with cigarettes to exclusive use of snus,[35] the product for which the company is seeking a modified risk designation has a completely different construction, use profile, and level of health risk than snus products. Therefore, whatever trends occurred in Scandinavian countries with Swedish snus cannot be assumed to apply equally to the Copenhagen snuff product. As mentioned previously, Altria/U.S. Smokeless Tobacco states in its application that more than one-third of adult smokeless tobacco users in the U.S. is a dual user with cigarettes.[36] By contrast, most snus users in Sweden exclusively use snus.[37] Moreover, when TPSAC considered the modified risk application for Swedish snus, on the question of whether "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," the Committee cast 6 votes "no," one vote "yes," with one abstention.

That one in three smokeless tobacco users in the U.S. also smokes cigarettes is not surprising given that many smokeless tobacco products have been marketed as a way to get a nicotine fix when smokers cannot smoke. For example, in 2009, Altria had marketed its own Marlboro snus products in "convenient foilpack[s]" that "ride[s] perfectly alongside your smokes" because they were slim enough to fit inside cigarette packs.[38] Such marketing discourages smokers from taking the one step that is sure to protect their health, which is to quit smoking entirely. Because this kind of messaging could undermine any modified risk statement about "switching completely," TPSAC must evaluate the proposed statement in the context of other smokeless tobacco marketing.

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[34] 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.

[35] Altria/U.S. Smokeless Tobacco, Executive Summary, at 39.

[36] Altria/U.S. Smokeless Tobacco, Executive Summary, at 7.

[37] Lund, KE & McNeill, A, "Patterns of Dual Use of Snus and Cigarettes in a Mature Snus Market," *Nicotine & Tobacco Research* 15(3):678-684, 2013.

TPSAC should consider whether or not a modified risk message – which could be misinterpreted by non-smokers, particularly youth – would result in higher rates of dual use instead of complete switching, especially since smokeless tobacco products have not been shown to help smokers quit.

CONCLUSION

In light of the strong scientific support for FDA's proposed rule limiting NNN in all smokeless tobacco, and the fact that Copenhagen snuff fine cut would not meet the proposed standard, FDA should issue the proposed rule in final form without further delay and deny this modified risk application on the ground that the product does not meet the new standard. Assuming, however, that FDA will proceed to further consideration of this modified risk application, TPSAC should consider the following issues:

1. Is the modified risk claim likely to lead persons, particularly youth, who have never used tobacco products, to initiate use of smokeless tobacco and/or progress to combustible products?

2. In assessing the individual and population-wide impact of the proposed modified risk claim, is the claim likely to lead smokers to completely switch from cigarettes to Copenhagen snuff fine cut or another smokeless product, or rather lead to increased dual use of cigarettes with Copenhagen snuff fine cut or other smokeless products?

3. Is the proposed modified risk claim likely to lead users of less hazardous smokeless products like snus to switch to Copenhagen snuff fine cut?

4. Is the proposed modified risk claim likely to be interpreted by consumers as applying to all Copenhagen products, not just the product that is the subject of the application?

5. Does the marketing plan submitted as part of the modified risk application sufficiently target current adult smokers or does it create a risk that the modified risk claim will reach non-users of tobacco products, including youth?

Respectfully submitted,

Campaign for Tobacco-Free Kids