Proposed vaping products' flavour regulations – a response

This submission responds to Health Canada's Consultation on Proposed vaping products' flavour regulations and order and related regulatory impact analysis.[1] [2]

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We confirm that signatories report no conflicts with respect to FCTC Article 5.3 and no financial conflicts of interest with respect to tobacco or e-cigarette companies under the International Committee of Medical Journal Editors (ICJME) reporting standard. We hope our views are of value as the government makes its decisions on this important and sensitive area of public health.

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[1]   Health Canada, Consultation: Proposed vaping products' flavour regulations and order, June 2021 [link]

[2]   Health Canada, Canada Gazette, Part I, Volume 155, Number 25: Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours), *Regulatory Impact Analysis Statement*, June 19, 2021. [link]

The case against banning flavoured e-liquids in Canada

Summary

Health Canada's case for banning vaping flavours as described in the memorandum supporting the measure is wholly inadequate, and the measure should not proceed on this basis. A realistic evidence-based appraisal would show the measure to be both economically damaging *and* detrimental to public health. The critical weaknesses are set out in the six sections of this submission and summarised here:

- Section 1. The objective, *reducing youth vaping*, is ill-conceived. This would be a poor objective if it meant more smoking among young people, fewer adults switching to vaping, and more adults relapsing to smoking. All of these consequences are likely. The objective should be to reduce *harms*, not just modify one behaviour in a mix of tobacco and substance use behaviours.

- Section 2. The analysis ignores likely unintended consequences arising from a flavour ban, making the naïve assumption that young people will respond to a flavour ban by doing nothing or something virtuous instead of vaping. However, there is a wide range of possible harmful responses to a vape flavour ban, including smoking, other substance use, black market access and participation, home mixing, and various workarounds. These do not feature in the justification.

- Section 3. The justification is based on a flawed understanding of the causes of teenage vaping and a greatly overstated role for flavours. Vaping, like smoking, is not primarily driven by product features like flavours. It arises from deeper causes – genetics, mental health, parental influence, community environment etc. Leaving the deeper causes intact while modifying a superficial influence will just cause a shuffling in the mix of risk behaviours.

- Section 4. The analysis understates or ignores the significant role that vaping and vaping flavours play in smoking cessation and displacement backed by evidence from multiple sources: clinical trials, observational studies, population data trends, market data and stock analyst insights, economic analyses and natural experiments, and thousands of user testimonies.

- Section 5. Health Canada has not developed the chain of reasoning necessary to show a flavours ban would have an overall positive effect. It would need to go show the flavour ban would positively affect vaping use and uptake, not lead to more adolescent smoking, and would not have adverse effects on adult tobacco use behaviours. This failure is most overt in the cost-benefit analysis.

- Section 6. The cost-benefit analysis on which the justification rests is fundamentally flawed. It is built on a false 'gateway' assumption that teenage vaping leads to adult smoking and that the impact of a vaping flavour ban will reduce future smoking. There is no basis for claiming a gateway effect, and an alternative "common liability" explanation for the data is far more credible. Over 93 percent of the public health benefits shown in the cost-benefit analysis break-even case relate to avoided *smoking-related impacts*. Yet, the evidence suggests vaping is a substitute for smoking and is more likely to divert adolescents from smoking. Under closer examination, the case falls apart.

1   The policy objective is poorly specified: achieving it may lead to more disease and death

The objective is stated as follows:

> The objective of the proposal is to protect young persons from inducements to use vaping products by further restricting flavour indications, limiting flavouring ingredients and prescribing sensory attributes standards. Overall, this is expected to contribute to reducing the appeal of vaping products to youth.

The problem with this objective is that even if successfully achieved and the appeal of vaping products to youth is reduced, achieving it could cause significant population harm. This would arise from, among other things:

- increased smoking among youth who are predisposed risk-taking behaviours

- reduced adult smoking cessation in the population at most immediate risk from smoking,

- harms to young people arising from harms to adult smokers

- societal consequences of alternative supply of flavoured products.

The model used for assessing this policy does not reflect these underlying realities of how such a ban will impact overall health.

The ultimate objective for Health Canada should be to secure public health gains and then allow a political decision to be made on whether the proposed restrictions and their intended and unintended consequences are acceptable. The justification provided by Health Canada does not allow for that assessment.

2   The analysis is naïve about trade-offs and unintended consequences

The stated purpose of the proposed measure is to "help address the rapid rise in youth vaping." This objective is inappropriate because the public health purpose should be to reduce harm. Even if the proposed measure successfully reduces teenage vaping, and that is open to dispute, there is a wide range of harms that such a measure could cause.

Given the known harms of smoking, it is unclear why a government or public health authorities would wish to intervene to regulate e-cigarettes in a way that degrades the competitive advantage of e-cigarettes relative to cigarettes and provides anti-competitive support for the cigarette trade.

The Royal College of Physicians (London) explained this issue:[1]

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[1]   Royal College of Physicians. Nicotine without smoke: tobacco harm reduction. London: RCP; 2016. [link] (Section 12.10 page 187)

However, if [a risk-averse, precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

How such a measure could "perpetuate smoking" and related harms include:

- *Reduced adult smoking cessation*. Adult smokers are at far greater and more immediate risk of serious disease than any teenage vaper. If Canada wishes to address the Sustainable Development Goal objective to reduce non-communicable disease burdens by one-third by 2030, it will need a relentless focus on adult smoking cessation. The harms avoided by a middle-aged adult quitting smoking are two orders of magnitude greater than the harm avoided by preventing vaping in an adolescent who would not have otherwise used nicotine. The assumption that vaping causes 20% of the harm of smoking is baseless and too high. But the time profile of harm is also different – an adult smoker faces near-medium-term risks of smoking-related disease. A teenage vaper faces distant if any risks (though the analysis falsely assumes vapers will take up smoking).[2]

- *Harm to adolescents arising from adult smoking*. The smoking behaviour of parents or other significant adults causes harm to young people through role-model effects that transmit smoking prevalence between generations, welfare and economic impacts on the family, caring burdens and grief associated with death or incapacitation, and direct exposure to tobacco smoke. The most disadvantaged young people (those most likely to smoke) benefit from the availability of attractive vaping products as an option for quitting smoking later in life. It is simply not possible to delineate the interests of adolescents in the way envisaged by the measure and the supporting analysis.

- *Reduced adolescent smoking cessation*. If vaping enters into the mix of young people's tobacco-use behaviour, it is <u>beneficial</u> if they would otherwise be smoking. The Environics survey cited by Health Canada shows a: [3]

    "*large majority [83%] of ever vapers have smoked at some point, and a majority still do (55%)*"

    This means those in the ever-vaping sample have some propensity to smoke and therefore are at a risk for which vaping is a *mitigation*. Health Canada's approach will tend to redirect them towards smoking. The relative harms of smoking and vaping mean that only a small diversion back to smoking will easily overwhelm any reduction in vaping among the minority of vapers that would not otherwise have used nicotine.

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2   In a discounted analysis with the 7% discount rate used in the Health Canada CBA, a given harm arising in 15 years would have five times the weight of the same harm arising in 40 years. Both the magnitude and timing of the harms inflicted or avoided matter.

3   Evironics Research Group, Longitudinal Vaper Panel Survey to Measure Attitudes and Behaviours regarding Vaping Products, published April 2018 [link][PDF] See Q26 & Q 28

- *Reduced diversion of young people from smoking at initiation or soon after*. Population-level evidence shows that vaping functions as a diversion from smoking for young people in the United States.[4] [5] This is consistent with observed US adolescent population trends.[6] Policies that reduce adolescent vaping will likely reduce the impact of a diversionary effect and so cause a relative increase in smoking and harm.

- *Increased black market activity*. A black market of unregulated versions of prohibited products will inevitably form – the main question is how large and how quickly it will grow. Even if smaller than the current legitimate market, it will be more harmful, increasing exposure of young people to a range of illegal substances and criminal networks as well as unregulated vaping products.   A ban on vaping flavours could, via contact with criminal networks, become a gateway to cannabis, opioids and criminal engagement. Entrepreneurial young people will also be empowered to source and sell prohibited products for which there is continuing demand, thus entering criminal supply chains as economic actors.

- *Increase in informal DIY home mixing of flavours*. Bans on flavours will increase risks arising from poor hygiene and experimentation with risky ingredients, including a wholesale trade in high strength nicotine liquids that would not be permitted or needed in the normal consumer environment.

- *Workarounds*. Sales of flavour agents will continue as additives to food or drink or for purposes like aromatherapy.   To the extent these are successful and widespread, they may mitigate some of the harms listed above while further illustrating the lack of feasibility for these regulations.

3   The justification offers a simplistic account of the causes of teenage vaping

3.1   Asking a young person why they smoke or vape does not explain why they smoke or vape

The analysis relies on a survey of the reasons stated by young people for vaping to infer that they use vaping products because they say they vape because they like the flavours. But this is a simplistic account of the reasons for any substance use. The trite answer "because I like it" is an easy response for anyone asked why they do anything. Yet much deeper and complex reasons explain, for example, smoking behaviour. A review of risk factors for smoking onset concluded:[7]

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4   Selya AS, Foxon F. Trends in electronic cigarette use and conventional smoking: quantifying a possible 'diversion' effect among US adolescents. *Addiction* 2021;add.15385. [access]

5   Sokol N, Feldman J. High school seniors who used e-cigarettes may have otherwise been cigarette smokers: evidence from Monitoring the Future (United States, 2009-2018). *Nicotine Tob Res* [Internet] 2021 [access]

6   Levy DT, Warner KE, Cummings KM, et al. Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. *Tob Control* 2019;28(6):629–635. [access]

7   Wellman RJ, Dugas EN, Dutczak H, et al. Predictors of the Onset of Cigarette Smoking: A Systematic Review of Longitudinal Population-Based Studies in Youth. *Am. J. Prev. Med*. 2016;51(5):767–778 [access]

Ninety-eight conceptually different potential predictors were identified in 53 studies. An increased risk of smoking onset was consistently (i.e., in four or more studies) associated with increased age/grade, lower SES, poor academic performance, sensation-seeking or rebelliousness, intention to smoke in the future, receptivity to tobacco promotion efforts, susceptibility to smoking, family members' smoking, having friends who smoke, and exposure to films, whereas higher self-esteem and high parental monitoring/supervision of the child appeared to protect against smoking onset.

Because there are quite strong associations between smoking and vaping, many of these causes will likely be common to both smoking and vaping. They also explain persistent misunderstandings about so-called 'gateway effects' (alternatively explained by confounding by common causes). They also suggest the mechanism by which vaping will be *beneficial* to the youth most at risk – i.e. diversion from smoking among those with risk factors for smoking.

3.2   There are deeper explanations for vaping

As suggested in the subs-section above, the reasons that young people vape are more complex than a single product characteristic. For example, Nicksic et al. (2019) examined the reasons given for youth vaping and: [8]

> …found two overarching factors, "alternative to cigarettes" and "larger social environment", which combine sub-categories to explain the main motivators of e-cigarette use

They listed 13 factors influencing e-cigarette adoption, among which the effect of flavours was weak:

> Items that loaded highly onto the "alternative to cigarettes" factor for youth and adults included using in places where cigarettes prohibited, less harmful to me and others, help quit smoking, no smell, and more acceptable. The "larger social environment" factor included people in the media use e-cigarettes, people who are important use them, enjoy socializing while using, and appealing advertising.

3.3   Underlying causes of vaping or smoking persist even if flavours are removed

The problem with removing one feature of the product that young users say they like is that it leaves the deeper drivers untouched. It is a simplistic false remedy to a behaviour with deeper roots. Perhaps Health Canada hopes that young people will turn to abstinence and spend their time and money on virtuous activities instead. But unless the deeper causes are addressed, there is no reason to assume that would be the result. We already know from history that young people can tolerate the harsh and unpleasant experience of novice smoking – smoking prevalence among 18–19-year-olds in Canada in

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8   Nicksic NE, Snell LM, Barnes AJ. Reasons to use e-cigarettes among adults and youth in the Population Assessment of Tobacco and Health (PATH) study. *Addict Behav*. 2019 Jun 1;93:93–9. [access]

2001 was 33 percent in men and 34 percent in women.[9] Flavours are not necessary for young people to take up nicotine, and the latent demand for it will persist after flavours are banned. The question is, therefore, how young people will respond.

3.4   Young people say they will smoke instead of vaping

If Health Canada does choose to rely on the stated intentions and preferences of young people, it should at least do this consistently. Researchers asked 18–34-year-olds what they would do if non-tobacco flavours were banned. A sizeable proportion said they would smoke:
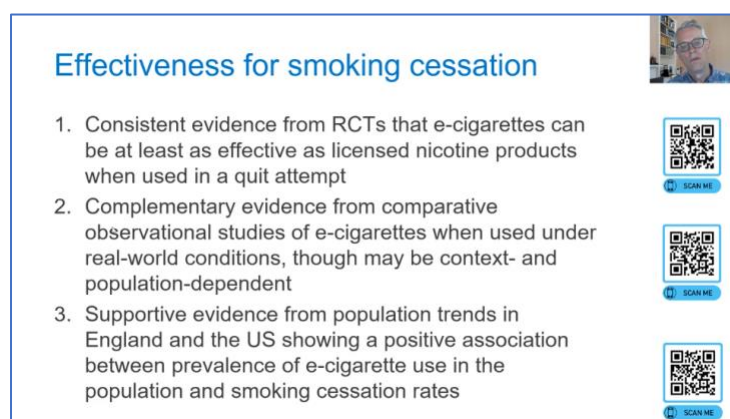
> If restricted to tobacco flavors, 39.1% of e-cigarette users reported being likely (very/somewhat) to continue using e-cigarettes (30.5% not at all likely); **33.2% were likely to switch to cigarettes** (45.5% not at all). Considering complete vape product sales restrictions, equal numbers (~39%) were likely vs. not at all likely to switch to cigarettes. (Emphasis added)

This would be consistent with other evidence suggesting that vaping is a substitute for smoking and diverts adolescents away from smoking.

4   The evidence strongly supports vaping as a pathway to quitting smoking

4.1   Evidence for vaping as an alternative to smoking

The evidence for vaping as a substitute for smoking and driver of smoking cessation comes from multiple sources, each with its own strengths and weaknesses, but taken together make a strong case – and stronger than the conventional smoking cessation treatments. British smoking cessation expert, Professor Robert West, summarised the state of evidence in a 2019 presentation.[10]   The slide from Professor West's presentation above summarises his view of the evidence, and a link to the full presentation is provided in the footnote.

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9   Statistics Canada, (archived content) Current Smoking Trends, Chart 3 & 4 [link]

10   Robert West, Should health professionals recommend smokers to switch to e-cigarettes? A reprise of a keynote lecture at the Society for Research in Nicotine and Tobacco European conference in Oslo September 2019 Vimeo video [link]

The following provides an overview of studies that support the evidence framework articulated in Professor West's presentation.

- *Randomised controlled trials.* Several recent trials show positive results.[11] [12] The most substantial clinical trial to date showed e-cigarettes with approximately twice the smoking cessation efficacy of NRT.[13]. There is an accumulating evidence base: the Cochrane Review now recognises evidence of efficacy, albeit somewhat qualified by the small number of studies.[14]

- *Observational data*. There is evidence that smokers who use e-cigarettes are more likely to quit smoking than those who do not.[15] [16]

- *Population trends*. There is evidence that smoking cessation activity also increases as the prevalence of e-cigarette use increases in a population.[17] [18] [19] [20]

- *Modelling studies*. Modelling studies based on the experience so far show very substantial public health potential even when parameterised with sceptical assumptions.[21] [22]

[11] Eisenberg MJ, Hébert-Losier A, Windle SB, et al. Effect of e-Cigarettes plus Counseling vs Counseling Alone on Smoking Cessation: A Randomized Clinical Trial. *JAMA - J Am Med Assoc* 2020;324(18):1844–1854. [[link](#)]

[12] Pulvers K, Nollen NL, Rice M, et al. Effect of Pod e-Cigarettes vs Cigarettes on Carcinogen Exposure Among African American and Latinx Smokers: A Randomized Clinical Trial. *JAMA Netw open* [Internet] 2020 [cited 2021 Jan 18];3(11):e2026324. [[link](#)]

[13] Hajek P, Phillips-Waller A, Przulj D, et al. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. *N Engl J Med* 2019;380(7):629–637. [[link](#)]

[14] Hartmann-Boyce J, McRobbie H, Lindson N, et al. Electronic cigarettes for smoking cessation. *Cochrane database Syst Rev* 2020 10(10):CD010216. [[link](#)]

[15] Jackson SE, Kotz D, West R, Brown J. Moderators of real-world effectiveness of smoking cessation aids: a population study. *Addiction* [Internet] 2019 [cited 2020 Dec 3];114(9):1627–1638. [[link](#)]

[16] Kotz D, Brown J, West R. "Real-world" effectiveness of smoking cessation treatments: A population study. *Addiction* 2014;109(3):491–499. [[link](#)]

[17] Beard E, West R, Michie S, Brown J. Association of prevalence of electronic cigarette use with smoking cessation and cigarette consumption in England: a time–series analysis between 2006 and 2017. *Addiction* 2020];115(5):961–974. [[link](#)]

[18] Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *BMJ*. 2017;358:j3262. [[link](#)]

[19] Levy DT, Yuan Z, Luo Y, Abrams DB. The relationship of e-cigarette use to cigarette quit attempts and cessation: Insights from a large, nationally representative U.S. Survey. *Nicotine Tob Res* 2018; [[link](#)]

[20] Beard E, West R, Michie S, Brown J. Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends. *BMJ* [Internet] 2016 [cited 2020 Dec 3];354:i4645. [[link](#)]

[21] Levy DT, Borland R, Lindblom EN, et al. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. *Tob Control* [Internet] 2018 [cited 2020 Dec 5];27(1):18–25. [[link](#)]

[22] Mendez D, Warner KE. A Magic Bullet? The Potential Impact of E-Cigarettes on the Toll of Cigarette Smoking. *Nicotine Tob Res* 2020; [[link](#)]
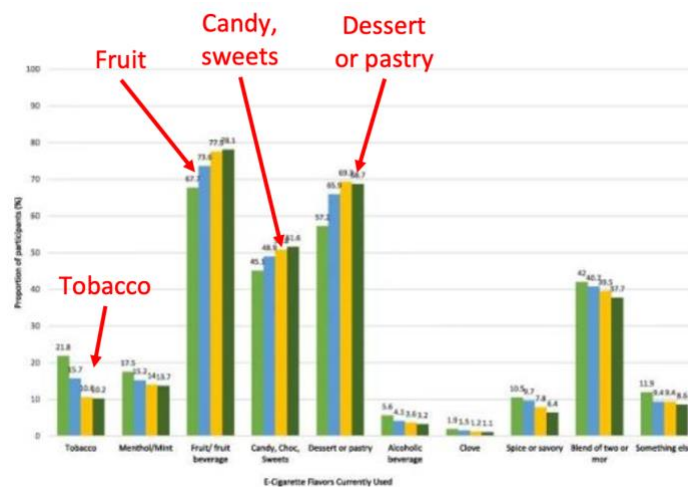
- *Economic data.* The response of demand for cigarettes and vaping products to price changes and regulatory interventions suggests they function as substitutes.[23]

4.2   The testimony of users is compelling

Millions of former smokers will testify that e-cigarettes – especially in non-tobacco flavours – were important in assisting their efforts to stop. Collections of testimonials provide compelling evidence of smoking cessation success stories.[24] Though this type of evidence is often dismissed as 'anecdote', no one trying to understand the impact of vaping on health would ignore user experience.[25] A detective would not ignore witnesses' testimony but include it in building a case drawing on multiple strands of evidence (forensic, phone records, identification, financial records, witnesses, etc.). Also, Health Canada cannot credibly accept the importance of lived and living experiences of people who use opioids while refusing to consider it for people who use nicotine.

4.3   Strong evidence that flavours play an important role in adult smoking cessation

Further, it is clear that adults make extensive use of non-tobacco flavours, including fruit and candy, even though these may be considered childish or even "kid-appealing". Russell and colleagues conducted a large survey of US users:[26] The data show extensive and increasing use of non-tobacco flavours in the United States. See the chart below showing high preferences for flavours among adults (authors' annotations in red):

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23   The substitution effect is clear from analysis that examines the impact on demand for e-cigarettes and cigarettes when taxation or restrictions are placed on e-cigarettes. Please see "*Economics of E-cigarettes: Background, Theory, and Evidence*" by Michael Pesko [access].

24   For example, see CASSA (US) testimonials, [link]

25   See Carl V Phillips, Science lesson 3: Anecdotes ARE scientific data, Patreon, 14 April 2019 [link]

26   Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* [Internet] 2018 [cited 2018 Jul 17];15(1):33. [link]

One study found 68% of American adult e-cigarette users had used non-tobacco flavours in the past 30 days. Of these, 45% had used fruit, 44% menthol or mint, and 26 per cent candy, chocolate or other sweet flavour.[27]

The adult behavioural and supply-side response to a flavour ban is difficult to predict. Still, the government did not attempt to estimate these effects in the justification for the flavour ban. There is evidence that the availability of non-tobacco flavours helps some adult smokers transition completely away from smoking.[28] In Section 2 above, we set out a range of possible behavioural responses to a flavour ban, some of which increase harm. However, given that smoking is far more harmful than vaping, the impact of only a small uptick in smoking would overwhelm any conceivable benefits from reductions in vaping.

5   Health Canada does not provide an adequate chain of reasoning to support its case

The logic of Health Canada's position requires navigating the following chain of reasoning to assess the merits of the ban. This reasoning has not been reflected in the cost-benefit analysis to justify the ban.

1. **Who cares about flavours?** For what proportion of young vapers are flavours an important reason why they vape, rather than just an expression of preferences having decided to take up vaping? This is the subset that will be affected by the proposed ban.

2. **Will prohibition prevent access or just change the suppliers?** Will banning flavours by law make flavoured products inaccessible to those young people who want them? Prohibitions generally change who supplies a product to criminal suppliers rather than making such products disappear. Prohibition might make access more difficult, but for what proportion will this be a barrier?

3. **How many will switch to vaping or other smoke-free products that are not prohibited**? For those no longer able or willing to access flavoured products via black markets, informal channels or by mixing their own, what proportion will stop vaping? How many will switch to vaping flavours that are not banned? How many will switch to other relatively safe nicotine products like pouches, heated or smokeless tobacco products? Health Canada does not consider these pathways.

4. **How many will take up smoking?** Of those who stop vaping because they cannot access flavours and the alternatives are not sufficiently appealing, what proportion will switch to a more harmful nicotine-using behaviour like smoking cigarettes? Given 83 percent of the vapers in the Environics survey were current or former smokers, switching to easily available cigarettes will be the chosen behavioural response for many. How many would be sufficient to offset any benefits from reduced

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[27] Bonhomme MG, Holder-Hayes E, Ambrose BK, Tworek C, Feirman SP, King BA, et al. Flavoured non-cigarette tobacco product use among US adults: 2013-2014. *Tob Control*. BMJ Publishing Group Ltd; 2016 Nov;25(Suppl 2):ii4-ii13. [link]

[28] Farsalinos KE, Romagna G, Tsiapras D, Kyrzopoulos S, Spyrou A, Voudris V. Impact of flavour variability on electronic cigarette use experience: an internet survey. *Int J Environ Res Public Health* 2013; 10: 7272–82.[link]

vaping? Would it be ethical to cause more serious harms to a smaller (likely more disadvantaged) group to reduce a relatively trivial harm to people who would not have otherwise used nicotine?

5. **How many will do something else risky?** Of those who stop vaping and do not turn to another way to use nicotine, what proportion will instead adopt a different risk behaviour – vaping or smoking cannabis or using their cash to drink more alcohol? Given that vaping is associated with a risk-taking propensity, what proportion will take up virtuous activities instead of vaping, smoking, or using other drugs?

6. **What would have happened without the ban?** For the group that does quit completely with no adverse behavioural responses because of the flavour ban, assessing a health benefit requires a counterfactual: what would they have done in the absence of a flavour ban? Unless they would otherwise have continued vaping for many years, it is unlikely they would suffer much harm, and therefore there would be little to add to the benefits side of the cost-benefit analysis. However, those young people diverted back to smoking by the ban would be likely to be more dependent and therefore may stick with smoking for longer – the ban would prompt a more harmful and more sustained behaviour.

7. **What are the distributional effects?** The group most likely to quit vaping completely would be the occasional or frivolous users with lower dependence. But this is also the group that is the least problematic and most likely to quit as they leave college, start a job, begin a family etc. The group more likely to divert to other nicotine products, smoking, or other risk behaviour will be those with a stronger nicotine dependence and likely to be experiencing various forms of disadvantage. For them, the flavour ban may promote adverse behaviour change, such as reverting to smoking, and add to their problems and health risks. It is quite possible that Health Canada's plan will address the exaggerated concerns of middle-class parents while making life worse for teenagers with more difficult lives.

8. **What are the offsetting harms to adults?** What is the toll of harm exacted on the actual population at risk: smoking-dependent adults, for whom quitting smoking is a major challenge, and vaping may help? Adult smokers advancing towards middle age start to face significant disease risks and loss of wellbeing. How does the flavour ban affect switching from smoking, migration from dual-use to exclusive use and relapse from vaping to smoking? As discussed above, harm to adults is mediated through the family circle and community to cause harm to children and adolescents.

9. **What is the net effect of the range of behavioural change prompted by the ban?** To assess the impact, the analysis must consider the range of behavioural responses above (1-5), then assess the harms associated with each response (6-7). To this, the analysis should add the further harms related to the effect on adults and the effect of harms to adults (e.g. parents) on children (8).

The preceding reasoning is designed to show that 'harm reduction' does not start suddenly at age-18 but is a concept that applies right through adolescence. Vaping can modify tobacco use patterns *beneficially* from any age. The danger of measures designed to make vaping less appealing is that it will work mainly for people for whom there should be little concern but work against the interests of the populations – adolescent and adult – at greatest risk. These people need harm reduction options.

6   The cost-benefit analysis is fundamentally flawed: the case should be rejected

Though there is a large volume of detail in the published regulatory impact analysis[29] and unpublished cost-benefit analysis[30], most of this serves mainly to obscure the importance of the few basic but false assumptions made about smoking and vaping on which the case turns, notably that teenage vaping leads to adult smoking, based on a crucial misreading of the science. Without these assumptions, the case fails completely.

6.1   A summary of the cost-benefit analysis

The analysis looks out over thirty years from 2022 and estimates the discounted present value of economic costs arising from the proposed flavour ban. In essence, the case finds $569 million (PV) in costs to government and business arising from a 12.15% decline in vaping demand[31]. It then uses a break-even analysis to show that these costs would be justified by monetized public health benefits – reductions in premature death and disease expressed as a monetary value[32] – if there was a 1.11 percent reduction in the vaping initiation rate. The 1.11 percent is not a prediction but a break-even calculation of the reduction in vaping initiation necessary for the monetized mortality and morbidity benefits to equal the $569 million economic costs. The analysis assumes the flavour ban proposal will achieve at least this and, therefore, that the public health benefits will outweigh the costs to business and government. This is the central case, in which it is assumed there is no decrease in the rate at which adults switch from vaping to smoking. A sensitivity analysis examines the consequence of a 1 percent and 10 percent reduction in adult switching from smoking to vaping and finds the break-even reduction in vaping initiation rate would be a 1.25 percent and 2.25 percent reduction, respectively.

6.2   Flaws in the analysis: many important public health assumptions are opaque

The detail provided on the economic costs is far greater than the assumptions and model design used to assess the public health benefits. For example, there is no transparency about the rates and times

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[29]   Health Canada, Regulatory Impact Analysis, Canada Gazette, Part I, Volume 155, Number 25: Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours) [link] See "Rationale"

[30]   Health Canada, Tobacco Control Directorate / Cannabis Cost Benefit Analysis Team, Controlled Substances and Cannabis Branch, Proposed Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours) and proposed Standards for Vaping Products' Sensory Attributes Regulations, Cost-Benefit Analysis, June 2021 [access]

[31]   The cost-benefit analysis lists a wide range of costs expressed in 22 equations using dozens of variables grouped under 4 headings totalling $569.4 million PV at 7% discount rate: A. Costs to vaping liquid manufacturers associated with the prohibition of flavouring ingredients – disposal of non-compliant products ($72.2 million); B. Costs to vaping industry associated with the prohibition of flavouring ingredients - profit loss ($461.3 million); C: Costs to manufacturers and importers associated with the prohibition of most flavouring ingredients – reformulation costs ($29.3 million); D. Government costs to Health Canada associated with implementation, compliance and enforcement costs ($6.6 million).

[32]   The analysis uses a value of statistical life (VSL) of $7.8 million to estimate premature mortality costs and an estimated annual morbidity cost of $2,600 (2019 dollars) for an adult aged 27 and older who smokes. The mortality and morbidity costs for vaping are assumed to be 20% of the smoking-related costs.

young people switch from vaping to smoking or to what extent they quit vaping. The assumptions about adults switching rates and how these evolve over time are unclear. The counterfactual is unclear: for example, in the absence of vaping or vaping flavours, how many young people would be smoking instead and therefore, their initial vaping would not have increased the total number of smokers? There is no visible segmentation to reflect the difference between infrequent 'experimental' or frivolous 'party' users and more intensive users. The US data suggests that the most intensive users would be those who have previously smoked.[33] A survey of youth e-cigarette use in Britain found that "*Regular use of e-cigarettes remains largely confined to current or ex-smokers*"[34].

6.3   Flaws in the analysis: a false assumption of a gateway effect where diversion is far more likely

The main problem with the analysis is that it is premised on vaping being a gateway to smoking. The reasoning simply assumes that teenage vaping leads to smoking and that smoking-related costs can be attributed to teenage vaping. It further assumes that a reduction in vaping will lead to a future reduction in smoking. To do this, it draws on a well-established association between smoking and vaping:

> *The key assumptions used in the modelling of benefit analysis include:*
> *It is assumed that some people who vape will eventually become smokers. It is assumed that vapers are roughly 7.5 times more likely to start smoking than those who don't vape.*

The problem here is that this relationship is an *association* and not causal: correlation is not causation. It arises from common causes or so-called "common liabilities" that are characteristics of the individual or their circumstances that incline the person both to vaping and to smoking.[35][36] These common causes include genetics, mental health, delinquency, parental smoking, poverty, school environment etc. [37][38][39] It does not mean the vaping caused the smoking, and it does not mean that making the vaping less appealing will eliminate the subsequent smoking. The reverse is more likely: making vaping less

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[33]   Jarvis M, Jackson S, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA? *Qeios* 2020 [link]

[34]   Action on Smoking and Health (UK) and YouGov. Use of e-cigarettes among young people in Great Britain,. June 2019. [link]

[35]   Phillips C V. Gateway effects: Why the cited evidence does not support their existence for low-risk tobacco products (and what evidence would). *Int J Environ Res Public Health* 2015; [link]

[36]   Vanyukov MM, Tarter RE, Kirillova GP, et al. Common liability to addiction and "gateway hypothesis": Theoretical, empirical and evolutionary perspective. *Drug Alcohol Depend* [Internet] 2012;123:S3–S17. [link]

[37]   Chan GCK, Stjepanović 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*. 2020;add.15246. [link]

[38]   Kim S, Selya AS. The Relationship Between Electronic Cigarette Use and Conventional Cigarette Smoking Is Largely Attributable to Shared Risk Factors. *Nicotine Tob Res* 2020; [link]

[39]   Hall W, Chan G. The "gateway" effect of e-cigarettes may be explained by a genetic liability to risk-taking. *PLOS Med* 2021;18(3): [link]
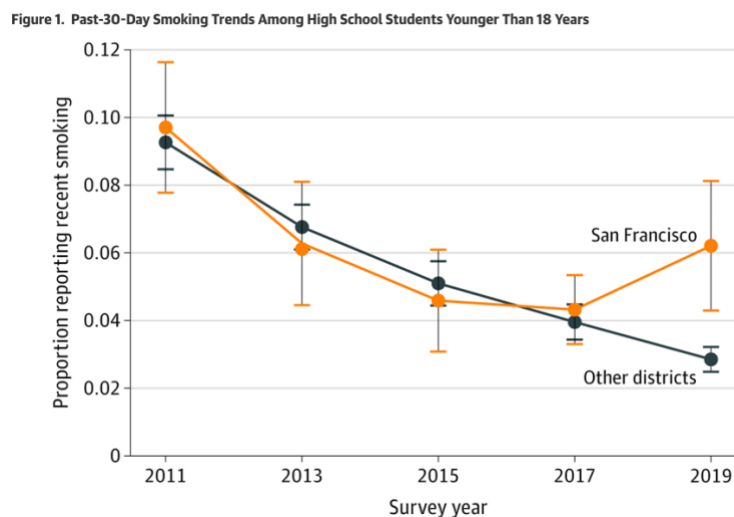
appealing will cause the young person to smoke instead. This is because the evidence points to vaping *as a diversion* from smoking.[40] [41] This is consistent with observed US adolescent population trends, which have seen a sharp decline in smoking as vaping has risen.[42]

In fact, Health Canada's cost-benefit analysis notes a finding by Yang et al. (2020)[43] from San Francisco in which an e-cigarette flavour ban was associated with an *increase in smoking*:

> *Yang (2020) used survey data gathered from San Francisco residents aged 18-34 and found that among the participants, e-cigarette use decreased from 56.5% to 45.2%.* ***This was partially offset by an increase in cigarette use from 27.4% to 37.1%****.* (Emphasis added)

It is unclear if and how this "increased smoking effect" has been included in the analysis, but it is hard to see how it could have been. Any noticeable increase in smoking destroys the case for the ban.

A subsequent analysis of the effect in San Francisco, not cited in the Health Canada case, showed a substantial increase in *adolescent* smoking in San Francisco following a flavour ban. [44] The figure from Friedman (2021) is shown– a flavour ban was associated with a sharp rise in smoking:

Figure 1. Past-30-Day Smoking Trends Among High School Students Younger Than 18 Years

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40   Selya AS, Foxon F. Trends in electronic cigarette use and conventional smoking: quantifying a possible 'diversion' effect among US adolescents. *Addiction* 2021;add.15385. [link]

41   Sokol N, Feldman J. High school seniors who used e-cigarettes may have otherwise been cigarette smokers: evidence from Monitoring the Future (United States, 2009-2018). *Nicotine Tob Res* 2021 [link]

42   Levy DT, Warner KE, Cummings KM, et al. Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. *Tob Control* 2019;28(6):629–635. [link]

43   Yang Y, Lindblom EN, Salloum RG, Ward KD. The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults. *Addict Behav Reports* [2020;11:100273. [link]

44   Friedman AS. A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California. *JAMA Pediatr* 2021 [link]

The increase in smoking observed in San Francisco was not replicated in districts that had not imposed a flavour ban.

Why would Health Canada not expect to see a similar effect, and how has this been captured as a cost of increased smoking in the cost benefit analysis? It clearly has not.

6.4   Flaws in the analysis: the claimed flavour ban benefits are dominated by reductions in *smoking*

If the assumption about vaping leading to smoking is wrong, then the whole case falls apart. The estimate of benefits shows that these are dominated by avoided smoking-related mortality and morbidity, including deaths from secondhand smoke exposure. See Table 2 from the cost-benefit analysis reproduced below:

Table 2: Public health benefits from the proposal: Break-even analysis

Benefits (Avoided cost)	Current best estimate cost scenario		
	Total avoided deaths	PV of benefits (in millions of dollars)	% of total benefits
Morbidity costs of cigarette use	NA	42	7.3
Morbidity costs of vaping product use	NA	3.6	<1
Deaths due to cigarette use	154	348	61
Deaths due to vaping product use	15	45	7.8
Deaths attributable to second-hand smoke exposure	57	131	23
Total	226	569	100

In the central break-even case, 93 percent of the benefits attributable to the ban on vaping flavours arise from reductions in <u>smoking</u>-related mortality (61%), <u>smoking</u>-related morbidity (7.3%) and secondhand <u>smoke</u> exposure (23%). Unless a flavour ban reduces smoking, there is no case. Yet all the evidence (see above) suggests vaping is a substitute for smoking, and restrictions on vaping will have the effect of increasing smoking.

The table shows that the cost-benefit analysis is highly sensitive to the impact of a vaping flavour ban on <u>smoking</u>. That means that if the flavour ban *increases* smoking in adolescents or adults, then the public health benefits claimed in the analysis will reverse and become detriments. In that event, Health Canada will have achieved the dubious distinction of causing economic damage, increasing public health detriments, and supporting the cigarette trade. This is the most likely outcome.

6.5   Flaws in the analysis: an excessive relative risk assumption

The assumption of a vaping risk equivalent to 20 percent of smoking risk has no basis in fact or evidence, and the unpublished report justifying this assumption is unconvincing.[45] The key data are emissions toxicity and biomarkers of exposure. Following a detailed expert review of biomarker studies, a 2018 expert assessment for Public Health England concludes:[46]

> Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this does not mean e-cigarettes are safe.

Though others will doubtless highlight this assumption, it is not the most important failing of the cost-benefit analysis. This is because the public health detriments are dominated (93%) by smoking impacts in the break-even analysis. Reducing the remaining seven percent to a lower level will barely affect the results. The main problem with the analysis is the unfounded assumption that vaping will causes more smoking and that reducing vaping initiation will reduce smoking.

6.6   Flaws in the analysis: failing to assess the overall impact of vaping

The modelling for Health Canada is incongruent with the most credible modelling in this field. Adult smokers are by far the largest market for these products, and flavours are integral to the experience for smokers.[47] Surveys suggest that adults like dessert, fruit, and candy flavours more than tobacco flavours.[48] There is no reason to assume a central case that adult switching will not change. In fact, the switching rate may become negative as existing vapers or dual users relapse.

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[45]   Industrial Economic Incorporated, *Elicitation of Expert Judgements on the Behavioural Impacts of a Nicotine Standard*. A report for Tobacco Products Regulatory Office, Health Canada, March 2017. [access].

[46]   McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [link] [Press release]

[47]   Gravely S, Cummings KM, Hammond D, et al. The association of e-cigarette flavors with satisfaction, enjoyment, and trying to quit or stay abstinent from smoking among regular adult vapers from Canada and the United States: Findings from the 2018 ITC four country smoking and vaping survey. *Nicotine Tob Res* 2021;22(10):1831–1841. [access]

[48]   Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* 2018;15(1):33. [link]

The use of e-cigarette flavours predicts for adult smoking cessation[49] [50]. Li et al. (2021) concluded, [51]

> Use of fruit and other sweet-flavored e-liquids is positively related to smokers' transition away from cigarettes.

There is also compelling evidence that the rise of Juul in the United States was very effective in helping adults to switch completely away from cigarettes.[52] There is now an abundance of evidence that smoke-free products such as e-cigarettes displace smoking for adults, and modelling suggests substantial public health gains arising from the introduction of vaping products. Levy et al. (2021) conclude:[53]

> The [smoking and vaping model] projects that under current patterns of US NVP [nicotine vaping product] use and substitution, NVP use will translate into 1.8 million premature smoking- and vaping-attributable deaths avoided and 38.9 million life-years gained between 2013 and 2060.

Mendez and Warner (2020) ran models with multiple combinations of assumptions coded into 360 scenarios and concluded:[54]

> The combination of assumptions produces 360 possible scenarios. 357 (99%) yield positive estimates of life-years saved (LYS) due to vaping by 2100, from 143 000 to 65 million. Most scenarios result in millions of individuals quitting smoking due to vaping.

> Vaping is highly likely to reduce smoking-produced mortality. Still, vaping is not "the" answer to the public health crisis created by smoking. Rather, it may well be a tool to add to the armamentarium of effective tobacco control measures.

By disabling a key feature of this tool, the broad selection of appealing flavours, Health Canada would be putting the public health benefits shown in this sort of modelling and potentially causing thousands of deaths in Canada while harming the vaping industry and supporting the cigarette trade.

September 2, 2021

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[49]   Jones DM, Ashley DL, Weaver SR, Eriksen MP. Flavored ENDS Use among Adults Who Have Used Cigarettes and ENDS, 2016-2017. *Tob Regul Sci* 2019;5(6):518–531. [[link](#)]

[50]   Friedman AS, Xu S. Associations of Flavored e-Cigarette Uptake with Subsequent Smoking Initiation and Cessation. *JAMA Netw Open* 2020;3(6):203826. [[link](#)]

[51]   Li L, Borland R, Cummings KM, et al. How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys. *Nicotine Tob Res* [Internet] 2021 [[link](#)]

[52]   Prakash S, Xu Y, Goldenson NI, Wissmann R, Gougelet R, Shiffman S. Transitions in smoking among adults newly purchasing the JUUL system. *Am J Health Behav* 2021;45(5):546–562. [[link](#)]

[53]   Levy DT, Tam J, Sanchez-Romero LM, et al. Public health implications of vaping in the USA: the smoking and vaping simulation model. *Popul Health Metr* 2021;19(1):19. [[link](#)]

[54]   Mendez D, Warner KE. A Magic Bullet? The Potential Impact of E-Cigarettes on the Toll of Cigarette Smoking. *Nicotine Tob Res* 2020 [[link](#)]