

Manager, Regulations Division,
Tobacco Products Regulatory Office,
Tobacco Control Directorate,
Controlled Substances and Cannabis Branch,
Health Canada, Ottawa, Ontario K1A 0K9

By email: hc.pregs.sc@canada.ca

Comment on Notice of Intent – Potential Measures to Reduce the Impact of Vaping Products Advertising on Youth and Non-users of Tobacco Products¹

I warmly welcome Health Canada's open-minded approach to the public health opportunities arising from new technologies, such as e-cigarettes, that have the potential to displace smoking and ultimately to obsolete the cigarette. However, the notice of intent raises concerns about the rise of youth vaping in Canada, and also notes that a significant rise in youth vaping has been observed in the United States.

The Canadian Student Tobacco, Alcohol and Drugs Survey (CSTADS) results from 2016-2017 indicate that 15% of students in grades 10-12 (Secondary IV and V in Quebec) used a vaping product in the past 30 days, up from 9% in 2014-15. This represents a 64% increase, or roughly 30% per year. Preliminary results from the International Tobacco Control Youth Tobacco and Vaping Survey suggest that there has been an increase in the proportion of 16- to 19- year old Canadians who have tried vaping in the last 30 days between September 2017 and September 2018. It appears that the rate of youth uptake is rapidly accelerating. Similar observations were noted in the United States, where the use of vaping products in the past 30 days rose from 12% in 2017 to 21% in 2018 (a 78% increase) among high school students.

The headline numbers from the United States have provoked alarm and, in my view, an over-reaction. Health Canada should take a dispassionate and more nuanced view of both the US and emerging Canadian data. The Attorney General of Iowa, Tom Miller, has written to the US FDA Commissioner, Scott Gottlieb, in some detail calling on the FDA not to over-react and to properly understand the underlying behaviours². I have analysed the claims made for a "teenage vaping epidemic" by public health bodies in the United States³.

I would like to summarise some of these arguments as input to Health Canada's deliberations on the interpretation of its own youth vaping data and the appropriate regulatory approach to e-cigarettes.

1. **How many adolescent vapers are regular, daily or compulsive users?** When data is reported as 'ever-use' or 'past-month' use, it is capturing very different behaviours under a single headline number. It is important to distinguish between experimental or frivolous use ("party use") and what is a more serious substance-using or problem behaviour. In the US, although past-month use had risen to 20.8% in 2018,

¹ Health Canada, Notice of Intent – Potential Measures to Reduce the Impact of Vaping Products Advertising on Youth and Non-users of Tobacco Products, 16 February 2019 [\[link\]](#)

² Miller T, Abrams R, Bates C, Glynn t, Kozlowski L, Niaura R, Sweanor D, *Youth tobacco and nicotine use – proportionate and responsible reaction*, 14 November 2018 [\[link\]](#)

³ Bates C. *The great American youth vaping epidemic. Really?* 23 January 2019 [\[link\]](#)

regular use (use on 20 days or more) was just 5.8%. This means more than 70% of the US high school vaping population *were not* regular users. Daily use for 2018 has not been disclosed by FDA, but a problem or compulsive behaviour would be reflected in daily use and probably use soon after waking – as with smoking, where the time between waking and first cigarette is one of the most reliable markers of dependence. Though any teenage use is undesirable, for public health purposes it is important to define realistic criteria for *problem use*, not just apply whatever criteria are used to collect the data.

2. **Are regular vapers mainly smokers?** The next stage of analysis should be to drill down into the regular or daily adolescent vaping users. In particular, it is important to understand whether regular vapers are also smokers or would-be smokers (i.e. they would smoke in the absence of vaping). For these users, the introduction of vaping may be *beneficial* – an alternative to smoking, part of an attempt to quit smoking or the potential for an earlier subsequent diversion from smoking. Data from the United States⁴, England⁵ and New Zealand⁶ show that regular or daily vaping is highly concentrated in adolescent smokers and former smokers, with very low levels (significantly less than 1%) of regular vaping among never-smokers. For Canada, similar analysis is also likely to show a very small proportion of never-smokers have become regular or daily vapers – and for some of these, it is possible that they would have gone on to become smokers in the absence of the vaping option.
3. **Is there a conflict between the interests of different adolescents?** Though often framed as conflict between the interests of adult smokers and teenage non-smokers, that is a misleading oversimplification. The issue here is that many of the supposed adolescent problem-users may actually be benefiting from vaping because they are also smokers or would-be smokers. There may be a conflict between the interests of *adolescent* smokers and *adolescent* never-users. As smokers are likely to be from lower socio-economic status backgrounds, the conflict between the interests of different groups of adolescents may be compounded by concern for inequalities. Or to put it put more bluntly: could an excessively risk-averse youth vaping policy end up protecting relatively well-off middle-class kids from minor or trivial risks at the expense of allowing poorer kids to avoid much more serious risks?
4. **How should policymakers conceptualise risk for different user pathways?** Policymakers should weigh concerns about new patterns of behaviour by the harm or benefit they are likely to cause. If it is accepted that vaping is much less risky than smoking, then the following considerations apply:
 - a. An adolescent who would have never used nicotine but takes up *occasional* vaping would likely experience no material harm;
 - b. An adolescent who would have never used nicotine but takes up *regular* vaping may face a small risk over the long term if they continue vaping for decades;

⁴ Collins LK, Villanti AC, Pearson JL, Glasser AM, Johnson AL, Niaura RS, et al. Frequency of youth e-cigarette, tobacco, and poly-use in the United States, 2015: Update to Villanti et al., “frequency of youth e-cigarette and tobacco use patterns in the United States: Measurement precision is critical to inform public health.” Vol. 19, Nicotine and Tobacco Research. Oxford University Press; 2017. p. 1253–4. [\[link\]](#)

⁵ McNeill A, Brose LS, Calder R, Bauld L & Robson D. Vaping in England, an evidence update. A report commissioned by Public Health England. London: Public Health England. 27 February 2019 [\[link\]](#)

⁶ Walker, N, Wong S, Youdan B, Broughton B, Bullen C, Beaglehole R. Use of e-cigarettes and conventional cigarettes in 14-15-year olds in New Zealand: results from repeated cross-sectional studies, 2014-2017. ASH New Zealand, National Institute for Health Innovation, poster for SRNT conference, February 2019. [\[link\]](#)

- c. An adolescent who would have never used nicotine but takes up vaping and then becomes a smoker faces a large additional risk over the long term, provided they don't reverse the behaviour later in life and switch back to vaping or quit. This requires a 'gateway effect'. Evidence for this remains elusive and is likely to become a less plausible pathway as smoking becomes more marginal in society;
- d. An adolescent smoker (or would-be smoker) who starts vaping may experience significant benefits by stopping smoking or diverting away from smoking sooner than they might otherwise have done;
- e. A middle-aged adult regular smoker who switches to vaping will experience a very substantial benefit to health and welfare over the relatively short term. If the aim is to bring down the burden of disease and premature death in the 2025-30 timeframe, then this is the key group. Conversely, policy measures brought in to address relatively low risks arising from teenage vaping could cause considerable harm to adults if they reduce the appeal, availability or affordability of the products and so diminish the rate of switching.

5. **Are policymakers focussing on the real problem behaviour – youth and adult *smoking*?** The analysis above suggests that policymakers should take an approach to vaping that is concerned with its impact on smoking of any combustible product. In the United States in 2017, 11.7% of high school students were past 30-day users of e-cigarettes and 12.9% were combustible tobacco product users. By 2018, the figure for e-cigarettes had risen to 20.8%. The 2018 figure for combustible use has not been disclosed. But when comparing these numbers, it is important to recognise that combustible products may be more than *20 times as harmful*⁷. If patterns of tobacco use were characterised by *harm-weighting*, as proposed the US National Tobacco Reform Initiative⁸, then policy-makers would be drawn to focus on the products and behaviours that most substantially affect health outcomes, and that would concentrate focus on *combustible products*. In the United States, the federal policy-focus since mid-2017 has almost entirely concentrated on vaping products, but the overwhelming burden of harm comes from the combustible products still in widespread use in both Canada and the United States.

6. **Will interventions cause unintended consequences and do more harm than good?** The Royal College of Physicians summarised the possible risks of unintended consequence arising from excessive regulation⁹:

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. (Section 12.10 page 187)

This balance should also be weighed by relative harm. The cost of a policy intervention that inadvertently causes more smoking is far higher than the benefit of a policy that intentionally reduces the vaping by the equivalent amount. Almost every e-cigarette policy is capable of increasing smoking via unintended consequences¹⁰. For example:

⁷ Royal College of Physicians (London) *Nicotine without smoke: tobacco harm reduction* 28 April 2016 [\[link\]](#)

⁸ National Tobacco Reform Initiative, *Summary of Comments on Draft Healthy People 2030 Tobacco Use Objectives*, January 2019 [\[link\]](#)

⁹ Tobacco Advisory Group of the Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [\[link\]](#)

¹⁰ Bates C. *Plausible unintended consequences of excessive regulation of low-risk nicotine products*, February 2019 [\[link\]](#)

- Bans or excessive restrictions on e-cigarette advertising protect the incumbent cigarette trade from competition from the much safer entrant vaping products and ongoing innovations. Controls on marketing should focus on responsible messaging and restricting promotional activity to times and locations that would disproportionately reach minors.
- Excessively large, bold or alarming warnings can convey signals that implicitly exaggerate relative risk and thereby degrade one of the key selling points of e-cigarettes to smokers.
- Bans on e-cigarette flavours implemented may deny adult or adolescent smokers the choices they would make and have the effect of reducing switching or increasing relapse.
- Excessive restrictions on vaping in public places could drive vapers back to smoking or reduce switching. Indoor vaping policy should be a matter for owners and managers unless and until there is evidence that vaping causes material risk to bystanders. Otherwise the issue should be treated as an issue of nuisance or etiquette and a matter for property owners.

Policymakers should proceed with caution and with great concern about getting the wrong balance between intended and unintended consequences of regulation. The measures proposed in the notice of intent should be judged by their potential to achieve a desired end, but also and especially the risk that they would cause harm to adults or adolescents through preventing migration from smoking to vaping.

Conclusion

Headline increases in youth vaping prevalence demand a nuanced analysis that makes meaningful distinctions between experimental use and regular or daily use, and drills down into the smoking behaviours of the regular users. It is likely that the more intensive vapers are also smokers and will derive benefits from vaping. While a political concern in response to increased teenage vaping prevalence is inevitable, it is important to ensure that reaction is based on facts, effectively addresses risks and benefits of policy changes, and has a strong rationale in public health terms. The overwhelming cause of nicotine or tobacco-related harm is from *smoking* and policymakers should consider the interactions between smoking and vaping in both adults and adolescents. Excessively risk-averse policies towards vaping may trigger unintended consequences that would harm both adults and adolescents by obstructing migration from smoking to vaping. Policymakers should consider these issues when responding to increases in youth vaping prevalence.

About the author

Clive D. Bates is Director of Counterfactual, a consulting and advocacy practice focussed on a pragmatic approach to sustainability and public health. He has had a diverse career in the public, private and not-for-profit sectors. He started out with the IT company, IBM, then switched career to work in the environment movement. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. In 2003 he joined Prime Minister Blair's Strategy Unit as a senior civil servant and worked in senior roles in government and regulators, and for the United Nations in Sudan.

Clive Bates does not have conflicts of interest with respect to tobacco, e-cigarette or pharmaceutical industries and confirms no issues arise with respect to Article 5.3 of the WHO FCTC.