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Consultation on Potential Regulatory Measures to Reduce Youth Access and Appeal of Vaping Products: Evidence and Recommendations from the U.S. Experience

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1. Health Canada should prohibit all flavors in all e-cigarette products

The tobacco companies, including their e-cigarette companies, add characterizing flavors like mint, menthol, fruit, and candy to tobacco to attract young and new users, often using the same flavorants that are in fruit-flavored candy, and sometimes at higher doses.[1] These flavors appeal to new users by masking the harsh taste of tobacco, and in the case of e-cigarettes, resulting in a more pleasant smell than that found with tobacco alone.

Flavor or "taste" is one of the most common persuasive marketing techniques used to promote food (mostly candy and snacks) to children on TV.[2] Exposure to ads for flavored

[1] Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. N Engl J Med. 2014;370(23):2250-2252.

[2] Jenkin G, Madhvani N, Signal L, Bowers S. A systematic review of persuasive marketing techniques to promote food to children on television. Obesity reviews. 2014;15(4):281-293.

products is positively associated with youth consumption,[3] and most money spent by youth is on food or beverages, particularly sweets.[4] Research on e-cigarettes shows the same thing, concluding: flavors play an important role for online e-cigarette marketing and boosts user interaction and positive emotion;[5] flavored (vs. unflavored) e-cigarette ads elicit greater appeal and interest in buying and trying e-cigarettes; and the appeal of ads marketing flavors is linked to rapid and persistent adoption of e-cigarettes among youth.[6]

Youth are Attracted to Flavored Tobacco Products

Looking at the experience in the United States, which is likely similar to the Canadian experience, the vast majority of youth in the US who try tobacco initiate with flavored tobacco products, including 81% of e-cigarette ever users, 65% of cigar ever users, and 50% of cigarette ever smokers.[7] Adolescents are more likely to report interest in trying an e-cigarette from a friend if it is menthol-, candy-, or fruit-flavored than if unflavored.[8] Flavor preferences are associated with higher e-cigarette use among adolescents.[9] Most adolescent current tobacco users cite flavors as a reason for use (including 81% for past 30-day e-cigarette users; 74% for past 30-day cigar users).[10] Three quarters of adolescent and young adult flavored tobacco product users reported they would quit if flavors were unavailable.[10]

Youth and young adult tobacco users are more likely than older adult tobacco users to use flavored products, including menthol cigarettes,[11] flavored smokeless tobacco,[12] and flavored cigars.[13] Young smokers (12-17 years of age) are three times as likely to smoke menthol

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[3] Cairns G, Angus K, Hastings G, Caraher M. Systematic reviews of the evidence on the nature, extent and effects of food marketing to children. A retrospective summary. Appetite. 2013;62:209-215.

[4] Kraak VI, Gootman JA, McGinnis JM. *Food marketing to children and youth: Threat or opportunity?* National Academies Press; 2006.

[5] Liang Y, Zheng X, Zeng DD, Zhou X. Impact of flavor on electronic cigarette marketing in social media. 2015:278-283.

[6] Vasiljevic M, Petrescu DC, Marteau TM. Impact of advertisements promoting candy-like flavoured e-cigarettes on appeal of tobacco smoking among children: An experimental study. *Tob Control*. 2016;25(e2):e107-e112.

[7] Ambrose B, Day H, Rostron B, et al. Flavored tobacco product use among us youth aged 12-17 years, 2013-2014. *J Am Med Assoc*. 2015;314(17):1-3. doi:10.1001/jama.2015.13802.

[8] Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. *Tob Control*. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.

[9] Morean ME, Butler ER, Bold KW, Kong G, Camenga DR, Cavallo DA, Simon P, O'Malley SS, Krishnan-Sarin S. Preferring more e-cigarette flavors is associated with e-cigarette use frequency among adolescents but not adults. PloS one. 2018 Jan 4;13(1):e0189015

[10] Loukas A, Jackson CD, Marti CN, Perry CL. Flavored tobacco product use among youth and young adults: What if flavors didn't exist? *Tob Regul Sci*. 2017;3(2):168-173.

[11] Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control*. 2016;25(Suppl 2):ii14-ii20. doi:10.1136/tobaccocontrol-2016-053329.

[12] Oliver AJ, Jensen JA, Vogel RI, Anderson AJ, Hatsukami DK. Flavored and nonflavored smokeless tobacco products: Rate, pattern of use, and effects. *Nicotine Tob Res*. 2013;15(1):88-92. doi:10.1093/ntr/nts093.

[13] Delnevo CD, Giovenco DP, Ambrose BK, Corey CG, Conway KP. Preference for flavoured cigar

cigarettes than smokers 35 years and older.[14] Research among approximately 4000 school-going youth shows that for 98% of them, first e-cigarettes used were flavored to taste like something other than tobacco, compared to 44.1% of older adults nationwide. Fruit and candy flavors predominated for all groups; and, for youth, flavors were an especially salient reason to use e-cigarettes.[15] Finally, a 2018 study showed that only 1.5% of adolescent and young adult e-cigarette users used tobacco flavored-Juuls and .9% used tobacco-flavored other e-cigarette products. Instead, the majority used fruit or dessert flavors (33% for Juul users and 64% for other e-cigarette users) and 27% of Juul users and 12% of other e-cigarette users used mint or menthol flavors.[16]

Youth Believe Ads for Flavored E-cigarettes Target Them

Using flavors in e-cigarettes is a key marketing strategy to reach and recruit youth. In a 2014 study of English-language websites, over 7,700 flavors for e-cigarettes were available, with greater than 240 new flavors being added per month.[17] What is most important is that youth find flavored e-cigarette ads are relevant to them.

In a U.S. study,[18] California adolescents and young adults (mean age 17.5, SD = 1.7), were asked to indicate whether eight different ads for flavored e-liquids (Figure 1), randomly displayed, target someone younger than them, their age, a little older, or much older. Overall, ads were found to target someone just a little older than them (age 18 – 26), their age, and those youger, but were not found to target someone much older. More than half of participants felt ads for *cherry*, *vanilla cupcake*, *caramel*, and *smoothie* flavors were for someone their age. These findings suggest that while the tobacco industry argues that flavored tobacco products, including sweet and fruit flavored products, are not meant to attract youth, youth see them as aimed at them. ***Further, these and similar findings suggest that Health Canada should prohibit all flavors in e-cigarettes.***

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brands among youth, young adults and adults in the USA. *Tob Control*. 2014;24(4):389-394. doi:10.1136/tobaccocontrol-2013-051408.

[14] Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control*. 2016:1-7. doi:10.1136/tobaccocontrol-2016-053329.

[15] Harrell MB, Weaver SR, Loukas A, Creamer M, Marti CN, Jackson CD, Heath JW, Nayak P, Perry CL, Pechacek TF, Eriksen MP. Flavored e-cigarette use: Characterizing youth, young adult, and adult users. Preventive medicine reports. 2017 Mar 1;5:33-40

[16] McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. JAMA Network Open, 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

[17] Zhu SH, Sun JY, Bonnevie E, Cummins SE, Gamst A, Yin L, Lee M. Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. Tobacco control. 2014 Jul 1;23(suppl 3):iii3-9

[18] McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Youth Say Ads for Flavored E-liquids are for Them. Addictive Behaviors, in press.

Figure 1. Flavored e-cigarette ads shown to adolescents and young adults to elicit perceptions of the age of audience being targeted for each ad.

There is not good evidence to support the industry claim that flavors are necessary to help adults quit smoking

Before considering whether flavorings help adult tobacco smokers quit smoking combustible tobacco products, it is important to emphasize that, while some smokers have successfully quit smoking using e-cigarettes (notably daily users of high nicotine delivery systems), most smokers who use e-cigarettes are *less* not more likely to quit smoking. A meta-analysis of existing studies reports that the odds of quitting cigarettes are significantly reduced (OR 0.77, 95% CI 0.06-0.99) among smokers who use e-cigarettes compared to smokers who do not use e-cigarettes.[19] ***In other words, the overall effect of e-cigarette use is to depress smoking cessation, and thus flavored e-cigarettes do not increase likelihood of cigarette cessation.***

A recent randomized control trial[20] randomized adult cigarette smokers to either nicotine replacement therapy or second-generation e-cigarettes, both coupled with behavioral support, to determine which product best helped adults quit smoking. They did find that while neither NRTs or the e-cigarettes helped the majority of adult smokers quit, the e-cigarettes were more effective overall, compared to the NRTs. While the e-cigarettes used in the trial included flavors, the effect of flavors on cessation was not addressed. Overall, the results suggest that e-cigarettes, ***used as part of a structured cessation program along with intensive counseling,*** could be effective at reducing cigarette use among adults already seeking or interested in cessation.

[19] Glantz S. While several studies have been published showing some e-cig users quit more, the overall picture remains negative. https://tobacco.ucsf.edu/while-several-studies-have-been-published-showing-some-e-cig-users-quit-more-overall-picture-remains-negative April 9, 2018; Kalkhoran S, Glantz SA. E-cigarettes and smoking cessation in real-world and clinical settings: A systematic review and meta-analysis. Lancet Respir Med 2016 Feb;4(2):116-28. The 2018 analysis updates the Kalkhoran, Glantz meta-analysis published in 2016, which is updated every time a new study is published. The conclusion that, overall, e-cigarettes depress quitting has remained stable.

[20] Hajek, P, Phillips-Waller, A., Przulj, D., Pesola, F., Myers Smith, K., Bisal, N., Li, J, Parrott, S., Sasieni, P., Dawkins, L., Ross, L., Goniewicz, M., Wu, Q, and McRobbie, H. A randomized trial of e-cigarettes versus nicotine replacement therapy. NEJM, 2019 Feb 14;380(7):629-637.

These recent findings argue that e-cigarettes should be used only in structured medically supervised environments and only through a prescription. This would keep e-cigarettes out of the hands of youth and ensure that only adult smokers are using the products, and are doing so under a health providers' care. Importantly, this study does not suggest that e-cigarettes are effective at helping all adult smokers quit smoking, nor does it support having e-cigarettes available on the mass market.

In the US, FDA noted the existence of preliminary data that some adults may use flavored noncombusted tobacco products (e.g., flavored e-cigarettes) to transition away from combusted tobacco, and said that "under a properly regulated framework that protects youth,"[21] flavors may help some currently addicted adult cigarette smokers switch to non-combustible forms of tobacco products. However, in a nationally-representative sample of US tobacco users, Smith and colleagues found that over 70% of respondents reported flavored tobacco products as first tobacco product used, and 54% reported current use of at least one flavored product. Those who reported first using a flavored product had increased odds of current flavored product use (OR 14.82, 95% CI 9.96 to 22.06) and being a current tobacco user (OR 1.55, 95% CI 1.08 to 2.22). Polytobacco users had greater odds of reporting current use of flavored products (OR 2.09, 95% CI 1.47 to 2.97) compared to single-product users. Adjusted analyses among current non-cigarette tobacco product users of at least one flavored tobacco product showed reduced odds of reporting a past-year quit attempt.[22]

Of 32 papers identified in a May 2018 literature review that considered e-cigarettes (or ENDS) and flavors and quitting (or cessation), only two included evidence on the effect of flavors on adult cigarette cessation. Chen[23] found that young adults (age 18-34) in Waves 1 and 2 of the Population Assessment of Tobacco and Health (PATH) Study who used e-cigarette flavors (sweet and fruity vs. tobacco and menthol/mint) were more likely to have reduced or stopped smoking cigarettes. In particular, e-cigarette users with one (AOR = 2.5, $p < 0.001$) and multiple non-tobacco or menthol flavors (AOR = 3.0, $p < 0.001$) were more likely to have reduced or quit smoking over the past year compared to non-e-cigarette users. (It is not clear how "smoking reduction" was defined.) While the longitudinal nature of this study is a strength, the failure to distinguish between reduction of number of cigarettes smoked and smoking cessation is a serious limitation. Tackett et al.[24] conducted a cross-sectional study of a convenience sample of 215 adult e-cigarette users recruited in vape shops in "a large metropolitan city in the Midwestern United States" in 2013. They found that most customers (86%) started using e-cigarettes as an aid to stopping smoking. While most started with tobacco flavored e-liquids, the authors found that those using non-tobacco and non-menthol flavored e-liquids (fruity, coffee,

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[21] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm601690.htm

[22] Smith DM, Bansal-Travers M, Huang J, Barker D, Hyland AJ, Chaloupka F. Association between use of flavoured tobacco products and quit behaviours: findings from a cross-sectional survey of US adult tobacco users. Tob Control. 2016 Nov;25(Suppl 2):ii73-ii80.

[23] Chen J. Flavored E-cigarette Use and Cigarette Smoking Reduction and Cessation-A Large National Study among Young Adult Smokers. Subst Use Misuse. 2018 Apr 6:1-15. doi: 10.1080/10826084.2018.1455704. [Epub ahead of print]

[24] Tackett AP, Lechner WV, Meier E, Grant DM, Driskill LM, Tahirkheli NN, Wagener TL. Biochemically verified smoking cessation and vaping beliefs among vape store customers. Addiction. 2015 May;110(5):868-74. doi: 10.1111/add.12878

candy, etc.) were significantly more likely to have stopped smoking cigarettes compared to e-cigarette users who used tobacco or menthol flavored e-liquids. Strengths of this study are that it observed the relationship between smoking behavior and flavors, and that most participants had their smoking status verified with exhaled CO. Weaknesses are that the study was cross-sectional and that there was no control group of smokers who did not use e-cigarettes. In addition, the authors note that "specialty vapor stores may be serving individuals with vaping characteristics distinct from those purchasing their products from convenience stores, gas stations, or online."

Smith et al.[22] reported results of a nationally representative, telephone-based survey completed in 2012 by 1443 US adult tobacco users asked about use of 9 tobacco products: cigarettes, e-cigarettes, cigars, cigarillos, little filtered cigars, pipes, hookah, smokeless tobacco and snus. They found that use of flavored tobacco products when users first started using tobacco products was associated with current flavored tobacco use and polytobacco use. Users of flavored non-cigarette products were less likely to have made a cigarette quit attempt than those who did not use flavored non-cigarette products (OR 0.45 95% CI 0.30-0.67), and were more likely to be current cigarette smokers (OR 1.55, 95% CI 1.08-2.22) than people who used non-flavored tobacco products (including cigarettes). Thus, this cross-sectional study shows that ***the presence of flavors was associated with* less *cigarette cessation.***

Mint and Menthol flavors should not be excluded from any flavor prohibitions in e-cigarette products

In the U.S. the FDA announced in November 2018[25] a proposed policy that would restrict youth access to flavored e-cigarettes and e-liquids, but the proposed policy specifically excluded mint, menthol, and tobacco-flavored e-cigarette products. The FDA's proposed policy leaves the industry free to use some of the most popular flavors that attract youth and should not be adopted by Health Canada.

Data from the most recent National Youth Tobacco Survey released in the U.S. in November 2018 show that "Among high school students, during 2017–2018, current use of any flavored e-cigarettes increased among current e-cigarette users (from 60.9% to 67.8%, p = 0.02); current use of menthol- or mint-flavored e-cigarettes increased among all current e-cigarette users (from 42.3% to 51.2%, p = 0.04) and current exclusive e-cigarette users (from 21.4% to 38.1%, p = 0.002)."[26] Finally, there is compelling recent evidence showing that youth use mint and menthol e-cigarettes. In a recent study published in JAMA Online Network, the authors found that almost 27% of youth in their study used mint or menthol flavored Juuls, and 12% used

[25] FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm

[26] CDC, National Youth Tobacco Survey (NYTS). Cullen KA, Ambrose BK, Gentzke AS, et al. *Notes from the Field*: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018. MMWR Morb Mortal Wkly Rep 2018;67:1276-1277. DOI: http://dx.doi.org/10.15585/mmwr.mm6745a5

mint or menthol other e-cigarette styles.[27] McKelvey and colleagues also showed that mint and menthol are used widely by youth, as noted earlier.[28]

Because these data show that the majority of high school students who use e-cigarettes use mint- or menthol-flavored products, Health Canada should not adopt a flavor restriction that would exclude mint or menthol and instead adopt regulations banning all flavors in all products as part of its overall effort to protect youth.

Despite tobacco industry claims that menthol simply adds flavor, tobacco industry documents have revealed that the industry manipulates menthol levels to control a cigarette's intensity to cater to new and long-term smokers.[29]

Menthol and other characterizing flavors appeal to new users by masking the harsh taste of tobacco, and bright packaging associates flavored tobacco products with candy and other flavors.[30,31] Additionally, tobacco products with a characterizing flavor including fruit-flavored e-cigarettes[32] and menthol cigarettes[14] are perceived to be less harmful than unflavored or tobacco-flavored products. In addition, menthol cigarettes are harder to quit.[33,34]

Mint and menthol target vulnerable youth. In the general population, differences in menthol use exist across race, gender, age, and sexual orientation. Rates of use of menthol flavored tobacco products are often higher in marginalized populations. African American smokers consistently have the highest menthol use rate.[35] Menthol use is also higher among female smokers;[27] Lesbian, Gay, and Bisexual smokers[36] (although see Rath et al 2013[37]); people

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[27] McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. JAMA Network Open, 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

[28] McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. JAMA Network Open, 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

[29] Kreslake JM, Wayne GF, Alpert HR, Koh HK, Connolly GN. Tobacco industry control of menthol in cigarettes and targeting of adolescents and young adults. Am J Public Health. 2008;98(9):1685-1692. doi:10.2105/AJPH.2007.125542.

[30] Yerger VB. Menthol's potential effects on nicotine dependence: a tobacco industry perspective. Tob Control. 2011;20(Suppl 2):ii29-i36. doi:10.1136/tc.2010.041970.

[31] Lewis MJ, Wackowski O. Dealing with an innovative industry: A look at flavored cigarettes promoted by mainstream brands. Am J Public Health. 2006;96(2):244-251. doi:10.2105/AJPH.2004.061200.

[32] Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. Tob Control. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.

[33] Pletcher MJ, Hulley BJ, Houston T, Kiefe CI, Benowitz N, Sidney S. Menthol cigarettes, smoking cessation, atherosclerosis, and pulmonary function. 2006;166.

[34] Trinidad DR, Pérez-Stable EJ, Messer K, White MM, Pierce JP. Menthol cigarettes and smoking cessation among racial/ethnic groups in the United States. Addiction. 2010;105(SUPPL.1):84-94. doi:10.1111/j.1360-0443.2010.03187.x.

[35] Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control*. 2016:1-7. doi:10.1136/tobaccocontrol-2016-053329.

[36] Fallin A, Goodin AJ, King BA. Menthol cigarette smoking among lesbian, gay, bisexual, and

with severe psychological distress; people with fewer years of education and lower income; and those who are unmarried or uninsured.[38]

In the US, the tobacco industry cultivated menthol use among African Americans by manipulating social factors of the civil rights era,[39] advertising menthol brand cigarettes, little cigars, and cigarillos in African American media and retail settings in African American neighborhoods,[40,41] and donating to African American leadership organizations.[42] The strategy has been so successful that even by 6th grade, African American youth were three times more likely to recognize menthol brands than their peers.[43]

In the draft version of the 2016 "deeming" rule in which the FDA took authority over e-cigarettes, FDA presented overwhelming evidence, supported by comments it received on the then-proposed rule, that menthol, as well as candy and fruit-flavored tobacco products, attract youth to tobacco use and deter quitting. In particular, FDA presented evidence demonstrating the impact of menthol and other flavors in enticing African Americans to begin and continue smoking:

> "FDA expects that the tobacco flavor in a tobacco product need not be naturally inherent to the product in order for a manufacturer to fall within the compliance policy described here, but rather may result from the addition of ingredients or other measures by the manufacturer to result in the presence of tobacco as a characterizing flavor. However, menthol flavored products will be treated the same as products with characterizing flavors other than tobacco for the purpose of this policy, because when it is used as a characterizing flavor, menthol has a similar impact on a product's appeal to youth and young adults as such other characterizing flavors. We note that newly-deemed flavored tobacco products that are not grandfathered may still need to address the public health implications of any added flavors, including tobacco flavor, in their pre-market review

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transgender adults. *Am J Prev Med*. 2015;48(1):93-97. doi:10.1016/j.amepre.2014.07.044.

[37] Rath JM, Villanti AC, Rubenstein RA, Vallone DM. Tobacco use by sexual identity among young adults in the united states. *Nicotine Tob Res*. 2013;15(11):1822-1831. doi:10.1093/ntr/ntt062.

[38] Hickman NJ, Delucchi KL, Prochaska JJ. Menthol use among smokers with psychological distress: findings from the 2008 and 2009 National Survey on Drug Use and Health. *Tob Control*. 2014;23(1):7-13. doi:10.1136/tobaccocontrol-2012-050479.

[39] Gardiner PS. The African Americanization of menthol cigarette use in the United States. *Nicotine Tob Res*. 2004;6 Suppl 1:S55-65. doi:10.1080/14622200310001649478.

[40] Henriksen L, Schleicher NC, Dauphinee AL, Fortmann SP. Targeted advertising, promotion, and price for menthol cigarettes in California high school neighborhoods. *Nicotine Tob Res*. 2012;14(1):116-121. doi:10.1093/ntr/ntr122.

[41] Kostygina G, Glantz SA, Ling PM. Tobacco industry use of flavours to recruit new users of little cigars and cigarillos. *Tob Control*. 2014:tobaccocontrol-2014-051830-. doi:10.1136/tobaccocontrol-2014-051830.

[42] Yerger VB, Malone RE. African American leadership groups: Smoking with the enemy. *Tob Control*. 2002;11(4):336-345. doi:10.1136/tc.11.4.336.

[43] Dauphinee AL, Doxey JR, Schleicher NC, Fortmann SP, Henriksen L. Racial differences in cigarette brand recognition and impact on youth smoking. *BMC Public Health*. 2013;13(1):170. doi:10.1186/1471-2458-13-170.

submissions."[44]

Unfortunately, FDA ignored this evidence and made an exclusion for menthol flavored tobacco products in the final rule that was implemented. ***Health Canada should not make the same mistake.***

Taken together, these data clearly show that youth do use mint and menthol flavors, that such flavorants are purposely added to attract both users and non-users, and that mint and menthol attract youth. Although much of these data are from research conducted in the U.S., they nevertheless support the inclusion of mint and menthol in any ban on flavored e-cigarette products in Canada.

Industry-funded research claiming that flavors do not attract youth is weak

As discussed above, the evidence that flavors attract youth is very strong and consistent. In contrast, the evidence to the contrary is limited to industry-funded research that has an obvious conflict of interest.

In particular, Shiffman et al.[45] reported the results of an online survey in which they concluded that "interest in e-cigarettes is very low among nonsmoking teens and is not affected by flavor descriptors." This conclusion is unlikely to be reliable because it is based on responses to a single question on interest in flavors that makes the results likely affected by floor (and ceiling) effects.[46,47] This paper was funded by the NJOY e-cigarette company and whose authors all work for Pinney Associates on projects with Reynolds American Inc. on smoking cessation and reduced risk tobacco products.[48] The paper suffers from serious methodological problems that biased the results against finding an effect of flavors. Contrary to Shiffman et al.'s findings, the impact of flavor descriptors on nonsmoking teens' and adult smokers' interest in e-cigarettes is not a reliable estimate of the effects of e-cigarette flavors on product desirability. The single question they used in the survey could not estimate the willingness of teens to try flavored e-cigarettes when presented with an opportunity.

One of the largest problems with the findings from Shiffman et al. was the measures used. Floor and ceiling effects occur when a measuring instrument is not sensitive enough to detect the real differences between participants when their answers are clumped at the low or high end of the possible range of values. An example of a floor effect would be testing mathematical knowledge using a problem that is so difficult that no one can solve it; thus, it will

[44] TAB B 2014-850 Deeming Final Rule Redline Changes, p.169. Available at: https://www.regulations.gov/document?D=FDA-2014-N-0189-83193

[45] Shiffman S, Sembower MA, Pillitteri JL, Gerlach KK, Gitchell JG. The impact of flavor descriptors on nonsmoking teens' and adult smokers' interest in electronic cigarettes. *Nicotine Tob Res* 2015:ntu333. doi: 10.1093/ntr/ntu333

[46] Martin P, Bateson PPG. *Measuring behaviour: An introductory guide*: Cambridge University Press; 1993.

[47] Newman AB, Cauley JA. *The epidemiology of aging*: Springer; 2012.

[48] Pinney Associates. Tobacco harm reduction. http://www.pinneyassociates.com/our-practices/tobacco-harm- reduction/

not reveal the true differences in mathematical knowledge. Shiffman et al. found almost no interest in any flavors of electronic cigarettes among teenagers who have never tried tobacco products (including e-cigarettes) and very low interest among adult smokers based on responses to a single question (albeit about 24 different flavors/products): "How interested would you be in using a [flavor] [product]?" The problem with just using a single question is that most people (especially those who are not yet tobacco users) are not interested in using a product even though they might be interested in trying it or using it in a specific situation, thus resulting in a floor effect.

To avoid the problem of a single question not measuring the variable of interest, surveys typically use more than one question to assess smoking behavior and intentions. For example, openness to smoking (or interest in smoking) is typically measured by at least two questions in most large surveys, such as the following questions from the National Youth Tobacco Survey:[49]

> "Do you think you will smoke a cigarette anytime during the next year? If one of your best friends offered you a cigarette, would you smoke it?"

As a result, Shiffman et al.'s findings of limited interest in flavors, especially among youth, is likely to be the result of an insensitive measurement method rather than a real effect.

A study of smokers' interest in smokeless tobacco illustrates the importance of how the question is worded.[50] Smokers reported very low interest in smokeless tobacco products (mean 1.5 on a 1-9 scale) when asked about use in general. However, when they were asked about smokeless tobacco use in specific situations, such as "How interested would you be in using this product when in a smokefree environment?" (mean=3.2) or for a specific reason, such as "to reduce health risk," they reported greater interest (mean interest=4.2).

In contrast to the hypothetical interest Shiffman et al. assessed, real world behavior indicates that while under 10% of the of adults who ever tried e-cigarettes reported that they tried them because of "appealing flavors,"[51] 43.8% of youth listed "good flavors" as the reason they tried e-cigarettes.[52]

There are also serious concerns about the ethics of the study. The authors state that the work was "exempt" from human subjects because they were using de-identified data collected by a third-party internet survey firm. While subject confidentiality is certainly an issue, so is the fact that Shiffman et al. were subjecting youth (as well as adults) to stimuli that could increase the

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[49] Centers for Disease Control and Prevention. National Youth Tobacco Survey (NYTS). [1] Retrieved January 15, 2015 from http://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm.
[50] Popova L, Ling P. Alternative tobacco product use and smoking cessation: A national study. *Am J Pub Health.* 2013;103:923-930. doi: 10.2105/AJPH.2012.3010
[51] Pepper JK, Ribisl KM, Emery SL, Brewer NT. Reasons for starting and stopping electronic cigarette use. *Int J Environ Res Pub Health* 2014;11(10):10345-10361. doi: 10.3390/ijerph111010345
[52] Kong G, Morean ME, Cavallo DA, Camenga DR, Krishnan-Sarin S. Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults. *Nicotine Tob Res* 2014:ntu257. doi: 10.1093/ntr/ntu257

respondents' likelihood to try an e-cigarette, thereby possibly introducing them to nicotine addiction. There is no acknowledgement of this risk to the subjects or steps taken after the survey was completed to mitigate these risks. Further, there is no discussion that informed consent from the minors' parents or the adults participating in the study was not obtained. The Shiffman study also suffers from poor quality because it fails to report or describe of any of these issues as limitations. Such studies typically include anti-tobacco education at the end to try and blunt the effect of any pro-tobacco or pro-e-cigarette effects of collecting the data. Finally, even studies conducted using a third- party and with data collected using Internet-based surveys usually have some form of IRB approval and consent process.

For these reasons, the Health Canada should not rely on the results in Shiffman et al.'s paper to dismiss the overwhelming evidence that flavors attract youth to e-cigarette use.

2. Health Canada should restrict the nicotine delivery (not just the nicotine concentration) in vaping products

Why nicotine delivery should be reduced: the original Benowitz and Henningfield proposal

The original proposal to reduce the nicotine content in cigarettes was published by Benowitz and Henningfield in 1994.[53] The rationale for that proposal was primarily to prevent youth who experimented with cigarette smoking from becoming addicted adult smokers. While most youth who try cigarettes begin for social reasons and indicate that they do not intend to remain smokers as adults, when surveyed 5 years later most have become addicted smokers and are unable to quit. A non-addicted person cannot truly appreciate what drug addiction is like, and therefore cannot make a reasonably informed consent to take that risk. Cigarettes are manufactured with nicotine content and delivery levels that will sustain addiction, based on tobacco company research. Thus, a young person who begins smoking for social reasons may transition to smoking for the pharmacologic effects of nicotine and ultimately become an addicted adult smoker. Cigarettes that deliver nicotine in levels that produce addiction are unreasonably dangerous in part because consent to their use by youth is impossible. Thus, reducing nicotine levels will likely significantly reduce the probability likelihood that a youth experimenting with cigarettes would become addicted.

It is important to regulate nicotine **delivery** *not just the concentration of nicotine in e-liquids*

The important determinant of the addictive potential of e-cigarettes is the nicotine ***delivery,*** not just the nicotine concentration in the e-liquid because it is possible to increase nicotine delivery from an e-cigarette by increasing the power (voltage) without changing the concentration of nicotine in the e-liquid.

In particular, Juul is working to develop a pod with lower nicotine content that will deliver the same "hit" by increasing the voltage in the device to get around European Union rules on nicotine in e-cigarettes. This is one more illustration of how Juul is acting like any other

[53] Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. The implications for tobacco regulation. N Engl J Med. 1994 Jul 14;331(2):123-5.

tobacco company in working to get around the rules. The fact that they are modifying the product in a way that increases the risks is especially cynical given that they claim to be interested in harm reduction.

Additionally, Juul's unprecedentedly high nicotine concentration pods labeled variously as "5%" (by weight) and "5.9%" (by volume) causes consumer confusion, especially among youth, and has triggered competitors to market e-liquids in similarly high nicotine concentrations, raising concerns about addictiveness and toxicity.[54]

Alan Shihadeh and Tom Eissenberg at VCU identified this loophole in the EU regulations in their 2015 paper "Electronic Cigarette Effectiveness and Abuse Liability: Predicting and Regulating Nicotine Flux"[55] when they wrote:

> While attending to variables in combination using nicotine flux offers regulatory advantages, the opposite case, failing to account for variables in combination, can lead to regulations that do not serve their intended purpose. For example, European Union Directive 2014/40/EU recently mandated a limit of 20mg/ml liquid nicotine concentration for the purpose of "allow(ing) for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette." This regulation fails to account for the fact that nicotine concentration alone does not determine nicotine yield and, almost certainly, nicotine delivery to the user. That is, recent data and theoretical analyses suggest that, depending on user-selected battery voltage and heater resistance as well as user puff topography, a given ECIG loaded with 20mg/ml liquid can emit an aerosol that contains far more or far less nicotine than the smoke from a standard cigarette.

In addition, running at a higher temperature increases nicotine delivery, as well as generation of the other toxic chemicals in e-cigarettes.

Industry efforts to minimize the health risks of nicotine should not affect Health Canada's rulemaking

Since the 1988 U.S. Surgeon General's Report on Nicotine Addiction, the tobacco industry has worked to undermine public perceptions of the addictiveness of nicotine, and to normalize its use. These efforts included coordinated programs, such as the 1980s-1990s promotion of the "Associates for Research in the Science of Enjoyment" (ARISE) whose members included prominent social scientists, physiologists and philosophers who toured the world promoting the health benefits of the use of legal substances, including tobacco, for stress relief and relaxation.[56] In addition, the cigarette companies worked for decades to shift the debate on tobacco from the

[54] Jackler RK, Ramamurthi D. (2019) Nicotine arms race: JUUL and the high-nicotine product market. *Tob Control.* 2019 Feb 6. pii: tobaccocontrol-2018-054796. doi: 10.1136/tobaccocontrol-2018-054796. [Epub ahead of print]

[55] Shihadeh A, Eissenberg T, Electronic Cigarette Effectiveness and Abuse Liability: Predicting and Regulating Nicotine Flux.. Nicotine Tob Res. 2015 Feb; 17(2): 158–162.

[56] Landman A, Cortese DK, Glantz S. Tobacco industry sociological programs to influence public beliefs about smoking. Soc Sci Med. 2008 Feb;66(4):970-81. doi: 10.1016/j.socscimed.2007.11.007. PubMed PMID: 18164524; PubMed Central PMCID: PMC2267871.

addictive qualities of nicotine and the adverse health effects of smoking to smokers' perceptions of the physiological benefits from nicotine, in order to counter declining cigarette sales and improve the tobacco industry's image using carefully crafted research programs and promotion of their findings to the scientific community, the other tobacco companies, and to the public. Communication strategies promoted messages that undermined perceptions of nicotine's potential health risks by comparing it with socially accepted substances such as caffeine and coffee. Tobacco industry documents describe a consistent and long-running effort by tobacco companies and their industry-funded scientific collaborators to promote nicotine while minimizing its health risks.[57]

With the growing popularity of alternative nicotine products, including but not limited to electronic cigarettes, many of the messages normalizing nicotine, trivializing addiction, or even promoting nicotine as a cognitive enhancer have been reflected in the public dialogue about nicotine. For example, authors in the popular press (such as newspaper, magazine articles, blogs, and books[58]) make assertions that nicotine has health benefits such as improved concentration and memory, relaxation, alertness, and use as a treatment for neurological disorders.

Adolescents' and Young Adults' Perceptions of Nicotine, and effects of perceptions of risk on using other tobacco products

Youth and young adults hold perceptions about nicotine that differ from those for other tobacco constituents. Wiseman et al. conducted a study of adolescents (age 13-17) and young adults (ages 18-25), utilizing focus groups to elicit participants' knowledge and beliefs related to the chemical constituents in novel (non-cigarette) tobacco products.[59] Nearly all participants were familiar with nicotine, arsenic, carbon monoxide, and formaldehyde. Whereas participants near universally raised health concerns and expressed negative views about arsenic, carbon monoxide, formaldehyde, and other less-familiar constituents (such as benzene and N-nitrosonornicotine), there was less agreement and some confusion related to the properties and health risks of nicotine. Participants agreed that nicotine was addictive and could cause illness at high doses but were uncertain about how nicotine influences the body. The study relayed a quote from a young adult tobacco non-user:

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[57] Glantz SA, Ling PM. Tobacco company strategies to identify and promote the benefits of nicotine. Tobacco Control. 2019 May;28(3):289-296.

[58] Alban, D. Nicotine: an unlikely brain enhancing drug. Be Brain Fit. Better Mind. Better Life. https://bebrainfit.com/nicotine-brain-enhancing-drug/ Accessed June 12, 2018.
Sutherland, R. The Wiki Man: So it might really be true – nicotine is good for your brain. The Spectator. 27 April 2013. https://www.spectator.co.uk/2013/04/so-maybe-its-true-smoking-does-make-you-smarter/ Accessed June 12, 2018.
Tri. Nicotine as a smart drug. Examined Existence. https://examinedexistence.com/nicotine-as-a-smart-drug/
Accessed June 12, 2018.
Hurley, D. Smarter: The new science of building brain power. Penguin Random House. December 2014.

[59] Wiseman KD, Cornacchione J, Wagoner KG, Noar SM, Moracco KE, Teal R, Wolfson M, Sutfin EL. Adolescents' and Young Adults' Knowledge and Beliefs About Constituents in Novel Tobacco Products. Nicotine Tob Res. 2016 Jul;18(7):1581-7.

"I know what nicotine is, but I don't honestly know that much about it."[60]

Nicotine-related beliefs differed between tobacco users and non-users, with nicotine users generally concerned about addiction. However, tobacco users typically shared positive views of nicotine. Wiseman, et al. quoted one young adult: "...I feel like nicotine, I don't know, it helps me concentrate a lot. Like if I'm stressed out, it's a good de-stresser...."[61]

Other research has shown that youth and young adults misperceive nicotine addiction, and that addiction is a particularly challenging for public health messaging. Adolescents may report that cigarettes are addictive, but they remain uncertain regarding the definition of addiction, and may fail to recognize that addiction means experiencing difficulty quitting and continuing to smoke longer than expected.[62] A qualitative study of young female adolescent smokers found that nicotine addiction was an unintended consequence of their smoking,[63] and children have reported perceptions that they may avoid addiction by avoiding enjoying the experience of smoking.[64] Elsewhere, adolescents have described addiction to tobacco as personally and easily avoidable, as long as tobacco products were not used at an intensity or duration that they did not intend to reach.[65]

Conversely, while some young people may seek nicotine in alternative tobacco products, the absence of nicotine from cigarettes may decrease perceptions of the harm of smoking. Similar to light, low tar, low additive, or low smoke cigarettes,[66,67,68] low nicotine cigarettes may be perceived as safer, which is likely to encourage use among young people. Youth who report using electronic cigarettes without nicotine perceive lower health risks from e-cigarettes and were more likely to have answer knowledge items about nicotine incorrectly.[69]

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[60] Wiseman KD, Cornacchione J, Wagoner KG, Noar SM, Moracco KE, Teal R, Wolfson M, Sutfin EL. Adolescents' and Young Adults' Knowledge and Beliefs About Constituents in Novel Tobacco Products. Nicotine Tob Res. 2016 Jul;18(7):1581-7.

[61] Wiseman KD, Cornacchione J, Wagoner KG, Noar SM, Moracco KE, Teal R, Wolfson M, Sutfin EL. Adolescents' and Young Adults' Knowledge and Beliefs About Constituents in Novel Tobacco Products. Nicotine Tob Res. 2016 Jul;18(7):1581-7.

[62] Roditis M, Lee J, Halpern-Felsher BL. Adolescent (Mis)Perceptions About Nicotine Addiction: Results From a Mixed-Methods Study. Health Education & Behavior. Vol 43, Issue 2, pp. 156 – 164. Aug 2015.

[63] Moffat, B.M. and Johnson, J.L. (2001) Through the haze of cigarettes: teenagers girls' stories about cigarette addiction. Qualitative Health Research , 11, 668–681.

[64] C. Wang, N. Henley, R. J. Donovan; Exploring children's conceptions of smoking addiction, Health Education Research, Volume 19, Issue 6, 1 December 2004, Pages 626–634, https://doi.org/10.1093/her/cyg087

[65] Couch ET, Darius E, Walsh MM, Chaffee BW. Smokeless Tobacco Decision-Making Among Rural Adolescent Males in California. J Community Health. 2017 Jun;42(3):544-550.

[66] Kropp RY, Halpern-Felsher BL. Adolescents' beliefs about the risks involved in smoking "light" cigarettes. Pediatrics. 2004 Oct;114(4):e445-51.

[67] Tindle HA, Shiffman S, Hartman AM, Bost JE. Switching to "lighter" cigarettes and quitting smoking.Tob Control. 2009 Dec;18(6):485-90.

[68] Shiffman S, Pillitteri JL, Burton SL, Rohay JM, Gitchell JG. Smokers' beliefs about "Light" and "Ultra Light" cigarettes. Tob Control. 2001;10 Suppl 1:i17-23.

[69] Pepper JK, Farrelly MC, Watson KA. Adolescents' understanding and use of nicotine in e-cigarettes. Addict Behav. 2018 Jul;82:109-113.

It is important to consider youth and adult risk perceptions in the context of recent experience with e-cigarettes and other novel tobacco products. The available evidence on currently marketed novel tobacco products (including e-cigarettes) conducted independent of the tobacco industry consistently shows that the introduction of novel nicotine products will attract adolescent non-users into initiating tobacco use. Adolescents' decisions to adopt use of any tobacco product are based on several considerations, including whether the product appeals to them, the product's flavors, smell and taste, the product's perceived harm, and the ease and location of use.[70] The marketing of new nicotine products with harm reduction claims makes it likely that these products will appeal to youth.

The experience with e-cigarettes, a nicotine product that has been promoted with harm reduction and "smokeless" messages, is directly relevant. Since e-cigarettes were first introduced in the U.S. less than a decade ago, there has been a rapid rise in their use.[71] E-cigarette use is especially common among adolescents and young adults. On the U.S. market since 2007, in 2016 past 30-day use of e-cigarettes has surpassed use of conventional cigarettes, with use prevalence of 11.3% among high school students (8.0% for cigarettes).[72] 2017 Monitoring the Future data show a growing divide between cigarette and e-cigarette use in 8th-12th graders (12% had used e-cigarettes in the past month, 5.4% had smoked cigarettes).[73] Among young adults 18-24 years old, 23.5% have ever used an e-cigarette.[74] Youth are also most likely to use flavored e-cigarette

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[70] McKelvey, K., Ramos, M., Roditis, M., Ramamurthi, D., Halpern-Felsher, B. A Qualitative Analysis of Adolescents' Appeal of Various Tobacco Products. In preparation.

[71] McMillen RC, Gottlieb MA, Schaefer RM et al., Trends in Electronic Cigarette Use Among U.S. Adults: Use is increasing in both smokers and non-smokers. Nicotine Tob Res. 2015 Oct;17(10):1195-202.

[72] Jamal A, Gentzke A, Hu SS, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2016. MMWR Morb Mortal Weekly Rep 2017; 66:597–603. DOI: http://dx.doi.org/10.15585/mmwr.mm6623a1.

Syamlal G, King BA, Mazurek JM. Tobacco Use Among Working Adults — United States, 2014–2016. MMWR Morb Mortal Weekly Rep 2017;66:1130–1135. DOI: http://dx.doi.org/10.15585/mmwr.mm6642a2.

Centers for Disease Control and Prevention. "National Youth Tobacco Survey (NYTS)." 2015. Web. 22 Aug. 2016; Centers for Disease Control and Prevention "Youth and Tobacco Use." 2016. Web. 22 Aug. 2016.

Barrington-Trimis JL, Urman R, Leventhal AM, et al. E-cigarettes, cigarettes, and the prevalence of adolescent tobacco use. Pediatrics. 2016;138(2):10.1542/peds.2015-3983. Epub 2016 Jul 11.

Gilreath TD, Leventhal A, Barrington-Trimis JL, et al. Patterns of alternative tobacco product use: Emergence of hookah and E-cigarettes as preferred products amongst youth. Journal of Adolescent Health. 2016;58(2):181-185.

NIDA. Tobacco/nicotine and E-cigs. https://www.drugabuse.gov/drugs-abuse/tobacconicotine-e-cigs. Updated 2017.

[73] Johnston, L.D., O'Malley, P.M., Miech, R.A., Bachman, J.G., Schulenberg, J.E., 2018. Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2017. University of Michigan Institute for Social Research, Ann Arbor, MI.

[74] QuickStats: Percentage of adults who ever used an e-cigarette and percentage who currently use e-cigarettes, by age group. National Health Interview Survey, United States, 2016. MMWR Morb Mortal Weekly Report, 2017;66:892. DOI: http://dx.doi.org/10.15585/mmwr.mm6633a6

and other tobacco products.[75] Flavors increase teens' intentions to use e-cigarettes and decrease their risk perceptions associated with e-cigarette use.[76]

Many adolescents at low risk of initiating nicotine use with conventional cigarettes initiate with e-cigarettes.[77] Adolescents who initiate nicotine use with e-cigarettes are more susceptible to smoking combustible cigarettes.[78] This experience with e-cigarettes raises the concern that

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[75] Ambrose BK, Day HR, Rostron B, et al. Flavored tobacco product use among us youth aged 12-17 years, 2013-2014. JAMA. 2015;314(17):1871-1873; Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. N Engl J Med. 2014;370(23):2250-2252; Feirman SP, Lock D, Cohen JE, Holtgrave DR, Li T. Flavored tobacco products in the united states: A systematic review assessing use and attitudes. Nicotine Tob Res. 2016;18(5):739-749; Wagoner KG, Cornacchione J, Wiseman KD, Teal R, Moracco KE, Sutfin EL. E-cigarettes, hookah pens and vapes: Adolescent and young adult perceptions of electronic nicotine delivery systems. Nicotine Tob Res. 2016.

[76] Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. Tob Control 2016; 25:ii62-ii66. Doi: 10.1136/tobaccocontrol-2016-053174.
Shang C, Huang J, Chaloupka FJ, Emery SL. The impact of flavour, device type and warning messages on youth preferences for electronic nicotine delivery systems: evidence from an online discrete choice experiment. Tob Control. Published online first: 2 Nov 2017. Doi: 10.1136/tobaccocontrol-2017-053754

[77] Dutra, LM, Glantz, SA. E-cigarettes and national adolescent cigarette use: 2004-2014. Pediatrics. 1239(2), 2017.
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Barrington-Trimis JL, Urman R, Leventhal AM, et al. E-cigarettes, cigarettes, and the prevalence of adolescent tobacco use. Pediatrics. 2016;138(2):10.1542/peds.2015-3983. Epub 2016 Jul 11
Best, C., Haseen, F., Currie, D., Ozakinci, G., MacKintosh, A.M., Stead, M., Eadie, D., MacGregor, A., Pearce, J., Amos, A., Frank, J., Haw, S., 2017. Relationship between trying an electronic cigarette and subsequent cigarette experimentation in Scottish adolescents: a cohort study. Tob. Control. http://dx.doi.org/10.1136/tobaccocontrol-
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Conner, M., Grogan, S., Simms-Ellis, R., Flett, K., Sykes-Muskett, B., Cowap, L., Lawton, R., Armitage, C.J., Meads, D., Togerson, C., West, R., Siddiqi, K., 2017. Do electronic cigarettes increase cigarette smoking in UK adolescents? evidence from a 12-month prospective study. Tob. Control. http://dx.doi.org/10.1136/tobaccocontrol-2016-053539. Epub ahead of print.
Wills, T.A., Sargent, J.D., Gibbons, F.X., Pagano, I., Schweitzer, R., 2017. E-cigarette use is differentially related to smoking onset among lower risk adolescents. Tob. Control 26, 534–539.

[78] Barrington-Trimis JL, Urman R, Leventhal AM, et al. E-cigarettes, cigarettes, and the prevalence of adolescent tobacco use. Pediatrics. 2016;138(2):10.1542/peds.2015-3983. Epub 2016 Jul 11
Soneji S, Barrington-Trimis JL, Wills TA, Leventhal AM, Unger JB, Gibson LA, Yang J, Primack BA, Andrews JA, Miech RA, Spindle TR, Dick DM, Eissenberg T, Hornik RC, Dang R, Sargent JD. Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis. JAMA Pediatr. 2017 Aug 01;171(8):788-797.
Barnett TE, Soule EK, Forrest JR, Porter L, Tomar SL. Adolescent electronic cigarette use: Associations with conventional cigarette and hookah smoking. Am J Prev Med. 2015;49(2):199-206.
Miech RA, O'Malley PM, Johnston LD, Patrick ME. E-cigarettes and the drug use patterns of adolescents. Nicotine Tob Res. 2016;18(5):654-659.
Leventhal AM, Strong DR, Kirkpatrick MG, et al. Association of electronic cigarette use with initiation of combustible tobacco product smoking in early adolescence. JAMA. 2015;314(7):700-707.

more adolescents will become dual and poly-users of e-cigarettes along with other tobacco products.[79] Adolescent and young adult smokers who use novel tobacco products often use two or more kinds of tobacco products concurrently.[80] Dual and poly-use of tobacco products is more common among youth than adults.[81]

Newer e-cigarette devices appear to deliver nicotine more effectively than early "cigalikes";[82] these products include larger tank systems and, most recently, the pod devices like the new JUUL device, which has rapidly come to dominate the e-cigarette market.[83] In the U.S., the FDA recently took several enforcement actions stop youth access and use of JUUL due to its rapid uptake among youth.[84] Young adults participating in research have described JUUL's standardized pods as "ridiculously strong," and have reported that the major benefit of the JUUL device was, "It's like a lot of nicotine, from what I understand."[85] At the same time, while seeking high levels of nicotine in JUUL, young adult users failed to recognize potential signs of nicotine addiction in their experiences using the devices, such as a propensity to use the device shortly after waking in the morning, or having environmental cues trigger cravings, such as meals or following exercise. Young adults have also reported increasing use of nicotine facilitated by e-cigarettes due to the ability to use the devices in places and times when smoking is prohibited.[86]

Wills TA, Sargent JD, Knight R, Pagano I, Gibbons FX. E-cigarette use and willingness to smoke: a sample of adolescent non-smokers. Tob Control. 2016 Apr;25(e1):e52-9.

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[83] Ramakanth Kavuluru, S.H., Ellen J. Hahn, *On the popularity of the USB flash drive-shaped electronic cigarette JUUL*. Tob Control, 2018.
Huang J, Duan Z, Kwok J, et al Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market Tobacco Control Published Online First: 31 May 2018. doi: 10.1136/tobaccocontrol-2018-054382

[84] Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes. April 24, 2018. FDA. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm

[85] Keamy-Minor E, McQuoid J, Ling PM. Young adult perceptions of JUUL and other electronic cigarette pod devices. BMJ Open 2019;9:e026306. doi: 10.1136/bmjopen-2018-026306

[86] McDonald EA, Ling PM One of several 'toys' for smoking: young adult experiences with electronic cigarettes in New York City Tobacco Control 2015;24:588-593.

Pulmonary Effects of Nicotine

It is generally assumed that the negative health effects of cigarettes are due to the many chemical species produced by combustion and not due to nicotine itself. However, recent experimental evidence suggests nicotine may significantly contribute to the pulmonary toxicity of cigarette smoke. Specifically, Garcia-Arcos and colleagues[87] exposed adult mice to the aerosol of saline, nicotine-free, or nicotine-containing e-liquid for 4 months and found that only the nicotine-laden aerosol increased airway and alveolar cell death and airspace enlargement reminiscent of COPD. Similarly, a 2018 study[88] reported that rats exposed to either subcutaneous nicotine or e-cigarette nicotine-containing aerosol for 5 weeks (achieving plasma nicotine concentrations comparable to habitual cigarette smokers) suffered emphysematous airspace enlargement and loss of lung vascular elements. ***Thus, animal studies in two different species are consistent with nicotine having direct pulmonary toxicity.***

Many important questions are raised by these findings, including: (a) To what extent are these findings generalizable to humans? (b) Does inhalational as compared to systemic nicotine have the same spectrum of toxicity? (c) What will be the lung health impact of increased dual use of combustible cigarettes and nicotine-laden aerosols from e-cigarettes (or other inhaled nicotine products such as heated tobacco products)? (d) Are adolescents with still-growing lungs at increased risk for nicotine-mediated pulmonary toxicity given the substantial literature implicating nicotine in disrupting lung development in animal models and humans?[89]

Increasing evidence demonstrates that components of e-cigarette aerosol may have a unique spectrum of toxicity relative to combusted cigarettes secondary to aerosolized propylene glycol,[90] flavorants including diacetyl,[91] and metals.[92] Studies have also unexpectedly found

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[87] Garcia-Arcos, I. et al. Chronic electronic cigarette exposure in mice induces features of COPD in a nicotine-dependent manner. Thorax 2016; 71: 1119–1129.

[88] Reinikovaite, V. et al. The effects of electronic cigarette vapour on the lung: direct comparison to tobacco smoke. Eur. Respir. J. 2018;51(4). pii: 1701661. doi: 10.1183/13993003.01661-2017. Print 2018 Apr.

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Varughese, S. et al. Effects of theatrical smokes and fogs on respiratory health in the entertainment industry. Am. J. Ind. Med. 2005; 47: 411–418.

harmful flame retardant chemicals (used in the production of plastic e-cigarette casings) in the aerosol[93] and the urine of users.[94]

Recent work reveals that e-cigarette users have major changes in the lung proteome,[95] and case reports of unique lung toxicity are accumulating.[96] Remarkably, a recent study showed that

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[91] Kreiss, K. et al. Clinical Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant. N. Engl. J. Med. 2002; 347: 330–338.
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chronic exposure to e-cigarette aerosol in mice caused multi-organ fibrosis,[97] demonstrating that whole-body toxicological assessments of these novel devices will be essential going forward.

Consistent with these animal results, a cross-sectional analysis of Wave 1 of the PATH dataset found that current (daily or nondaily) e-cigarette users were nearly twice as likely to have been diagnosed with COPD (including COPD, chronic bronchitis, or emphysema) than people who did not use e-cigarettes (adjusted odds ratio, 1.86; 95% CI, 1.22-2.83).[98] This study controlled for other tobacco product usage and secondhand smoke exposure using propensity score matching.

3. Health Canada should regulate design features that maximize addiction potential and appeal to youth

Bluetooth-enabled or other technologies that would automatically remind consumers to continuously use an e-cigarette device or to reorder nicotine liquids or nicotine pods have the potential to allow manufacturers to customize the dose, speed of delivery, and continuous use of nicotine to maximize the additive potential for individual users.[99] Juul's chief executive Kevin Burns said the new Bluetooth technology that Juul will be testing in Canada soon that will let users monitor on their smartphones how many puffs that are taking will allow Juul to have "a much more intimate relationship" with customers and help "coach" them to manage their nicotine intake.[100] However, this kind of technology featuring two-way communications not only raises privacy concerns, but also has the potential of allowing Juul and other e-cigarette companies to maximize the nicotine delivery to maintain nicotine addiction, in addition to urging consumers to buy more nicotine-laced products to maintain their addiction. ***Health Canada should prohibit these kinds of technologies and two-way communications in e-cigarettes and other new tobacco products.***

In addition to technological design features in devices that could create and maintain nicotine addiction in youth, the physical design of some products are especially attractive to youth and could encourage youth and other non-users to initiate with e-cigarettes and ultimately become addicted to nicotine. For example, the "tech appeal" of pod devices and in particular, the slick design of Juul that resembles USB memory sticks and other user-friendly personal electronics could encourage uptake among young people.[85] Additionally, because the pod devices are discrete, portable, and create discreet clouds of aerosol, they are convenient and lend

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themselves to inconspicuous use in places where tobacco use is generally prohibited.**Error! Bookmark not defined.** Moreover, the pod devices may reduce the social stigma previously associated with conventional cigarettes and with earlier generation large "box mod" devices.**Error! Bookmark not defined.** Because these devices are associated with personal electronic devices instead of with tobacco products that are deadly and stigmatized, and are supported by aggressive social media advertising, use of these products may become normalized.**Error! Bookmark not defined.** ***By prohibiting all advertising and prohibiting all flavors, combined with increased public education campaigns that counter industry messaging normalizing nicotine use,***[Error! Bookmark not defined.] ***Health Canada would address these issues and decrease initiation among young people and non-smokers.***

4. Health Canada should prohibit online sales of vaping products

Health Canada should ban online sales of vaping products to protect youth. There is significant evidence that underage youth purchase vaping products online,[101] in addition to accessing e-cigarettes from friends and vape shops, and age verification systems do not effectively block youth internet sales.

Youth Under Age 18 Purchase Tobacco on the Internet.

There is strong evidence demonstrating that youth under age 18 purchase tobacco products on the Internet.[102,103] Indeed, the Internet serves as a significant means of acquiring tobacco for youth, with Internet sales serving as a way to circumvent the age restrictions and face-to-face age verification requirements. Fix et al.[104] showed that Internet sales of tobacco increased significantly among 9th grade students living in New York State. In 2004- 2005, youth were 2.6 times more likely to purchase cigarettes over the Internet than were similar students just 4-5 years earlier. The rates went from 1.6% in 2001 to 5.2% in 2005. Moreover, 9% reported that they intended on purchasing cigarettes through the Internet (see also Abrams et al.[105]). Using a large representative sample of 10th and 12th graders in California, Unger and colleagues showed that 2.2% of the youth had tried to buy cigarettes on the Internet, and 32% of those who had tried cigarettes rated the Internet as their most recent source for cigarettes. Internet sales were highest among younger adolescents, males and frequent smokers. As Internet use explodes among youth, these numbers are almost certainly much larger today.

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[101] Meyers, MJ., Delucchi, K., Halpern-Felsher, B. Access to Tobacco Among California High School Students: The Role of Family Members, Peers, and Retail Venues. J of Adol Hlth, 61 (2017) 385e388

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Additional evidence for the importance of full restriction of Internet sales of tobacco products has been submitted to the FDA (Docket Number: FDA-2011- N-0467; http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0467).[106] In particular, Williams, Ribisl, and Jo, from the University of North Carolina, provided ample evidence that youth do purchase tobacco on the Internet, and can do so easily without age verification.[107]

It is Easy to Circumvent Age Restrictions

While nominal age verification for Internet sales can occur in a number of ways, it is extremely easy for an adolescent under age 18 to circumvent these age restrictions. For example, some websites simply require the user to click on a button verifying that he/she is over 18, or to enter his/her birth date and click on a button to verify or certify this date. These processes are the most common methods for age verification; however, it is easy for anyone under age 18 to bypass the age restriction by simply lying about their age. Other websites require online age verification via entering a driver's license number, or copying their actual license and submitting those through the website. While somewhat more effective than the simple check or click system, this process is used and enforced less often, and still allows for an adolescent under age 18 to submit a false driver's license or ID card. Still other Internet tobacco sales websites require age verification at the time of delivery. However, these policies are rarely enforced, and when they are, it is still easy for an adolescent to provide false proof of age (see Ribisl et al.,[108] Williams[109]).

Williams and colleagues[110] examined compliance with state laws explicitly regulating the sales of cigarettes via the Internet, and found little compliance of the law. Another study noted that almost all (96.7%) of underage youth were easily able to purchase tobacco online, compared with 12%-17% being able to purchase tobacco from other commercial venues (Jensen et al., 2004). Malone and Bero[111] reported that only 36 of the 141 Internet sites examined prohibited the purchase of cigars to minors. Adolescents 11-15 years old were easily able to purchase cigarettes on the Internet, 93.6% were successful at obtaining cigarettes on the Internet using credit cards, and 88.9% were able to complete their Internet sales using money orders. Age was never verified in these transactions.[112] Ribisl and colleagues[113] reported that almost 20% of

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[106] https://tobacco.ucsf.edu/fda-should-restrict-internet-sales-all-tobacco-products-including-e-cigarettes
[107] Ribisl KM, Williams RS, Kim AE. 2003. Internet sales of cigarettes to minors. JAMA 290: 1356-1359; https://tobacco.ucsf.edu/fda-ignored-information-internet-sales-submitted-response-2011-anprm-deeming-rule

[108] Ribisl KM, Kim AE, Williams RS. 2002. Are the sales practices of Internet cigarette vendors good enough to present sales to minors? American Journal of Public Health 92(6):940-941
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[110] Williams, RS, et al., "Internet cigarette vendors' lack of compliance with a California state law designed to prevent tobacco sales to minors," *Archives of Pediatrics and Adolescent Medicine* 2006; 160:988-989
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cigarette-selling websites do not say sales to minors are prohibited, more than half require only that the buyer say they are of legal age (e.g., by clicking a button that says "I am over age 18"), another 15% require only that the buyer types in their date of birth, and only 7% require any driver's license information. Attorneys general from at least 15 states have conducted Internet stings and found that children as young as 9 years old were able to purchase cigarettes easily, with a New York sting operation finding that 24 of 26 websites sold to kids under 18.[114] A *JAMA* study found that more than 96% of minors aged 15-16 were able to find an Internet cigarette vendor and place an order in less than 25 minutes, with most completing the order in seven minutes (Jensen et al., 2004).[115]

Internet Advertising is Pervasive

Failing to restrict Internet sales of all tobacco products is also problematic given that youth are constantly exposed to advertising of these products on the Internet. Of particular concern is the advertisement of e-cigarettes, and especially ads with particular appeal to youth, such as those promoting candy and other flavored e-cigarettes (see also the Stanford Research into the Impact of Tobacco Advertising (SRITA), http://srita.stanford.edu; Trinkets and Trash, http://www.trinketsandtrash.org).

Internet and social media marketing of tobacco products, including the more recent addition of e-cigarettes and other new products, is exploding, causing Internet sales of e-cigarettes and other tobacco products to skyrocket. Most social media content is industry-generated, which is carefully planned with specific keywords and mostly directed at youth to adopt a particular lifestyle. For example, a study found that 80% of all tweets were automated or promotional in nature.[116]

Further, there is pervasive false or unsubstantiated claims on products received online, that youth may not have the health literacy or access to information to be able to see through. Another study showed that the contents of packages received through online sales were rarely indicated on package exteriors. More than half of products received online did not include a health warning, and some had unsupported claims, such as lack of secondhand smoke exposure.[117]

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[113] Ribisl KM, Kim AE, Williams RS. 2002. Are the sales practices of Internet cigarette vendors good enough to present sales to minors? American Journal of Public Health 92(6):940-941

[114] Unger, JB, et al., "Are adolescents attempting to buy cigarettes on the Internet," *Tobacco Control* 2001; 10:360-63 [citing Sherer, R, "States crack down on Web tobacco sales," *The Christian Science Monitor,* Nov. 8, 2000 and ABC News, "Getting smokes online: Children buying cigarette with click of mouse," March 6, 2001

[115] Jensen JA, Hickman NJ, Landrine H, Klonoff EA (2004). Letters: Availability of tobacco to youth via the Internet *JAMA*: 291(15):1837

[116] Clark EM, Jones CA, Williams JR, et al. Vaporous marketing: uncovering pervasive electronic cigarette advertisements on Twitter. PLoS One. 2016;11(7):e0157304.) and (Vandewater EA, Clendennen SL, Hébert ET, Bigman G, Jackson CD, Wilkinson AV, Perry CL. Whose Post Is It? Predicting E-cigarette Brand from Social Media Posts. Tobacco Regulatory Science. 2018 Mar 1;4(2):30-43

[117] Kong AY, Derrick JC, Abrantes AS, Williams RS. What is included with your online e-cigarette order? An analysis of e-cigarette shipping, product and packaging features. Tobacco control. 2018 Nov 1;27(6):699-702

All e-cigarette liquids advertised online included a description that promotes flavor. Most descriptions included images that are associated with a sensation (e.g., 43% of menthol E-cig liquid images included mint leaves or ice). Menthol and apple descriptions or images were more likely than tobacco descriptions or images to promote appeals related to chemesthesis (e.g., cool, warm, moist; $p < .05$).[118]

Summary:

(1) There is a large body of strong and consistent scientific evidence that flavors play a central role in attracting youth to e-cigarettes. In contrast, there is not good evidence to support industry claims that flavors are necessary to help adults quit smoking.
(2) Nicotine delivered to the user depends on both the concentration of nicotine in the e-liquid and the voltage that the e-cigarette run at; e-cigarette companies can get around limitations on nicotine concentration in the e-liquid by simply increasing the voltage of the device so that the coil gets hotter.
(3) Many modern e-cigarettes, including Juul, are capable of two-way communication with the manufacturer, which creates the possibility that the e-cigarette company could "tune" the device to maximize addictive potential and consumption on an individual level.

Because of these facts, Health Canada should adopt the following measures to address the burgeoning vaping crisis and youth e-cigarette epidemic:

(1) Prohibit *all* flavors in all e-cigarette products, including mint and menthol;
(2) Restrict the nicotine delivery (not just the nicotine concentration) in vaping products;
(3) Prohibit any communication between e-cigarette devices and any individual (including the user and manufacturer) for any purpose, including apps on smart phones;
(4) Apply the same advertising and promotion restrictions as apply to conventional cigarettes; and
(5) Prohibit online sales of e-cigarettes.

[118] Soule EK, Sakuma KL, Palafox S, Pokhrel P, Herzog TA, Thompson N, Fagan P. Content analysis of internet marketing strategies used to promote flavored electronic cigarettes. Addictive behaviors. 2018 Nov 14