



March 4, 2021

Mr. Mathew Cook
Manager
Scientific Regulations Division
Tobacco Products Regulatory Office
Tobacco Control Directorate
Controlled Substances and Cannabis Branch
Health Canada
Address Locator 0301A
150 Tunney's Pasture Driveway
Ottawa, Ontario
K1A 0K9
Email: hc.pregs.sc@canada.ca

Re: Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020: *Concentration of Nicotine in Vaping Products Regulations*, December 19, 2020

Dear Mr. Cook:

Juul Labs Canada Ltd. (JLC or the Company) respectfully submits these comments in response to Health Canada's proposed regulation to implement a 20 mg/mL nicotine concentration limit on vaping products. Our company's mission is to transition the millions of Canadian adult smokers away from combustible cigarettes, eliminate their use, and combat underage usage of our products.

We support completely the Canadian Government in its goal to reduce tobacco use to less than 5% prevalence by 2035 and share Canada's Tobacco Strategy goal to "protect the health of young people and non-smokers from the dangers of tobacco use."¹ We believe that Canada can accelerate the end of smoking by embracing tobacco harm reduction and maintaining adult smoker access to non-combustible alternatives with sufficient appeal and nicotine delivery to push Canada's nearly 4 million adult smokers away from cigarettes.

We fear the proposed regulation's restrictions on higher-nicotine-concentration vaping products may have a limited effect on underage vaping rates, while having considerable negative unintended consequences for adult smokers seeking alternatives. Harm reduction for adults who smoke can be achieved while at the same time preventing underage use through evidence-based interventions.

The proposed regulation is intended to "primarily benefit youth by contributing to the reduction in the number of young persons who experiment with vaping products, which can lead to exposure to and dependence on nicotine and transition into tobacco use."² However, the evidence underpinning this claim is limited: the data do not show that the availability of higher-nicotine-concentration products has led to the unacceptable rise in use of vaping products by youth.

¹ Health Canada. Canada's Tobacco Strategy. 2020. <https://www.canada.ca/en/health-canada/services/publications/healthy-living/canada-tobacco-strategy.html>

² Page 4218, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

It is unclear from the data cited in the proposed regulation whether higher-nicotine-concentration vaping products differentially appeal to those underage, and it is unlikely that the removal of these products will decrease experimentation. Additionally, the data do not suggest there is a substantial causal “gateway” from vaping products to conventional cigarettes.

Conversely, there is evidence that the proposed regulation’s restriction on higher-nicotine-concentration products would disproportionately and adversely affect adults who smoke and seek a nicotine alternative to compete with cigarettes. Data show that these higher-nicotine-concentration products are particularly helpful in facilitating complete switching for those who have longer smoking histories and are more dependent on cigarettes.

We are at risk of losing the harm reduction opportunity vaping products provide because of the lack of trust in our category, and the Company. This has been largely driven by unacceptable increases in underage use. We are committed to what we call a “reset” – working collaboratively with all stakeholders to create the regulatory frameworks that prevent underage use and, at the same time, preserve adult smoker access to vapour alternatives that can compete with combustible cigarettes. That collaboration begins with open engagement, particularly as JLC and the category work to earn trust and establish a license to operate in society.

In this submission, we propose a number of strategy and policy considerations focused on limiting appeal and restricting access of vaping products, which are informed by the scientific literature as well as analyses of Canada youth use data. In the US, where these strategies and policies are being implemented, encouraging trends in underage vaping use data suggest there is an early indication that they are working. JLC believes there is an opportunity to learn from these successes to implement the same strategies and policy considerations in Canada.

These evidence-based tobacco control strategies include:

- **Reducing appeal:**
 - Limiting the ways and channels in which vaping products can be marketed to ensure that they appeal to adult smokers and limit the potential for unintended exposure among nonusers, especially youth; and
 - Expanding enforcement and compliance programs to ensure illegal flavour categories (confectionary, dessert, cannabis, soft drink, energy drink, or flavours that could be appealing to young persons) are removed from the market and responsible product marketing standards are upheld (no cartoons, no social media, etc.).
- **Restricting access:**
 - Increasing the federal minimum age of purchase to 21 for all tobacco and nicotine products;
 - Expanding enforcement and compliance programs to ensure retailers responsibly sell these products; and
 - Implementing enhanced access controls among retailers both in brick-and-mortar stores and online, which can automatically age-verify consumers to limit direct purchase by those underage and restrict the amount of product that can be purchased for social sourcing.

JLC supports risk-proportionate regulation for vapour and other non-combustible alternative products. Such a policy framework, at its core, applies the most stringent regulations to the

riskiest products (e.g., combustible cigarettes) and encourages current adult users to transition to potentially less harmful alternatives (e.g., vaping products). Within this framework, JLC believes that non-combustible alternatives, like vaping products, must be able to compete with combustible cigarettes by delivering sufficient nicotine to reduce cravings and the urge to smoke. We are concerned that if enacted, the proposed nicotine concentration limit would unintentionally protect cigarettes — reinforcing their position as the most efficient, simple, appealing, and lethal nicotine delivery product on the Canadian market.

If Health Canada proceeds with the proposed regulation, we respectfully request the Department consider a premarket review process through which products with higher nicotine concentrations could be introduced to the Canadian market if manufacturers can commit to evidence-based plans to limit appeal and restrict access of their products to those underage.

Our submission is structured to provide an in-depth overview of current data concerning underage use prevalence and trends, including reasons for appeal and sources of access. Relying on this data, we propose a number of tailored, evidence-based measures to further limit appeal and restrict access.

We then examine current scientific evidence concerning the importance of nicotine delivery to adult smoker switching, considering the potential extensive negative consequences of the proposed regulation to adult smokers. The proposed regulation appears to assume that restrictions on higher-nicotine-concentration products will decrease nicotine exposure, thereby limiting underage appeal and dependence.

Regulating nicotine exposure based on the level of nicotine in an e-liquid fails to take into account several factors that affect nicotine delivery beyond nicotine concentration. Because of this, the proposed regulation is unlikely to achieve the objective of lowering nicotine exposure in many vaping products. It will, however, disadvantage a class of products – temperature-controlled, closed systems – which evidence indicates are particularly appealing and effective in transitioning adult smokers off of cigarettes.

The submission next proposes an alternative pathway to market for products above 20 mg/mL for which manufacturers are implementing evidence-based interventions to combat underage use. We also address the potential barriers to implementation of the proposed regulation, including potential expansion of illicit markets that would further undermine Health Canada's tobacco control policy goals. Finally, we close with a discussion of the overall likely negative impact of the proposed regulation in light of the scientific evidence introduced throughout the submission.

A handwritten signature in blue ink, consisting of a stylized, overlapping loop followed by a long horizontal stroke.

Michael Nederhoff
President
Juil Labs Canada Ltd.

Table of Contents

1	<i>Examining Youth Use in Canada and Tailoring Prevention Measures to Limit Appeal and Restrict Access</i>	5
1.1	Prevalence and Trends in Canadian Underage Use	6
1.1.1	There is Not Clear Data on Prevalence of Nicotine Concentration by Age Group	7
1.2	Canadian Youth Cite Multiple Reasons for Use	9
1.3	Flavours	11
1.4	Limiting Underage Appeal Through Evidence-Based Measures	12
1.4.1	Limiting Flavours	13
1.4.2	Marketing Tailored to Adult Smokers	13
1.5	Sources of Underage Access to Vaping Products	14
1.5.1	Youth Primarily Access Vaping Products Through Social Sources	14
1.5.2	Frequent Underage Users are More Likely to Purchase Vaping Products Directly from a Retailer	15
1.6	Restricting Underage Access Through Evidence-Based Measures	16
1.6.1	The Impact of Tobacco 21	17
1.6.2	Enhanced Access Controls	19
1.7	Gateway Hypothesis	20
1.7.1	Common Liability Theory	21
1.7.2	Underage Smoking Prevalence is at Historic Lows	22
1.7.3	Dependence on Cigarettes is Higher Than Dependence on Vaping Products	23
2	<i>The Importance of Nicotine to Adult Smoker Switching and Potential Negative Impact of Proposed 20 mg/mL Nicotine Concentration Limit</i>	24
2.1	The Tobacco Harm Reduction Framework: Lower Toxicity, Appeal, and Sufficient Nicotine Delivery	25
2.2	High Concentration Nicotine Vaping Products Help Smokers Switch Off of Cigarettes	28
2.2.1	Market Data Indicate High Concentration Nicotine Vaping Products Help Smokers Switch Off of Cigarettes	28
2.2.2	Clinical Pharmacokinetic Studies Demonstrate JUUL Products at Concentrations Above 20 mg/mL Provide Satisfying Nicotine Delivery for Adult Smokers, Albeit at Lower Levels than Combustible Cigarettes	30
2.2.3	Behavioural Studies Demonstrate High Switch Rates Among Adult Smokers, With the Highest Rates in the US and Canada Where Nicotine Concentrations Above 20 mg/mL are Available	31
2.3	Multiple Factors, Including Nicotine Concentration, Affect Nicotine Delivery	36
3	<i>Risk-Proportionate Regulation to Establish a Pathway for Responsibly Marketed Products Above 20 mg/mL</i>	38
4	<i>Examining the Proposed Regulation's Regulatory Analysis</i>	39
4.1	Costs to Adults Who Smoke and Dual Users	39
4.2	Reduced Initiation Rates among Adolescents	41
5	<i>Conclusion</i>	42

1 Examining Youth Use in Canada and Tailoring Prevention Measures to Limit Appeal and Restrict Access

JLC is committed to combating underage use of vaping products, including JUUL products, today and in the future. We believe industry has a key role to play in the effort to reduce underage use of vaping products. JLC will work with Health Canada, policymakers, law enforcement, and other stakeholders to reduce underage vaping, particularly use of the JUUL System.

The proposed regulation seeks to address underage use through greater restrictions on nicotine concentrations in vaping products, suggesting that higher-nicotine-concentration vaping products have a greater appeal to Canadian youth than do lower-nicotine-concentration products. The proposed regulation connects the introduction of higher-nicotine-concentration vaping products, introduced to the Canadian market in 2018 following passage of the Tobacco and Vaping Products Act (TVPA), with increased use of vaping products by those underage.

The ban is intended to “primarily benefit youth by contributing to the reduction in the number of young persons who experiment with vaping products, which can lead to exposure to and dependence on nicotine and transition into tobacco use.”³ Underlying the proposed regulations is the assumption that vaping product use acts as a “gateway” to conventional cigarette smoking among youth. This theory, commonly referred to as a “gateway effect,” posits that vaping product use causes people — particularly those underage — who would have otherwise not smoked combustible cigarettes to begin doing so after initiating vaping product use.

JLC takes a comprehensive, data-driven approach to underage use prevention focused on two pillars: limiting the appeal of and restricting access to the JUUL System for those underage. As part of our efforts to limit the appeal of our products, we halted the import of flavoured products, other than Tobacco and Mint, seven months in advance of any provincial regulations coming into force. Additionally, several months before the federal regulations prohibiting vaping products promotion where “youth have access” came into effect, we voluntarily stopped all public-facing marketing activity.

We are also focusing on initiatives to limit access of our products to those underage. This includes our mystery shopping program and retailer training to better ensure minimum purchase age laws are upheld at retail, while also enforcing product quantity limits and strict online age verification controls to further reduce access. Online we sell only through JUUL.ca and AltVape, which meets our strict age verification requirements. Additionally, we monitor Amazon, eBay, Kijiji, and other social media platforms to flag inappropriate posts and listings for removal in non-age-gated online marketplaces.

Additionally, JLC supports Health Canada’s enactment, through the TVPA, of a number of its comprehensive regulations aimed at reducing youth use, including marketing, flavour, and access restrictions. We are committed to working with Health Canada to help implement these and additional enforcement efforts as we all work to reduce underage use.

³ Page 4218, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

These two pillars – appeal and access – can be adopted for all tobacco and nicotine products to reduce underage use of such products. Understanding reasons those underage give for using vaping products as well as how they access tobacco should inform efforts to curtail underage use.

Below, we examine tobacco and vaping use trends in Canada specifically, and draw upon the scientific literature on underage use in other countries, including the US, to propose a number of tailored underage prevention measures. We believe the data indicate that greater enforcement of existing regulations on advertising and prohibited flavours are needed to curb underage appeal.

We also support Canada implementing Tobacco 21 — raising the minimum purchase age of tobacco and vaping products to 21 across the country — a crucial tobacco control tool that would significantly restrict underage access. Finally, to further restrict underage access, we propose Health Canada consider mandating enhanced access controls, including advanced age verification and product quantity limits, at retail and online, discussed in more detail in [Section 1.6.2](#).

1.1 Prevalence and Trends in Canadian Underage Use

In examining trends in prevalence of current (past 30-day) use of vaping products, it is clear that youth use of vaping products has increased in recent years, tracking the growth of the vaping product market post-TVPA.

As shown in Table 1, recent estimates suggest that one-quarter to two-fifths of youth reported having ever tried a vaping product. Current use (use within the past 30-days) prevalence is generally less than half the prevalence rate of ever use of vaping products in any year, reflecting a high degree of discontinuation, indicating that much use of these products is transient or experimental.

Table 1 Prevalence of Youth Vaping Product Use by Data Source

	Ages/Grades	Includes Ages>18	Time Fielded	Ever Use	Use in the Past 30 Days	Past Month Frequent Use
CTNS '19 ⁴	15-19	Yes	October 29– December 17	36%	15%	4.7%- daily; 3.3%- weekly
CSTADS '18- '19 ⁵	G7-12	Yes	October 2018– June 2019	N/R	17.7%	7% - daily; 4.5% - weekly
ITC '19 ⁶	16-19	Yes	August- September 2019	40.6%	17.8%	5.7% (20+days/month)

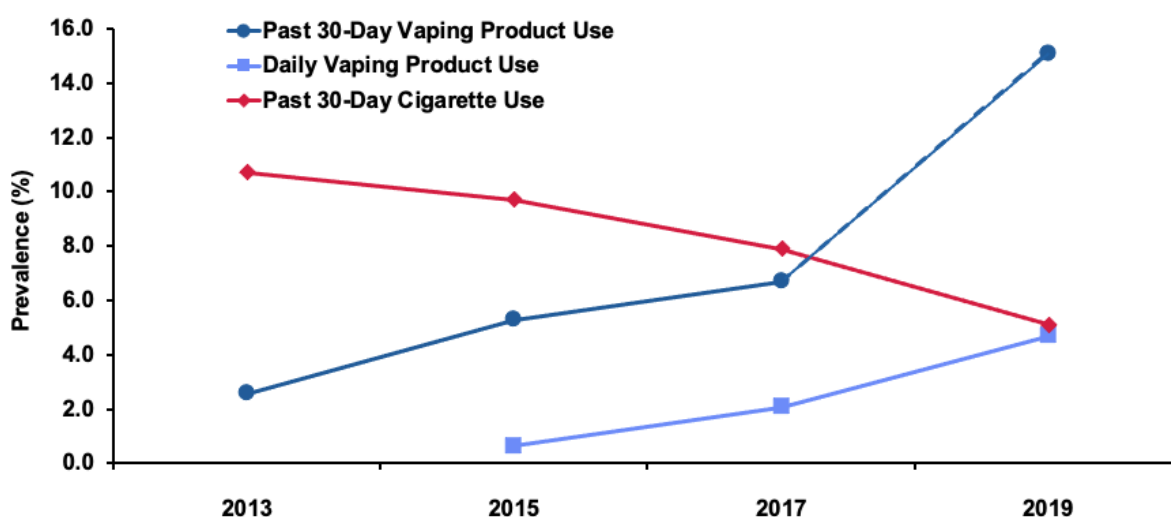
⁴ Health Canada. Canadian Tobacco and Nicotine Survey (CTNS): summary of results for 2019. 2020. <https://www.canada.ca/en/health-canada/services/canadian-tobacco-nicotine-survey/2019-summary.html>

⁵ Propel Centre for Population Health Impact at the University of Waterloo. Canadian Student Tobacco, Alcohol and Drug Survey. 2018-2019.

⁶ Hammond, D., Rynard, V. L., & Reid, J. L. (2020). Changes in Prevalence of Vaping Among Youths in the United States, Canada, and England from 2017 to 2019. *JAMA Pediatrics*, 174(8), 797-800. doi:10.1001/jamapediatrics.2020.0901

“Frequent use” of vaping products is defined differently by survey. Canadian Tobacco and Nicotine Survey (CTNS) and Canadian Student Tobacco, Alcohol and Drugs Survey (CSTADS) report on daily and weekly use, while the ITC Youth Tobacco and Vaping Survey (ITC) defines “frequent use” as use 20+ days per month⁷. In most recent studies, frequent use represented about a third of past 30-day users. While there is variation in rates across surveys, the trends over time suggest that the increase in current vaping product use was accompanied by increases in frequent use from 2017–19. Figure 1 shows current/past 30-day use has risen in recent years, and the proportion of past 30-day users who reported vaping daily has also risen. During this time, smoking rates have continued to decline.

Figure 1 Past 30-Day Use of Cigarettes and Vaping Products and Daily Use, Canadians aged 15-19 (CTADS 2013-2017; CTNS 2019)



Overall, the data show use of vaping products has increased in recent years, while also showing that use is not typically persistent or frequent. Among youth current vaping product users (i.e., those reporting use of vaping products in the past 30 days), a small but increasing subset report using vaping products frequently. This measure is an indicator of more established tobacco and nicotine product use behaviour, rather than intermittent or experimental use, however neither is acceptable and both must be addressed.

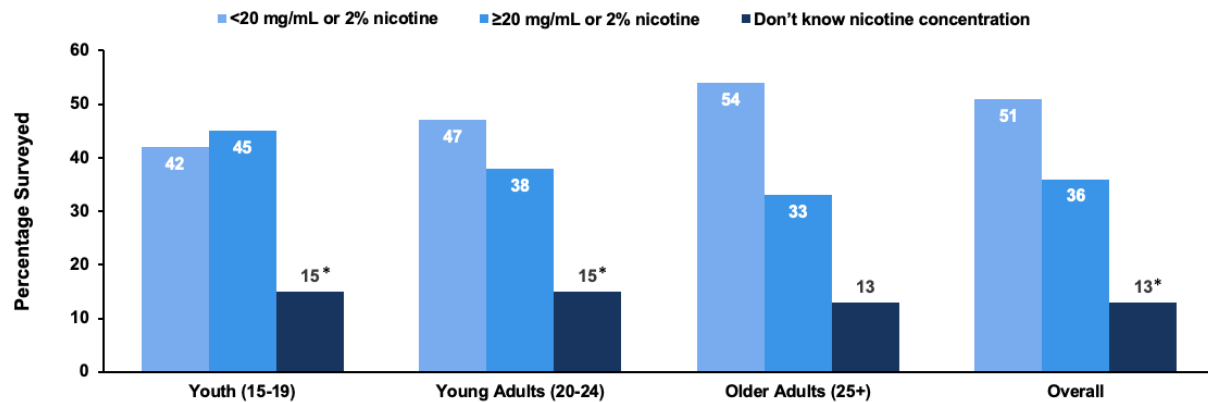
1.1.1 There is Not Clear Data on Prevalence of Nicotine Concentration by Age Group

There are very limited data on prevalence of nicotine concentration use by age group, and the proposed regulation underestimates significantly the prevalence of higher-nicotine-concentration use by adults, as discussed in [Section 2.2](#).

The proposed regulation cites the Social Values and Psychographic Segmentation of Tobacco and Nicotine Users and Non-Users survey, conducted in late 2019/early 2020 of Canadians aged 15+ to assess nicotine concentrations used by age. The data are presented in Figure 2.

⁷ Hammond, D., Rynard, V. L., & Reid, J. L. (2020). Changes in Prevalence of Vaping Among Youths in the United States, Canada, and England from 2017 to 2019. *JAMA Pediatrics*, 174(8), 797-800. doi:10.1001/jamapediatrics.2020.0901

Figure 2 Social Values and Psychographic Segmentation of Tobacco and Nicotine Users and Non-Users; Report for Health Canada



*"Don't know" has been imputed as the values were not provided

The report broadly claims that those under 24 using vaping products are more likely to use nicotine concentrations of 20 mg/mL or higher than older vapers.⁸ This study is relied on extensively by Health Canada as a justification for a prohibition on higher-nicotine-concentration products based on its prevalence estimates, despite the authors of the study themselves cautioning against using it in this such way.

It is problematic to rely on this report and the underlying survey for determining the prevalence of use of higher-nicotine-concentration products. The survey was a non-probabilistic convenience sample and the report specifically notes: "Because the online sample is based on those who initially self-selected for participation in the panel, no estimates of sampling error can be calculated, and the results cannot be described as statistically projectable to the target population. Additionally, due to the use of non-probability online opt-in panels for data collection, this survey should not be relied upon for incidence rates of Behaviour."

This survey asked past 30-day users to identify what concentration they used based on information displayed on their product. This suggests it surveyed those who own their own device or are loyal to a specific brand, which could mean that the survey included more established, frequent users and did not include those who did not own their own device. Social sources are the main source of access for vaping products, and trying or borrowing a friend's device is quite common.^{9,10} As discussed below in [Section 2.2.1](#), the proposed regulation also likely underestimates the prevalence of use of high-nicotine-concentration products by adults (including those who currently smoke and those who have already switched) and the impact a nicotine concentration restriction would have on them.

Given the concerns about the generalizability of the Social Values and Psychographic Segmentation of Tobacco and Nicotine Users and Non-Users report and a lack of other

⁸ Earncliffe Strategy Group. (ARCHIVED) Social Values and Psychographic Segmentation of Tobacco and Nicotine Users and Non-Users (PDF). February 2020.

⁹ Pepper, J. K., Coats, E. M., Nonnemaker, J. M., & Loomis, B. R. (2019). How Do Adolescents Get Their E-Cigarettes and Other Electronic Vaping Devices? *Am J Health Promot*, 33(3), 420-429. doi:10.1177/0890117118790366

¹⁰ Boak, A., Elton-Marshall, T., Mann, R., & Hamilton, H. (2020). Drug use among Ontario students, 1977-2019: Detailed findings from the Ontario Student Drug Use and Health Survey (OSDUHS). *Toronto, ON: Centre for Addiction and Mental Health*.

statistically projectable data on use by nicotine concentration, it is unclear to what extent youth are using high-nicotine-concentration products, the salience of nicotine-concentration as part of youth decision-making about vaping, and in turn to what extent the proposed regulations would alter vaping behaviour among youth.

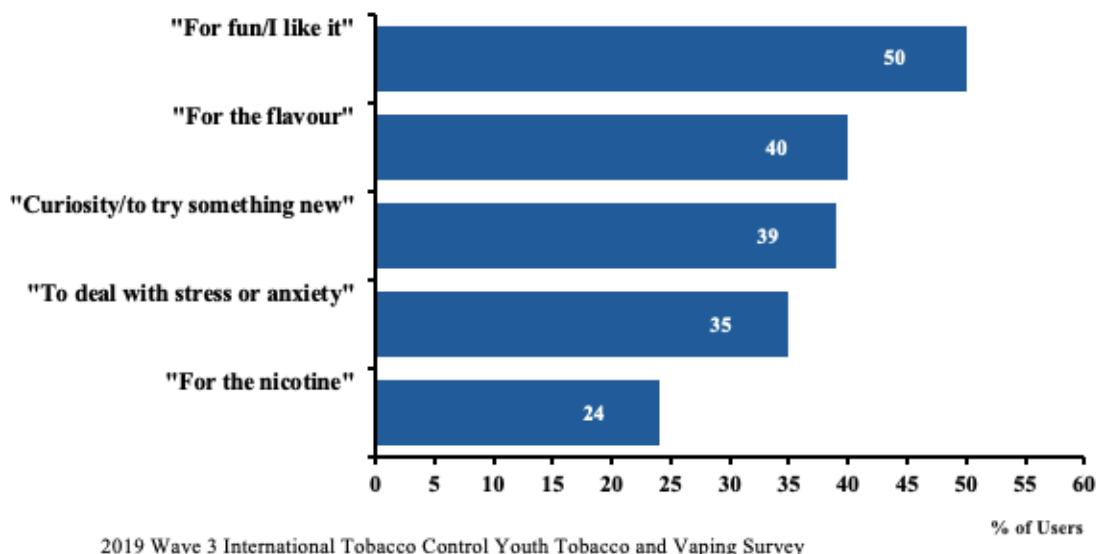
1.2 Canadian Youth Cite Multiple Reasons for Use

Assessments of the reasons given for using vaping products can help inform strategies to reduce use among those underage. The proposed regulation present data from CSTADS, which show that the prevalence of current (past 30-day) and daily youth vaping product use increased from 2018 to 2019. The proposed regulation suggests that the availability of higher-nicotine-concentration products on the market since 2018 are causally associated with these trends, but the available data do not clearly support this conclusion.

The proposed regulation cites unpublished results from the 2019 International Tobacco Control Youth Tobacco and Vaping Survey on reasons for vaping product use among those between 16-19 who reported past 30-day use, as shown in Figure 3. “For the nicotine” was fifth in a list of five reasons highlighted by Health Canada, with the number one reason “for fun/I like it” being reported by over twice as many youth (50% vs 24%).

Figure 3 ITC Reasons for Use

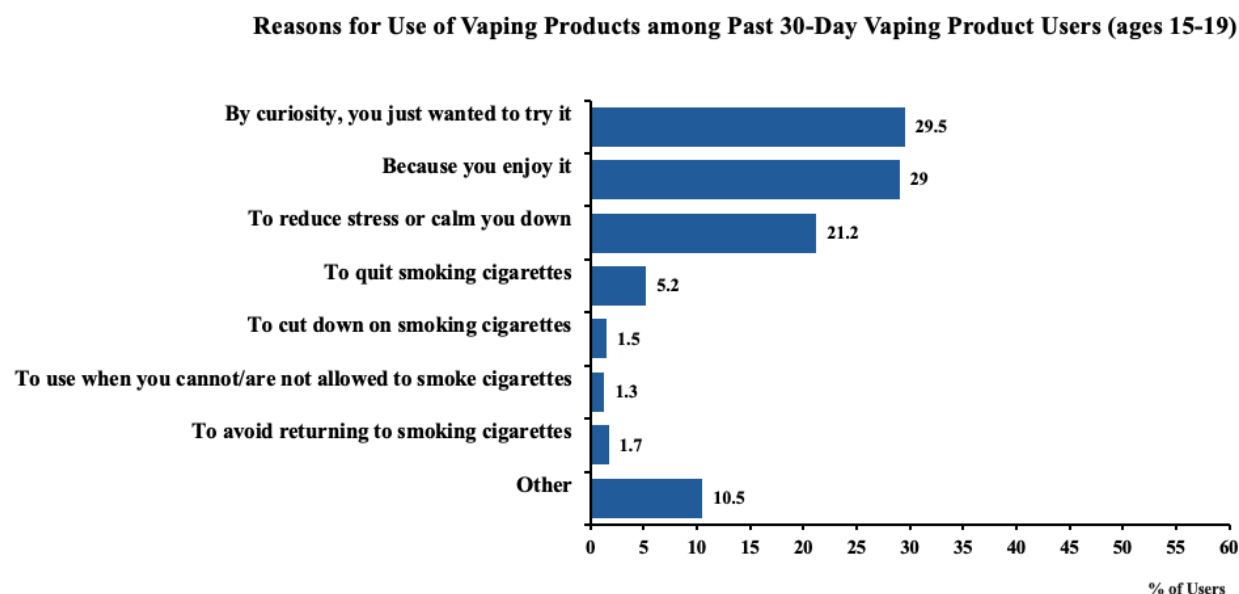
Reasons for Use of Vaping Products among Past 30-Day Vaping Product Users (ages 16-19)



These results are not stratified by the actual concentration of nicotine in the vaping products used by respondents, therefore we do not know the reasons given for use by youth who report using higher-nicotine-concentration products. Additionally, the survey did not ask specifically about the relative appeal of high-nicotine-concentration products. While youth report using vaping products “for the nicotine,” it is unclear from these data whether youth who selected this as a reason for use are referring to the effects of nicotine itself or the appeal of higher-nicotine-concentration products.

Data from the 2019 CTNS, shown in Figure 4, are similar to the ITC data and were also highlighted in the proposed regulation: “the reasons youth vape are not uniform. The most commonly reported reasons for vaping among youth who used a vaping product in the past 30 days were curiosity (29%), because they enjoyed it (29%), and to reduce stress (21%).”¹¹

Figure 4 CTNS Reasons for Use



Health Canada also cites comments made in focus groups of 103 occasional and frequent vapers aged 13-19, as evidence of “the importance many [youth] place on vaping products with higher concentrations of nicotine.”¹² In this sample of youth vapers many cited a “head rush” or “buzz” as an appealing aspect of vaping. While not representative of the population, the focus groups also provide insight as to the role of societal influences in initiation, as well as the different patterns of use across frequent versus occasional vapers. Notably, societal influences, including peer pressure, was the primary driver of initiation and “nobody admitted to being alone when they vaped for the first time.”

Consistent with the published literature, these data demonstrate that youth use vaping products for a variety of reasons, including curiosity and experimentation, social influences, the effects of nicotine, an interest in harm reduction (e.g., to reduce or abstain from smoking), and flavours. In the US National Youth Tobacco Survey, a majority reported curiosity or a wish to experiment as

¹¹ Page 4230, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

¹² Quorus Consulting Group Inc. (2020). Exploratory Research on Youth Vaping, retrieved from: <https://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2020/069-19-e/report.pdf>

a reason they used vaping products,^{13,14,15,16} Many cite social reasons for vaping product use, particularly the fact that they see these products as popular among their peers.^{17,18,19}

Additional data indicate while the effects of nicotine may appeal to some youth users, others report experiencing negative side effects of nicotine. In a survey of youth and young adults from Nova Scotia who reported weekly use of vaping products, 29% of respondents reported ‘nicotine effects’ as a negative aspect of vaping product use, whereas 27.5% reported ‘nicotine rush’ as a positive aspect.²⁰

The proposed regulation hypothesizes, “availability of high-nicotine-concentration vaping products... is not the only factor believed to have contributed to the rise in youth vaping” and states, “other key factors include an increase in promotional activities relating to vaping products, including on social media, and the use of a wide variety of flavours and innovative design features.”²¹ Reasons for underage use of vaping products are complex and varied; it is unclear what net proportion of underage vaping product use would be mitigated by the proposed restrictions on higher-nicotine-concentration products.

1.3 Flavours

Many underage users often report that flavours are one reason for using vaping products, including JUUL products. Like adults, most youth vaping product users choose flavoured products,^{22,23,24,25} and many first used flavoured vaping products.^{26,27} Flavours are not the

¹³ Patrick ME, Miech RA, Carlier C, O'Malley PM, Johnston LD, Schulenberg JE. Self-reported reasons for vaping among 8th, 10th, and 12th graders in the US: Nationally-representative results. *Drug Alcohol Depend.* Aug 1 2016;165:275-8. doi:10.1016/j.drugalcdep.2016.05.017;

¹⁴ Wang, T. W., Gentzke, A. S., Creamer, M. R., Cullen, K. A., Holder-Hayes, E., Sawdey, M. D., . . . Neff, L. J. (2019). Tobacco Product Use and Associated Factors Among Middle and High School Students - United States, 2019. *Morbidity and mortality weekly report. Surveillance summaries (Washington, D.C. : 2002)*, 68(12), 1-22. doi:10.15585/mmwr.ss6812a1

¹⁵ Steinberg, L., Albert, D., Cauffman, E., Banich, M., Graham, S., & Woolard, J. (2008). Age differences in sensation seeking and impulsivity as indexed by behavior and self-report: evidence for a dual systems model. *Dev Psychol*, 44(6), 1764-1778. doi:10.1037/a0012955

¹⁶ MacPherson, L., Magidson, J. F., Reynolds, E. K., Kahler, C. W., & Lejuez, C. W. (2010). Changes in sensation seeking and risk-taking propensity predict increases in alcohol use among early adolescents. *Alcoholism: Clinical and Experimental Research*, 34(8), 1400-1408.

¹⁷ Ambrose, B. K., Day, H. R., Rostron, B., Conway, K. P., Borek, N., Hyland, A., & Villanti, A. C. (2015). Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. *Jama*, 314(17), 1871-1873. doi:10.1001/jama.2015.13802

¹⁸ Kong, G., Morean, M. E., Cavallo, D. A., Camenga, D. R., & Krishnan-Sarin, S. (2015). Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*, 17(7), 847-854. doi:10.1093/ntr/ntu257

¹⁹ Patrick, M. E., Miech, R. A., Carlier, C., O'Malley, P. M., Johnston, L. D., & Schulenberg, J. E. (2016). Self-reported reasons for vaping among 8th, 10th, and 12th graders in the US: Nationally-representative results. *Drug and Alcohol Dependence*, 165, 275-278. doi:10.1016/j.drugalcdep.2016.05.017

²⁰ Al-Hamdani, M., Hopkins, D. B., Hardardottir, A., & Davidson, M. (2020). Perceptions and Experiences of Vaping Among Youth and Young Adult E-Cigarette Users: Considering Age, Gender, and Tobacco Use. *J Adolesc Health*. doi:10.1016/j.jadohealth.2020.08.004

²¹ Page 4201, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

²² Cullen KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. *JAMA*. 2019;322(21):2095-2103.

²³ Dai, H., & Hao, J. (2016). Flavored Electronic Cigarette Use and Smoking Among Youth. *Pediatrics*, 138(6), e20162513. doi:10.1542/peds.2016-2513

²⁴ Kong, G., Morean, M. E., Cavallo, D. A., Camenga, D. R., & Krishnan-Sarin, S. (2015). Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults. *Nicotine & tobacco research*, 17(7), 847-854. doi:10.1093/ntr/ntu257

²⁵ Soneji, S. S., Knutzen, K. E., & Villanti, A. C. (2019). Use of Flavored E-Cigarettes Among Adolescents, Young Adults, and Older Adults: Findings From the Population Assessment for Tobacco and Health Study. *Public Health Rep*, 134(3), 282-292. doi:10.1177/0033354919830967

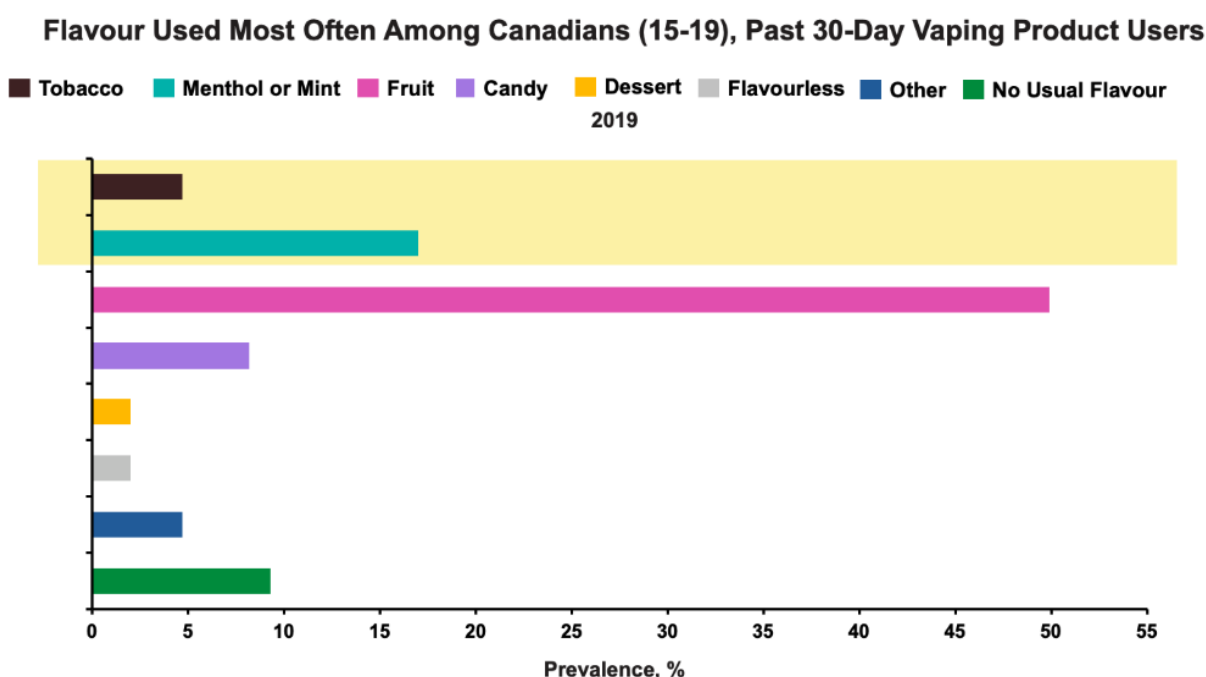
²⁶ Ambrose, B. K., Day, H. R., Rostron, B., Conway, K. P., Borek, N., Hyland, A., & Villanti, A. C. (2015). Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. *Jama*, 314(17), 1871-1873. doi:10.1001/jama.2015.13802

²⁷ McKelvey, K., Baiocchi, M., & Halpern-Felsher, B. (2018). Adolescents' and Young Adults' Use and Perceptions of Pod-Based Electronic Cigarettes. *JAMA Network Open*, 1(6), e183535. doi:10.1001/jamanetworkopen.2018.3535

predominant reason that youth cite for vaping product use, so flavour availability needs to be carefully balanced with providing options for adult smokers while limiting appeal to youth.

Figure 5 shows the flavours most commonly used by Canadians between the ages of 15-19, including regular use of flavours prohibited by the TVPA, like “candy” and “dessert.” In January 2020, JLC voluntarily stopped importing all non-tobacco and non-menthol-based (NTM)-flavoured products and only sells tobacco and mint at this time. These flavours are highlighted in yellow in Figure 5.

Figure 5 Flavour Used Most Often Amongst Canadians (15-19), Past 30-Day Vaping Product Users, CTNS 2019



1.4 Limiting Underage Appeal Through Evidence-Based Measures

To address and reduce underage use of the JUUL System, JLC is undertaking and proposing a series of programmatic and specific actions. These actions are built on findings from scientific literature, which identifies contributing factors of underage appeal of vaping products and reasons for use. Health Canada has implemented a number of regulations under the TVPA aimed at limiting underage appeal, including restrictions on:

- Confectionary, dessert, cannabis, soft drink, or energy drink flavour categories;
- Advertising that can be seen or heard by youth and a ban on lifestyle advertising, sponsorship promotions, etc.

In accordance with the evidence and direction of Health Canada's priorities as reflected in the TVPA, JLC has focused on two core components to limit the appeal of the JUUL System to those who are underage:

- Limiting flavour offerings; and

- Limiting the ways and channels in which the JUUL System is marketed.

1.4.1 Limiting Flavours

As discussed in [Section 1.2](#), youth endorse multiple reasons for using vaping products, including flavours.^{28,29,30,31,32,33} Flavour availability can also facilitate adult smokers' complete switching away from combustible cigarettes. JLC believes policies can and should balance the need to limit appeal of vaping products amongst those underage with the need to ensure the availability of noncombustible products with flavours to support adult smokers as they switch completely away from smoking.

Multiple data sources show that youth report using primarily fruit-flavoured vaping products. JLC believes limiting the JUUL System flavour offerings at this time to Virginia Tobacco, Golden Tobacco, and Mint can lend itself to an appropriate balance for public health.

1.4.2 Marketing Tailored to Adult Smokers

Exposure to tobacco and vaping product marketing can contribute to perceptions of appeal and a desire to try the product. Coupled with "curiosity" as a predominant reason youth endorse for trying vaping products, exposure to product advertising and promotion could drive interest and experimentation.³⁴ Moreover, the frequency at which those underage are exposed to product marketing may increase their susceptibility to use of vaping products.³⁵

JLC's marketing and media guidelines ensure the Company's commercial communications are appropriately tailored to adults who smoke and delivered through narrow marketing channels to limit the potential for unintended exposure to those who do not use tobacco or vaping products, especially those underage. JLC only engages in direct mail communications with age-verified adult smokers (where permitted).

Additionally, JLC fully supports and complies with federal marketing regulations that restrict the promotion of vaping products to protect those underage from being exposed to advertisements that can be seen or heard by youth, whether in brick and mortar stores, online, or other media channels. This prohibition includes the display of vaping products at point-of-sale where youth could have access.

²⁸ Evans-Polce RJ, Patrick ME, Lanza ST, Miech RA, O'Malley PM, Johnston LD. Reasons for Vaping Among U.S. 12th Graders. *J Adolesc Health*. Apr 2018;62(4):457-462. doi:10.1016/j.jadohealth.2017.10.009;

²⁹ Bold, K. W., Kong, G., Cavallo, D. A., Camenga, D. R., & Krishnan-Sarin, S. (2016). Reasons for Trying E-cigarettes and Risk of Continued Use. *Pediatrics*, 138(3), e20160895. doi:10.1542/peds.2016-0895

³⁰ Kong, G., Morean, M. E., Cavallo, D. A., Camenga, D. R., & Krishnan-Sarin, S. (2015). Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults. *Nicotine & Tobacco Research* 17(7), 847-854. doi:10.1093/ntr/ntu257

³¹ Lee, J. A., Lee, S., & Cho, H.-J. (2017). The Relation between Frequency of E-Cigarette Use and Frequency and Intensity of Cigarette Smoking among South Korean Adolescents. *International journal of environmental research and public health*, 14(3), 305. doi:10.3390/ijerph14030305

³² Suris, J. C., Berchtold, A., & Akre, C. (2015). Reasons to use e-cigarettes and associations with other substances among adolescents in Switzerland. *Drug Alcohol Depend*, 153, 140-144. doi:10.1016/j.drugalcdep.2015.05.034

³³ Wang, T. W., Gentzke, A. S., Creamer, M. R., Cullen, K. A., Holder-Hayes, E., Sawdey, M. D., . . . Neff, L. J. (2019). Tobacco Product Use and Associated Factors Among Middle and High School Students - United States, 2019. *Morbidity and mortality weekly report. Surveillance summaries (Washington, D.C.: 2002)*, 68(12), 1-22. doi:10.15585/mmwr.ss6812a1

³⁴ Agaku, I. T., & Ayo-Yusuf, O. A. (2014). The effect of exposure to pro-tobacco advertising on experimentation with emerging tobacco products among US adolescents. *Health Education & Behavior*, 41(3), 275-280.

³⁵ Hammond D, Reid JL, Burkhalter R, Rynard VL. E-cigarette marketing regulations and youth vaping: cross-sectional surveys, 2017-2019. *Pediatrics* 2020; 146(1): e20194020. doi: 10.1542/peds.2019-4020. doi: 10.1542/peds.2019-4020

We do not engage in social media promotions or advertising, and we support a category-wide ban on the use of social media.

Similar to its selection of product flavours for distribution in Canada, JLC is striking a balance through its existing marketing: supporting adult smokers as they transition away from combustible cigarettes, while limiting the potential appeal of the JUUL System among those who are underage.

1.5 Sources of Underage Access to Vaping Products

Curtailing youth access to vaping products would most effectively address youth use.

Understanding how youth access these products, and especially whether this varies by patterns and frequency of use, is necessary to combat underage use.

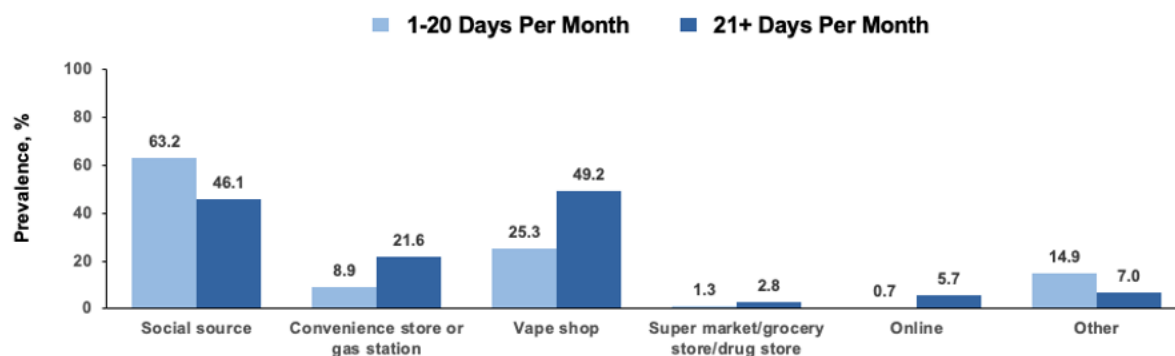
Taken together, the data on sources of access indicate that raising the national age of purchase to 21 and implementing enhanced access controls to automate age verification and product quantity limits would be particularly effective in restricting underage access in Canada.

1.5.1 Youth Primarily Access Vaping Products Through Social Sources

Data across key surveys demonstrate that youth primarily access vaping products through social sources — that is, through a friend, family member, or other person they know — rather than direct purchasing in a retail setting. This finding has been consistent over time across data sources that have measured this annually in nationally representative samples, including in CTNS. The reliance on social sources is consistent with the predominance of infrequent use, likely reflecting social influences or social experimentation/curiosity rather than stable patterns of use and purchase. Conversely, frequent users (20+ days per month) are more likely to purchase the products directly, whether online or from retail stores.

2019 CTNS data, depicted in Figure 6, show that nearly 60% of those between 15-19 access vaping products through social sources, including being given or offered them by a friend or family member, asking someone else to purchase it, and buying from a friend or family member. Among those between 15-19 who obtain vaping products through direct retail purchasing, the most common sources were vape shops (32.7%) and convenience stores/gas stations (11.4%).

Figure 6 Sources of Access Past 30-Day Vaping Products Users, CTNS 2019



*This is a multiple-choice question; participants could give multiple responses and so percentages need not sum to 100%.

In the US, studies using statewide samples to assess youth sourcing of vaping products found comparable results.^{36,37,38} Other nationally representative studies have also found that youth most commonly access vaping products through social sources (e.g., peers, relatives) giving or offering them products. Among youth in the US FDA’s Population Assessment of Tobacco and Health (PATH) study, 57% of 15- to 17-year-old current vaping product users primarily obtained them by asking someone or because of someone offering.^{39,40}

The finding in PATH that youth users largely ask for or are offered products from someone they know also aligns with another key finding from the literature — that many adolescents borrow devices rather than acquiring and using their own, “suggesting that borrowing is part of users’ social experience, not just a means of acquisition”.⁴¹ Social exchange contributes to how a product can grow in popularity among users who did not make their own brand purchasing decisions.

This suggests that underage use prevention efforts that reduce access among those who might share or distribute products to others can be effective in reducing underage use. Robust product quantity restrictions at all vaping product retailers, along with age-verification, would most directly address both direct purchases and also these straw purchases.

Enhanced access controls, which include both advanced age-verification and product quantity restrictions, are discussed in more depth below in [Section 1.6.2](#).

1.5.2 Frequent Underage Users are More Likely to Purchase Vaping Products Directly from a Retailer

While a minority of youth current users of vaping products in Canada purchase the products themselves in stores and online, frequent users of vaping products (i.e., those indicating use on 20 or more of the past 30 days) are far more likely to report purchasing in retail settings.

Figure 7 below shows differences in the proportions of sources of access amongst past 30-day vaping product users in CTNS 2019 by frequency of use. Less frequent users are more likely to report accessing their device through social sources rather than directly purchasing themselves, while frequent users consistently reported more frequent direct purchase.

³⁶ Baker, H. M., Kowitt, S. D., Meernik, C., Heck, C., Martin, J., Goldstein, A. O., & Ranney, L. (2019). Youth source of acquisition for E-Cigarettes. *Preventive Medicine Reports*, 16, 101011. doi:<https://doi.org/10.1016/j.pmedr.2019.101011>

³⁷ Kong, G., Morean, M. E., Cavallo, D. A., Camenga, D. R., & Krishnan-Sarin, S. (2017). Sources of electronic cigarette acquisition among adolescents in Connecticut. *Tobacco regulatory science*, 3(1), 10-16. doi:10.18001/TRS.3.1.2

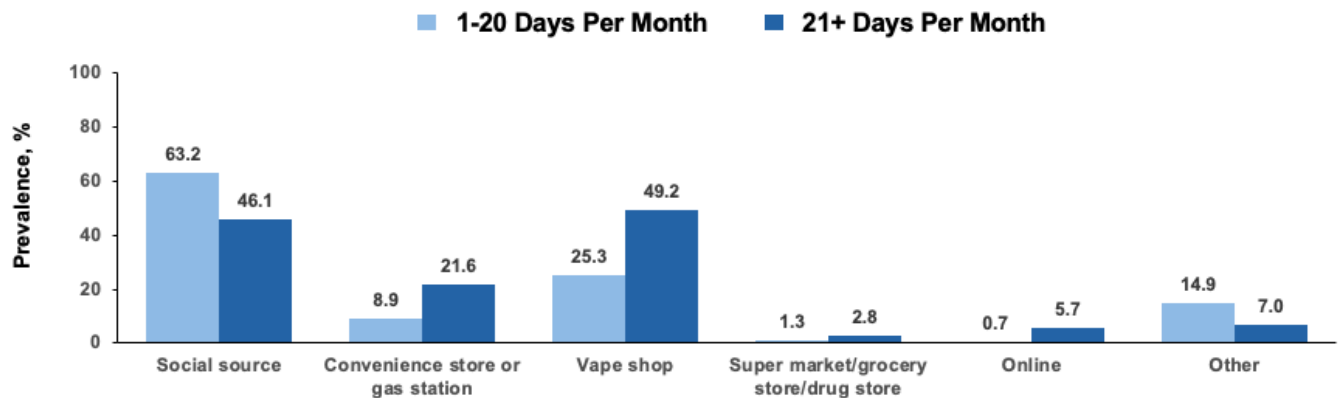
³⁸ Meyers, M. J., Delucchi, K., & Halpern-Felsher, B. (2017). Access to Tobacco Among California High School Students: The Role of Family Members, Peers, and Retail Venues. *Journal of Adolescent Health*, 61(3), 385-388. doi:10.1016/j.jadohealth.2017.04.012

³⁹ Liu, S. T., Snyder, K., Tynan, M. A., & Wang, T. W. (2019). Youth Access to Tobacco Products in the United States, 2016-2018. *Tob Regul Sci*, 5(6), 491-501. doi:10.18001/trs.5.6.2

⁴⁰ Tanski, S., Emond, J., Stanton, C., Kirchner, T., Choi, K., Yang, L., . . . Hyland, A. (2019). Youth Access to Tobacco Products in the United States: Findings From Wave 1 (2013-2014) of the Population Assessment of Tobacco and Health Study. *Nicotine Tob Res*, 21(12), 1695-1699. doi:10.1093/ntr/nty238

⁴¹ Pepper, J. K., Coats, E. M., Nonnemaker, J. M., & Loomis, B. R. (2019). How Do Adolescents Get Their E-Cigarettes and Other Electronic Vaping Devices? *Am J Health Promot*, 33(3), 420-429. doi:10.1177/0890117118790366

Figure 7 Sources of Access Past 30-Day Vaping Products Users by Frequency (Device Access), CTNS 2019



It is likely that frequent users are also the source for sharing with their peers, and as such, reducing their access could also reduce less frequent use. As these friend or peer sources are themselves likely under the age 21,⁴² Tobacco 21 and robust enforcement, as well as enhanced sales and distribution controls described in [Section 1.6](#), are likely to reduce access to such social sources among underage high school/social networks.

1.6 Restricting Underage Access Through Evidence-Based Measures

Restricting underage access is a key component of combating underage use. Health Canada, along with provincial governments, have implemented a number of access controls including:

- Prohibiting the sale of vaping products to young persons (under 18). Sending and delivering these products to young persons is also prohibited.
- Regularly performing inspections of vaping product retailers, specialty establishments, manufacturers, online-based establishments, and any other establishments where vaping products are sold, promoted, manufactured, or labelled.

Despite significant progress in restricting access, those who are underage still find ways to obtain and use tobacco and vaping products within and outside customary retail channels. Underage access is driven by a lack of age-verification and through social sourcing.

To further restrict access to vaping products by underage Canadians, JLC is focused on two key measures:

- Advocating for raising the federal age to purchase tobacco and vaping products to 21 (Tobacco 21).
- Implementing category-wide Enhanced Access Controls at retail and online to automate advanced age verification and bulk purchase limits.

⁴² Institute of Medicine. (2015). *Public health implications of raising the minimum age of legal access to tobacco products*: National Academies Press Washington, DC.

1.6.1 The Impact of Tobacco 21

Tobacco 21 laws fight one of the largest contributors of social-sourcing and have the potential to dramatically reduce underage use rates. While raising the legal age to purchase tobacco and vaping products to 21 is not the only strategy for reducing underage use, we believe it is critical because it will prevent high-school seniors and recent high-school graduates from purchasing tobacco and vaping products directly as well as sharing them with underage users. Additionally, we believe that in order to reach Canada's Tobacco Strategy goal of 5% tobacco use by 2035, Tobacco 21 laws would be an effective regulatory tool to help accelerating a decline in prevalence, achieving that goal.

There are early data that suggest Tobacco 21 can have a major impact on how young people acquire vaping products. Prior to the enactment of Tobacco 21 in the US in December 2019, many states designated 18 as the age of legal purchase of vaping products. Using NYTS, Rodu *et al.* compared the primary source for vaping products from among those below 18 and those above 18: the dominant source of vaping products for current users below 18 is social sourcing (friends, family, and other individuals, reported by 77% of respondents), while the primary source for high school vaping product users aged 18 and above is from retailers such as convenience stores or vape shops (60% of respondents).⁴³

An early appraisal of Tobacco 21 laws in the US by Friedman *et al.* articulates the expected impact of the policy: "As tobacco-21 laws may shape peer access and behavior, these policies could have both direct (own access) and indirect effects (e.g., reducing peer smoking). ... Thus, when a given youth and their friends react to this policy in the same way, they may reinforce each other's responses, amplifying the policy's impact (i.e., a "social multiplier effect")."⁴⁴

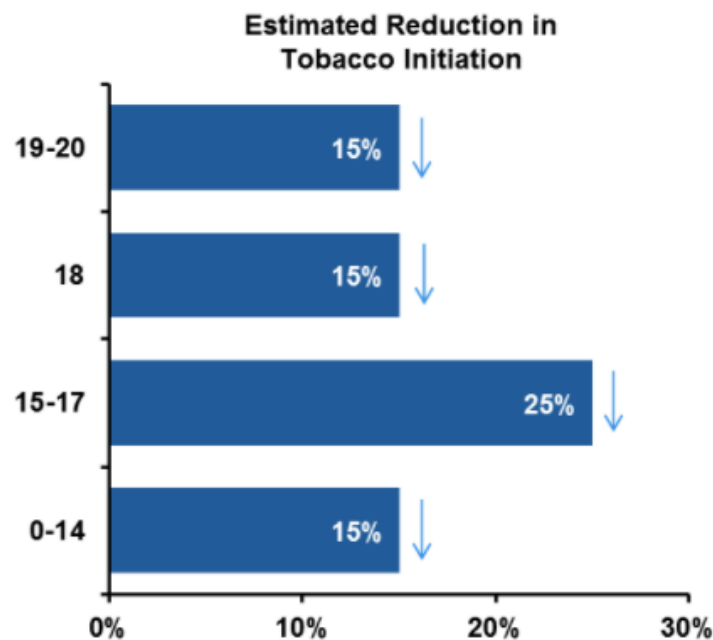
The Institute of Medicine (now the National Academies of Science, Engineering and Medicine) published a report on increasing the minimum purchase age for tobacco products, which included robust population modeling to predict the effect of Tobacco 21 in the US.⁴⁵ As represented in Figure 8, the report found that there would be an estimated reduction in tobacco initiation of at least 15% across all age groups below 20, with the largest expected decrease (25%) for the age cohort of 15-17 year olds.

⁴³ Rodu B. 2019 NYTS Data Reveals Teen Vaping Up, Smoking Eradication Within Reach. <https://rodutobaccotruth.blogspot.com/2020/01/2019-nyts-data-reveals-teen-vaping-up.html>. Updated January 10, 2020, Accessed March 2020.

⁴⁴ Friedman, A. S., Buckell, J., & Sindelar, J. L. (2019). Tobacco-21 laws and young adult smoking: quasi-experimental evidence. *Addiction (Abingdon, England)*, 114(10), 1816–1823. <https://doi.org/10.1111/add.14653>

⁴⁵ Committee on the Public Health Implications of Raising the Minimum Age for Purchasing Tobacco Products; Board on Population Health and Public Health Practice; Institute of Medicine. Washington (DC): National Academies Press (US); 2015 Jul 23. ISBN-13: 978-0-309-31624-8 ISBN-10: 0-309-31624-3

Figure 8 **Estimated Reduction in Tobacco Initiation by Age Cohort with Tobacco 21, Institutes of Medicine 2015**



Restrictions that effectively prevent underage purchases would also have the greatest effect on the most frequent youth vaping product users — those indicating a higher degree of direct purchases. Importantly, based on research on adolescent social networks, it is likely that the friends and classmates of youth using tobacco and vaping products are themselves underage, especially in the context of Tobacco 21 laws.⁴⁶ This suggests that increasing the minimum purchasing age to 21 will lead to a reduction in direct retail purchases by youth users, as well as a reduction in social sourcing among high schoolers, as none will be able to legally obtain tobacco and vaping products.

JLC supports Tobacco 21 legislation and is committed to working with governments to enact these effective policies. We are encouraged to see provinces like Prince Edward Island raise the minimum age for purchasing all tobacco and vaping products to age 21, as of March 1, 2020.



We think it is critical to pursue a federal law as well, and we are advocating for other industry stakeholders to join us and support such an effort. To date, the Canadian Cancer Society, Canadian Lung Association, and the Council of Chief Medical Officers of Health have publicly recommended the federal government consider adopting Tobacco 21 laws.

⁴⁶ Institute of Medicine. (2015). *Public health implications of raising the minimum age of legal access to tobacco products*: National Academies Press Washington, DC.

1.6.2 Enhanced Access Controls

Enhanced Access Controls consist of two separate types of requirements: (i) advanced age-verification; and (ii) automated product-quantity limits. Figure 9 defines each of these requirements.

Figure 9 Enhanced Access Controls Requirements

 Retail-level Brick-and-mortar		 Retail-level E-commerce (JUUL.com)
REQUIREMENTS		
ADVANCED AGE VERIFICATION	Automated ID scanning to verify age (21 years or older)	Two-factor authentication to verify the purchaser
	Automated ID scanning to verify ID validity	Third-party check of the purchaser's personal information, including name, date of birth, address and partial SSN, against public records to verify age
	Requires salesclerk to verify the scanned ID credentials against front of the purchaser's ID	— OR —
	Prevents clerk override	Third-party check of the purchaser's uploaded government-issued ID and real-time photograph (i.e., selfie) to verify age
AUTOMATED PRODUCT QUANTITY LIMITS	Automatically limits the amount of JUUL products to 2 JUUL Device and/or 5 packs of JUULpods per transaction	Automatically limits the amount of JUUL products to 2 JUUL Devices per calendar month and/or 15 packs of JUULpods per month and 10 JUUL Devices per year

At retail, Enhanced Access Controls may be implemented through a Retail Access Controls Standards (RACS) compliant point-of-sale system. RACS is a set of technology standards built into the existing software of a point-of-sale system. The updated software is coded to recognize “restricted” products (in this case tobacco and nicotine products) and automatically implement ID scanning and product quantity limits *prior* to allowing any payment transaction to proceed. RACS technology standards are adaptable to a wide range of point-of-sale systems covering the vast majority of the current market. Once installed, these RACS standards automate the transaction from beginning-to-end to ensure tobacco and vaping products are sold to verified legal-aged purchasers.

Whenever a transaction contains restricted tobacco and vaping products, a RACS-compliant point-of-sale POS system will:

1. Require I.D. scanning to verify age and I.D. validity;
2. Limit the amount of product that can be purchased; and
3. Prevent manual override by the retail clerk.

Initial data have demonstrated the effectiveness of this automated technological solution. The Company’s affiliate, Juul Labs Inc. (JLI) piloted RACS with three retail partners across almost 200 individual retail stores in the US. As part of this pilot, JLI conducted almost 2,000 compliance checks for these pilot locations to measure compliance with both age-verification and bulk-purchasing requirements. Following RACS implementation, the study

observed compliance failure rates of less than one percent, a dramatic decline from pre-RACS compliance failure rates.^{47,48}

Similar standards can, and should, be applied to online sales. We support Health Canada's recent announcement of its intention to implement online age verification requirements for all tobacco and vaping products. Juul.ca and AltVape employ a third-party age verification system, both of which meet Enhanced Access Control requirements, as detailed in Figure 9. We fully support category-wide implementation of a similar standard.

As has been observed with efforts to reduce youth smoking,⁴⁹ reducing youth experimentation with tobacco and vaping products with enhanced access controls should not only decrease prevalence rates but also make it more difficult for current users to access products frequently, and to transition to regular or more frequent use. Product-quantity limits would restrict individuals from buying products to share with or sell to multiple underage users.

Finally, JLI is developing technology for a JUUL Locked Device, which would be shipped "locked" and would require the consumer to pass independent age- and identity-verification to ensure he or she is 21 years of age or older before the product can be "activated" and used. The same technology would allow JLC to limit the number of activated devices a verified consumer can have. The JUUL Locked Device would afford additional access control opportunities.

1.7 Gateway Hypothesis

In addition to understanding underage reasons for use and sources of access, it is also important to examine what, if any, impact vaping has on subsequent smoking behaviour and initiation. We understand Health Canada's concern that experimentation with vaping, particularly among those underage, could cause users to transition to subsequent smoking.

The gateway hypothesis describes a causal chain where the use of one substance — generally a substance with a lower risk profile — promotes the use of a second, higher-risk substance. The hypothesis proposes that the use of the second substance would not have occurred if not for the use of the first, and that use of the "gateway product" causes an individual to start using the second substance. In the case of vaping products, the gateway hypothesis proposes that the use of vaping products causes an individual to start smoking traditional combustible cigarettes. While various mechanisms for the association have been proposed in the published literature, in all cases, the gateway hypothesis specifically asserts causality and a temporal pathway that starts with vaping products use.

The proposed regulation states that youth vaping products-users may transition from vaping products to more harmful conventional cigarettes because vaping products "renormalize

⁴⁷ Prakash, S., Joselow, J., O'Hara, J., & Wissmann, R. (2020). Initial Findings from a Pilot Program of a Novel System to Improve Retailer Compliance for Tobacco Product Purchases. Retrieved from: <https://www.juullabscience.com/wp-content/uploads/sites/8/2020/09/SRNT-Initial-Findings-from-a-Pilot-Program-of-a-Novel-System-to-Improve-Retailer-Compliance-for-Tobacco-Product-Purchases.pdf>

⁴⁸ Chen, T., Prakash, S., Zion, A., Joselow, J., Shiffman, S., & Kasmer, P. (2021). *Improving Retailer Compliance for Tobacco Purchases: Pilot Study Findings [Unpublished Manuscript]*.

⁴⁹ U.S. Department of Health and Human Services. (2014). *The health consequences of smoking: 50 years of progress. A report of the Surgeon General*. Retrieved from Atlanta, GA: https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf

smoking behaviour,”⁵⁰ and that nicotine dependence leads to cigarette use. While there are some studies reporting that the use of vaping products among those underage is associated with later use of combustibles, a deeper examination of common liability reasons for use, coupled with population trends demonstrating historically low smoking rates and findings that vaping products produce less dependence than cigarettes, do not support the existence of a gateway.

1.7.1 Common Liability Theory

The overlap between smoking and vaping product use is also explained by the “common liability” theory, and it is likely that common factors underlie the use of both products. Individuals may be predisposed to use tobacco products in general. Under this “common-liability” hypothesis, youth who experiment with cigarettes and vaping products do so because these behaviours have shared underlying risk factors, and the presence or absence of one product does not influence use of the other. This explains why associations between vaping products and cigarette use among youth are found in almost all data for which these risk factors are not controlled.

Studies offering evidence for the gateway effect have been criticized for high sample attrition and inadequate adjustment of confounding variables.⁵¹ For example, two studies with data from the University of Waterloo’s COMPASS used structural equation modelling and logistic regression to examine the associations between use of vaping products and conventional cigarettes,⁵² and tobacco and vaping products,⁵³ among Canadian youth.

These studies reported positive associations between vaping product use and subsequent use of cigarettes and other tobacco products, but the same studies also reported positive associations between use of cigarettes and other tobacco products and subsequent use of vaping products. In other words, the reported associations were bidirectional; a strong indication that the apparent relationships are explained by pre-existing risk factors.

Chan *et al.*⁵⁴ have strongly criticized similar studies purporting to show a gateway between youth vaping product use and subsequent smoking for insufficient adjustment for confounding variables. The COMPASS studies above adjusted for gender, grade, ethnicity, Province, weekly spending money, number of friends who smoke, past month cannabis use and binge-drinking at baseline. However these comprise only two of the six key potential confounders highlighted by Chan *et al.* as being strongly associated with smoking (peer smoking and alcohol and other substance use, the missing confounders being parental smoking, academic performance/school commitment, susceptibility to future smoking, and deviant behaviours).⁵⁵

⁵⁰ Hallingberg B, Maynard OM, Bauld L, et al. Have e-cigarettes renormalised or displaced youth smoking? Results of a segmented regression analysis of repeated cross sectional survey data in England, Scotland and Wales. *Tob Control*. Mar 2020;29(2):207-216. doi:10.1136/tobaccocontrol-2018-054584

⁵¹ Lee P, Fry J. Investigating gateway effects using the PATH study. *F1000Res*. 2019;8:264. doi:10.12688/f1000research.18354.2

⁵² Aleyan S, Hitchman SC, Ferro MA, Leatherdale ST. Trends and predictors of exclusive e-cigarette use, exclusive smoking and dual use among youth in Canada. *Addict Behav*. Oct 2020;109:106481. doi:10.1016/j.addbeh.2020.106481

⁵³ Aleyan S, Gohari MR, Cole AG, Leatherdale ST. Exploring the Bi-Directional Association between Tobacco and E-Cigarette Use among Youth in Canada. *Int J Environ Res Public Health*. Nov 1 2019;16(21)doi:10.3390/ijerph16214256

⁵⁴ Chan GCK, Stjepanovic D, Lim C, et al. Gateway or common liability? A systematic review and meta-analysis of studies of adolescent e-cigarette use and future smoking initiation. *Addiction*. Sep 4 2020;doi:10.1111/add.15246

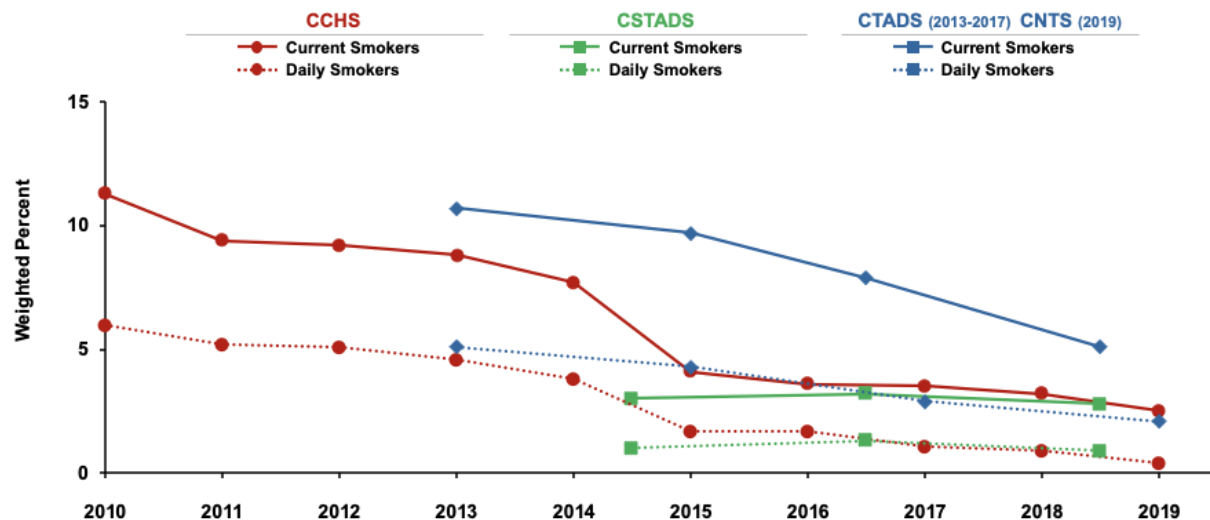
⁵⁵ Derzon JH, Lipsey MW. Predicting tobacco use to age 18: a synthesis of longitudinal research. *Addiction*. Jul 1999;94(7):995-1006. doi:10.1046/j.1360-0443.1999.9479955.x

Kim & Selya showed that the association disappears entirely when more comprehensively adjusting for confounding variables.⁵⁶ Furthermore, the COMPASS studies above also reported that the associations between vaping products and cigarette/other tobacco product use became weaker over time, which could be explained by these behaviours being experimental and not resulting in the long-term use patterns associated with a gateway effect and with morbidity and mortality in later life.

1.7.2 Underage Smoking Prevalence is at Historic Lows

In addition to these concerns around common liability, real world data do not support a meaningful causal gateway effect. Smoking rates in Canada — among both youth and adults — are at historic lows following passage of the TVPA and introduction of higher-nicotine-concentration vaping products. If vaping products acted as a “gateway” to smoking, we would expect increases in smoking rates at the population level as more people use vaping products. On the contrary, cigarette smoking rates among youth and adults continue to decline across all major Canadian surveys:

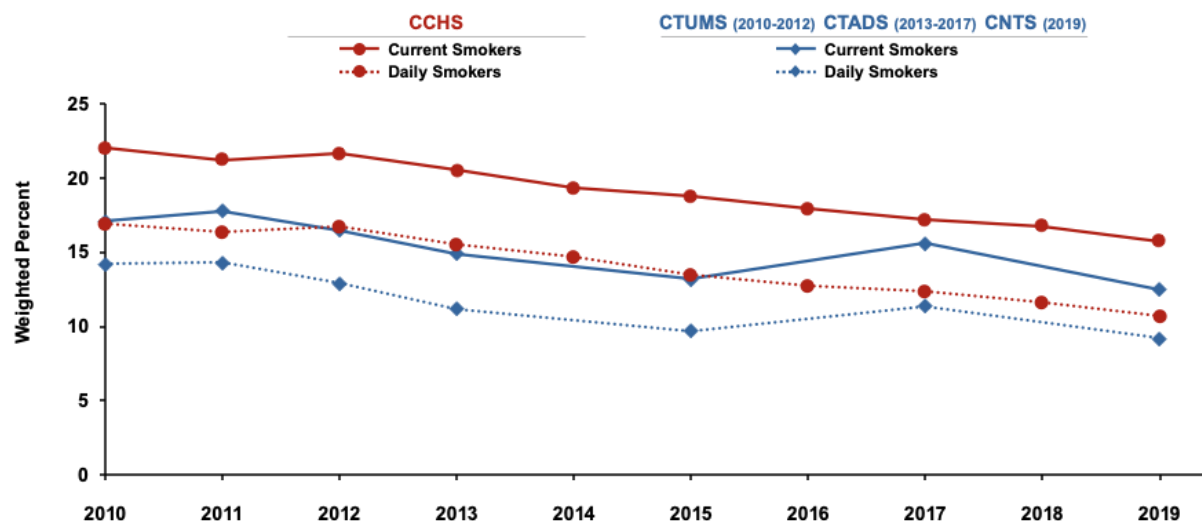
Figure 10 Smoking Prevalence among Youth in Canada 2010-2019*



*The solid lines represent the prevalence of current (daily or occasional smokers), and the dotted lines represent the prevalence of daily smokers. The shaded area reflects the time following the passage of the TVPA.

⁵⁶ Kim S, Selya AS. The Relationship Between Electronic Cigarette Use and Conventional Cigarette Smoking Is Largely Attributable to Shared Risk Factors. *Nicotine Tob Res.* Jun 12 2020;22(7):1123-1130. doi:10.1093/ntr/ntz157

Figure 11 Smoking Prevalence among Adults in Canada 2010-2019



It is also important to note that a significant ITC study finding a dramatic, and troubling, increase in underage Canadian smoking rates between 2017 and 2018 has since been corrected to find rates declined in line with nationally representative surveys presented in Figure 10 and Figure 11. The original June 2019 BMJ study asserted that current smoking prevalence had increased from 10.7% to 15.5% among adolescents age 16-19.⁵⁷ The authors have since amended their weighting and corrected their findings to conclude past 30-day smoking prevalence showed no significant change from 10.7% to 10.0%.⁵⁸

These downward trends in cigarette smoking among youth have followed a similar, albeit more pronounced, pattern in the US. A recent study by Meza *et al.* of nearly 1.3 million 8th, 10th, and 12th graders found that the decline in use of cigarettes and smokeless tobacco accelerated 2-5 times faster between 2012 and 2019 — the time during which vaping product use began to increase — compared to previous periods.⁵⁹

This has led to historically low levels of both cigarette and smokeless tobacco use among adolescents in the United States. Meza *et al.* note, “Although the increasingly rapid reductions in cigarette use cannot be attributed to increased e-cigarette use, they closely follow the introduction of e-cigarettes into the market and their increase in prevalence and at least suggest that the recent increase in e-cigarette use has not slowed the decrease in smoking prevalence among youth.”

1.7.3 Dependence on Cigarettes is Higher Than Dependence on Vaping Products

There are other limitations inherent to the gateway theory. A key assumption of the gateway hypothesis and the rationale underlying the proposed regulation is that the mechanism occurs

⁵⁷ Hammond, D., Reid, J. L., Rynard, V. L., Fong, G. T., Cummings, K. M., McNeill, A., . . . White, C. M. (2019). Prevalence of vaping and smoking among adolescents in Canada, England, and the United States: repeat national cross sectional surveys. *BMJ*, 365, 12219. doi:10.1136/bmj.12219

⁵⁸ Prevalence of vaping and smoking among adolescents in Canada, England, and the United States: repeat national cross sectional surveys. (2020). *BMJ*, 370, m2579. doi:10.1136/bmj.m2579

⁵⁹ Meza R, Jimenez-Mendoza E, Levy DT. Trends in Tobacco Use Among Adolescents by Grade, Sex, and Race, 1991-2019. *JAMA Netw Open*. Dec 1 2020;3(12):e2027465. doi:10.1001/jamanetworkopen.2020.27465

through nicotine dependence (i.e., vaping product use → nicotine dependence → cigarette use). However, empirical evidence for this mechanism occurring is lacking.

Selya *et al.* used a cross-lagged autoregressive model to show that cigarette smoking, rather than vaping product use, drove subsequent changes in cigarette and vaping product use and nicotine dependence.⁶⁰ Compared to cigarettes, vaping products are consistently found to have lower nicotine dependence^{61,62} and lower potential to induce dependence,⁶³ raising further doubts about the nicotine dependence mechanism of the gateway hypothesis.

A recent study on US youth showed that there is no population-level increase in nicotine dependence, which would likely be seen if the gateway effect were occurring.⁶⁴ A psychometric analysis comparing the characteristics of dependence on cigarettes compared to vaping products found no common underlying factor, but only product-specific factors;⁶⁵ this raises doubts as to whether dependence on vaping products is “transferrable” to dependence on cigarettes in the way postulated by the “gateway” hypothesis.

2 The Importance of Nicotine to Adult Smoker Switching and Potential Negative Impact of Proposed 20 mg/mL Nicotine Concentration Limit

Smoking tobacco remains Canada’s single leading cause of preventable disease and premature death.⁶⁶ Despite progress made to help smokers quit and prevent non-smokers from starting, 12% of Canadians aged 15 and over smoke (3.7 million people).⁶⁷ Half of them will die from a smoking-related disease, resulting in nearly 48,000 deaths per year.⁶⁸ Nearly seven in ten smokers want to quit, and about half try to quit each year. But fewer than ten percent of those who try will succeed.⁶⁹ The best way for smokers to reduce their risk of disease would be to quit all tobacco and nicotine. Many, however, will not.

For those who will not stop using nicotine, switching completely to a non-combustible alternative can reduce their exposure to harmful constituents in smoke and their risk of smoking-related disease. This concept is described in Health Canada’s “Canada’s Health Strategy” overview: “Completely replacing cigarettes with a vaping product will significantly reduce a smoker’s exposure to toxic and cancer-causing chemicals. Adults can access vaping products

⁶⁰ Selya AS, Dierker L, Rose JS, Hedeker D, Mermelstein RJ. The Role of Nicotine Dependence in E-Cigarettes' Potential for Smoking Reduction. *Nicotine Tob Res.* Sep 4 2018;20(10):1272-1277. doi:10.1093/ntr/ntx160

⁶¹ Shiffman S, Sembower MA. Dependence on e-cigarettes and cigarettes in a cross-sectional study of US adults. *Addiction.* Oct 2020;115(10):1924-1931. doi:10.1111/add.15060

⁶² Kaplan, B., Alrumaih, F., Breland, A., Eissenberg, T., & Cohen, J. E. (2020). A comparison of product dependence among cigarette only, ENDS only, and dual users: Findings from Wave 3 (2015-2016) of the PATH study. *Drug Alcohol Depend*, 217, 108347. doi:10.1016/j.drugalcdep.2020.108347

⁶³ Glasser AM, Collins L, Pearson JL, et al. Overview of Electronic Nicotine Delivery Systems: A Systematic Review. *Am J Prev Med.* Feb 2017;52(2):e33-e66. doi:10.1016/j.amepre.2016.10.036

⁶⁴ Jackson SE, Brown J, Jarvis MJ. Dependence on nicotine in US high school students in the context of changing patterns of tobacco product use. *Addiction.* Jan 6 2021;doi:10.1111/add.15403

⁶⁵ Rest EC, Mermelstein RJ, Hedeker D. Nicotine Dependence in Dual Users of Cigarettes and E-Cigarettes: Common and Distinct Elements. *Nicotine Tob Res.* Oct 24 2020;doi:10.1093/ntr/ntaa217

⁶⁶ Canadian Lung Association. Smoking and Tobacco Statistics. 2020. Retrieved from: https://www.lung.ca/lung-health/lung-info/lung-statistics/smoking-and-tobacco-statistics#_ftn1

⁶⁷ Health Canada. Canadian Tobacco and Nicotine Survey (CTNS): summary of results for 2019. 2020. <https://www.canada.ca/en/health-canada/services/canadian-tobacco-nicotine-survey/2019-summary.html>

⁶⁸ Page 4230, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

⁶⁹ Babb S, Malarcher A, Schauer G, Asman K, Jamal A. Quitting Smoking Among Adults - United States, 2000-2015. *MMWR Morb Mortal Wkly Rep.* Jan 6 2017;65(52):1457-1464. doi:10.15585/mmwr.mm6552a1

containing nicotine as a less harmful alternative to smoking.”⁷⁰ Widespread, complete switching to non-combustible products by adult smokers can improve public health.

JLC is concerned that higher-nicotine-concentration limits in vaping products will suppress switching among smokers and drive many people who use vaping products back to cigarettes. Providing a satisfying nicotine delivery experience is a key element in facilitating switching among adult smokers. The proposed regulation will affect the majority of the nicotine e-liquid market and constrain nicotine delivery in many vaping products to well below that of cigarettes, particularly in closed systems with demonstrated high switching rates amongst adults.

Ultimately, we are concerned that if enacted, the proposed regulation would have the unintended consequence of further reinforcing combustible cigarettes as the most satisfying, accessible, efficient, and lethal nicotine product on the market.

2.1 The Tobacco Harm Reduction Framework: Lower Toxicity, Appeal, and Sufficient Nicotine Delivery

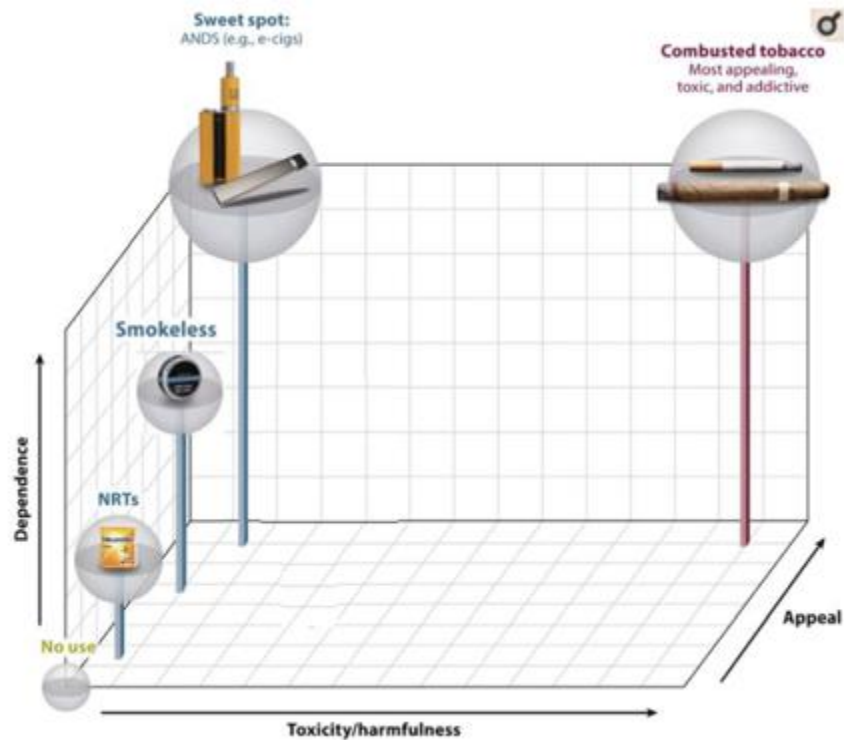
In order to realize their harm reduction potential, vaping products must be appealing and should be permitted to deliver a competitive nicotine experience to cigarettes in order to satisfy smokers’ cravings and promote complete switching away from smoking.

Abrams *et al.*⁷¹ proposed a Three-Dimensional Framework for Harm Minimization that ranks Alternative Nicotine Delivery Systems (ANDS) based on relative: “(a) harmfulness; (b) appeal; and (c) satisfaction including dependence.” To compete with cigarettes, a highly effective nicotine-delivery product that smokers have used for years, if not decades, ANDS must provide sufficient appeal and nicotine delivery to reduce the urge to smoke. Thus, products which are low in toxicity/harmfulness but also low in appeal and dependence potential are unlikely to switch large numbers of smokers. For example, Nicotine Replacement Therapy (NRT) products have proven efficacy in a smoking cessation setting but have not displaced smoking at the population level.

⁷⁰ Health Canada, “Canada’s Health Strategy.” 2018. ISBN: 978-0-660-26713-5. Pub.: 180103. <https://www.canada.ca/content/dam/hc-sc/documents/services/publications/healthy-living/canada-tobacco-strategy/overview-canada-tobacco-strategy-eng.pdf>

⁷¹ Abrams DB, Glasser AM, Villanti AC, Pearson JL, Rose S, Niaura RS. Managing nicotine without smoke to save lives now: Evidence for harm minimization. *Prev Med.* Dec 2018;117:88-97. doi:10.1016/j.ypmed.2018.06.010

Figure 12 Three-Dimensional Framework for Harm Minimization (Abrams *et al.*)



Multidimensional framework for nicotine containing products, considering (1) harmfulness, (2) appeal, and (3) dependence. Reproduced from Abrams *et al.*, 2018 The top, back, right corner depicts the most popular (appealing), highly satisfying (dependence), and toxic space (combusted products), whereas no use at all is zero on all three axes. The bottom, front, left space depicts products that have low toxicity but little appeal or satisfaction (e.g., nicotine replacement therapies - NRTs). Minimizing risk while making a net population health impact requires products to successfully compete with and replace smoking. Thus, the sweet spot, where ANDS or NNP's products might fall, is depicted by high appeal and satisfaction but low toxicity along with products such as Swedish-type snus, which has successfully displaced cigarettes in Sweden.

To optimize their potential benefit for adult smokers, ANDS must occupy the “Sweet Spot” of the framework with drastically lower toxicity/harmfulness but also sufficient appeal and dependence-potential. According to Abrams *et al.*, “some new innovations in e-cigarettes do begin to occupy this sweet spot because some smokers have found an e-cigarette with sufficient appeal for them to sustain use and quit smoking.”⁷²

High reinforcement potential or “abuse liability” can be a positive feature in products that are designed to compete with cigarettes for adults who smoke, better enabling the non-combustible alternative to pull smokers away. In its marketing order for IQOS, a non-combustible heated tobacco product, the US FDA stated, “The data indicate that [IQOS] has addictive potential and abuse liability similar to [combustible cigarettes]. This is important as it signifies [IQOS] can provide an adequate nicotine source for dependent populations, including current [combustible cigarette] users.”⁷³

⁷² Abrams DB, Glasser AM, Villanti AC, Pearson JL, Rose S, Niaura RS. Managing nicotine without smoke to save lives now: Evidence for harm minimization. *Prev Med.* Dec 2018;117:88-97. doi:10.1016/j.ypmed.2018.06.010

⁷³ United States Food and Drug Administration. Premarket Tobacco Product Marketing Orders Decision Summary - IQOS System Holder and Charger 2019. Accessed 01/26/2021. <https://www.fda.gov/media/124247/download>

In addition to nicotine delivery, other elements of appeal play a crucial role in transitioning smokers away from cigarettes, including device design and ease-of-use. Non-combustible products that present less risk than smoking cannot improve overall public health unless significant numbers of adult smokers switch completely to them. Many adult smokers who tried early vaping products found them unsatisfying.⁷⁴ They were complicated to operate,⁷⁵ unpalatable, and often failed to deliver sufficient nicotine to support complete switching.⁷⁶ New innovations and improvements in vaping products provide a better user experience, more efficient nicotine delivery, and help reduce smokers' cravings.^{77,78}

Population-level data are consistent with reports of smokers' dissatisfaction with early vaping products devices, demonstrating both low levels of complete switching and high levels of dual use of both cigarettes and vaping products. An analysis of Waves 1 and 2 of the US PATH study (2013-2015) found that the majority of early vaping product users went back to smoking.⁷⁹

The JUUL System was developed to address the shortcomings of earlier products. These improvements — including a convenient, easy-to-use design and consistent nicotine delivery that more closely resembles the experience of smoking — have helped make JUUL products more appealing for adult smokers and facilitate complete switching. The JUUL System provides a unique opportunity for millions of adult smokers, who would otherwise continue using cigarettes, to find a satisfying alternative.

In contrast to closed systems, open systems with their modifiable features and refillable tanks require a user willing to learn a new technology, refill tanks, and consistently maintain the device. While many smokers enjoy this hobbyist element of vaping and have successfully transitioned with open systems, there are a large number of smokers who find them confusing and unappealing. For them, simple, closed systems with the ability to provide satisfying levels of nicotine offer a more viable alternative to cigarettes. The proposed regulation would unfairly disadvantage these smokers by limiting the nicotine delivery of these products.

This huge potential to reach — and switch — new smokers is evident in the market data collected by Euromonitor following implementation of the TVPA and the introduction of closed systems above 20 mg/mL to the Canadian market. As the report commissioned by Health Canada notes, closed systems' technology (convenient, portable, and easy-to-use while providing a consistent and satisfying nicotine delivery experience) and accessibility (ability for smokers to purchase in the convenience and gas channel where cigarettes are sold) have driven growth in the category.⁸⁰ These market data, coupled with the testimonials of thousands of switchers, demonstrates that no one product will work for every smoker. It is imperative that smokers have

⁷⁴ Coleman B, Rostron B, Johnson SE, et al. Transitions in electronic cigarette use among adults in the Population Assessment of Tobacco and Health (PATH) Study, Waves 1 and 2 (2013-2015). *Tob Control*. Jan 2019;28(1):50-59. doi:10.1136/tobaccocontrol-2017-054174

⁷⁵ Etter JF. Electronic cigarettes: a survey of users. *BMC Public Health*. May 4 2010;10:231. doi:10.1186/1471-2458-10-231

⁷⁶ Etter JF, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction*. Nov 2011;106(11):2017-28. doi:10.1111/j.1360-0443.2011.03505.x

⁷⁷ Abrams DB, Glasser AM, Villanti AC, Pearson JL, Rose S, Niaura RS. Managing nicotine without smoke to save lives now: Evidence for harm minimization. *Prev Med*. Dec 2018;117:88-97. doi:10.1016/j.ypmed.2018.06.010;

⁷⁸ Dawkins L, McRobbie H. Changing Behaviour: Electronic Cigarettes. British Psychological Society.; 2017. Accessed 01/28/2021. <https://beta.bps.org.uk/sites/beta.bps.org.uk/files/Policy%20-%20Files/Changing%20behaviour%20-%20electronic%20cigarettes.pdf>

⁷⁹ Coleman B, Rostron B, Johnson SE, et al. Transitions in electronic cigarette use among adults in the Population Assessment of Tobacco and Health (PATH) Study, Waves 1 and 2 (2013-2015). *Tob Control*. Jan 2019;28(1):50-59. doi:10.1136/tobaccocontrol-2017-054174

⁸⁰ Study of the Market Size, Characteristics, and Growth Trends of the Vaping Products Market in Canada. A custom report compiled by Euromonitor International for Health Canada. February 2020.

a range of non-combustible alternatives available to them, including both open and closed systems, as they switch away from cigarettes.

2.2 High Concentration Nicotine Vaping Products Help Smokers Switch Off of Cigarettes

JLC is concerned that nicotine concentration limits will push many people who use vaping products back to cigarettes. The proposed regulation assumes lower nicotine concentration will have no effect on switching to vaping, however real-world market data, clinical research, and behavioural studies indicate otherwise.

2.2.1 Market Data Indicate High Concentration Nicotine Vaping Products Help Smokers Switch Off of Cigarettes

Increasing evidence demonstrates vaping products serve as a substitute for cigarettes, both in Canada and other countries around the world. From 2013 to 2017, cigarette volume declines in Canada averaged only 2-3% per year.⁸¹

Data sourced from Statistics Canada and analyzed in a 2019 C.D. Howe Institute Intelligence Memo demonstrates a significant decline of 8.5% (population-adjusted) in cumulative past-year sales (2018-2019) of cigarettes coinciding with vaping products becoming federally legal for sale in June 2018.⁸²

The Euromonitor report commissioned by Health Canada makes clear that closed systems are quickly becoming the preferred product: “Prior to 2018 and the entrance of closed advanced market leaders JUUL and Vype (now Vuse), the market for vaping devices was comprised almost wholly of open advanced vaping systems. In 2016, open advance systems comprised 99.9% of the market in value terms. In 2019 the share decreased to 56% and is expected to drop to 36% by 2024.”⁸³ 62% of all nicotine containing e-liquid sales are from products with nicotine concentrations of higher than 20mg.”⁸⁴ Consistent with this, 90% of JLC’s sales in Canada.

A cap on higher-nicotine-concentration vaping products would result in a significant contraction of the market, leaving adults who currently smoke and those who have switched completely to vaping with fewer viable alternatives to cigarettes. The proposed regulation would especially affect those who purchase vaping products at retailers where cigarettes are sold, like convenience and gas retail channels, which expanded vaping distribution by over 27,000 stores since the legalisation of vaping products.⁸⁴ We believe it should be as easy for an adult who smokes to buy non-combustible alternatives as it is to buy cigarettes. Having viable alternatives to cigarettes is critically important to improve health disparities in those who still smoke, especially amongst

⁸¹ Irvine I. Canadians concerned about vaping. Retrieved from: <https://www.cdhowe.org/intelligence-memos/ian-irvine-%E2%80%93vilification-vaping>. Updated December 4, 2019, Accessed February 13, 2021.

⁸² Irvine I. Canadians concerned about vaping. Retrieved from: <https://www.cdhowe.org/intelligence-memos/ian-irvine-%E2%80%93vilification-vaping>. Updated December 4, 2019, Accessed February 13, 2021.

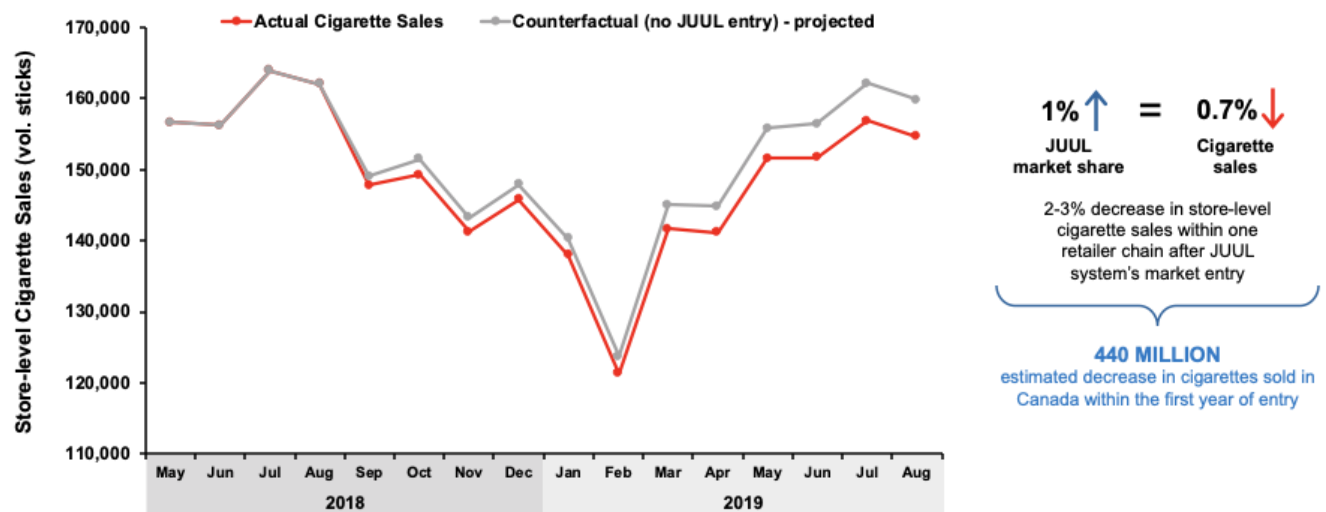
⁸³ Study of the Market Size, Characteristics, and Growth Trends of the Vaping Products Market in Canada. A custom report compiled by Euromonitor International for Health Canada. February 2020.

⁸⁴ Study of the Market Size, Characteristics, and Growth Trends of the Vaping Products Market in Canada. A custom report compiled by Euromonitor International for Health Canada. February 2020.

Canadians who live in rural areas, including the Territories, where smoking rates remain stubbornly high.^{85,86,87}

JLC has evaluated the impact of JUUL market entry on cigarette sales across Canada from 2018 to 2019 using store-level sales data from a major national C&G retailer, shown in Figure 13. Our results suggest that JUUL market entry was, on average, significantly correlated with a 2-3% reduction in store level cigarette sales. Further, every 1 percentage point increase in JUUL market share was associated with an approximately 0.7% decrease in store-level cigarette sales. This analysis of store-level sales data suggest that local availability of vaping products like JUUL have the potential to reduce local cigarette consumption.

Figure 13 Monthly Cigarette Sales Declines After JUUL System Market Entry



This in-market data suggest there will be a direct effect on adult vapers and calls into question the proposed regulation's use of the Social Values and Psychographic Segmentation of Tobacco and Nicotine Users and Non-Users survey to determine the prevalence of nicotine concentration use by age. As discussed above in [Section 1.1.1](#), the report was a non-probabilistic convenience sample and not appropriate for estimating population-level prevalence rates. Further, the report does not seem in line with the market data.

Additionally, the Social Values survey fails to consider and incorporate that such higher concentration products were not widely available in the marketplace until the latter half of 2018 following passage of the TVPA. Before the TVPA, lower-nicotine-concentration products were widely available, even though they were not legally marketed. Beyond the issues with using the Social Values survey to assess prevalence at the population level, the analysis does not acknowledge or correct for the impact of this important regulatory dynamic (e.g., to limit the

⁸⁵ Northwest Territories Health and Social Services. (2010) *Health Status Report*. Retrieved from <https://www.hss.gov.nt.ca/sites/hss/files/nwt-health-status-report.pdf>

⁸⁶ Nunavut Department of Health. *Tobacco Free*. Retrieved from <https://livehealthy.gov.nu.ca/en/tobacco-free>

⁸⁷ Cunningham, J. A., Chaiton, M., Leatherdale, S. T., Godinho, A., & Schell, C. (2020). Targeting mailed nicotine patch distribution interventions to rural regions of Canada: protocol for a randomized controlled trial. *BMC Public Health*, 20(1), 1757. doi:10.1186/s12889-020-09810-2

comparison only to those vapers who had started vaping *after* the legalization of the market and availability of higher concentration products). This is particularly relevant in light of the market data indicating a massive shift to closed systems following implementation of the TVPA. As discussed below [Section 2.2.2](#), due to the range of factors impacting nicotine delivery of vaping products the proposed regulation will primarily restrict the delivery of these closed systems.

2.2.2 Clinical Pharmacokinetic Studies Demonstrate JUUL Products at Concentrations Above 20 mg/mL Provide Satisfying Nicotine Delivery for Adult Smokers, Albeit at Lower Levels than Combustible Cigarettes

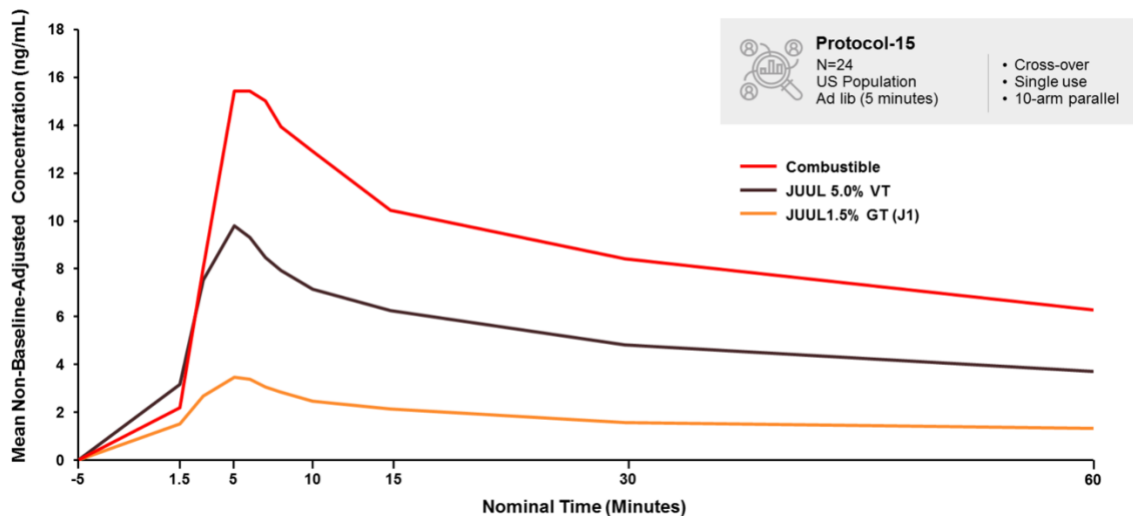
Providing a nicotine effect and experience competitive with combustible cigarettes is critical to facilitate an adult smoker's transition from combustible cigarette use. JLI's clinical studies demonstrate a nicotine absorption curve for the JUUL System at 5.0% (59 mg/mL) that is competitive with, but generally lower than, a combustible cigarette.

JLI has conducted six pharmacokinetic (PK) studies of the JUUL System and three are in the published literature. These studies demonstrated that nicotine delivery from the JUUL System was generally lower than that from combustible cigarettes and significantly higher than 4 mg nicotine gum. The JUUL System delivers nicotine within the range of comparator vaping products and IQOS, but towards the higher end of that range. These results show that the JUUL System can act as a substitute for and support complete switching away from combustible cigarettes.

A recently published PK study of the JUUL System with adult smokers compared the higher concentration 59 mg/mL JUUL product to the 18 mg/mL JUUL product. It found that the higher concentration 59 mg/mL product delivered significantly greater levels of nicotine and significantly reduced craving and withdrawal compared to the 18 mg/mL concentration product. Based on the data, researchers concluded that the lower nicotine delivery and craving relief from the 18 mg/mL JUUL pods may limit the product's ability to provide a satisfying alternative to cigarette smoking — particularly for more dependent adult smokers.⁸⁸

⁸⁸ Goldenson NI, Fearon IM, Buchhalter AR, Henningfield JE. An Open-Label, Randomised, Controlled, Crossover Study to Assess Nicotine Pharmacokinetics and Subjective Effects of the JUUL System with Three Nicotine Concentrations Relative to Combustible Cigarettes in Adult Smokers. *Nicotine Tob Res.* Jan 25 2021;doi:10.1093/ntr/ntab001

Figure 14 Pharmacokinetic Curves of the JUUL System with JUULpods in 5.0% (59 mg/mL) and 1.5% (18 mg/mL) Nicotine Concentrations Compared to Combustible Cigarettes



The proposed regulation to limit nicotine to 20 mg/mL in vaping products will significantly restrict nicotine delivery to well below that of cigarettes, particularly for the closed systems many smokers find to be an appealing alternative due to their compact design and ease of use. Ultimately, this protects cigarettes from competition by making non-combustible vaping alternatives less appealing compared to cigarettes.

As discussed below, an unintended consequence of this may be to drive former adult smokers currently using such vaping products back to conventional cigarettes to satisfy their cravings while also inhibiting switching among current adult smokers. This would undermine Health Canada's goals to reduce the burden of smoking-related death and disease.

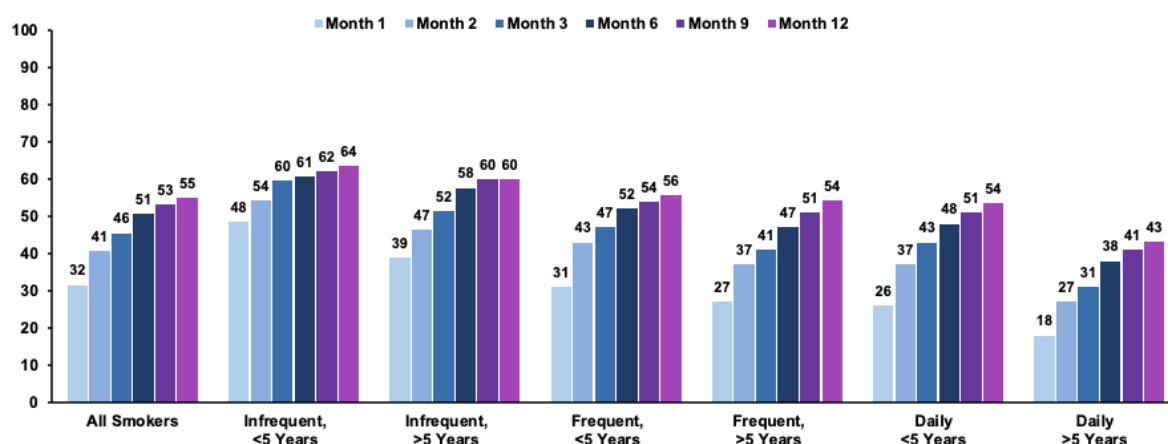
2.2.3 Behavioural Studies Demonstrate High Switch Rates Among Adult Smokers, With the Highest Rates in the US and Canada Where Nicotine Concentrations Above 20 mg/mL are Available

The importance of the JUUL System's nicotine delivery to facilitate switching is further reflected in behavioural studies demonstrating high switch rates among adult smokers, particularly in jurisdictions where the JUUL System is available in nicotine concentrations above 20 mg/mL. Data from real-world longitudinal observations of large cohorts of adult smokers show that use of the JUUL System by current smokers is strongly associated with complete switching away from cigarettes (defined as no past 30-day combustible cigarette use).

JLI sponsored a longitudinal prospective cohort study called Adult JUUL Users Switching and Smoking Trajectories (ADJUSST) Study. A large sample (~55,000) of US adults who had recently purchased a JUUL Starter Kit were enrolled in a study that aimed to assess their behaviour six times over a 12-month period. The primary outcomes were past 30-day smoking and JUUL use, assessed 1, 2, 3, 6, 9, and 12 months after the initial purchase.

Over 50% of respondents reported complete switching away from cigarettes 12 months following purchase, as displayed in Figure 15. Rates of complete switching increased over time, as rates of dual use decreased across a wide range of smoking histories, including daily smokers who had been smoking for longer than five years. In ADJUSST, baseline smokers who reported more frequent JUUL use, greater satisfaction from initial JUUL use, and higher JUUL dependence were significantly more likely to subsequently switch completely at 12 months.

Figure 15 High Switching Rates Seen across a Broad Range of Adult Smoker Histories Using JUUL over 12 Months (ADJUSST)



Note. Infrequent Short-Term Smokers, N=1,674-1,857; Infrequent Long-Term Smokers, N=1,199-1,382; Frequent Short-Term Smokers, N=924-1,074; Frequent Long-Term Smokers, N=1,505-1,820; Daily Short-Term Smokers, N=1,153-1,357; Daily Long-Term Smokers, N=4,971-5,950.

Switching: “No” response to the question, “In the past 30 days, have you smoked a cigarette, even one or two puffs?”

Infrequent, Short-Term Smokers, smoked 1-19 days in the past 30 days and regular smoking ≤5 years.

Infrequent, Long-Term Smokers, smoked 1-19 days in the past 30 days and regular smoking >5 years.

Frequent, Short-Term Smokers, smoked 20-29 days in the past 30 days and regular smoking ≤5 years.

Frequent, Long-Term Smokers, smoked 20-29 days in the past 30 days and regular smoking >5 years.

Daily, Short-Term Smokers, smoked 30 days in the past 30 days and regular smoking ≤5 years.

Daily, Long-Term Smokers, smoked 30 days in the past 30 days and regular smoking >5 years.

These high switching rates at 12 months were seen across racial and ethnic minorities (Figure 16), lower-income populations (Figure 17), and those with mental health conditions (Figure 18) and chronic illness (Figure 19). While the study did not specifically collect data on Canadian Indigenous populations, it does indicate that a wide range of adults, including racial and ethnic minorities, can benefit from switching completely to the JUUL System from cigarettes.

This is particularly important in Canada because smoking rates in Indigenous Canadians is two to five times higher than the general population⁸⁹ and is a significant driver of health inequality. Indigenous Canadians suffer high burdens of smoking-related mortality⁹⁰ and could benefit from having access to less harmful alternatives to compete with the combustible cigarettes they know and use.

⁸⁹ Health Canada. Canada’s Tobacco Strategy. 2020. <https://www.canada.ca/en/health-canada/services/publications/healthy-living/canada-tobacco-strategy.html>

⁹⁰ First Nations Information Governance Centre. (2012). *First Nations Regional Health Survey (RHS) 2008/10: National report on adults, youth and children living in First Nations communities*. First Nations Information Governance Centre.

In the ADJUSST study, switching rates increased as dual use decreased across a broad range of smokers using JUUL over 12 Months:

Figure 16 High Switching Rates Seen over 12 Months amongst Racial and Ethnic Subpopulations (ADJUSST)

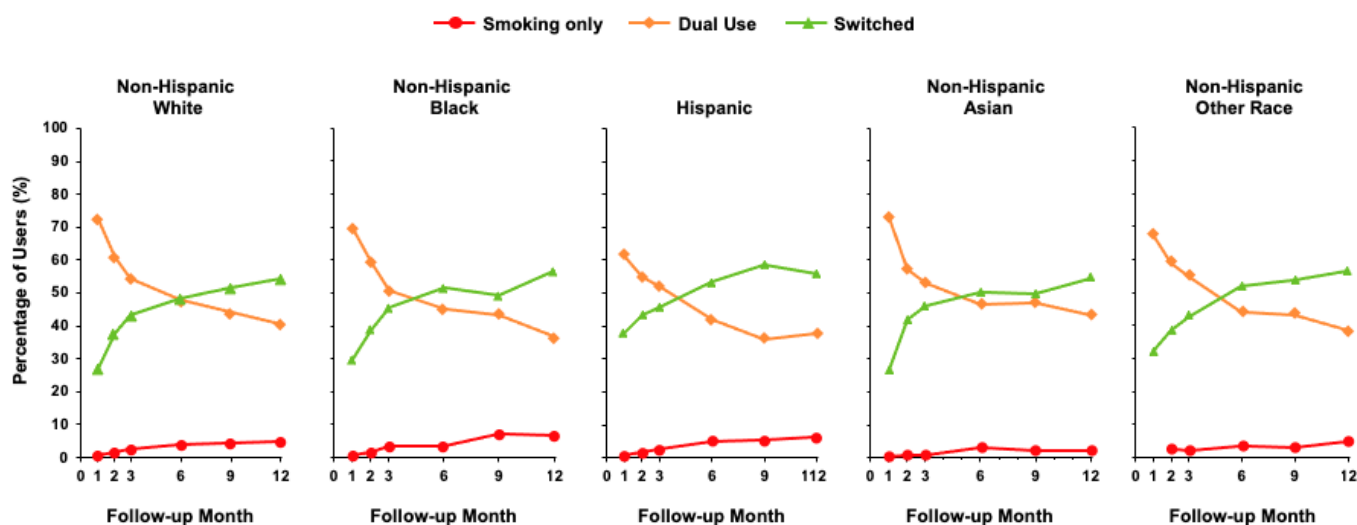


Figure 17 High Switching Rates Seen over 12 Months amongst All SES Populations (ADJUSST)

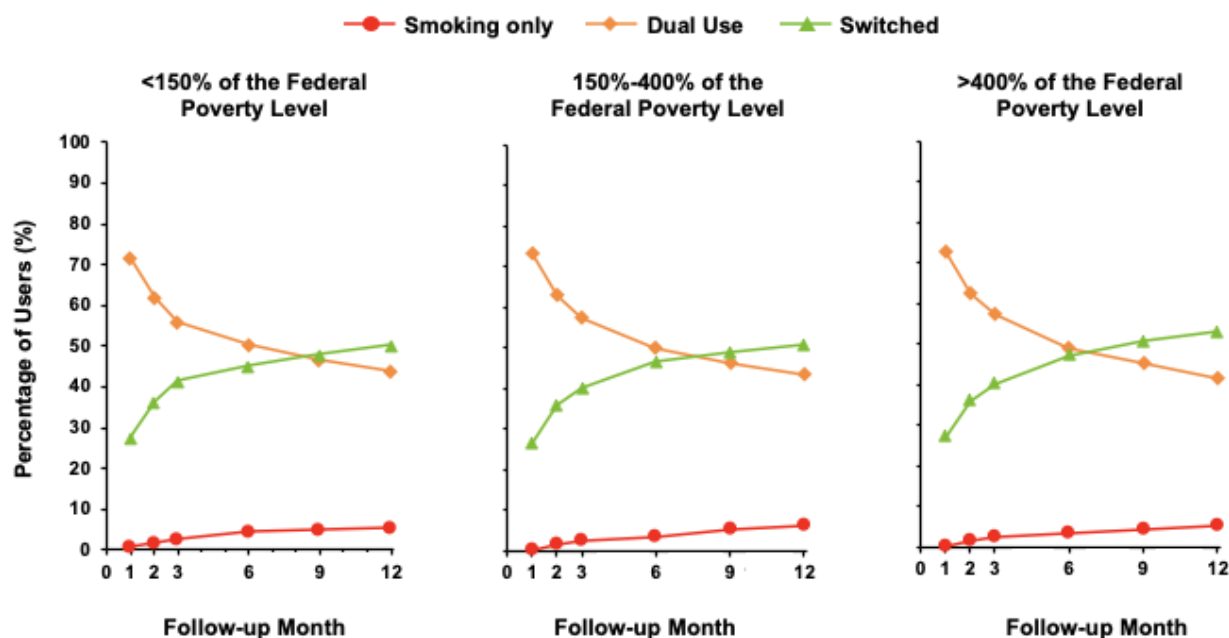


Figure 18 High Switching Rates Seen over 12 Months amongst Those with Depression and Anxiety Disorders (ADJUSST)

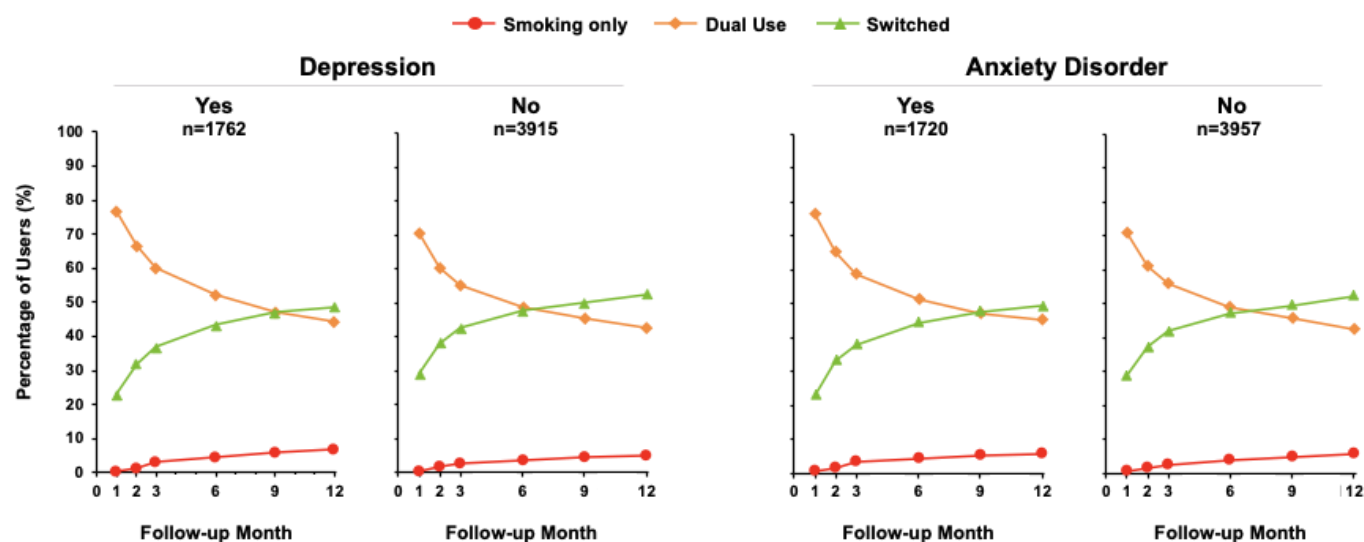
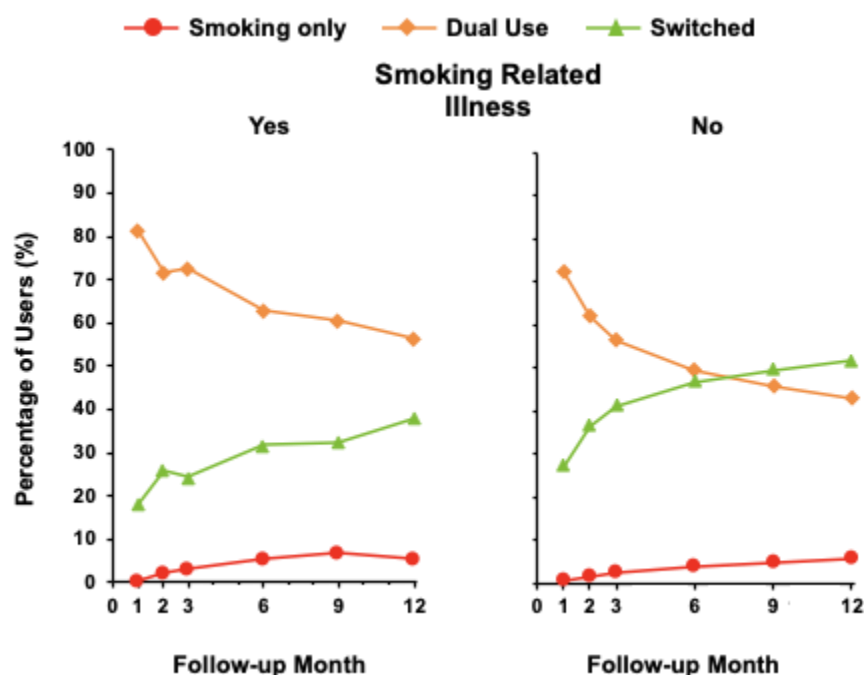


Figure 19 High Switching Rates Seen over 12 Months amongst Those with Smoking-Related Illnesses (ADJUSST)



There is limited recent and longer-term longitudinal data assessing differences in switching away from smoking by vaping product nicotine concentration. Differences across regulatory settings may provide data to address this question. JLI conducted three parallel longitudinal studies that enrolled adults who smoke in the US, Canada, and UK to assess switching following their

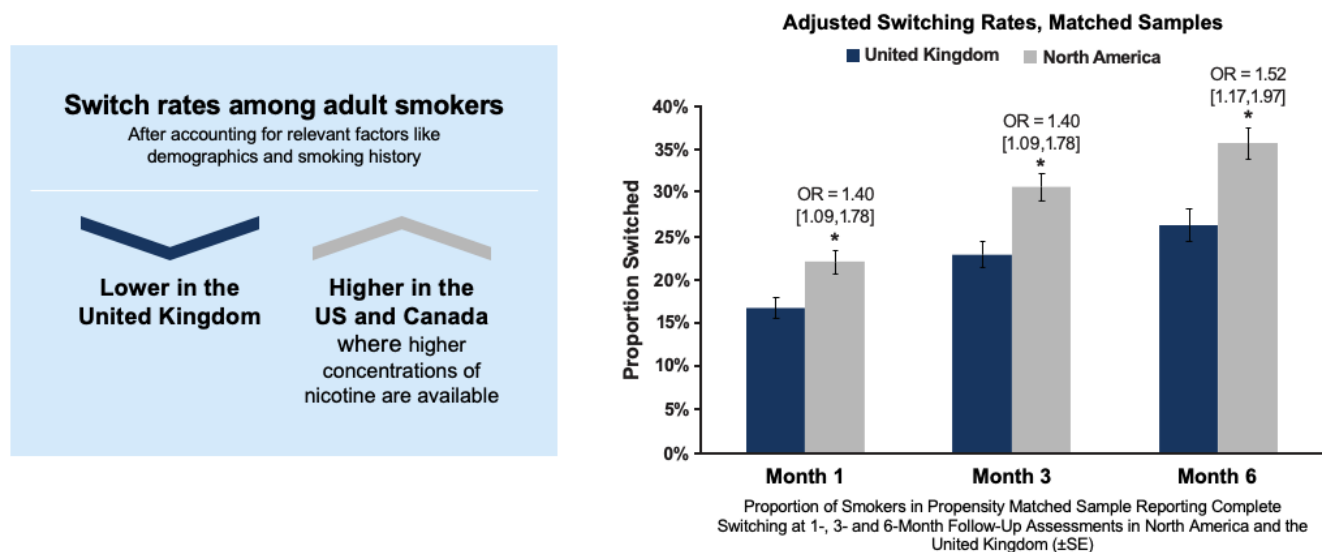
purchase of the JUUL System in a retail store or online. The study compared switching rates with the JUUL System in the UK, where JUULpods are available only in 18 mg/mL and 9 mg/mL nicotine concentrations, to North America (US and Canada), where JUULpods are available in 59 mg/mL (5.0%) and 35 mg/mL (3.0%).

The study found that while rates of complete switching from cigarettes to the JUUL System among adult smokers who purchase JUUL products in the United Kingdom are encouraging, they are over 40% lower than switch rates among similar smokers in the United States and Canada, where the higher concentration JUUL products are available.⁹¹

As discussed below, nicotine delivery of vaping products is affected by a range of factors including user behaviour, nicotine concentration, battery power, and coil temperature. Since all participants in the study were users of the JUUL System, a closed-system vaping product that does not permit adjustment of power or coil temperature, these and other device factors were held constant — hence variations by region likely reflect differences in nicotine concentration and delivery.

In both the UK and North America, the vast majority of adult smokers in the study (over 80%) used JUUL products with the highest nicotine concentration available, calling into question the proposed regulation’s assertion that a nicotine ceiling would not affect adult smokers. Given that initial satisfaction was a predictor of switching in ADJUST and the importance of adequate nicotine delivery in pulling smokers away from cigarettes, these results are unsurprising.

Figure 20 Switching in North America vs. the United Kingdom



Note. *Significantly greater than United Kingdom ($p < 0.05$)

S. Shiffman, N. Goldenson, Y. Ding, S. Prakash, C. Hatcher, E. Augustson. "Differences in Rates of Adult Smokers Switching Away from Smoking Using JUUL System Products, Across Jurisdictions with Different Maximum Nicotine Concentrations (North America and the United Kingdom)." Presented 9/25/20 at the 3rd Scientific Summit on Tobacco Harm Reduction.

⁹¹ Shiffman S, Goldenson NI, Ding Y, Prakash S, Hatcher C, Augustson EM. Differences in Rates of Adult Smokers Switching Away from Smoking using JUUL System Products, Across Jurisdictions with Different Maximum Nicotine Concentrations (North America and the United Kingdom). 2020; Accessed 01/26/2021. <https://www.juullabscience.com/wp-content/uploads/sites/8/2020/09/Differences-in-Rates-of-Adult-Smokers-Switching-Away-from-Smoking-Using-JUUL-System-Products-Across-Jurisdictions-with-Different-Maximum-Nicotine-Concentrations.pdf>

In another pharmacokinetic study comparing the 59 mg/mL and 18 mg/mL JUUL products, Dr. Phillips-Waller *et al.* found, “Juul EU does not deliver nicotine as effectively as either Juul US, or refillable e-cigarettes, and *may thus have more limited potential in helping smokers stop smoking* (emphasis added).” The authors concluded, “Despite retaining the ease of use and the discrete appearance of Juul US, our results suggest that Juul EU is likely to be less appealing to smokers. Given the nicotine delivery profile and effects on urges to smoke, it may be less effective in helping smokers quit than Juul US, and probably also less than refillable EC products.”⁹²

The authors question the public health benefit of a 20 mg/mL nicotine concentration restriction, “The findings support questions raised about the rationale of the [20 mg/mL] nicotine content limit for e-cigarettes, stipulated in the EU Tobacco Products Directive (TPD; Medicine and Healthcare products Regulatory Agency 2020). The proposed regulation allows cigarettes to deliver the nicotine levels that smokers seek, but disallows much less risky competitive products to do so. The consequence of this could be that at least some smokers who could have switched to less dangerous alternatives with comparable nicotine delivery are unable to access them.”

In summary, we fear that the proposed regulations restricting nicotine delivery will have substantial negative effects on current smoking adults’ motivation and ability to switch away from cigarettes, contributing to a greater health burden than if the proposed regulations were instead replaced with more tailored underage use prevention measures aimed at limiting appeal and restricting access.

2.3 Multiple Factors, Including Nicotine Concentration, Affect Nicotine Delivery

The proposed regulation appears to assume that limiting nicotine concentrations in vaping products will limit and/or decrease nicotine exposure, thereby limiting underage appeal and dependence. However, regulating nicotine exposure based on the level of nicotine in an e-liquid fails to take into account the multitude of factors impacting nicotine delivery and will not achieve the objective of lowering nicotine exposure in many vaping products.

Vaping products are a highly heterogeneous category of products, consisting of both open and closed systems, with a wide range of various features, including ingredients, temperature settings, battery power, and other customizable options. In light of this heterogeneity, the actual nicotine delivery of vaping products is similarly driven by a combination of factors,⁹³ including:

- The nicotine content of the liquid;
- The product’s characteristics (e.g., ingredients and heating temperature); and
- User behaviour.

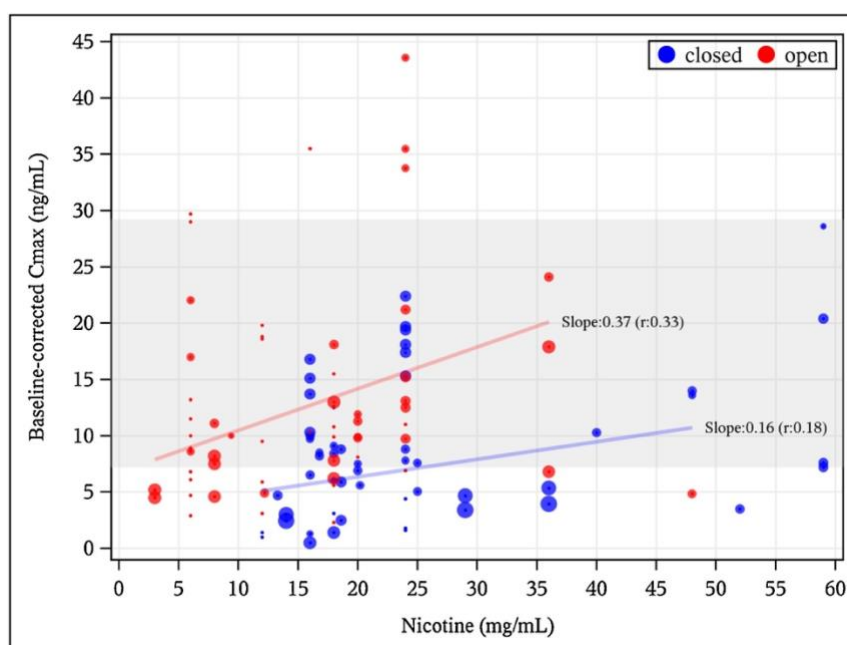
As a result, limiting nicotine concentration in e-liquids will not always lower nicotine delivery (i.e., the amount of nicotine a consumer is exposed to when using a product), particularly for users of open systems as they titrate to achieve the level of nicotine they seek. In a pooled data analysis of 27 pharmacokinetic studies, researchers “... observed that open-tank (refillable) electronic cigarettes, which often enable users to vary device power, can deliver high nicotine

⁹² Phillips-Waller, A., Przulj, D., Smith, K.M. et al. Nicotine delivery and user reactions to Juul EU (20 mg/ml) compared with Juul US (59 mg/ml), cigarettes and other e-cigarette products. *Psychopharmacology* 238, 825–831 (2021). <https://doi.org/10.1007/s00213-020-05734-2>

⁹³ Talih, S., Salman, R., El-Hage, R., Karam, E., Karaoghlanian, N., El-Hellani, A., . . . Shihadeh, A. (2020). Might limiting liquid nicotine concentration result in more toxic electronic cigarette aerosols? *Tob Control*. doi:10.1136/tobaccocontrol-2019-055523

levels to consumers, sometimes at greater doses than a conventional tobacco cigarette, even at the lower nicotine liquid concentrations typically available.”⁹⁴ Researchers found that devices with nearly 60 mg/mL concentrations could deliver lower plasma nicotine levels than different devices with 6 mg/mL concentrations.⁹⁵

Figure 21 Nicotine C_{\max} from open (refillable) versus closed (non-refillable) electronic cigarettes (Jacobson *et al.*)



Note: Association between Cmax and nicotine by electronic cigarette type (open or closed systems). All papers with available Cmax base-line adjusted values. Models with intercept and slope at random. Gray area representing Nicotine range from conventional cigarettes. The size of the marker reflects the relative weight of the study in the pooled data analysis

The JUUL System is a closed system vaping product that incorporates robust firmware and temperature control to ensure consistent performance, limit thermal degradation of e-liquid constituents, and minimize the formation of Harmful and Potential Harmful Constituents (HPHCs). As a result of its low temperature and compact design, the JUUL System aerosolizes smaller amounts of total particulate matter than many other products, particularly open systems. Because low amounts of aerosol (i.e. the carrier on which nicotine travels) are produced with each temperature-regulated puff, the JUUL System requires higher concentrations of nicotine in the e-liquid in order to deliver satisfying levels of nicotine to the user with lower volumes of aerosol.

As discussed above, [Section 2.2.2](#), the impact of the JUUL System’s technological and design features is evident in pharmacokinetic studies measuring actual nicotine delivery across a range of nicotine concentrations. The JUUL System in 1.5% (18 mg/mL) delivers significantly less

⁹⁴ Jacobson, K., Martinez, J., Larroque, S., Jones, I., & Paschke, T. (2020). Nicotine pharmacokinetics of electronic cigarettes: A pooled data analysis from the literature. *Toxicology Reports*, 8. doi:10.1016/j.toxrep.2020.12.016

⁹⁵ Jacobson, K., Martinez, J., Larroque, S., Jones, I., & Paschke, T. (2020). Nicotine pharmacokinetics of electronic cigarettes: A pooled data analysis from the literature. *Toxicology Reports*, 8. doi:10.1016/j.toxrep.2020.12.016

nicotine and is less effective in relieving smokers' cravings than the JUUL System in 5.0% (59 mg/mL). Real-world observational behavioural data indicates that this lower nicotine delivery results in lower switching rates in adult smokers in jurisdictions like the UK, where nicotine concentration is limited to 20 mg/mL.

Regulating nicotine exposure based on the level of nicotine in an e-liquid also fails to consider user behaviour, the third factor impacting nicotine delivery. We note with concern that the proposed regulation does not appear to cite any of the published literature examining the impact of nicotine concentration limits on “compensatory puffing” and subsequent exposure to toxicants in vaping aerosol.

In order to achieve a satisfying level of plasma nicotine concentration from products which deliver less nicotine-per-puff, users have been known to compensate by simply taking more puffs or longer puffs.^{96,97,98} This compensatory puffing behaviour has the potential to expose the user to more toxicant per unit of nicotine.^{99,100} The proposed regulation aims to limit nicotine exposure by regulating nicotine content, but this may cause users to inhale more total aerosol to titrate to the level of nicotine they seek, potentially increasing their exposure to HPHCs.¹⁰¹

3 Risk-Proportionate Regulation to Establish a Pathway for Responsibly Marketed Products Above 20 mg/mL

Should Health Canada proceed with the proposed regulations, JLC respectfully requests consideration of a risk-proportionate alternative pathway to market for responsibly marketed products with nicotine concentrations above 20 mg/mL. As discussed above, regulating nicotine exposure on the basis of nicotine concentration in an e-liquid is not fit for purpose and will not uniformly limit nicotine exposure in the products that remain on the market.

JLC supports risk-proportionate regulation for vaping and other non-combustible alternative products. Such a policy framework, at its core, applies the most stringent regulations to the riskiest products (e.g., combustible cigarettes) and encourages current adult users to migrate to potentially less harmful alternatives (e.g., vaping products). To be clear, risk-proportionate regulation does not mean a “lenient” approach to non-combustible alternatives. It certainly does not mean an unregulated marketplace. Rather, robust, informed regulation of tobacco and nicotine products will always be appropriate.

Within this framework, JLC believes that non-combustible alternatives, like vaping products, must be able to compete with combustible cigarettes—especially on nicotine delivery. The regulatory balance should be weighted in favour of harm reduction to move adults who smoke away from the most harmful tobacco and nicotine products (e.g., combustibles) towards

⁹⁶ Kosmider L, Kimber CF, Kurek J, Corcoran O, Dawkins LE. Compensatory Puffing With Lower Nicotine Concentration E-liquids Increases Carbonyl Exposure in E-cigarette Aerosols. *Nicotine Tob Res.* Jul 9 2018;20(8):998-1003. doi:10.1093/ntr/ntx162

⁹⁷ Dawkins L, Cox S, Goniewicz M, et al. 'Real-world' compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure. *Addiction.* Oct 2018;113(10):1874-1882. doi:10.1111/add.14271

⁹⁸ Kosmider L, Cox S, Zaciera M, et al. Daily exposure to formaldehyde and acetaldehyde and potential health risk associated with use of high and low nicotine e-liquid concentrations. *Sci Rep.* Apr 16 2020;10(1):6546. doi:10.1038/s41598-020-63292-1

⁹⁹ Kosmider L, Cox S, Zaciera M, Kurek J, Goniewicz M, L., McRobbie, H., . . . Dawkins, L. (2020). Daily exposure to formaldehyde and acetaldehyde and potential health risk associated with use of high and low nicotine e-liquid concentrations. *Sci Rep*, 10(1), 6546. doi:10.1038/s41598-020-63292-1

¹⁰⁰ Dawkins L, Cox S, Goniewicz M, et al. 'Real-world' compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure. *Addiction.* 2018;113(10):1874-1882.

potentially less harmful non-combustible alternatives. An alternative pathway is one such way to strike that balance.

We recognize the concern that vaping products that appeal to adults may also appeal to youth. An alternative pathway could allow access to market for such products only if manufacturers are able to demonstrate that they can effectively implement enhanced access controls to limit underage access to their vaping products, commit to reduce appeal to underage users, and show that their product can support adults who smoke to switch completely away from smoking.

As part of this pathway, Health Canada could mandate that companies conduct postmarket monitoring to support Health Canada's ongoing assessment of the individual health and population-level effects of higher-nicotine-concentration products. In addition to adverse event reporting, manufacturers could commit to conduct ongoing studies to evaluate the effect of their product on the population as a whole, among both intended users and nonusers (including those who are underage). Health Canada could also require that manufacturers submit, among other items requested, fully developed protocols, study materials, and final reports and results.

We believe an alternative pathway, with demonstrated, effective controls for limiting underage appeal and access, can provide adults who smoke continued access to vaping products and other non-combustible alternatives, helping to achieve Canada's goal of 5% prevalence by 2035.

4 Examining the Proposed Regulation's Regulatory Analysis

The proposed regulation was informed in part by a cost-benefit analysis, in which costs to the vaping industry were weighed against the benefits to the population (primarily due to reduced vaping product initiation rates among adolescents). A sensitivity analysis on this regulatory model examined additional costs to the vaping industry, to retailers, to adults who smoke and dual use, and to the government.

The regulatory model and sensitivity analysis is a notable strength of the proposed regulation, as this analysis considers important costs and unintended consequences of the proposed regulations. However, some numerical assumptions lack empirical support in the best available data to date, and the model lacks other important costs and unintended consequences of the proposed regulations. These omissions and imprecise assumptions have the potential to severely bias the resulting cost-benefit analysis. We focus our comments on nicotine use behaviour resulting from the proposed regulations, specifically on the assumed costs of adult smoking behaviour and on the assumed benefits to adolescent initiation rates.

4.1 Costs to Adults Who Smoke and Dual Users

The proposed regulation describes the costs to adults who smoke (exclusively or dual use with vaping products) as follows: "Some current smokers who would try vaping products may find that vaping products at 20 mg/mL nicotine or below are not satisfying to them and could therefore end up being dual users or remain smokers. These persons would continue to be exposed to harmful chemicals from the long-term use of tobacco products."¹⁰² This is an important consideration; however, this effect may be understated in the model, and other

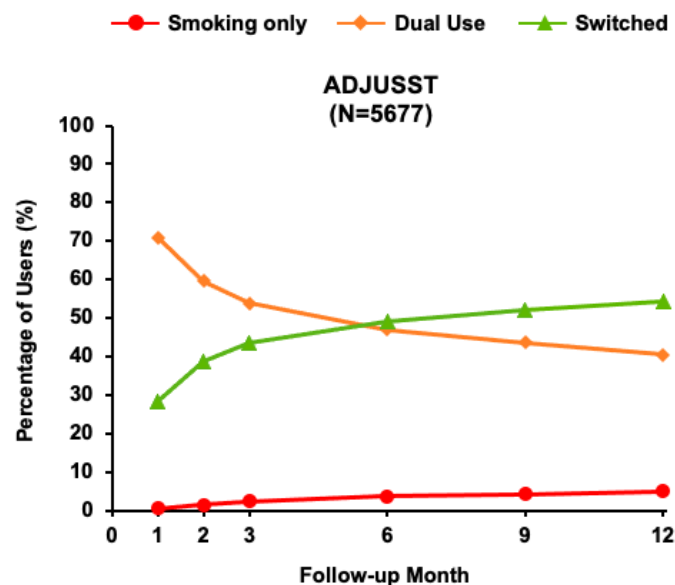
¹⁰² Page 4216, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

important considerations on dual users and adults who smoke are not accounted for in the regulatory analysis.

First, the model appears to treat dual users as a stable group. However, longitudinal studies of adults who smoke show that after vaping product initiation, many switch completely away from cigarettes.¹⁰³ In other words, dual use appears to be a transitional state in switching away from smoking; and this more often happens among heavier and/or more frequent users of vaping products^{104,105} – i.e. those with higher total nicotine intake.

ADJUSST, a large, naturalistic cohort study of US adults (21+) who purchased a JUUL Starter Kit in late 2018 (with 59 mg/mL JUULpods), showed that established smokers had high rates of dual use initially,¹⁰⁶ but this declined curvilinearly over time so that by 12 months after JUUL product initiation, the majority had switched completely away from cigarettes.¹⁰⁷ Thus, dual use appears to be a transitional state away from smoking for many smokers, highlighting the importance of product appeal and ability to be a satisfying alternative to cigarettes during this transition.

Figure 22 Dual Use Decreases Over 12 Months as it is Displaced by Complete Switching Amongst Established Smokers at Baseline



The model fails to consider how the proposed regulations might impact this process. It is likely that some dual users will relapse to exclusive smoking due to compliant vaping products being

¹⁰³ Zhu SH, Zhuang YL, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *BMJ*. Jul 26 2017;358:j3262. doi:10.1136/bmj.j3262

¹⁰⁴ Biener L, Hargraves JL. A longitudinal study of electronic cigarette use among a population-based sample of adult smokers: association with smoking cessation and motivation to quit. *Nicotine Tob Res*. Feb 2015;17(2):127-33. doi:10.1093/ntr/ntu200

¹⁰⁵ Zhuang YL, Cummins SE, Sun JY, Zhu SH. Long-term e-cigarette use and smoking cessation: a longitudinal study with US population. *Tob Control*. Oct 2016;25(Suppl 1):i90-i95. doi:10.1136/tobaccocontrol-2016-053096

¹⁰⁶ Selya AS, Shiffman S, Greenberg M, Augustson E. Dual Use of Cigarettes and JUUL: Trajectory and Cigarette Consumption. *Am J Health Behav*. 2021.

¹⁰⁷ Goldenson NI, Shiffman S, Hatcher C, Lamichhane D, Gaggari A, Le GM, Prahasth S, Augustson EM. Switching Away from Cigarettes Across 12 Months Among Adult Smokers Purchasing the JUUL System. *Am J Health Behav*. 2021.

unsatisfying or unappealing. This is noted in the potential costs to adults who smoke and dual users, but the sensitivity analysis appears to only incorporate potential effects on adults who smoke, rather than dual users who are prevented from switching. Dual users who find 20 mg/mL liquids unsatisfying may return to smoking in whole or in part, with corresponding health risks. Thus, the model underestimates the costs to dual users of the proposed regulations.

Second, the model assumes that 75% of current vapers of >20 mg/mL will switch to conforming liquids, with a subsequent sensitivity analysis around this estimate. However, this only includes current vapers, not potential future vapers who are deterred from trying vaping because of the inadequacy or inconvenience of conforming vaping products. Such future potential vapers (former smokers) are described in the proposed regulation,¹⁰⁸ but there does not appear to be any impact of this variable in the model.

Third, the sensitivity analysis for the break-even calculation appropriately assumes that the proposed regulation may decrease the rate at which smokers switch to vaping. The proposed regulation estimates a range of 1% (medium-cost scenario) to 10% (high-cost scenario). This is a legitimate potential cost of the proposed regulation, as potential switchers may be deterred because of the inadequacy or inconvenience of vaping products conforming to the regulation. However, these values likely underestimate the impact and do not appear to be based on existing research.

As discussed above, Juul Labs' data suggest that the *odds* of switching are 1.4-1.5 times higher in an environment that does not limit nicotine concentration to 20 mg/mL, corresponding to switching rates that are over 40% *lower* in a regulatory environment capping the nicotine concentration at 20 mg/mL.¹⁰⁹ This negative impact may be greater in a real-world setting when examining the full population impact, as this figure does not include adult smokers who decided not to even purchase a vaping product because of the reduced appeal of lower-nicotine-concentration liquids.

Considering that “the switch rate had the most impact on the costs results,”¹¹⁰ this marked potential underestimation of the proposed regulation's detrimental impact to switching rates suggests that the costs to adults who smoke are drastically underestimated in the model.

4.2 Reduced Initiation Rates among Adolescents

The proposed regulation performs a break-even analysis, identifying the degree to which adolescent vaping initiation would have to decrease in order for the benefits to break even with the cost. The break-even analysis finds that, using the highest-cost scenario in the sensitivity analysis, the vaping initiation rate among youth would have to decrease by 4.11% in order to overcome the costs of the proposed regulations.¹¹¹ Importantly, this value is not a *prediction* of how the proposed regulations will affect the youth initiation rate, and the plausibility of this result occurring is not considered.

¹⁰⁸ Page 4216, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

¹⁰⁹ Shiffman S, Goldenson NI, Ding Y, Prakash S, Hatcher C, Augustson EM. Differences in Rates of Adult Smokers Switching Away from Smoking using JUUL System Products, Across Jurisdictions with Different Maximum Nicotine Concentrations (North America and the United Kingdom). 2020; Accessed 01/26/2021. <https://www.juullabscience.com/wp-content/uploads/sites/8/2020/09/Differences-in-Rates-of-Adult-Smokers-Switching-Away-from-Smoking-Using-JUUL-System-Products-Across-Jurisdictions-with-Different-Maximum-Nicotine-Concentrations.pdf>

¹¹⁰ Page 4214, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

¹¹¹ Page 4223, Canada Gazette Part I, Vol. 154, No. 51, December 19, 2020

Considering the strong evidence for common liability (i.e. predisposition to use nicotine products), the reductions in vaping initiation rates identified in the break-even analysis are unlikely to occur in reality as a result of the proposed regulation. Instead, the proposed regulation may result in cigarettes remaining the most efficient, appealing, and accessible method of nicotine delivery. As a result, the proposed regulations are likely to impose a net cost in Canada.

5 Conclusion

JLC supports the Canadian Government in its goal to reduce tobacco use to less than 5% by 2035 and shares Canada's Tobacco Strategy goal to "protect the health of young people and non-smokers from the dangers of tobacco use."¹¹² JLC believes this can be accomplished by a robust and appropriate regulatory framework for vaping products, and that it should be designed to be proportionate to the risk of these products relative to combustible cigarettes. We support a risk-proportionate regulatory framework in Canada that guards against appeal of and access to all tobacco and nicotine products for underage users while facilitating adult smokers' transition to less harmful products.

Following a close examination of the data concerning reasons for underage use and sources of access in Canada, we agree with Health Canada that additional underage prevention measures are needed at the category level. In addition to supporting ongoing compliance with existing advertising and flavour restrictions, JLC urges Health Canada to consider additional measures such as a ban on social media advertising. To reduce underage access, we also support Tobacco 21 at the federal level, which public health research suggests can reduce underage adoption and use of tobacco products by at least 15%. Finally, JLC believes innovative technology solutions, including advanced age verification through automated ID scanning at retail and third-party verification online, can further limit underage access to vaping products.

We understand Health Canada's concerns about a potential gateway effect amongst youth who experiment with vaping products and then could transition to established smoking. Fortunately, the data, including population-level trends evidencing historically low smoking rates among those underage, do not indicate this is occurring.

We urge Health Canada to take into account competing explanations to the "gateway" hypothesis (namely, the common liability theory), which are essential for predicting the net population impact of unintended use of non-combustible alternative products by non-smokers, particularly those underage. In considering the proposed regulation, we also believe it is necessary to consider the importance of appeal in helping adults who smoke to switch completely to a less harmful product; as well as the importance of nicotine delivery and titration across devices and users.

We are also concerned about the expansion of illicit markets of higher-nicotine-concentration vaping products should Health Canada proceed with this proposed regulation. As there is still likely to be demand for these products, third-party actors may expand introduction of counterfeit, compatible, and diverted products to the Canadian market, undermining underage use mitigation

¹¹² Health Canada. Canada's Tobacco Strategy. 2020. <https://www.canada.ca/en/health-canada/services/publications/healthy-living/canada-tobacco-strategy.html>

efforts and posing additional health and safety risks to consumers beyond those of legitimate and regulated vaping products.

We believe there are key outstanding questions in the proposed regulation's regulatory model, including essential assumptions about the costs and benefits of the proposed regulations and quantification of key parameters of the model based on the best available evidence to date. The regulatory model includes assumed likely costs of the proposed regulation to adults who smoke, however we believe those costs are underestimated in light of the most recent available evidence.

Most notably, the current proposed regulations, especially in the absence of any accompanying or preceding regulation affecting combustible cigarettes, may increase more harmful conventional smoking by allowing cigarettes to be much more effective and satisfying nicotine delivery products than the now-nicotine-constrained vaping products.

Our company's mission is to transition the millions of Canadian adult smokers away from combustible cigarettes, eliminate their use, and combat underage usage of our products. To accomplish that mission, we are committed to working with governments, regulators, and other stakeholders in Canada to create a responsibly regulated and adequately safeguarded vaping product category.