

Submission

By

**THE
NEW ZEALAND
INITIATIVE**

to

The Ministry of Health

on the public consultation document

**Smokefree Environments and Regulated Products Act 1990:
Proposals for regulations**

11 March 2021

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INTRODUCTION AND SUMMARY

- 0.1 This submission on the public consultation document *Smokefree Environments and Regulated Products Act 1990: Proposals for regulations* is made by The New Zealand Initiative, a think tank supported primarily by chief executives of major New Zealand businesses. The purpose of the organisation is to research to contribute to developing sound public policies in New Zealand to help create a competitive, open and dynamic economy and a free, prosperous, fair, and cohesive society.
- 0.2 The Initiative is funded by the subscription fees of its members. The Initiative's membership spans the breadth of the New Zealand economy, from telecommunications and banking to construction, retail, and tertiary education. It also includes two tobacco companies. Our work remains independent; the breadth and diversity of our membership ensure we are not reliant on any one company or sector's continued membership. Our members in the tobacco industry have not been provided an opportunity to give feedback on this submission.
- 0.3 The Initiative has, over the past several years, undertaken research into tobacco harm reduction policies because of our concern for the inequities caused by the existing tobacco control regime. That research includes *Smoke and Vapour: The changing world of tobacco harm reduction* (2018) and *The Health of the State* (2016). We have maintained a watching brief in this policy area and regularly provide public commentary on policy developments. We also submitted on the Smokefree Environments and Regulated Products (Vaping) Amendment Bill in April 2020.
- 0.4 Before the Smokefree Environments and Regulated Products (Vaping) Amendment, increasing numbers of smokers had shifted from smoking to vaping. Smoking rates declined, and vaping rates increased. While there was much concern about youth uptake of vaping in the absence of a regulatory framework, youth vaping rates remained very low. While youths might experiment with vaping, very few became vapers – as the Proposal for Regulations documents. ASH's Year 10 survey also finds that while 3.1% of Year 10 students use e-cigarettes daily, less than 1% of never-smoking youths use e-cigarettes daily, and less than 5% of never-smoking youths use e-cigarettes monthly.¹
- 0.5 We worry that many of the proposed regulations risk making it harder for smokers to shift to less harmful alternatives. It will be more difficult for potential vapers to find their preferred products, to find advice about alternatives, to be informed about developments in the product area, and to find places in which vaping is permitted. All of these will make vaping relatively less attractive and risk discouraging switching.
- 0.6 While there are trade-offs that need to be managed in some cases, like discouraging youth uptake while encouraging adult smokers to switch to vaping, in other cases, the regulations will make vaping more difficult to little benefit.
- 0.7 We address below several of the questions raised in the Document. Numbering is set by proposal number and by question number. So, 2.5 addresses matters raised in Question 5, which is part of Regulatory Proposal 2. We do not address all questions raised.

¹ See the 2019 ASH Year 10 Snapshot, available at https://www.ash.org.nz/ash_year_10.

Regulatory Proposal 1: Defining an internal area.

- 1.0 The Document asks about appropriate definition of “internal areas” for purposes of the ban on indoor vaping. The Initiative’s submission on the Bill in 2020² urged the government to allow property owners to come to their own decisions about whether to allow or to forbid vaping on their premises, whether indoor or outdoor. Similarly, ASH’s “A Surge Strategy for Smokefree 2025”³ recommended excluding vapers from smoking bans and urged that businesses should be able to set their own rules for on-premise vaping, whether indoor or outdoor. The legislation instead chose to make vaping more like smoking.

The regulatory proposal here worsens that problem, further blurring the distinction between smoking and vaping. It risks pushing vapers out into the rain with smokers and potentially into risky night-time environments.

We urge the Ministry to reconsider its approach unless substantial credible evidence develops demonstrating more than trivial bystander risk from vaping in realistic outdoor conditions.

If the Ministry insists on setting rules for outdoor vaping, our recommendations follow:

- 1.1 We suggest a combination proposal may be most attractive. A venue could comply for outdoor settings either by complying with wall and roof restrictions as outlined in (c), or by demonstrating compliance with a PM2.5 air quality standard as described below. Some venues might not wish to purchase a monitoring device; others might appreciate the design flexibility that can come by relying on an air quality monitor to demonstrate their site’s compliance.

All other options raise workability issues.

Option b would consider the balcony of my house, partially covered by a glass roof, to be an indoor area – despite that it is regularly too windy to sit on the balcony to read a newspaper or to have dinner. Similarly, windy bar balconies would be considered to be indoors. An umbrella at an outdoor picnic table could transform a picnic table into an indoor venue if unfurled. It is, in short, ludicrous. Option c could quickly prove unworkable. Many outdoor dining areas at pubs and restaurants will have roll-down plastic temporary walls in case of inclement weather. So, whether they were compliant would depend on whether the temporary walls could be rolled up quickly enough if a compliance officer were spotted. Official use of tape measures would be expected.

The rules seem to seek to reduce bystanders’ exposure to exhaled vape. Rather than set standards requiring specific architectural features that may or may not remedy that potential problem, why not consider a PM2.5 concentration standard? Monitoring devices for PM2.5 are now less than \$100. Standards for air quality in vaping areas would need to be set, and those standards would need to reflect prevailing local air quality. But if a venue can maintain below-threshold PM2.5 concentrations, should it

² Crampton, Eric. 2020. “Submission on the Smokefree Environments and Related Products (Vaping) Amendment Bill.” The New Zealand Initiative. Available at <https://www.nzinitiative.org.nz/reports-and-media/submissions/submission-smokefree-environments-and-regulated-products-vaping-amendment-bill/>

³ Bates, Clive, Professor Robert Beaglehole et al. 2019. “A Surge Strategy for Smokefree Aotearoa 2025: The role and regulation of vaping and other low-risk smokefree nicotine products.” Action on Smoking and Health. Available at https://www.ash.org.nz/surge_strategy_smokefree2025.

matter whether those concentrations are achieved by having no roof, open walls, some roof and some walls, a wide-open window in a tent, or adequate ventilation system?

- 1.2 We do not support option c. But if option c were to proceed, it is difficult to see why 50% or any other number should be preferred. On a windy day, even 80% coverage would be consistent with clean air – depending on the locations of the gaps relative to the wind. On a calm day, or if the walls and roof coverage were set to block airflow, greater open spaces could be needed to ensure airflow. It would be very easy for 50% to be far too strict in some parts of Wellington but be consistent with accumulated vape clouds in other areas. Air quality standards seem more appropriate.

2.0 Regulatory Proposal 2: Specialist vape retailer approvals

- 2.3 We agree that vape retailers in rural locations should be subject to lower thresholds for proportion of sales that must come from vaping products. But we worry that even these will be too restrictive in places currently not served by specialist vape shops. Suppose a town was unable to support even a single specialist vape shop prior to the Act. In that case, it will be even less likely to support such a shop if the regulations prohibit the retailer from also selling other products. And some places that currently have a couple of shops that also sell other products would risk losing one or both, leaving vapers with little choice.

It might be appropriate, in those areas, to allow the sale of a broader range of vape products at dairies. The result of the regulations otherwise could be to make it easier to acquire cigarettes than flavoured vape products in some communities. That surely cannot be consistent with the harm-reduction purposes of the Act.

The Ministry may also worry about the incentives it here creates. If a vape shop cannot diversify to other product lines if consumer demand changes, it will have stronger incentive to maintain that specific customer base. Ex-smokers transitioning may begin with frequent vaping at higher concentrations, then taper down. If that consumer base diminishes over time, the shop should be allowed to transition to other products.

- 2.4 We suggest that more liberal standards apply in places currently, for want of a better term, vape deserts: areas with few retail options.
- 2.5 Regulations enabling dairies or other non-specialist retailers in ‘vape deserts’ to carry a greater range of products and flavours should be considered. If the Ministry does not view those as currently warranted, it should at least monitor for resumption of smoking in places where the regulations will block vapers’ access to their preferred products. So that regulation can quickly be reassessed if these kinds of harms eventuate.

3.0 Regulatory proposal 3: Promotion, information and advice

3.1 *Display of vaping products in retail settings*

- 3.1.6 We agree that the display of vaping products should not be regulated at this stage. It is important that those who might switch from smoking to vaping can see the available options.

3.2 *Price lists given to retailers for tobacco only*

- 3.2.7 This regulation covers heated tobacco products. Devices for heating tobacco sticks can undergo constant innovation and improvement. Manufacturers may wish to provide information about changes to their devices directly on those price lists and would be constrained against doing so.

The Ministry here will require manufacturers to engage in conduct that, if they had decided to do it on their own by mutual agreement, would likely bring the attention of the Commerce Commission. Preventing communications that might encourage retailers to shift product lines or brands is anticompetitive in effect. Manufacturers will not be able to distinguish their products for retailer attention. It seems odd to mandate something that would be forbidden in other contexts.

- 3.2.8 We see no basis for restricting manufacturers' communications with retailers. Rights to freedom of speech should only be infringed if there is a compelling reason.

3.3 *Public health Messages*

- 3.3.9 We would defer to the views of practitioners in the area who would be better placed to know what additional information, if any, might be needed to help support smokers who wish to switch.

3.4 *Vaping product information in retail settings*

- 3.4.10 The proposal seeks to limit retailers' communications with customers for the protection of customers. But these restrictions would lead to outcomes contrary to the Act's harm-reduction purposes and to no benefit. The kinds of conduct that should be restricted are already restricted by other legislation. The Fair Trading Act already constrains against misleading and deceptive conduct (Part 1 Section 9-12); Unsubstantiated representations (Part 1 Section 12A-12D); and False Representations (Part 1 Section 13-16). The Act already constrains against the kind of conduct that could pose a problem. Additional restrictions would consequently need to pass a reasonably high hurdle to be warranted: harmful kinds of information provision are already forbidden, so additional restrictions risk preventing retailers from providing useful information to those wishing to switch.

The proposal could seriously limit essential information for consumers. Consider a smoker at a generic non-specialist outlet. The Ministry proposes prohibiting oral communications other than those identifying the available products and noting that switching is less harmful than smoking. The Ministry also proposes banning written materials about different products on offer. How could a smoker who wants to switch decide among the available options? If they have been a heavier smoker, which product concentration might work best for them? What are the differences between the different brands? How does a vape pen compare to a heated tobacco product? The smoker is in the shop, and the retailer is prohibited from telling the smoker about alternatives. The only written information that would be allowed is a small sign reminding the smoker that alternatives are less harmful.

Or consider a case where the manufacturer has changed a product with which the customer is familiar. The customer may have questions about the change and how it affects that product relative to others. The retailer is forbidden from discussing the change or its implications, and is forbidden against providing even a pamphlet from the manufacturer.

Where misleading communication is already forbidden by the Fair Trading Act, We propose that the retailer be able to talk with customers about the products on offer, and to provide written materials about the products that manufacturers might provide for that purpose.

The proposed regulations will make it harder for smokers to obtain the information that would help them switch. They are consequently contrary to the harm-reduction purposes of the Act.

3.4.11 The proposed statements are fine, if they do not constrain retailers against providing additional useful information that is not in breach of the Fair Trading Act.

3.4.12 The more that vaping is made to look like smoking, the greater the likelihood that smokers will view vaping as comparably risky. Vaping should be sharply distinguished from smoking. Making vaping notices look the same as smoking notices risks blurring the distinction between harmful and less harmful activities.

3.5 *Product availability notices in retail premises*

3.5.13 The same point made at 3.4.12 applies here as well.

3.6 *Point-of-sale information on purchase age*

3.6.14 Purchase age notices are reasonable. They also make it easier for retailers to dissuade any minors who may wish to argue the toss.

3.6.15 The proposed notices, again, look too much like the notices for smoking. Vaping should be sharply distinguished from smoking.

3.7 *Suitably qualified health workers*

3.7.16 The vaping community self-organised to encourage smokers to follow other vapers' paths out of smoking long before registered or qualified practitioners emerged. That community has developed its own expertise over the past decade and its own experts.

The regulation, as it stands, severely disempowers the communities that developed to support smokers' transitions away from smoking. The advice that experienced ex-smokers can provide could also be much more useful, compassionate and nuanced than advice from professionals who have never experienced the transition away from smoking first-hand. We very strongly urge that those communities be enabled to recognise the expertise that has developed through practice.

To put it bluntly, the government spent a decade ignoring vaping, or pretending it to be no safer than smoking, or pretending that there was inadequate evidence to suggest that vaping was effective in assisting smokers in quitting. During that time, vapers, often including Māori health providers, developed their own culturally-relevant expertise. And now, many of those experts who hold no NZQA qualification will be deemed unqualified by the edict of the Ministry and *prohibited* from continuing to help others to follow their path out of smoking.

The Ministry of Health is displacing the expertise and cultural standing of other communities who were more hindered than helped by government over the past decade favouring some NZQA certificate designed by another part of the bureaucracy. Is “colonialism” the right term for this kind of thing?

There must be some additional category here, a (iv) option, that would recognise the experts whose expertise came through a decade of helping smokers’ transitions rather than through some NZQA certificate. We again strongly urge consultation with the affected communities.

If the Ministry is determined to pursue this very misguided approach, please at least ensure that the training is easily accessible from a wide range of polytechnics and other providers, rather than restricted to a small number of training providers or a single training provider. The Ministry should not be establishing monopoly suppliers of compulsory training through regulation.

4. Regulatory proposal 4: Packaging

4.19 The best evidence thus far is that heated tobacco products are more harmful than vaping but less harmful than smoking. The proposed labelling is consistent with that level of risk. But it may stand regular review. If new products come to market that are safer than existing heated tobacco products and more in line with vaping, those products should be subject to labelling requirements like those in place for vaping. The proposed regulations do not allow this flexibility because they are a ‘tobacco product’, when it is the heating mechanism that varies the risk.

4.21 The proposed regulation would prohibit products from noting that they might be safer than other products or safer than prior versions of the same product. An unintended consequence of this rule, and a consequence at odds with the harm-reduction purposes of the Act, would be a reduction in manufacturers’ incentives to further improve product safety. It is not hard to imagine further innovations that improve safety. If claims about safety relative to other products or relative to prior versions of the same product are consistent with the Fair Trading Act, why should they be prohibited?

The regulation would also have the consequence of prohibiting manufacturers from advertising on the packaging the existence of any product recycling schemes for their containers or pods, or biodegradability of that packaging or containers or pods. This seems entirely inconsistent with other government efforts to encourage alternatives to single-use plastics. Safe disposal of waste nicotine containers can be difficult. If a manufacturer *has* a recycling scheme for safe disposal of those containers, it seems odd to prohibit their telling customers about it on the packaging. Some customers might prefer to purchase a product whose manufacturer provides such a scheme.

Manufacturers would have less incentive to develop these schemes if they are forbidden from telling potential customers about them.

This seems contrary to other government objectives around, for example, waste minimisation.

5. Regulatory Proposal 5: Product notification and safety

5.2: Product safety requirements

5.2.33 We agree that UK legislation can be a good starting point, but we would urge that the Ministry consult with current vapers about whether products important in the New Zealand market would be adversely affected. We would also recommend that sufficient lead time be provided to manufacturers. Complying with new product standards can require reformulating liquids. Consultation with manufacturers, especially smaller New Zealand companies, would be warranted; they may need up to twelve months after final regulations have been published to clear out older stock and change production lines.

5.2.34 Nicotine strength limitations as proposed may do harm. The point of strength limitations and volume restrictions are, in part, to prevent accidental poisoning; child-resistant packaging requirements seem sufficient to that end. Or instead, if they are not sufficient to that end, there are broader implications. Why would the government restrict the maximum allowable total quantity of nicotine in a container but not the maximum allowable total quantity of other substances that also pose ingestion risk? Is it safe that potentially lethal total quantities of pharmaceutical medications are dispensed in child-resistant packaging? Should Tide Pods only be dispensed in tiny packages?⁴

Total volume restrictions will mean a proliferation of containers. If a vaper wants a 20 mg/mL product in strength, and the maximum quantity of nicotine is 500 mg, then that is a 25 mL container. While the UK regulations result in even smaller containers, a 25 mL container is *tiny*. Has the Ministry consulted with vapers about how much liquid they typically purchase at one go? On a quick consultation online, standard container sizes show sales of vape liquid in 10 mL, 30mL, and 100mL containers. Someone who currently buys a 100mL container of 20 mg/mL product would have to buy ten 10 mL containers instead, or four 25mL containers, possibly at higher cost, if manufacturers respond by providing that new size container. All of that, again, means more packaging waste. What purpose is served by this if containers must also be child-resistant?

Concentration limitations can also do harm. Achieving a desired 'hit' of nicotine with a less concentrated liquid requires that vapers vape more often, with consequently increased exposure to everything else in the mix. And if part of the 'habit forming'

⁴ The insufficiently-online may wish to consult the rather depressing Wikipedia article on consumption of laundry detergent, which resulted in deaths and in the manufacturer airing advertisements pleading that people not eat their laundry detergent. https://en.wikipedia.org/wiki/Consumption_of_Tide_Pods

It is darkly amusing that it would be illegal for a vape company to air advertisements warning against eating their products in the unlikely event that Kiwis should ever decide to be as silly as Americans.

part of the experience is the physical act of using the product, there may be habituation risk in requiring vapers to vape more frequently.

Many vapers prefer to mix their own vape liquid. The simplest way of mixing liquids to achieve a desired nicotine concentration is to purchase a nicotine concentrate twice as strong as the desired consumption concentration and mix it one-to-one with flavourings. No math is required in calculating one-to-one ratios. Consider the last time you had to mix petrol and oil for the lawnmower. It is not hard, but it is not the most obvious thing either—especially when you are in a lawn-mowing mood and have not a calculator to hand. Allowing one-to-one mixes makes things easy, with less risk of surprises. Mandating a maximum concentration of 20 mg/mL makes it impossible to mix one's own vape liquid if the desired consumption concentration is 20 mg/mL and harder than it needs to be if the desired concentration is 15 mg/mL. Pop quiz for the regulator: if you have a container with 20 mg/mL nicotine, and you want a final concentration of 15 mg/mL, how much flavouring do you need to add? Is it 3:1? 2:1? Some other ratio? Diluting a 30 mg/mL concentrate to get to a 15 mg/mL flavoured vape liquid is far easier. Please consult with actual vapers about the difficulties this may wind up posing for those who mix their own liquids.

If container size limits and concentration limits, despite child-resistant packaging, are necessary because vape liquid can come with enticing aromas, there may be an alternative solution. Nicotine concentrate, without flavouring, could be allowed in larger bottles at higher concentrations for those who prefer to mix their own liquids. The nicotine concentrate would not entice children; the flavourings, without nicotine, would be less risky.

A maximum nicotine salt concentration of 50mg/mL may constrain against some of the products used by heavy smokers as they shift away from smoking. Please consult with the vaping community.

Tobacco control and vaping experts Clive Bates and David Sweanor have assessed the merits of 20mg/mL strength limits in proposed Canadian regulation and have provided strong warning against such measures. They suggest that strength limits:⁵

- “Create a barrier to stopping smoking for more dependent smokers;
- May cause harm to adolescent smokers;
- Undermines the design of easier-to-use but effective devices that support the early stages of switching;
- Obstructs future innovation;
- Higher consumption of liquid and greater toxic exposure;
- Stimulating a black market;
- Favouring the cigarette trade.”

⁵ Bates, Clive and David Sweanor. 1 March 2021. “Proposal to limit permitted nicotine e-liquid strength to 20mg/mL: Comment by Clive Bates and David Sweanor.” Submission to the Tobacco Control Directorate, Health Canada. Available at <https://clivebates.com/documents/CanadaBatesSweanorMarch2021.pdf>

We have appended Bates and Sweanor's submission on the Canadian regulations and endorse it.

5.2.35 While the discussion document suggests alignment with UK and EU rules, and Canadian rules, different places will have different rules for different reasons.

Some prohibitions will be based on very reasonable safety considerations. It seems unlikely that any manufacturers would ever deliberately include radioactive substances in their vape liquids, but banning them will do no harm.

But other ingredients may have been banned elsewhere to make the products potentially less attractive, for reasons like the Ministry's prohibition on generic shops selling a wider variety of flavourings. Is the ban on glucose motivated by safety or a policy decision that flavourings should not be sweet?

We urge that prohibitions be based only on legitimate safety concerns. The ban on sweet flavourings will have a consequence for those vapers for whom those flavourings were important in helping them to shift away from smoking. Please consult with vapers about the effects of this ban on the products that help them to stay away from smoking. Any potential harms of those flavourings need to be weighed against the harms imposed when smokers find fewer paths out of smoking.

[Appendix 1: Bates and Sweanor Submission on nicotine concentration rules.](#)

Proposal to limit permitted nicotine e-liquid strength to 20mg/ml

Comment by Clive Bates and David Sweanor

1st March 2021

Tobacco Products Regulatory Office
Tobacco Control Directorate
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1. We write as public health advocates in favour of the strategy of tobacco harm reduction.¹ We welcome the opportunity to comment on Health Canada's proposal to limit the strength of nicotine e-liquids to 20mg/ml.² There is little evidence to show this measure would have a beneficial public health impact and much to suggest it is a bad idea that will do more harm than good.

Recognise perverse unintended consequences of regulation

2. **Significant perverse consequences are not recognised in the regulatory impact analysis.** It is likely that the effect of a limit on nicotine strengths where these are already popular will: provide regulatory protection to the cigarette trade; inhibit the transition of the consumer nicotine market to far less dangerous non-combustible products; cause more smoking among both adults and adolescents; add to the burden of disease and death caused by tobacco use; prevent or obstruct users from taking action to protect their own health, on their own initiative and at their own expense; stimulate black market activity, user workarounds, home mixing and favour use of devices with higher power combined with higher liquid volume intake, and hence greater toxicant exposure.
3. **No benefits to youth demonstrated.** The analysis does not adequately examine the impact the measure will have on adults and adult smoking. However, the most significant flaw is that the regulatory impact analysis fails to account for the effect on *adolescent smoking* and the likely role that stronger vaping products play in diverting prior tobacco users away from smoking. Evidence from the United States suggests more intensive teenage vapers are likely to be prior tobacco users^{3 4} and that teenage vaping is likely a diversion from teenage smoking.^{5 6} Given that e-cigarettes are an economic substitute for cigarettes,⁷ it is quite possible that teenage vaping has a net positive effect on adolescent health because of its interaction with adolescent smoking.⁸

¹ See [About the authors](#) at the end of this submission

² Government of Canada, Department of Health. Canada Gazette, Part I, Volume 154, Number 51: Concentration of Nicotine in Vaping Products Regulations, 19 December 2020. [\[link\]](#)

³ Tam J, Brouwer AF. Comparison of e-cigarette use prevalence and frequency by smoking status among youth in the United States, 2014–19. *Addiction* 2021 add.15439. [\[link\]](#)

⁴ 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 [\[link\]](#)

⁵ Selya AS, Foxon F. Trends in Electronic Cigarette Use and Conventional Smoking: Quantifying a Possible “Diversion” Effect among U.S. Adolescents. *Addiction* [Internet] 2021 [cited 2021 Jan 11];add.15385. [\[link\]](#)

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. [\[link\]](#)

⁷ Pesko MF, Warman C. The Effect of Prices on Youth Cigarette and E-Cigarette Use: Economic Substitutes or Complements? *SSRN Electron J* 2017 [\[link\]](#)

⁸ Friedman AS. How does electronic cigarette access affect adolescent smoking? *J Health Econ* 2015;44:300–308. [\[link\]](#)

4. **Canadian data is consistent with vaping displacing adolescent smoking.** The trends in youth nicotine use in Canada show a sharp decline in smoking as vaping increased, as shown in the figure below:⁹

Figure. Prevalence of Cigarette Smoking, Vaping, and Dual Use Among Youths Aged 16 to 19 Years, 2017 to 2019, by Country

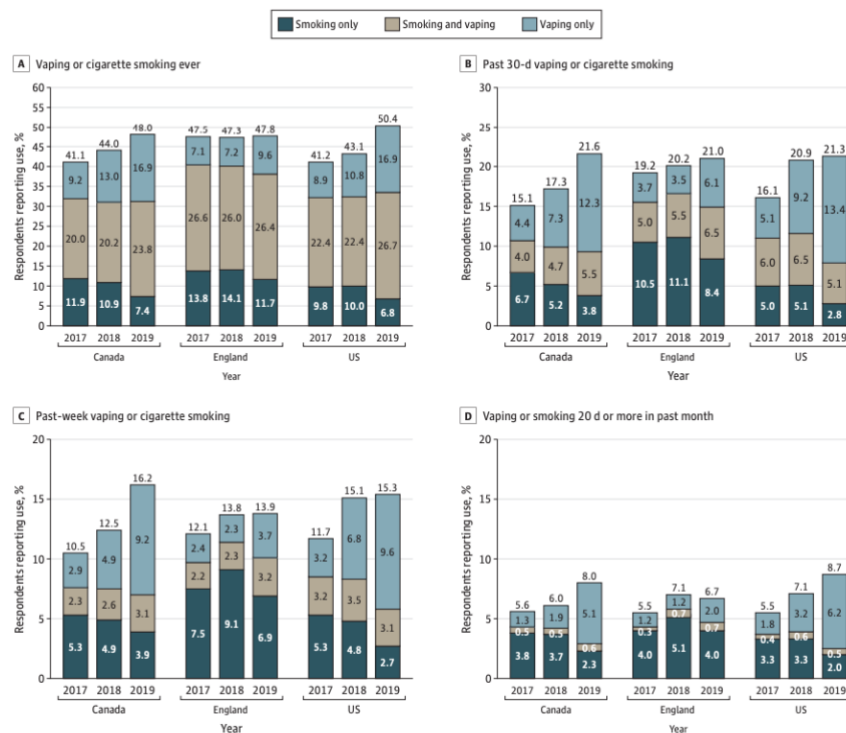


Figure 1: Adolescent smoking and vaping in the UK, the US, and Canada (Hammond et al. 2020)

The United States, which has had a high-pitched moral panic about youth vaping, has a lower adolescent smoking rate than Canada. The UK, which already has the 20mg/ml in place through the European Tobacco Products Directive, has a lower adolescent vaping rate but a higher smoking rate.

5. **Failure to address the interaction of smoking and vaping.** The central problem is how a proposal like this interacts with the smoking and other risk behaviours of adults and adolescents. As the Royal College of Physicians (London) puts it:¹⁰

If [a risk-averse and 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. (Section 12.10 page 187)

6. **How the 20mg/ml regulation will tilt the balance toward cigarettes.** In terms of the warning in the Royal College of Physicians statement above, the nicotine cap would have three possible harmful effects in favour of cigarettes:

- It will make some more compact products pharmacologically less effective than cigarettes and thus grant cigarettes a marketing advantage in the Canadian market, especially for more highly dependent smokers.

⁹ Hammond D, Rynard VL, Reid JL. Changes in prevalence of vaping among youths in the United States, Canada, and England from 2017 to 2019 JAMA Pediatr. 2020 174(8):797–799. [\[link\]](#)

¹⁰ Tobacco Working Group. Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [\[link\]](#)

- b. It will make many safer products less acceptable by making smaller, more compact devices with adequate nicotine delivery impossible to make. Users will have to use higher power, higher volume devices to achieve satisfactory nicotine delivery or smoke.
 - c. It will be a barrier to pro-health innovation in which new devices draw on stronger liquids to reduce the power inputs and temperatures, reduce the physical size, or improve the pharmacological performance.
7. **No evidence for gateway effects.** It might be worth taking these risks with adult and adolescent health if e-cigarettes functioned as a gateway to smoking or other risk behaviours. But there is no compelling evidence that they do.^{11 12} The alternative explanation for the observed associations between e-cigarette use and smoking relates to the individual’s characteristics and their circumstances that incline them to both vaping and smoking. Given the similarities between the two habits (albeit with radically different risk to health), it is not surprising that whatever reasons people have to smoke are also reasons to vape. These common characteristics – genetics, mental health, family, community, delinquency, etc.) are sometimes known as common liabilities, common risk factors or confounders. These provide a more credible explanation for at least part of the observed associations between smoking and vaping.^{13 14} Common liabilities also mean that vaping will tend to be concentrated among those with a propensity to smoke – and therefore likely to be beneficial.
8. **Flawed and implausible cost-benefit analysis.** The cost-benefit analysis presented in the regulatory impact analysis looks sophisticated at first sight, but its main public health finding is predicated on a single simplistic assumption:

The proposed Regulations are expected 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. Long-term benefits would be realized in terms of avoided tobacco- and vaping-related mortality and morbidity, including from exposure to second-hand smoke.

Because the value of life used in such analyses is so high (\$7.9 million in this case), any case will be dominated by the effects of changes in smoking status. The model assumes a gateway effect, implying that a cap on that stronger liquids will prevent net additional smokers resulting in reduced mortality, morbidity and secondhand exposures. Over 90% of the benefit is attributable to *reduced smoking*, which supposedly arises from eliminating a potent *competitor to cigarettes*. This is absurd. All the evidence (and common sense) points the other way: vaping is a low-risk economic substitute and diversion from smoking, and this applies both to adults and adolescents. The likely and foreseeable unintended consequences of *the cap* are increased adult and adolescent smoking and more dual-use. These more realistic consequences have either been ignored or relegated to a break-even or sensitivity analysis. The model findings are an artefact of assumptions about the beneficial impacts of the cap, which, through circular reasoning, inevitably reinforce the modelled case for it.

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- ¹¹ 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. [\[link\]](#)
 - ¹² Lee PN, Coombs KJ, Afolalu EF. Considerations related to vaping as a possible gateway into cigarette smoking: an analytical review. *F1000Research* 2019;7:1915. [\[link\]](#)
 - ¹³ 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. [\[link\]](#)
 - ¹⁴ 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; [\[link\]](#)

Appreciate the valuable role of higher strength liquids in innovation

9. **How high-strength liquids *don't* work – understanding titration and compensation.** Before regulating in this area, it will be helpful to thoroughly understand the role that relatively high nicotine strength plays in the nicotine product market. The most fundamental error is the idea that nicotine strength is somehow a proxy for nicotine exposure or 'addictiveness'. It is not. This is because the users control their exposure to nicotine through a widely understood process known as nicotine titration.¹⁵ This effect has been well documented in smokers for several decades.^{16 17} The user behaviours change to achieve a desired level of nicotine, for example, by puffing more deeply or more often – a process known as 'compensation'. It means that users consume lower volumes of higher strength liquid by adjusting their puffing patterns. But it also means that users will consume higher volumes of lower strength liquid – potentially creating higher exposures to toxicants generated by heating liquids.^{18 19 20} *Lowering the maximum nicotine strength on the market does not necessarily reduce nicotine exposure and may increase toxicant exposure.*
10. **How high-strength liquids *do* work.** The primary function of stronger nicotine liquids is *to enable a satisfactory exposure to nicotine from a compact, low-power device*. Small form factor pod devices, like the Juul, have three synergistic design features: (1) high liquid strength to allow for lower volumes of liquid for a given dose of nicotine; (2) the use of acid additives to form nicotine salts to reduce harshness and improve pharmacokinetics by ensuring more nicotine is delivered via the lung than upper respiratory tract; (3) lower power and operating temperature from smaller batteries to allow a compact device and lower exposure to products of thermal decomposition. These three features combine to make a product that is a powerful competitor to cigarettes – a compact device that is easy to use but has good nicotine delivery and sensory characteristics at vastly reduced risk compared to smoking. It is an ideal entry point for smokers who need a simple but effective transition from smoking to vaping.
11. **Innovation and its enemies.** These compact, high-strength, low-power products have been effective at helping smokers to switch to vaping as an alternative to smoking^{21 22}. The formula of good nicotine delivery combined with convenience has been successful commercially and led Juul to

¹⁵ Dawkins LE, Kimber CF, Doig M, Feyerabend C, Corcoran O. Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. *Psychopharmacology (Berl)* 2016;233(15–16):2933–2941. [\[link\]](#)

¹⁶ Benowitz NL, Hall SM, Hering RI, Jacob P, Jones RT, Osman AL. Smokers of Low-Yield Cigarettes Do Not Consume Less Nicotine. *N Engl J Med*. 1983 Jul 21;309(3):139–42. [\[link\]](#)

¹⁷ Russell MAH, Jarvis M, Iyer R, Feyerabend C. Relation of nicotine yield of cigarettes to blood nicotine concentrations in smokers. *Br Med J*. 1980 Apr 5;280(6219):972–6. [\[link\]](#)

¹⁸ Kośmider 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* 2018 [\[link\]](#)

¹⁹ 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 [Internet]* 2020;10(1):6546. [\[link\]](#)

²⁰ 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. [\[link\]](#)

²¹ Russell C, Haseen F, McKeganey N. Factors associated with past 30-day abstinence from cigarette smoking in adult established smokers who used a JUUL vaporizer for 6 months. *Harm Reduct J* 2019;16(1).

²² Goldenson NI, Le G, Auguston EM. Switching Away from Cigarettes Among Adult Smokers Who Purchased the JUUL System: 12-Month Follow-Up Results from Two Large Longitudinal Studies, Poster 3rd Scientific Summit on Tobacco Harm Reduction 2020 September 25, 2020. Juul Labs Inc. [\[link\]](#)

dominate the nicotine vaping market in the United States.²³ As e-cigarette use rose rapidly among adults, cigarette sales began an unusually rapid decline. However, a moral panic about a youth vaping epidemic eventually caused a backlash and excessive regulation and hostility that caused the decline in cigarette sales to stall.²⁴ In contrast, the Juul products available in the UK under the European Union nicotine cap of 20mg/ml restrictions are not effective in competition with cigarettes.^{25 26 27} Canada's proposal is essentially to obstruct an innovation that has worked well to liberate smokers from smoking. However, this is based on a paper-thin rationale that does not consider the likely behavioural responses of adults, adolescents, or the marketplace.

Base policy on an understanding of pharmacokinetics

12. **Clarity or confusion over nicotine pharmacokinetics?** The key concept and concern for regulators should be the psychotropic reward of nicotine delivery, not nicotine e-liquid strength. This is a function of the peak level of nicotine reached in the brain and time to achieve this. These characteristics are known as pharmacokinetics (PK). Higher peaks more rapidly are more likely to provide a reward comparable to cigarettes. Many smokers still report that e-cigarettes do not provide a satisfying alternative to cigarettes.²⁸ For any individual, this reward is a function of the user, the device, and the e-liquid. The central question for health agencies like Health Canada is: should these devices compete with cigarettes in nicotine delivery, or should Health Canada use regulation to ensure that cigarettes have a protected market for high-speed, high-peak nicotine pharmacokinetics? The proposed limit puts Health Canada firmly on the side of the cigarette trade.
13. **Other vaping products can achieve high nicotine delivery with weaker liquids.** As explained above, high-strength liquids are tightly linked to the feasibility of compact low-power devices. High power, high volume devices using weaker liquids can achieve an effective nicotine delivery if that is what the user is seeking.^{29 30 31} A ban on higher strength liquids may cause some users to revert to smoking or to quit vaping or never start. It is also likely that young people, driven by curiosity and seeking to emulate adult behaviours, will not simply quit vaping and do something virtuous instead. They may

²³ Huang J, Duan Z, Kwok J, et al. Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market. *Tob Control* 2019;28(2):146–151. [[link](#)]

²⁴ Jennifer Maloney, Smoking's long decline is over. Wall Street Journal 28 January 2021 [[link](#)]

²⁵ Phillips-Waller A, Przulj D, Smith KM, Pesola F, Hajek P. 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 (Berl)* [Internet] 2020 [cited 2020 Dec 5];1–7. [[link](#)]

²⁶ Hajek P, Pittaccio K, Pesola F, Myers Smith K, Phillips-Waller A, Przulj D. Nicotine delivery and users' reactions to Juul compared with cigarettes and other e-cigarette products. *Addiction* 2020;115(6):1141–1148. [[link](#)]

²⁷ Goldenson NI, Fearon IM, Buchhalter AR, Heningfield 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* 2021 [[link](#)]

²⁸ Yong HH, Borland R, Cummings KM, et al. Reasons for regular vaping and for its discontinuation among smokers and recent ex-smokers: findings from the 2016 ITC Four Country Smoking and Vaping Survey. *Addiction* 2019;114(S1):35–48. [[link](#)]

²⁹ Jacobson K, Martinez J, Larroque S, Jones IW, Paschke T. Nicotine pharmacokinetics of electronic cigarettes: A pooled data analysis from the literature. *Toxicol Reports* 2021;8:84–95. [[link](#)]

³⁰ Ramôa CP, Hiler MM, Spindle TR, et al. Electronic cigarette nicotine delivery can exceed that of combustible cigarettes: A preliminary report. *Tob Control* 2016;25(E1):e6–e9. [[link](#)]

³¹ Voos N, Goniewicz ML, Eissenberg T. What is the nicotine delivery profile of electronic cigarettes? [Internet]. Expert Opin. Drug Deliv. 2019 [cited 2021 Mar 1];16(11):1193–1203. [[link](#)]

adjust by using larger, higher power devices using higher volumes of lower strength liquids with greater toxicant exposure. This possibility is not addressed in the regulatory impact assessment.

14. **Applying the wrong regulatory paradigm.** To a pharmaceutical regulator, a high nicotine reward would be described negatively as ‘abuse liability’. The regulator would typically aim to attenuate the reward and moderate the pharmacokinetics to prevent dependence. However, most pharmaceuticals are not used in a situation where there is a dominant, widely available incumbent consumer product, the cigarette, that has both high abuse liability and is a cause of severe harm. Several studies wrestle with this contradiction, not always successfully.^{32 33}

Avoid repeating the errors and flawed analysis of the European Union

15. **There is no case to follow the European Union.** It may be reassuring to adopt a rule built into the 2014 European Union Tobacco Products Directive (TPD)³⁴. It should not be. This limit was the outcome of an undignified haggle between member state bureaucrats and owes little to science or reason. The European Commission misunderstood and then misused the available science to justify this measure. Several scientists cited by the Commission to justify its approach pointed out the error when the legislation was crafted.^{35 36 37} It is difficult to know if the Commission’s refusal to acknowledge the deficiencies in its reasoning was cynical and calculated or simply because the negotiations were political and too far advanced for the Commission to admit its error.
16. **The European Union had the right objective but the wrong approach.** The European Union was, in fact, trying to create a non-discriminatory ‘level playing field’ for competition between cigarettes and e-cigarettes. Non-discrimination is a principle of the EU internal market, but it was poorly executed in this case. In recital 38 of the TPD, a roughly appropriate goal is specified:

This concentration [20mg/ml] allows for a delivery of nicotine that is *comparable to the permitted dose of nicotine derived from a standard cigarette* during the time needed to smoke such a cigarette. (emphasis added)

The problem is that the basis for competition is not, in fact, the quantity of nicotine in a device but the *nicotine delivery experience* that can be achieved by a user, a function of its pharmacokinetics.

17. **Tilting the playing field towards cigarettes.** With this limit on vaping technology in place in the European Union, cigarettes can deliver a higher peak of blood-nicotine than vaping products that have been most competitive elsewhere – therefore leaving the most dangerous product with a considerable advantage in the marketplace. The supposedly level playing field was tilted in favour of cigarettes by the Directive. It should have been kept level or tilted towards the safer product.

³² Stiles MF, Campbell LR, Graff DW, Jones BA, Fant R V., Henningfield JE. Pharmacodynamic and pharmacokinetic assessment of electronic cigarettes, combustible cigarettes, and nicotine gum: implications for abuse liability. *Psychopharmacology (Berl)* 2017;234(17):2643–2655. [\[link\]](#)

³³ Shihadeh A, Eissenberg T. Electronic Cigarette Effectiveness and Abuse Liability: Predicting and Regulating Nicotine Flux. *Nicotine Tob Res* [Internet] 2015 [cited 2021 Feb 28];17(2):158–162. [\[link\]](#)

³⁴ European Union Tobacco Products Directive 2015/40EU, 2014. [\[link\]](#) The nicotine cap is specified at Article 20(3)(b).

³⁵ Farsalinos K. The European Commission has misinterpreted my scientific research on nicotine in e-cigarettes, 10 Jan 2014 [\[link\]](#)

³⁶ Etter, JF and 14 experts, Scientific Errors in the Tobacco Products Directive, A letter sent by scientists to the European Union. 17 January 2014. [\[link\]](#)

³⁷ Dawkins LE. Please Do Not Distort My Words To Justify Your Policy, 13 January 2014. [\[link\]](#)

Summarising the likely adverse consequences of the proposed nicotine cap

18. To conclude, we believe there are several legitimate challenges to the proposal for a nicotine cap that have not been satisfactorily addressed in the regulatory impact analysis.
- 1) **Creates a barrier to stopping smoking for more dependent smokers.** The proposed nicotine cap will deter more dependent smokers from switching in the first place. It will make the consumer transition from smoking to vaping harder for those most at risk.
 - 2) **May cause harm to adolescent smokers.** The impact of the cap will not be neatly divided between the interests of adult smokers and adolescent non-users. The cap could harm adolescents through an adverse effect on their smoking behaviour. Adolescents with a prior smoking habit and higher dependence become more intensive users of e-cigarettes.
 - 3) **Undermines the design of easier-to-use but effective devices that support the early stages of switching.** The cap works against more compact devices that use low volumes of liquid at a higher strength, which do not require refilling or complicated configuring. The larger devices may deter ordinary smokers through initial cost and complexity. The easy-to-use and compact devices are often valued by smokers as they try something unfamiliar, not knowing if it will work.
 - 4) **Obstructs future innovation.** It is also a barrier to new product designs that would use stronger liquids to provide prospective consumers with better or cheaper products to compete with cigarettes and reach smokers who do not currently find e-cigarettes satisfying. Canada would be imposing a constraint that could hold back the endgame for smoking.
 - 5) **Higher consumption of liquid and greater toxic exposure.** It will mean some users will switch devices to consume greater quantities of weaker e-liquids using higher-powered devices with potentially greater toxicant exposure. While these elevated risks remain very low compared to smoking, there is no justification to *increase* them using regulation.
 - 6) **Stimulating a black market.** Bans will promote a black market in the products that are banned. Canada's border with the United States will facilitate illicit trade either because these products are readily available legally or in a black market developed to work around US federal and state regulation. It will also encourage users to mix their own liquids from near-pure imported nicotine – a dangerous substance and risky procedure.
 - 7) **Favouring the cigarette trade.** Limits on ISO or Health Canada Intensive nicotine yield do not materially limit the nicotine delivery of cigarettes to the user. Most smokers can compensate and self-titrate to achieve the nicotine hit they want from cigarettes on the market. In contrast, the 20mg/ml limit is a significant design constraint for the e-cigarette category, especially for the compact and convenient devices that smokers are likely to turn to first.

A better approach – controls on access and marketing

19. We hope we have shown how simple-sounding regulation could easily backfire and cause more harm than it does good. Given the relative risks, the overwhelming focus of tobacco and nicotine policy should be on reducing *smoking* in both adults *and adolescents*. Given vaping is among the least troubling of all adolescent risk behaviours, there is little justification for protecting the cigarette trade from innovative vaping product designs by imposing distorting regulation that works against the interests of smokers. Any regulatory measures to control youth vaping should focus on age-specific controls on access and on marketing or branding targeted at children, but not on modifying a fundamental design parameter of the most advanced products for no demonstrable benefit.

About the authors

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The authors report no conflicts of interest concerning tobacco, vaping or pharmaceutical industries.