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Tobacco Products Regulatory Office
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Via email: hc.pregs.sc@canada.ca

Re: Consultation on “Proposals for the regulation of vaping products”

National Smokeless Tobacco Company (“NSTC”) submits these comments in response to Health Canada’s solicitation for public input on its consultation entitled “Proposals for the regulation of vaping products” (“Consultation”) in support of amendments to the Tobacco Act and the Non-smokers’ Health Act.

The Consultation presents an opportunity to implement a comprehensive tobacco harm reduction strategy that focuses on reducing tobacco-related morbidity and mortality among the population of adult tobacco consumers who cannot or will not quit smoking. Health Canada states that “[w]hile quitting is the best way for someone to improve their health, harms could also be reduced for people who use tobacco, but that are not able to quit by switching to less harmful sources of nicotine.” Such a strategy should complement proven cessation and prevention efforts.

Effective regulation must be science- and evidence-based. Science and evidence demonstrate that it is the process of setting tobacco on fire, combustion, which is responsible for many of the harms of smoking. Smokeless tobacco, which is neither burned nor smoked, is a less harmful

1 NSTC is the Canadian distributor of smokeless tobacco products sold in Canada under the brand names of Copenhagen® and Skoal®. “We” is used throughout to refer to NSTC.
3 NSTC also incorporates herein comments dated October 11, 2011, we previously filed with Health Canada entitled “Comments on Health Canada Consultation Document ‘Looking Forward: The Future of Federal Tobacco Control.’” We also incorporate comments dated April 13, 2017 we previously submitted in response to Health Canada’s consultation entitled “Consultation on ‘Seizing the Opportunity: The Future of Tobacco Control in Canada.’”
5 See Rt. Hon. Prime Minister Justin Trudeau’s Mandate Letter to the Minister of Science, “We are a government that believes in science – and a government that believes that good scientific knowledge should inform decision-making,” available at http://pm.gc.ca/eng/minister-science-mandate-letter.
source of nicotine than smoking.\textsuperscript{7} As the Commissioner of the U.S. Food and Drug Administration (“FDA”) recognized “it’s cigarettes that are the primary cause of tobacco-related disease and death.”\textsuperscript{8}

Despite the fact that smokeless tobacco presents less risk than smoking, the Consultation only considers e-vapour products which could have the effect of implying that e-vapour is the only reduced risk product Canadian smokers can and should choose. Health Canada should recognize that there is not a one-size-fits-all approach to smoking harm reduction and while switching to e-vapour may help some smokers quit, switching to smokeless tobacco may help others. We believe that smokeless tobacco has an important role to play to “reduce smoking related disease, death and health inequalities.”\textsuperscript{9}

In order to maximize the harm reduction potential of non-combustible nicotine containing products, adult tobacco consumers must actually use them. As noted in Health Canada’s “Consultation on ‘Seizing the Opportunity: The Future of Tobacco Control in Canada’” (“FTCS Consultation”), governments could use a “range of tools (e.g., public education campaigns) to actively encourage those who cannot quit tobacco use to switch completely to less harmful products, while continuing to inform youth and non-users of their harms.”\textsuperscript{10} We believe that the government should provide adult smokers with accurate information about the relative risks of various tobacco products, including smokeless tobacco products, to encourage smokers to switch to these less harmful products. These products cannot achieve their full potential unless smokers know about the relative risks and choose to use them.

The Consultation’s Proposal No. 9 (the “Proposal”):

Proposes to establish regulations that would specify the conditions upon which manufacturers, retailers and others could use authorized relative risk statements in vapor product promotions.\textsuperscript{11}

We agree that informing smokers about the relative risks of tobacco products is critically important to harm reduction. We believe, however, that smokeless tobacco has an important role to play to “help reduce smoking related disease, death and health inequalities.”\textsuperscript{12} The Proposal should be expanded beyond e-vapour to allow the use of government developed relative risk statements in smokeless tobacco promotions.

Specifically, to maximize tobacco harm reduction, Health Canada should:

\textsuperscript{7} See M. Zeller et al., The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the United States, Tob. Control J.; vol. 18: 324-332 (2009), at 325; (“Strategic Dialogue”), see also Hatsukami et al., supra, at S546.


\textsuperscript{9} FTCS Consultation, p. 12.

\textsuperscript{10} FTCS Consultation, p. 12.

\textsuperscript{11} Consultation, p. 8 (Emphasis added).

\textsuperscript{12} FTCS Consultation, p. 12.
- Recognize that smokeless tobacco could play a central role in harm reduction.
- Expand Proposal No. 9 to allow manufacturers of all non-combustible tobacco products, including smokeless tobacco, to promote their products using authorized relative risk statements developed by the government.
- Create reasonable regulations for allowing manufacturers to promote their products with relative risk statements.

About NSTC

NSTC is an affiliate of the U.S. Smokeless Tobacco Company, which is a wholly-owned subsidiary of Altria Group, Inc. NSTC is the Canadian distributor of smokeless tobacco products sold in Canada under the brand names Copenhagen® and Skoal®, the smokeless tobacco category’s leading brands in Canada. NSTC has been distributing smokeless tobacco products in Canada since 1913. NSTC’s headquarters are located in Pointe-Claire, Quebec and its products are manufactured in Nashville, Tennessee.

At NSTC, we are a leader in responsibly providing smokeless tobacco products to adult tobacco consumers. One of our goals is to help reasonable tobacco regulation succeed by supporting the development and implementation of regulations that improve public health and recognize individual adult tobacco consumer preferences.

NSTC markets a total of 17 individual smokeless tobacco products across different sizes (14, 15, 23, and 34 gram cans), forms (long cut, fine cut, and pouches), and tobacco varieties.13 The suggested retail selling price for a standard 34-gram can of NSTC products varies from $19.99 to $30.19, depending on the province, plus applicable sales taxes.14 This high price reflects the high federal excise tax burden on smokeless tobacco products. Overall, smokeless products represent a small component of total tobacco sales in Canada. For the year ended December 31, 2015, smokeless tobacco accounted for 0.5% of all tobacco sold in Canada,15 and is used by tens of thousands of adult tobacco consumers.

NSTC’s products are for adult tobacco consumers only. Children should not use any tobacco products. We support and participate in programs to help reduce the underage use of tobacco products. For example, we support We Expect ID, a program that focuses on keeping tobacco products out of children’s hands by providing retailers a variety of education and training materials to effectively train their employees on the importance of age verification. We also support initiatives and actions by governments to help prevent underage access to tobacco products, including enhanced age verification legislation and penalties for non-compliance.

13 Not all products are available in all provinces.
14 NSTC Suggested Retail Prices, April 2017.
Smokeless Tobacco Products Are Substantially Less Hazardous Than Cigarettes

Despite massive, long-standing public health campaigns against using tobacco products, many Canadians continue using tobacco products and more use cigarettes than any other tobacco product. For these adult consumers, products with lower health risks than cigarettes offer a promising opportunity to reduce their risk of harm. Making sure that products with reduced harm potential are available to these consumers and that consumers have accurate information about their relative risks should be a critical part of protecting the public health.16

There is an overwhelming scientific, medical, and public health consensus that smokeless tobacco products, including those distributed by NSTC in Canada, are substantially less hazardous than cigarettes. This consensus is based on extensive and compelling scientific evidence, including epidemiological disease risk data in human populations from the U.S. and other countries. As early as 2001, the U.S. Institute of Medicine (“IOM”) observed that smokeless tobacco products posed a lower overall risk than cigarettes.17 Since that time, panel after panel of experts have critically and thoroughly examined the evidence and reached the same conclusion: using smokeless tobacco products is undeniably far less hazardous than smoking cigarettes.

A 2009 article entitled “The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the United States” (“Strategic Dialogue”) critically examines the role that smokeless tobacco products could play in harm reduction.18 The Strategic Dialogue is the outcome of more than two years of dialogue by a group of twenty-six scientists and researchers, including the current Director of the United States FDA’s Center for Tobacco Products, which convened to develop guidance for future efforts to reduce the harm caused by tobacco products.19

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16 Disourging initiation and promoting cessation, particularly among those not legally permitted to buy tobacco products because they are underage, are and should remain core strategies to reduce tobacco-related harm. While prevention and cessation efforts can successfully reduce harm, however, it is highly unlikely that they will eliminate tobacco use altogether. There is growing consensus that public health policies based solely on prevention and cessation are not sufficient in the real world. Indeed, a regulatory approach that forces cigarette smokers to choose between smoking, on the one hand, and not using tobacco at all, on the other, could have the consequence of preserving cigarette smoking as the dominant form of tobacco use in Canada.


18 See M. Zeller et al., Strategic Dialogue.

19 The Strategic Dialogue participants were: Cathy Backinger (National Cancer Institute, Bethesda, Maryland, USA); Neal Benowitz (University of California, San Francisco, California, USA); Lois Biener (University of Massachusetts, Boston, Massachusetts, USA); David Burns (University of California, San Diego, California, USA); Pamela Clark (University of Maryland, College Park, Maryland, USA); Greg Connolly (Harvard School of Public Health, Boston, Massachusetts, USA); Mirjana Djordjevic (National Cancer Institute, Bethesda, Maryland, USA); Thomas Eissenberg (Virginia Commonwealth University, Richmond, Virginia, USA); Gary Giovino (University at Buffalo, SUNY, Buffalo, New York, USA); Dorothy Hatsukami (University of Minnesota, Minneapolis, Minnesota (co-chair)); Cheryl Healdton (American Legacy Foundation, Washington, DC, USA); Stephen Hecht (University of Minnesota, Minneapolis, Minnesota, USA); Jack Henningfield (Pinney Associates, Bethesda, Maryland, USA); Corinne Husten (Partnership for Prevention, Washington, DC); Kimberly Kobus (University of Illinois, Chicago, Illinois, USA); Scott Leischow (University of Arizona, Tucson, Arizona, USA); David Levy (Pacific Institute for Research & Evaluation, Calverton, Maryland, USA); Stephen Marcus (National Cancer Institute, Rockville, Maryland, USA); Matthew Myers (Campaign for Tobacco-Free Kids, Washington, DC, USA); Mark Parascandola (National Cancer Institute, Rockville, Maryland, USA); Prabhu Ponksh (HealthMatrix Inc., McLean, Virginia, USA); Peter Shields (Georgetown University, Washington, DC, USA); Paul Slovic (Decision Research, Eugene, Oregon, USA); David Sweanor (University of Ottawa, Ottawa, Ontario, Canada); Kenneth Warner (University of Michigan, Ann Arbor, Michigan, USA); and Mitchell Zeller, (Pinney Associates, Bethesda, Maryland (co-chair)). Id. at 331.
It confirms that there is a “very pronounced” continuum of risk among different tobacco and nicotine-containing products.20

The Strategic Dialogue concludes that cigarette smoking is “undoubtedly” more hazardous than non-combustible tobacco products. Smokeless tobacco is a non-combustible product:

There is a very pronounced continuum of risk depending upon how toxicants and nicotine, the major addictive substance in tobacco, are delivered. Cigarette smoking is *undoubtedly* a more hazardous nicotine delivery system than various forms of non-combustible tobacco products for those who continue to use tobacco, which in turn are more hazardous than pharmaceutical nicotine products.21

Others have similarly confirmed the continuum of risk concept,22 which can be represented as follows:

**Continuum of Risk**

![Diagram showing the continuum of risk between smoking conventional cigarettes and smoking cessation](image)

Smoking conventional cigarettes is at one end of the continuum, presenting the highest health risk to the individual tobacco consumer due to the combustion and inhalation of tobacco smoke. Smoking cessation is at the opposite end. Noncombustible tobacco products, such as smokeless

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20 Id. at 325.
21 Id. (emphasis added). *See also id.* at 327 (“On the continuum of risk, non-combustible tobacco products are more likely to reduce harm than a smoked form of tobacco for individuals who would otherwise be using conventional cigarettes.”).
22 *See e.g.*, D.K. Hatsukami et al., Developing the science base for reducing tobacco harm, Nic. & Tob. Res.; vol. 0: S537-S553 (2007) at S546 (“Hatsukami et al. (2007)”; *see also Zeller, M. Reflections on the 'endgame' for tobacco control*, Tob. Control 2013; 22:i40-41. (if a new approach to reduce consumption of cigarettes “is to succeed, it will be because policy makers and tobacco control advocates have overcome their reluctance and finally embraced a concept known as the 'continuum of risk'.”); Zeller, M. *Three years later: an assessment of the implementation of the Family Smoking Prevention and Tobacco Control Act*, Tob. Control 2013; 21:453-54 (“Experts agree that there is a distinct ‘continuum of risk’ when it comes to products that deliver nicotine.”).
tobacco products, are substantially lower on the risk continuum than cigarettes – closer, in fact, to medicinal nicotine and smoking cessation than to continued smoking.\textsuperscript{23}

The United States FDA recently announced a new comprehensive approach to tobacco harm reduction that recognizes the continuum of risk. The FDA announced that a “key piece of the FDA’s approach is demonstrating a greater awareness that nicotine – while highly addictive – is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.”\textsuperscript{24} Our smokeless tobacco products are used orally and include snuff and snus in loose and pouch forms. They are not burned or inhaled.

The Scientific Committee on Emerging and Newly Identified Health Risks (“SCENIHR”) advises the European Commission’s Health & Consumer Protection Directorate-General, which is responsible for updating various European Union laws relating to the safety of food and other products, consumer rights, and the protection of public health. In 2008, after examining the scientific evidence, SCENIHR issued a final report concluding that the overall health risks of smokeless tobacco products of the types found in Sweden and North America are “clearly” and “substantially” less than the overall health risks of cigarettes:

Overall therefore, in relation to the risks of the above major smoking-related diseases, and with the exception of use in pregnancy, [smokeless tobacco products] are clearly less hazardous, and in relation to respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking. The magnitude of the overall reduction in hazard is difficult to estimate, but as outlined above, for cardiovascular disease is at least 50%, for oral and GI cancer probably also at least 50%, and for respiratory disease close to 100%.\textsuperscript{25}

SCENIHR found the body of evidence so compelling that it described its finding regarding the relative risks of cigarettes and smokeless tobacco as “undeniable”:

It is undeniable that for an individual substitution of tobacco smoking by the use of moist snuff would decrease the incidence of tobacco related diseases.\textsuperscript{26}

In addition to those noted above, many other medical and scientific organizations have examined the relative health risks of smokeless tobacco products and cigarettes and reached similar conclusions. In a 2002 report, the Royal College of Physicians (“RCP”), the oldest medical

\textsuperscript{23} Strategic Dialogue at 325; see also Hatsukami et al. (2007) at S546.
\textsuperscript{26} Id. at 14 (emphasis added).
organization in the United Kingdom, concluded that “the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product,” and that “[s]ome smokeless tobacco products . . . may offer substantial reductions in harm compared to smoking.” The RCP followed up with a second study in 2007, again concluding that the overall health risks of using smokeless tobacco are “considerably” and “substantially” less than those of cigarette smoking:

The health risks of smokeless tobacco are considerably lower than those associated with combustible tobacco products as it is largely the combustion process that makes tobacco use so deadly.29

In 2008, an international group of experts that provides scientific and technical advice on tobacco products to the World Health Organization (“WHO”) similarly recognized that smokeless tobacco products are less hazardous than cigarettes. The WHO Study Group on Tobacco Product Regulation (“TobReg”) concluded, “[u]sers of smokeless tobacco products generally have lower risks for tobacco-related morbidity and mortality than users of combustible tobacco products such as cigarettes.”30

The American Council on Science and Health (“ACSH”) has also weighed in, issuing a number of reports and statements about smokeless tobacco over the last several years. ACSH is a public health-oriented consumer education consortium with a board comprised of 350 physicians, scientists, and policy advisors.31 In a report released in 2006, ACSH concluded that, “[o]verall, the use of smokeless tobacco confers only about 2% of the health risks of smoking,” emphasizing that in contrast to cigarette smoking, smokeless tobacco poses no risk of lung cancer or chronic pulmonary diseases and little risk, if any, of other cancers.32 In a subsequent publication, ACSH noted that almost 80% of peer-reviewed scientific and medical articles have acknowledged the differential risks between smokeless tobacco and cigarettes and concluded that the “health risks associated with ST [smokeless tobacco] use are vastly lower than those of smoking.”33

29 Id. at 18 (emphasis added).

February 2007, ACSH President Elizabeth Whelan and Executive and Medical Director Dr. Gilbert Ross released a statement on behalf of the ACSH for a Senate hearing on the then-proposed FDA regulation of tobacco. See American Council on Science and Health, Statement for Senate Hearing on FDA Regulation of Tobacco (Feb. 27, 2007), available at https://www.gpo.gov/fdsys/pkg/CHRG-110shrg33769/pdf/CHRG-110shrg33769.pdf. In its statement, the ACSH addressed what it termed the “fallacy that all tobacco products are equally harmful to public health” and pointed out that “[s]cientific studies have proven that they are not, and a rapidly-growing body of evidence confirms that they are not.” Id. at 174. In October 2008, ACSH Executive and Medical Director Dr. Ross stated in a letter to the medical journal Lancet that “the health risks of smokeless tobacco are at least an order of magnitude less than those of cigarettes.” G. Ross, Smokeless Tobacco for Cigarette Cessation, Lancet; vol. 372: 1271 (2008).
A close examination of data from the American Cancer Society Cancer Prevention Study II ("CPS II") supports the same conclusion. This study is among the largest known prospective cohort studies to compare mortality among former U.S. cigarette smokers who substituted using smokeless tobacco for cigarette smoking with those who quit using tobacco entirely. Although all-cause mortality after twenty years follow-up for smokers who switched to smokeless tobacco was higher than quitting altogether, this result was marginal and, as the authors discuss, may simply be the result of residual confounding.

In addition, Altria Client Services ("ALCS") conducted an extensive analysis of the comparative health risks of smokeless tobacco and cigarettes using two large United States, nationally representative linked mortality data sets: The National Health Interview Survey ("NHIS") mortality linkage and the National Longitudinal Mortality Study ("NLMS"). Both data sets are more recent than CPS II and contain similar numbers of smokeless tobacco users. Among smokeless tobacco users in these data sets, the all cause and all cancer mortality risks were not elevated while mortality risks were significantly elevated among cigarette smokers (Figure 1). These data directly demonstrate the significant risk differential between smokeless tobacco use and cigarettes.

The NLMS mortality linkage includes survey years 1993 through 2005 linked to National Death Index. The data have five years of mortality follow-up for all survey years, with each decedent’s underlying cause of death assigned to one of 113 aggregate causes. The analyses were limited to respondents at least 18 years old at survey who are never users of both pipe tobacco and cigars, and for whom analysis weight, follow-up time, vital status, and model covariates are known. This data set included 210,090 total observations including 3,492 current smokeless tobacco users.

NHIS mortality linkage includes survey years 1987, 1991-1992, 1998, 2000, and 2005 because these surveys identified smokeless tobacco use, pipe use, and cigar use. ALCS’s research analyzed both the publicly available data (includes 10 most common underlying causes of death) and the restricted access data (includes 113 underlying causes of death). The data are linked to the 2011 National Death Index update and therefore include between six and 24 years of mortality follow-up. Restrictions were the same as for the NLMS. This data set included 154,391 total observations including 3,006 current smokeless tobacco users.

Mortality hazard ratios were estimated using Cox proportional hazards regression analyses for leading causes of mortality, and other selected mortality causes attributed to tobacco use. The

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34 Cancer Prevention Study II, sponsored by the American Cancer Society, is a large, ongoing prospective cohort study of 1.2 million U.S. adults that began in the fall of 1982. It was designed to examine the effect of tobacco use on death rates from cancer and other tobacco-related diseases.
36 ALCS provides certain services, including regulatory affairs, to the Altria family of companies, including NSTC.
37 Pipe and cigar users were excluded from our analyses.
39 Results from our analyses of the NHIS mortality linkage shown in Figure 1 are based on a 10-year follow up.
following covariates were used: gender, race (white, non-white), age, BMI (not available in the NLMS data), education, family income, health status, tobacco use, and cigarettes per day (limited to current or former smokers in NHIS).

As shown in Figure 1, ALCS detected statistically significant excess risks among current cigarette smokers for mortality from all causes, all cancers, diseases of the heart and chronic lower respiratory diseases. The magnitudes of these excess risks among cigarette smokers are entirely consistent with prior studies, supporting the reliability of ALCS’s analyses. Among current smokeless tobacco users, however, ALCS detected no excess risks for mortality from all causes, all cancers, diseases of the heart or chronic lower respiratory disease. These analyses of two large, independent, nationally representative data sets in which ALCS directly compared the mortality risks of smokeless tobacco use and cigarette smoking clearly demonstrate that smokeless tobacco is associated with vastly lower mortality risks than cigarette smoking.

<table>
<thead>
<tr>
<th>Mortality outcome</th>
<th>Current SLT users</th>
<th>Current cigarette smokers</th>
<th>Hazard ratio (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All causes</td>
<td>0.88 (0.67-1.15)</td>
<td>1.08 (0.95-1.22)</td>
<td>1.87 (1.74-2.02)</td>
</tr>
<tr>
<td>All cancers</td>
<td>1.01 (0.57-1.79)</td>
<td>1.04 (0.82-1.31)</td>
<td>2.90 (2.54-3.32)</td>
</tr>
<tr>
<td>Diseases of the heart</td>
<td>1.07 (0.69-1.67)</td>
<td>0.79 (0.60-1.04)</td>
<td>1.62 (1.41-1.86)</td>
</tr>
<tr>
<td>Chronic lower respiratory diseases</td>
<td>0 deaths</td>
<td>0.43 (0.20-0.94)</td>
<td>6.79 (4.87-9.47)</td>
</tr>
</tbody>
</table>

Bold numbers are statistically elevated.

Figure 1. Comparison of the hazards for select mortality outcomes between current smokeless tobacco users and current cigarette smokers.

In sum, these and many other scientific reports demonstrate beyond credible dispute that the health risks of moist smokeless tobacco products are substantially less than cigarettes.

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41 See, e.g., L.T. Kozlowski L.T. & B.O. Edwards, “Not Safe” is Not Enough: Smokers Have a Right to Know More Than There is No Safe Tobacco Product, Tob. Control J.; vol. 14: ii3-ii7, ii5 (Suppl. II 2005) (“Smokeless tobacco (SLT), for example, is substantially safer than cigarettes.”) (emphasis added); Kozlowski, L.T., “Effect of Smokeless Tobacco Product Marketing and Use on Population Harm from Tobacco Use: Policy Perspective for Tobacco-Risk Reduction, Am. J. of Preventative Medicine; vol. 33 (6S): S379-S386, S379 (2007) (recognizing the “considerable scientific consensus that smokeless tobacco products as sold in the United States, although not safe, are less dangerous than cigarettes to physical health.”) (emphasis added); M. Broadstock, New Zealand Health Technology Assessment (NZHTA), Department of Public Health and General Practice, Christchurch School of Medicine and Health Science, Systematic review of the health effects of modified smokeless tobacco products at 82 (Christchurch, New Zealand: NZHTA 2007) (“The evidence from this review suggests that the harm of using snus, relative to non tobacco use, is significantly less than found for smoking with respect to cancers of the head, neck and gastro-intestinal region, and cardiovascular disease events.”) (emphasis added); Gartner et al., Assessment of Swedish snus for tobacco harm reduction: an epidemiological
Adult Tobacco Consumers Are Alarmingly Misinformed About The Relative Risks Of Smokeless Tobacco

Despite the overwhelming scientific consensus that smokeless tobacco products like the ones sold in Canada are substantially less hazardous than cigarettes, a study shows that Canadian smokers continue to hold misconceptions regarding the relative risks of tobacco products. A study of young adult Canadian smokers shows that a significant portion incorrectly perceive smokeless tobacco products to be as harmful, or more harmful, than cigarettes:

Overall, 27.9% of respondents answered incorrectly that all four ST products were equally or more harmful to health than cigarettes. Depending on the product, between 30% and 47% of respondents incorrectly believed that ST and cigarettes are equally harmful, and a small proportion incorrectly believed that ST is more harmful than cigarettes.

Similarly, studies show that the vast majority of smokers in the United States also believe that smokeless tobacco is as harmful as cigarette smoking. For example, in 2005, a survey of over 2,000 adult U.S. smokers found that only 10.7% correctly agreed that smokeless tobacco products are less hazardous than cigarettes, while 82.9% disagreed and 6.4% did not know. As noted by the public health scientists who reported this finding:

Here, smokers are misinformed in the opposite direction. Epidemiologic data suggest that [smokeless tobacco products] sold in the United States are significantly less dangerous than cigarettes…In short, this U.S. national sample of adult smokers holds beliefs about the relative harm reduction potential of modified cigarettes and [smokeless tobacco products] that are contrary to the available scientific evidence.

Data from the Population Assessment of Tobacco and Health (“PATH”), a nationally representative survey of over 46,000 people in the United States, undertaken by the National Institutes of Health and funded by the FDA, found similar misconceptions. People do not understand that smokeless tobacco is substantially lower risk than cigarettes; 8.6% of the


44 Id. (emphasis added). Another study, published in 2007, examined adult smokers’ beliefs in the U.S, Australia, Canada, and the United Kingdom and found that among the four, “U.S. smokers were least likely to believe that SLT is less harmful, even though it is an available option for them.” R.J. O'Connor et al., Smokers' beliefs about relative safety of other tobacco products: Finding from the ITC Collaboration, 9 Nic. & Tob. Res. J. 1033-42 (2007).

45 “The Population Assessment of Tobacco and Health (‘PATH’) Study is a national longitudinal study of tobacco use and how it affects the health of people in the United States. People from all over the United States will take part in this study. The PATH Study is the first large research effort undertaken by the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) since Congress gave FDA authority to regulate tobacco products in 2009.” Additional information available at https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx.
population correctly believes that smokeless tobacco is less harmful than cigarettes, while 27.6% of the population incorrectly believes that smokeless tobacco is more harmful than cigarettes. Overall, 90% of the population thinks smokeless tobacco is as harmful, or more harmful, than cigarettes.\footnote{Data excerpted from Andrew Hyland, Ph.D., on behalf of the PATH Study Team, Presentation at the Annual Meeting of the Society for Research on Nicotine and Tobacco: Highlighted Findings From Wave 1 of the Population Assessment of Tobacco Health (PATH) Study (March 2016).}

However, according to data in the 2010-2011 wave of the Tobacco Use Supplement to the Current Population Survey ("TUS-CPS"), many long term cigarette smokers tried to quit cigarette smoking by switching to other combustible tobacco products,\footnote{Soulakova JN, Crockett LJ. Unassisted Quitting and Smoking Cessation Methods Used in the United States: Analyses of 2010-2011 Tobacco Use Supplement to the Current Population Survey Data. Nicotine Tob Res. 2016.} perhaps suggesting that consumers are unaware that in fact there is no health benefit to switching from one combustible tobacco product to another and may illustrate a broader misunderstanding of the relative risks of various tobacco products. Furthermore, some smokeless tobacco consumers switch from smokeless tobacco to cigarettes as a means to quit using smokeless tobacco. For example, Ebbert et al. reported that 9% of ST users attending a smokeless co-treatment program began using combustible products in the next week rather than using smokeless tobacco.\footnote{Ebbert JO, Klinkhammer MD, Stevens SR, et al. A survey of characteristics of smokeless tobacco users in a treatment program. Am J Health Behav. 2005;29(1):25-35.} Among a sample of male college students, 24% of former smokeless tobacco users reported using cigarettes to cease using smokeless tobacco.\footnote{Chakravorty B, Chakravorty S. Cessation related perceptions and behavior of former and current smokeless tobacco users. J Am Coll Health. 1997;46(3):133-138.} These findings collectively support that tobacco consumers make tobacco product use decisions inconsistent with the continuum of risk, likely because they do not understand the correct risk differential between combustible and non-combustible tobacco products.

The goals of harm reduction can only be achieved if smokers actually know about the relative risks of different tobacco products and, as a result, choose to use products that present a lower risk than cigarettes. The significant and alarming misconceptions held by smokers about the relative risks of different tobacco products support expanding Proposal No. 9 to allow for factual relative risk statements for smokeless tobacco.

\textbf{Accurate Risk Information May Encourage Adult Smokers to Use Lower Risk Tobacco Products}

As the Strategic Dialogue points out, "[p]olicies that shift the population to less harmful products should be explored taking into account their impact on prevention and cessation efforts and overall tobacco-related mortality."\footnote{Strategic Dialogue at 331 (emphasis added).} Therefore, manufacturers of smokeless tobacco should be allowed to communicate accurate and non-misleading information about the relative risks of their products.
We believe that because the difference in risk between cigarette smoking and smokeless tobacco use is so pronounced, the movement of adult smokers from cigarettes to smokeless tobacco products is likely to have a net public health benefit. Speaking to this issue, ACSH concluded:

Some government and health organizations and health professionals may be reluctant to tell people that smokeless tobacco use is less dangerous than cigarette smoking out of concern that this information might prompt non-users of tobacco to start using smokeless tobacco. However, the overall public health impact of any increase in smokeless tobacco use is extremely unlikely to outweigh the beneficial effect of cigarette smokers switching to smokeless tobacco, since it would require 50 people to start using smokeless tobacco to equal the degree of health risk associated with one person smoking.⁵¹,⁵²

Data excerpted from “Highlighted Findings from Wave 1 of the Population Assessment of Tobacco and Health,”⁵³ a United States government study of thousands of participants, supported the conclusion that relative risk statements could move smokers to less risky products.

The study asked, “[i]f a tobacco product made a claim that it was less harmful to health than other tobacco products, how likely would you be to use that product?”

Over 50% of established smokers said they were at least somewhat likely to use a product with a relative risk claim. If some or all of those established smokers switched entirely to smokeless tobacco products, there would likely be a health benefit to individuals and to public health. This data supports authorizing relative risk statements for categories of products that present less risk than cigarettes.

⁵¹ K. Meister, Helping Smokers Quit at 7.
⁵² This observation is bolstered by the results a study by the National Cancer Institute (“NCI”) in which a team of U.S. public health researchers, including experts in epidemiology, medicine, statistics, and economics, evaluated the health risks of smokeless tobacco products compared to cigarettes. See D.T. 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 & Prevention; vol. 13: 2035-2042, 2037 (2004).
⁵³ See Hyland, supra note 46.
Figure 2. Data excerpted from Highlighted Findings From Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study presented at the 2016 annual meeting of the Society for Research on Nicotine and Tobacco. Question: “If a tobacco products made a claim that it was less harmful to health than other products, how likely would you be to use that product?”

On the other hand, if authorized relative risk statements are only available for e-vapour products, adult tobacco consumers could be misled into believing smokeless tobacco, which would not have a relative risk statement, presents risks similar to cigarettes. As discussed above, this misconception is already significant, with 90% of the US population thinking smokeless tobacco is as harmful, or more harmful, than cigarettes. The absence of relative risk statements on smokeless tobacco may encourage, rather than correct, the misconceptions discussed above.

There is also evidence that some cigarette smokers switch to use of smokeless tobacco products and stop smoking cigarettes. According to data in the 2010-2011 wave of the TUS-CPS, 4.0% of long-term cigarette quitters switched to smokeless tobacco product use. Similar data from the 2000 wave of the NHIS indicate that a population weighted 358,668 men switched to smokeless tobacco during their most recent quit attempt.

Relative risk statements, developed by the government and used in product promotions under an established regulatory framework, may influence smokers to try and ultimately switch to less

\*54 Data excerpted from Andrew Hyland, Ph.D, Highlighted Findings From Wave 1 of the Population Assessment of Tobacco Health (PATH) Study (March 2016).
harmful products like smokeless tobacco. Therefore, Health Canada should expand Proposal No. 9 to allow manufacturers of all non-combustible tobacco products to provide consumers with accurate information about the relatives risks of these products compared to cigarettes through the use of government developed relative risk statements.

**Health Canada Should Develop Relative Risk Statements That Are Scientifically Accurate Based On The Weight Of Evidence And Actively Encourage Smokers To Switch To Less Harmful Products**

The Proposal indicates that Health Canada “Could set out…the conditions upon which manufacturers, retailers and others could use these statements in vaping product promotions, including on product packages.”

We believe that scientific standards for developing and evaluating relative risk statements must be rigorous. These standards, however, cannot be so stringent that they essentially prevent manufacturers from promoting their products with factual relative risk statements. Health Canada must strike a balance to ensure that it sufficiently evaluates relative risk statements without unduly inhibiting their introduction into the marketplace. Further, the relative risk statements should affirmatively encourage smokers to switch products. The relative risk statements should not include so many disclaimers or qualifications as to make the statements confusing or ineffective in encouraging smokers to switch to less harmful products.

Given the potential public health benefit, we encourage Health Canada to adopt an approach for evaluating and issuing reduced risk statements that do not let some uncertainty inhibit the availability of authorized relative risk statements if the overall weight of evidence supports such a statement.

**Conclusion**

Health Canada has an opportunity to reduce tobacco-related harm by helping individuals who would otherwise continue to smoke cigarettes move to demonstrably less hazardous products like smokeless tobacco. We urge the government to recognize the continuum of risk in the regulation of smokeless tobacco products.

Cigarette smoking is the overwhelming cause of tobacco related harm. Experts agree that smokeless tobacco presents significantly less risk than cigarette smoking. Despite this fact, tobacco users are alarmingly misinformed about the relative risks of different tobacco products. Health Canada should expand Proposal No. 9 to allow smokeless tobacco manufacturers to use relative risk statements in their product promotions. This could drive smokers to switch to

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57 Consultation, p. 8.
smokeless tobacco and could reduce smoking related morbidity and mortality. Importantly, Health Canada should create reasonable regulations for allowing smokeless manufacturers to promote their products to adult smokers using these statements.

In the United States, the FDA Commissioner indicated that “we must recognize the potential for innovation to lead to less harmful products, which, under FDA’s oversight, could be part of a solution.”59 Smokeless tobacco is such a product and could be part of a solution under effective, evidence-based regulation by Health Canada.

We appreciate the opportunity to provide our views and look forward to future opportunities to engage with Health Canada. If you have questions, please feel free to contact me. I can be reached at j.f.turcotte@nstco.ca or 514-697-5577.

Sincerely,

J.F. Turcotte
President
National Smokeless Tobacco Company, Limited

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