

# B.C.'s Good Intentions

Physicians for a Smoke-Free Canada supports British Columbia's proposals to regulate nicotine.<sup>1</sup>

## The proposed regulatory actions.

In November 2019, the B.C. government proposed a new suite of actions in response to rapid increases in youth vaping. These wide-ranging actions mirror the comprehensive approach developed for tobacco control, providing a system of protections for children covering access, affordability, addictiveness, education, packaging, consumer protection, engagement, social normalization and enforcement.

The measure include:

1. *Regulate nicotine content in vapour products.*
2. *Restrict the sale of flavoured vapour products.*
3. *Implement new labelling requirements to include plain packaging and health warnings.*
4. *Strengthen restrictions on public advertising.*
5. *Enhance compliance and enforcement of provincial laws and regulations controlling vapour products.*
6. *Increase the provincial sales tax on vapour products and accessories.*
7. *Create a provincial youth advisory committee to support and advise on youth vaping, education, social awareness and other initiatives.*
8. *Distribute the B.C. Lung Association Vaping Prevention Toolkit to all schools for students, parents and educators.*
9. *Launch a 'stop vaping' youth social awareness and marketing campaign.*
10. *Enhanced QuitNow resources for youth wanting to quit vaping.*

The commentary below follows the structure of the Intentions Paper issued by the B.C. Ministry of Health in December 2019.<sup>2</sup>

## 1. Prescribing nicotine as a 'health hazard'.

The best-known harm of nicotine is its power to addict users to regular use of cigarettes, oral tobacco, e-cigarettes or other contaminant-containing drug delivery systems. In addition to this major health risk, nicotine harms human health in other well documented ways.<sup>3</sup>

### RECOMMENDATION.

- a) **B.C. should prescribe nicotine as a 'health hazard'. The use of the "Health Act" to prescribe nicotine is both justified and necessary.**

## 2. Restricting Nicotine Concentration in Vaping Products

The restrictions proposed in the Intentions paper (maximum strength of 20 mg/ml, maximum pod size of 2 ml and maximum container size of 10 ml) are essentially aligned with those currently in place in the European Union as a result of its 2014 revision of the Tobacco Products Directive.<sup>4</sup> While the connection between nicotine concentration and youth uptake of e-cigarettes is still under review, it is important to note that concerns about youth vaping in the European Union are much less pronounced than they are in North America where nicotine levels are much higher.

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1 Government of British Columbia. Vapour Products Intention Paper. <https://www2.gov.bc.ca/assets/gov/health/vaping/vapour-products-intentions-paper.pdf>

2 Government of British Columbia. Vapour Products Intention Paper. <https://www2.gov.bc.ca/assets/gov/health/vaping/vapour-products-intentions-paper.pdf>

3 U.S. National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. 2014. Chapter 5. Nicotine. <https://www.ncbi.nlm.nih.gov/books/NBK294308/>

4 European Commission. Revision of the Tobacco Products Directive. 2014. [https://ec.europa.eu/health/tobacco/products/revision\\_en](https://ec.europa.eu/health/tobacco/products/revision_en)

On December 25, 2019, Health Canada set a maximum nicotine concentration level of 66 mg/ml.<sup>5</sup> The Regulatory Impact Assessment Statement issued with this decision a) noted the objection of the health community, b) indicated that the department would continue to “monitor” evidence of the need for a lower level and c) explained that the rationale for this high level was based only on ingestion toxicity concerns.

*Most public health organizations, healthcare professionals, academics and researchers, NGOs and some respondents from the general public requested that the maximum nicotine concentration for vaping products be lowered from 66 mg/mL because of risks associated with nicotine beyond acute poisoning. Many respondents requested a limit of 20 mg/mL to align with limits set in several other jurisdictions (including the European Union, Israel, Iceland and South Korea) and indicated that this would reduce the risk of youth and non-smokers becoming addicted to nicotine. Some respondents also indicated this would mitigate specific risks to adolescents related to nicotine exposure and developing brains. One NGO also indicated that a limit of 20 mg/mL in vaping products would mitigate negative cardiovascular and respiratory impacts on youth and adults. Some public health organizations indicated that the 20 mg/mL maximum nicotine concentration would further protect against ingestion poisoning incidents and fatalities, poisoning from regular use, accidental overconsumption and self-harm*

*Health Canada will continue to monitor emerging evidence around vaping and may consider additional actions to limit nicotine concentration in vaping products in the future for reasons other than their ingestion toxicity*

*The maximal concentration limit for nicotine of 66 mg/mL is based on a peer-reviewed toxicity evaluation of the ingestion of pure nicotine. The limit is consistent with how a very toxic consumer chemical is identified in the CCCR, 2001.*

Health Canada officials have acknowledged that they are currently developing advice on reducing maximum nicotine concentration levels. The federal regulatory system typically takes a minimum of 24 months to implement regulations after a policy decision has been reached. (Plain packaging of cigarettes, for example, was included in the 2015 mandate letter of the Minister of Health, but will only be fully implemented in February 2020). For this reason, in September 2019 health organizations called on the federal government to use its power under the *Health Act* and issue an Interim Order to set maximum nicotine concentration levels while permanent regulations are being developed.<sup>6</sup>

#### RECOMMENDATIONS.

- b) While encouraging the federal government to put immediate restrictions on nicotine levels, B.C. should simultaneously implement provincial restrictions and align maximum concentrations and quantities for nicotine and vaping liquids with the European standards.**
- c) B.C. should encourage the federal government to prohibit the use of additives which enhance nicotine uptake or which facilitate inhalation of nicotine.**

### **3. Restrict the Sale and Distribution of E-substances and Nicotine Containing Products**

The Intentions Paper notes that the province wishes to a) establish classes of vaping retailers, b) require retailers to notify the Ministry if they sell vaping products and c) meet their obligations as “operators” under the *Public Health Act*.

These actions will help address the regulatory void in which vaping products are currently sold and are a good interim measure until better retail licensing and vaping distribution systems are developed.

#### RECOMMENDATIONS.

- d) B.C. should move quickly to implement the proposed restrictions on the sale and distribution of e-liquids and devices.**
- e) B.C. should review the current retail environment for tobacco and nicotine products with the aim of establishing a retail and distribution system that is more appropriate to the risks of these products. The recent experience with cannabis retailing in Canada, the historic experience with alcohol and the experience of other countries in developing controls on the wholesale and retail distribution of harmful products can inform this review.**

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<sup>5</sup> Canada Gazette. Vol. 53, no. 26. Vaping Products Labelling and Packaging Regulations. SOR/2019-353

<sup>6</sup> Action on Smoking and Health, Canadian Cancer Society, Canadian Medical Association, Canadian Lung Association, Coalition québécoise pour le contrôle du tabac, Heart & Stroke, Ontario Campaign for Action on Tobacco and Physicians for a Smoke-Free Canada. Press release. Protection delayed is protection denied: Health groups call for immediate federal action to protect young people from the risks of vaping products. September 19, 2019.

#### 4. Restrict the Sale of Flavoured Vapour Products

The approach towards flavours in vaping products proposed by British Columbia is to limit their sale to retailers where age-verification is required.

This is a sensible approach, but is not the only option being forwarded in Canada and in other countries. Legislated bans on vaping flavours have been adopted in a number of U.S. jurisdictions,<sup>7</sup> Nova Scotia has announced its intention to ban vaping flavours other than tobacco flavours,<sup>8</sup> Prince Edward Island legislated authority to regulate flavours<sup>9</sup> and the Quebec government has requested advice on how to manage flavours.<sup>10</sup> Canadian health charities have called for restrictions on the manufacture and sale of flavours in vaping products.<sup>11</sup>

It should be noted that restricting sales to age-gated stores will not prevent youth from accessing these products. Retailers do not have a good track record with respect to compliance with health laws: many of them sold vaping products before such sales were made legal in 2018 and even in 2019, 80% were found to be non-compliant with federal regulations.<sup>12</sup> Health Canada surveys found more than one-third of underage vapers reported that they usually bought their devices and liquids from vape shop, and only 58% are regularly asked to provide proof of age when buying vaping products.<sup>13</sup>

There is substantial evidence linking flavourings to youth uptake of vaping.<sup>14</sup> The conclusions of a systematic review conducted by the Nordic Welfare Council last year validate more aggressive controls than B.C. is proposing:

*Flavour additives are a leading cause of young people trying tobacco products or e-cigarettes.*

*New users have a preference for the particularly sweet flavours, such as those of sweets, fruit, chewing gum, soft drinks, etc.*

*Young people also have a perception that e-cigarettes with the flavour of fruit, for example, are less harmful to health than e-cigarettes with the flavour of tobacco.*

*If the product also contains nicotine, this may lead to dependence and potentially interest in trying other, more harmful tobacco products.*

*Restrictions and regulations on flavour additives in e-cigarettes and e-liquids will therefore most likely have an impact on the use of these products by young people.*

#### RECOMMENDATIONS.

- f) **B.C. should prohibit the sale of flavoured vaping products in stores which are not age-restricted.**
- g) **B.C. should strongly encourage the federal government to implement Canada-wide flavour restrictions.**

#### 5. New Labelling, Packaging and Health Warning Requirements

B.C. proposes to require that a) vaping products be labelled in ways that caution that nicotine is addictive, b) which provide information on the concentration of nicotine, c) which display a hazard symbol and text, d) that list the ingredients and e) which are in plain packaging.

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7 Tobacco Free Kids. States and Localities that have restricted the sale of flavored tobacco products. January 2020. <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>

8 Nova Scotia. Province Bans Sales of Flavoured E-Cigarettes, Commits to Legislation. December 5, 2019 - 9:45 AM. <https://novascotia.ca/news/release/?id=20191205001>

9 Prince Edward Island. Bill 21 . An Act to Amend the Tobacco and Electronic Smoking Device Sales and Access Act <https://docs.assembly.pe.ca/download/dms?objectId=e2b3ef82-ac40-48dc-b77e-4276c9cb8c64&fileName=bill-112.pdf>

10 <https://www.cbc.ca/news/canada/montreal/vaping-special-task-force-1.5372147>

11 Action on Smoking and Health, Canadian Cancer Society, Canadian Medical Association, Canadian Lung Association, Coalition québécoise pour le contrôle du tabac, Heart & Stroke, Ontario Campaign for Action on Tobacco and Physicians for a Smoke-Free Canada. Press release. Protection delayed is protection denied: Health groups call for immediate federal action to protect young people from the risks of vaping products. September 19, 2019.

12 Health Canada. Press Release. Health Canada proposes to ban advertising of vaping products wherever they can be seen or heard by youth. December 19, 2019. "More than eighty percent of the specialty vape shops inspected were found to be selling and promoting products in violation of the law."

13 EnviroNics Research. Vapers Panel Survey to Measure Attitudes and Behaviours Regarding Vaping Products. POR 083-18 <http://epe.lac-bac.gc.ca/100/200/301/pwgs-c-tpsgc/por-ef/health/2019/083-18-e/report.pdf>

14 A summary is available at: Physicians for a Smoke-Free Canada. What research tells us about young people and e-cigarette flavours. December 2019. <https://smoke-free-canada.blogspot.com/2019/12/what-research-says-about-young-people.html>

Although the federal government, subsequent to the publication of the intentions paper, has largely implemented the first three of these requirements, the adopted measures are not sufficient to provide British Columbians or other Canadians with the information they deserve to know before using these products. Federal measures for the last two (ingredients and plain packaging) are missing or inadequate.

- The addiction warning proposed by B.C. and now required by Health Canada is inadequate. The risks of using vaping products go beyond addiction. Appendix A provides a list of other health harms, and proposes additional health warning labels that should be required on products sold in B.C.
- British Columbians (and other Canadians) should be better informed and therefore there should be a requirement that ingredients be listed with greater detail than will be provided by Health Canada's regulation. Health Canada backed down from proposals to require information on additives in vaping products, electing instead to adopt the industry position that the general term "flavours" could be used to describe all flavouring agents.<sup>15</sup> Under Health Canada regulations, for example, there is no requirement for manufacturers to indicate whether the product contains diacetyl, even though this is associated with lung damage.<sup>16</sup>
- Plain packaging is now required for tobacco products in a number of countries (including Canada). Israel is the only country to date to require plain packaging of e-cigarettes.

#### RECOMMENDATIONS.

- h) **B.C. should ensure its citizens are adequately informed of the health risks associated with vaping, and these warnings should meet the standards for duty to warn that were set by the Quebec Courts.<sup>17</sup> In the absence of federal leadership, B.C. should independently (or in collaboration with other provinces) develop mandatory, rotating, graphic health warning messages for vaping product packaging.**
- i) **B.C. should require full ingredient disclosure on all products inhaled or ingested into the human body.**
- j) **B.C. should require plain packaging of all vaping products and liquids.**

## 6. Strengthen Restrictions on Public Advertising

B.C. proposes to extend its restrictions on advertising to protect children from being exposed to pro-vaping messaging in public places.

Subsequent to the release of the Intentions Paper, Health Canada has proposed to achieve largely the same objective through federal regulation.<sup>18</sup> Their proposal, however, will not address the vulnerability of non-smoking young adults to vaping promotion. For example, it will allow promotional videos to be shown in bars, festivals, vape shops and other areas where children are not permitted. It should be noted that older children frequently gain access to these locations.

#### RECOMMENDATIONS.

- k) **B.C. should be prepared to implement advertising restrictions if Health Canada's proposals are weakened or delayed.**
- l) **B.C. should implement additional provincial restrictions on advertising for vaping products in adult-only venues, such as limiting them to signs only.**

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15 Canada Gazette. Vol. 53, no. 26. Vaping Products Labelling and Packaging Regulations. SOR/2019-353. RIAS, page 6539

16 Landman, ST. et al. Life-threatening bronchiolitis related to electronic cigarette use in a Canadian youth. CMAJ. December 2019.

17 Létourneau c. JTI-MacDonald Corp., 2015 QCCS 2382. Para 227.

18 Canada Gazette, Part I. Vol. 153, No. 51. Vaping Products Promotion Regulations. <http://www.gazette.gc.ca/rp-pr/p1/2019/2019-12-21/html/reg1-eng.html>

## Recommendations for complementary reforms

In the proposals included in the Intention Paper and the measures announced in November, the B.C. government has provided a comprehensive set of public health responses to the vaping crisis. Sadly, even these are likely to be insufficient to restore progress against vaping and tobacco use or address the likely consequences of the upsurge in youth vaping.

B.C. and its municipalities have historically adopted tobacco control measures ahead of other provinces, such as its 1970 ban on tobacco advertising, the first 100% smoke-free bylaws and the most comprehensive support for population-wide access to stop smoking medication. In recent years, B.C. has stepped back from this leadership role.

Data from the most recent Canadian Student Tobacco Alcohol and Drug survey show that B.C. no longer has the lowest prevalence of youth smoking (Quebec, Manitoba and Alberta have caught up and Ontario appears to be in the lead), and it has one of the higher rates of vaping prevalence. These results are shown below.

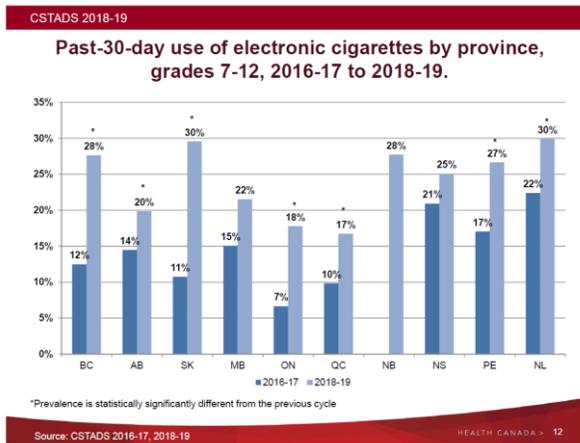
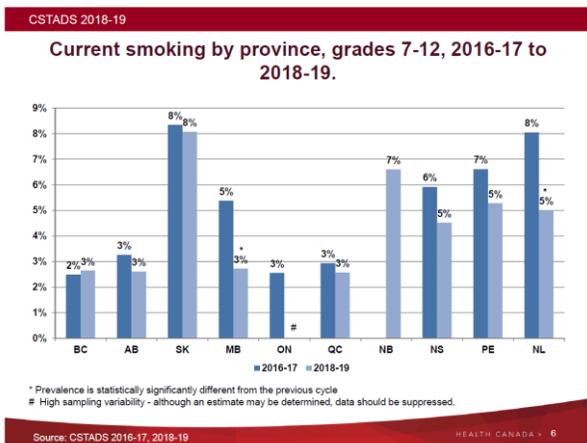
Additional measures to discourage tobacco use and e-cigarette use are available which would reinforce and complement those that B.C. has announced.

### RECOMMENDATIONS.

#### m) B.C. should adopt the best practices in place in other Canadian provinces, such as:

- bans on sale of tobacco products in pharmacies
- a province-wide ban on smoking on patios, parks and beaches
- increasing the legal age to be sold tobacco or vaping products to 21 years
- ensuring protection from second-hand smoke in multi-unit dwellings
- increasing provincial investments in tobacco control and support for local capacity
- engaging in effective mass media.
- Imposing a tax on vaping products and liquids equivalent to 75% of provincial taxes on cigarettes.

#### n) B.C. should schedule regular evaluations and reviews of vaping-control and tobacco-control policies in order to facilitate updating its tobacco control strategies and measures as needed. Evaluation should be made on the achievement of specific, measurable goals. For example, the goal for reducing youth vaping for the next cohort of middle and high school students should be set at 3% or less, and smoking at half that (1.5%).



# Appendix A

## Health warning messages for vaping product packages

A number of health and legal authorities have taken actions which support the adoption of mandatory vaping product package warnings and which also support more expansive warnings than those currently proposed.

Canadian courts have established criteria for a manufacturers' duty to warn. As these requirements relate to a consumer information needs, they are criteria which can also be applied to the design of warnings for vaping products. For example, The Quebec Superior Court ruled in 2015 that:<sup>19</sup>

*The duty to warn "serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product";*

*Manufacturers of products to be ingested or consumed in the human body have a higher duty to inform;*

*Where the ordinary use of a product brings a risk of danger, a general warning is not sufficient; the warning must be sufficiently detailed to give the consumer a full indication of each of the specific dangers arising from the use of the product;*

*The manufacturer's knowledge that its product has caused bodily damage in other cases triggers the principle of **precaution whereby it should warn of that possibility**;*

*The obligation to inform includes the duty to provide instructions as to how to use the product so as to avoid or minimize risk.*

In April 2019, the Canadian Council of Chief Medical Officers of Health, expressed concerns that vaping may "lead to a resurgence in smoking or create new public health problems."<sup>20</sup> Some U.S. state public health authorities have recently issued public warnings about potential risks of lung disease from vaping.<sup>21</sup>

More than one-third of European Union countries have opted to require a package warning label which cautions that non-smokers should not use vaping products, in addition to the warning that the products contain nicotine and are highly addictive.<sup>22</sup> Iceland and Israel have recently required health warning labels and have both elected to identify health risks beyond addiction.<sup>23 24</sup>

<sup>25</sup>A list of EU member states which have opted to caution non-smokers against using vaping products is shown in Figure 1.

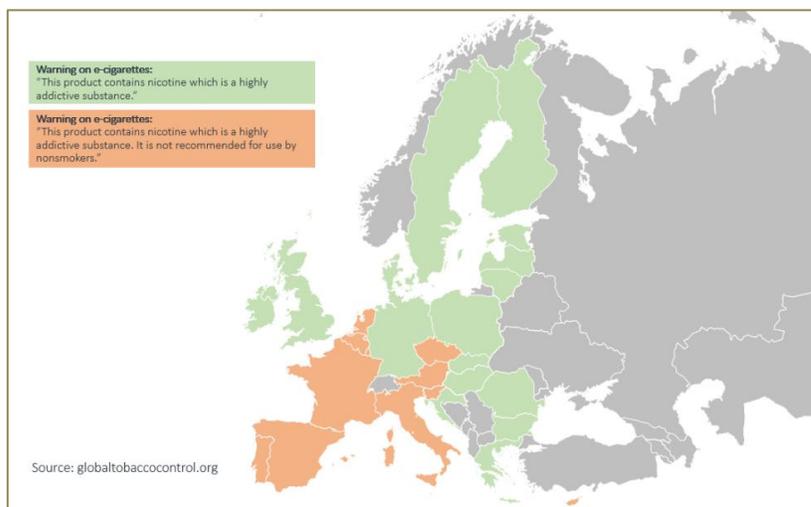


Figure 1 E-cigarette warnings required by EU member states

19 Létourneau c. JTI-MacDonald Corp., 2015 QCCS 2382. Para 227.

20 Statement from the Council of Chief Medical Officers of Health on the increasing rates of youth vaping in Canada. April 11, 2019. <https://www.canada.ca/en/public-health/news/2019/03/statement-from-the-council-of-chief-medical-officers-of-health-on-the-increasing-rates-of-youth-vaping-in-canada.html>

21 Hasan, I. Lung disease in teens could be linked to vaping, Minnesota Health Department says. Newsweek. August 14, 2019.

22 Directive 2014/40/EU of the European Parliament and of the Council.

23 Iceland Ministry of Welfare. Act on electronic cigarettes and refill containers for electronic cigarettes, No. 87/2018.

24 Reglugerð um merkingar á umbúðum rafrettna og áfyllinga og efni upplýsingabæklings sem fylgja skal rafrettnum og áfyllingum. <https://www.reglugerd.is/reglugerdir/eftir-raduneytum/hrn/nr/0255-2019>

25 Government of Israel. Restriction of advertising and marketing of tobacco products law, 2019. (Translation). <https://www.tobaccocontrol.org/files/live/Israel/Israel%20-%20Amdt.%207%20to%20Marketing%20Law.pdf>

# The health risks of e-cigarette use for which warning labels are justified.

## Heart disease and stroke

Although the 2018 review by the National Academies of Science, Engineering and Medicine found there was “no evidence” available to assess the impact of electronic cigarette smoking on increased cardiac risks,<sup>26</sup> subsequent studies have provided evidence to support conclusions that these products increase the risks of heart disease and stroke.

E-cigarette vapour produces ultrafine particles, as small or smaller than those produced by conventional cigarettes.<sup>27</sup> These ultrafine particles carry nicotine deep into the lungs, triggering inflammatory processes that lead to cardiovascular disease. E-cigarettes damage the vascular endothelium, thereby inhibiting the ability of arteries to dilate in response to increased blood flow.<sup>28 29</sup> E-cigarette aerosol induces adverse changes to blood platelets, including activation, aggregation and adhesion.<sup>30 31</sup> These and other adverse biological changes lead to an increased risk of heart disease and stroke from e-cigarettes.<sup>32 33 34 35 36</sup> Dual use of both e-cigarettes and conventional cigarettes is the most common form of e-cigarette consumption. Dual use increases the risk of heart disease compared to exclusive use of one product or the other.

To fulfil their duty to warn, vaping products manufacturers should be warning that use of vaping products increases the risk of heart disease and stroke.

## Lung diseases

E-cigarette vapour damages the epithelial cells that line airways, thereby interfering with their normal healthy functioning.<sup>37</sup><sup>38 39 40</sup> E-cigarette vapour also causes a number of other physiological changes that compromise the normal, healthy functioning of airways and lungs.<sup>41.42 43</sup> Consistent with these observations of biological changes as a result of exposure to e-cigarette aerosol, e-cigarette use also increases the risk of chronic obstructive pulmonary disease and other respiratory

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- 26 National Academies of Sciences, Engineering and Medicine. Public Health Consequences of e-Cigarettes. Washington, DC: The National Academies Press; 2018.
  - 27 Fuoco F, Buonanno G, Stabile L, Vigo P. Influential parameters on particle concentration and size distribution in the mainstream of e-cigarettes. *Environ. Pollut.* 2014; 184: p. 523-529.
  - 28 Lee W, Zhou Y, Ong S, Tian L, Baker N, Bae H, et al. Assessing cardiovascular risks associated with e-cigarettes with human induced pluripotent stem cell-derived endothelial cells. In Society for Research on Nicotine and Tobacco 25th Anniversary Abstracts Abstract # PA15-4; 2019; San Francisco.
  - 29 Mohammadi L, Derakhshandeh R, Han D, Huang A, Whitlatch A, Schick S. Relative endothelial toxicity of tobacco smoke and e-cigarette aerosol: a functional and mechanistical assessment. In Society for Research on Nicotine and Tobacco 25th Anniversary Abstracts Abstract # PA15-24; 2019; San Francisco.
  - 30 Glantz S, Bareham D. E-cigarettes: use, effects on smoking, risks, and policy implications. *Annu Rev Public Health.* 2018; 39: p. 215-235
  - 31 Karim Z, Hernandez K, Rivera J, Khasawneh F, Alshbool F. In utero exposure to e-cigarettes modulates platelet function and increases the risk of thrombogenesis, in mice. In Society for Research on Nicotine and Tobacco 25th Anniversary Abstracts Abstract # PA15-1; 2019; San Francisco.
  - 32 Alzahrani T, Pena I, Temesgen N, Glantz S. Association between electronic cigarette use and myocardial infarction. *American Journal of Preventive Medicine.* 2018 October; 55(4): p. 455-461.
  - 33 Ndunda P, Muutu T. Electronic cigarette use is associated with a higher risk of stroke. *International Stroke Conference 2019 Oral Abstracts.* Abstract 9. *Stroke.* 2019; 50(Supplement 1.9).
  - 34 Bhatta D, Glantz S. Electronic cigarette use an myocardial infarction among adults in the United States Populatiion Assessment of Tobacco and Health. In Society for Research on Nicotine and Tobacco. Annual Meeting. Abstract No. POS4-99; 2019; San Francisco.
  - 35 Middlekauff H. Cardiovascular impact of electronic cigarette use. *Trends in Cardiovascular Medicine.* <https://doi.org/10.1016/j.tcm.2019.04.006>. 2019.
  - 36 Osei AD, et al. Association Between E-Cigarette Use and Cardiovascular Disease Among Never and Current Combustible-Cigarette Smokers. *Am J Med.* 2019.
  - 37 Chun L, Moazad F, Calfee C, Matthay M, Gotts J. Pulmonary toxicity of e-cigarettes. *American Journal of Physiology: Lung Cell Molecular Physiology.* 2017 May; 313: p. L193-L206.
  - 38 Ghosh A, Coakley R, Mascenik T, Rowell T, Davis E, Rogers K. Chronic e-cigarette exposure alters the human bronchial epithelial proteome. *AJRCCM* <https://11.1164/rccm.201710-2033OC>. 2018 February.
  - 39 Jabba S, Caceres A, Erythropel H, Zimmerman J, Jordt S. Flavor solvent adducts in electronic cigarette liquids are modulators of respiratory irritant receptors and cytotoxic to human lung epithelial cells. In Society for Research on Nicotine and Tobacco 25th Anniversary Abstracts Abstract # PA45-2; 2019; San Francisco.
  - 40 Ghosh A, Coakley R, Davis E, Ghio A, Muhlebach M, Esther C. E-cigarette use causes enhanced lung protease levels. In Society for Research on Nicotine and Tobacco 25th Anniversary Abstracts Abstract # PA4-1; 2019; San Francisco.
  - 41 Glantz S, et al, op cit.
  - 42 Bhatta D, et al., op cit.
  - 43 Jabba, S et al., op cit.

diseases.<sup>44 45 46</sup> Like the risk of heart disease, dual use of e-cigarettes and combustible cigarettes further increases the risk of lung disease compared to exclusive use of one product or the other. Decades of observation of the dangers of cigarette use has shown that cardiovascular diseases, related metabolic diseases and lung diseases account for two-thirds of deaths caused by smoking.<sup>47</sup> The weight of available evidence indicates that, compared to combustible cigarette use, using e-cigarettes does not reduce the risk of cardiovascular diseases or lung diseases. Most e-cigarette users are dual users and for these people use of e-cigarettes increases the risk of cardiovascular and lung diseases.

Warnings on vaping products manufacturers should therefore address the increased risk of chronic obstructive pulmonary disease and other respiratory diseases. They should also be warning against dual use of e-cigarettes and combustible cigarettes.

### **Cancer**

Although e-cigarettes eliminate some carcinogens and greatly reduce the levels of others, there are still carcinogens in e-cigarette aerosol that damage DNA.<sup>48</sup> It has also been observed that e-cigarettes deregulate genes associated with cancer.<sup>49</sup> E-cigarettes deliver large amounts of nicotine. While not a carcinogen itself, nicotine speeds growth of cancerous tumours.<sup>50</sup>

While there are as yet no studies demonstrating increased risk of cancer in e-cigarette users, the biological evidence suggests very strongly that such evidence will appear when more people engage in prolonged use of e-cigarettes over many years. Because dual users can also be expected to be at greater risk and because e-cigarettes can suppress population-level cessation, the use of e-cigarettes may also increase or maintain cancer caused by cigarettes.

E-cigarettes marketed in Canada have been shown to produce carcinogenic emissions, including benzene.<sup>51</sup>

### **The impact of vaping on smoking cessation**

A recent randomized control trial (RCT) of e-cigarettes as a quitting device found in a highly controlled research setting that 18% of e-cigarette users had successfully quit smoking after one year.<sup>52</sup> In real-world settings, however, the results are quite different. A meta-analysis of 37 real-world studies showed that, overall, users of e-cigarettes were less likely to quit smoking.<sup>53</sup> Some individuals using approved smoking cessation drugs do find them helpful, and some e-cigarette users have also found these devices helpful in quitting smoking. At a population level, however, the results are different. While neither approved therapeutic drugs for smoking cessation nor e-cigarettes are particularly effective in the real world for increasing rates of smoking cessation, at least the therapeutically-approved treatments do no harm. However, in the recent RCT of e-cigarettes, 80% were still using e-cigarettes with addictive levels of nicotine after one year.<sup>54</sup>

Warnings on vaping products should include the warning that, for most people, use of vaping products decreases the likelihood of successful smoking cessation and carries substantial risk for prolonged addiction to nicotine.

### **Risks particular to young people.**

Youth are being drawn to e-cigarettes in unacceptably large numbers. Dozens of studies have shown that youth who begin their careers of nicotine addiction on e-cigarette are more likely to go on to become cigarette smokers. One recent well-done

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- 44 Perez M, Atuegwu E, Oncken C, Mortensen E. E-cigarette use is associated with emphysema, chronic bronchitis and COPD. In American Thoracic Society Interantional Conference Abstract #A6245/402; 2018; San Diego.
  - 45 Wills T, Pagano I, Williams R, Tam E. E-cigarette use and respiratory disorder in an adult sample. *Drug and Alcohol Dependence*. 2019; 194: p. 363-370.
  - 46 Bhatta D, Glantz S. Electronic cigarette use is associated with respiratory disease among adults in the United States Population Assessment of Tobacco and Health: a longitudinal analysis. In Society for Research on Nicotine and Tobacco 25th Anniversary Abstracts Abstract # POS2-146; 2019; San Francisco.
  - 47 US Department of Health and Human Services. The Health Consequences of Smoking - 50 years of progress. A report of Surgeon General Rockville: US DHHS, Public Health Service, Office of the Surgeon General; 2014.
  - 48 Lee HW, Park SH, Weng MW, Wang HT, Huang WC, Lepor XR, et al. E-cigarette smoke damages DNA and reduces repair activity in mouse lung, heart, and bladder as well as in human lung and bladder cells. *PNAS*. [www.pnas.org/cgi/doi/10.1073/pnas.1718185115](http://www.pnas.org/cgi/doi/10.1073/pnas.1718185115). 2018 January 29.
  - 49 Tommasi S, Caliri A, Caceres A, Moreno D, Meng L, Chen Y. Deregulation of biologically significant genes and associated molecular pathways in the oral epithelium of electronic cigarette users. *International Journal of Molecular Sciences* doi:10.3390/ijms20030738. 2019 February; 20: p. 738.
  - 50 Heeschen C, Jang J, Weis M, Pathak A, Kaji S. Nicotine stimulates angiogenesis and promotes tumor growth and atherosclerosis. *Nat. Med.* 2001; 7: p. 833-839.
  - 51 Pankow, JF. Benzene formation in electronic cigarettes. *PlosOne* 2017.
  - 52 Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N. A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New England Journal of Medicine* doi: 10.1056/NEJMoa1808779. 2019 Jan 30.
  - 53 Weaver, SR. et al. Are electronic nicotine delivery systems helping cigarette smokers quit? Evidence from a prospective cohort study of U.S. adult smokers, 2015–2016. *PLOS One*. July 2018.
  - 54 Hajek, P. op cit.

study found youth who started on e-cigarettes were four times more likely to go on to become cigarette smokers.<sup>55</sup> American researchers have recently concluded that e-cigarettes increase the amount and frequency with which these nicotine users smoke cigarettes. “Use of e-cigarettes by US young adults, most of which is not intended to help reduce smoking, is related to more rather than less frequent and intensive cigarette smoking.”<sup>56</sup>

Youth who vape misperceive the powerfully addictive nature of nicotine and are unaware of the increased risk they face for a lifetime of nicotine addiction and cigarette use.<sup>57 58 59</sup> Unfortunately, the style of warning proposed for Canada has been found to be not very effective in persuading people of these risks, especially when compared with graphic health warnings that provide information on other health risks.<sup>60 61 62 63</sup>

### **U.S. Health Authority conclusions about health risk to young persons**

In 2016, the U.S. Surgeon General produced a report on e-cigarette use among youth and young adults,<sup>64</sup> concluding that:

*The use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.*

*E-cigarette aerosol is not harmless. It can contain harmful and potentially harmful constituents, including nicotine. Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain.*

U.S. health authorities continue to warn<sup>65</sup> that

*Nicotine can harm the developing adolescent brain. The brain keeps developing until about age 25.*

*Using nicotine in adolescence can harm the parts of the brain that control attention, learning, mood, and impulse control.*

*Each time a new memory is created or a new skill is learned, stronger connections – or synapses – are built between brain cells. Young people’s brains build synapses faster than adult brains. Nicotine changes the way these synapses are formed.*

*Using nicotine in adolescence may also increase risk for future addiction to other drugs.*

*Young people who use e-cigarettes may be more likely to smoke cigarettes in the future.*

Following the report of the first death related to the outbreak of severe lung disease in those who use e-cigarette devices, the U.S. CDC repeated its caution that “E-cigarettes are not safe for youth, young adults, pregnant women, or adults who do not currently use tobacco products.”<sup>66</sup>

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- 55 Berry K, Fetterman J, Benjamin E, et al. Association of electronic cigarette use with subsequent initiation of tobacco cigarettes in US youths. JAMA Network Open doi:10.1001/jamanetworkopen.2018.7794. 2019; 2(2): p. e187794.
- 56 Olsson M, Wall M, Lio SM, Sultan R, Blanco C. E-cigarette use among young adults in the US. American Journal of Preventive Medicine. 2019 May; 56(5): p. 655-663.
- 57 Roditis M, Halpern-Felsher B. Adolescents’ perceptions of risks and benefits of conventional cigarettes, e-cigarettes, and marijuana: a qualitative analysis. Journal of Adolescent Health doi:10.1016/j.jadohealth.2015.04.002. 2015 August; 57(2): p. 179-185.
- 58 McKelvey K, Halpern-Felsher B. Adolescent cigarette-smoking perceptions and behavior: Tobacco control gains and gaps amidst the rapidly expanding tobacco products market from 2001 to 2015. Journal of Adolescent Health doi: 10.1016/j.jadohealth.2016.09.025. 2017 February; 60(2): p. 226-228.
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- 60 Brewer, NT et al. Impact of e-cigarette health warnings on motivation to vape and smoke. Tobacco Control. July 2019.
- 61 Sontag, J et al. US young adults’ perceived effectiveness of draft pictorial e-cigarette warning labels. Tob Control. 2019 Jun 5.
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- 63 Wackowski, OA, et al. Considerations and Future Research Directions for E-Cigarette Warnings-Findings from Expert Interviews. Int J Environ Res Public Health. 2017.
- 64 U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General
- 65 U.S. Centers for Disease Control. Quick Facts on the Risks of E-cigarettes for Kids, Teens and Young Adults. Web-page. [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html)
- 66 U.S. Centers for Disease Control. CDC Director’s Statement on the first death related to the outbreak of severe lung disease in people who use e-cigarette or “vaping” devices. Media Statement. August 23, 2019 <https://www.cdc.gov/media/releases/2019/s0823-vaping-related-death.html>

## **Risks particular to pregnancy**

There is no evidence that e-cigarettes pose no risk to pregnancy outcomes. In its 2018 report, the National Academy of Science in Medicine concluded that there was insufficient evidence to conclude whether or not material cigarette use affects fetal development. It did not conclude that there was sufficient evidence that nicotine or vaping did not adversely affect pregnancy outcomes.<sup>67</sup>

E-cigarettes are not recommended cessation devices for pregnant women, and should not be assessed as such. Important to this discussion is the risk that the regulation conflates the science and clinical opinions with respect to NRT (which is rarely used by non-smokers) and vaping (in which a significant portion are never smokers).<sup>68</sup> While some experts and authorities have recommend NRT as a cessation tool for pregnant smokers, if counselled by a physician, the same is not true with respect to ENDS.

To the contrary. Vaping products are generally recommended against as cessation methods during pregnancy. Earlier this year, the American College of Protective Medicine issued a practice statement in which it advised that “Clinicians should screen pregnant women for the use of ENDS as part of tobacco screening. Those who smoke or vape should be advised to quit all nicotine products and provided with evidence-based tobacco cessation interventions including behavioral interventions and financial incentives,” and “Clinicians should advise pregnant women who smoke cigarettes to use evidence-based treatments (e.g., behavioral counseling and financial incentives) rather than recommending ENDS.”<sup>69</sup>

Major health authorities and scientists recommend that pregnant women be advised to not use e-cigarettes. The U.S. Office on Smoking and Health accepts that “prenatal nicotine exposure contributes substantially to adverse health outcomes in infants,” and cautions that “tolerating acceptance of electronic cigarette use among pregnant smokers as part of a broader public health strategy to reduce smoking puts this population at great risk.”<sup>70</sup> There are several recent published scientific research papers which caution against the use of electronic cigarettes by pregnant women.<sup>71 72 73 74 75 76 77</sup>

Women have a right to be informed of the risks of using e-cigarettes when pregnant. Their children deserve protection. Human rights advocates have expressed concern with the use of e-cigarettes (and their attendant risks) by pregnant women. In light of human rights guaranteed under international treaties, including the Universal Declaration of Human Rights, the Convention on the Elimination of All Forms of Discrimination Against Women and the Convention on the Rights of the Child, they argue that “there is an ethical and legal obligation to communicate these potential risks clearly to healthcare providers and pregnant women who might use e-cigarettes as an alternative to smoking, and to support pregnant women in stopping smoking with safe, evidence-based treatment.”<sup>78</sup>

### **1. Recommendations for package warnings for vaping products.**

As with cigarettes, vaping products are associated with a range of health risks. As with cigarettes, these risks are too numerous to be identified in a single package warning. As with cigarettes, vaping products are purchased on a frequent basis. As with cigarettes, graphic health warnings have been shown to be more effective. As with cigarettes, a system of rotating messages is warranted for vaping products.

#### **Health risks for which vaping product package warnings should be developed.**

Regulations should require that packaging includes warnings of the following risks:

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- 67 National Academy of Sciences, Engineering and Medicine. Public Health Consequences of E-cigarettes.
  - 68 Health Canada Public Opinion Research Vapers Panel Survey to Measure Attitudes and Behaviours Regarding Vaping Products POR 083-18 found 29% of vapers aged 20-24 had never smoked and 13% of those aged 25-34 had never smoked. Overall 17% of women who vaped had never smoked cigarettes.
  - 69 Livingston, CJ et al. Electronic Nicotine Delivery Systems or E-cigarettes: American College of Preventive Medicine's Practice Statement. American Journal of Preventive Medicine. January 2019.
  - 70 England, LJ. Nicotine and the Developing Human: A Neglected Element in the Electronic Cigarette Debate. Am J Prev Med. 2015
  - 71 Breland, A et al. Electronic nicotine delivery systems and pregnancy: Recent research on perceptions, cessation, and toxicant delivery. Birth Defects Res A Clin Mot Teratol. 2019.
  - 72 Suter, MA Is there evidence for potential harm of electronic cigarette use in pregnancy? Birth Defects Res A Clin Mot Teratol. 2015
  - 73 Beeza-Loya, S. et al. Perceptions about e-cigarette safety may lead to e-smoking during pregnancy. Bull Menninger Clin. 2015.
  - 74 McCubbin, A. et al. Perceptions and use o electronic cigarettes in pregnancy.” Health Education Research. 2017.
  - 75 Wittington, JR et al. The Use of Electronic Cigarettes in Prewgnancy: A Review of the Literature. Obstet Gynecol Surv. 2018.
  - 76 Orzabal, M et al.. Impact of Electronic Cigarette Aerosols on Pregnancy and Early Development. Curr Opin Toxicol. 2019.
  - 77 Li, Gerard et al. Heat or Burn? Impacts of Intrauterine Tobacco Smoke and E-Cigarette Vapor Exposure on the Offspring’s Health Outcome. Toxics. 2018.
  - 78 Van der Eijk, Y et al. E-cigarette use in pregnancy: a human rights-based approach to policy and practice. Acta Obstetricia et Gynecologica Scandinavica. 2018.

- Vaping products may increase the risk of cardiovascular diseases.
- Vaping products may increase the risk of lung diseases.
- Vaping products are not effective smoking cessation devices for most people.
- Dual use of vaping products and combustible cigarettes increases the risk of disease compared to exclusive use of either product.
- Use of vaping products during pregnancy may harm the fetus
- Young people who vape can harm the parts of their brain that control attention, learning, mood and impulse control.
- Nicotine can harm adolescent brain development, which continues into the early to mid-20s

**Design factors which should be included in vaping package warnings:**

Manufacturers should be required to place warnings on at least 50% of two principal display surfaces, with one side each for English and French. The warnings should be required on the top of the packages, so as to prevent obstruction of the warning when the package is displayed at retail. An illustration of the obscuring of current warning labels is shown in Figure 5.

Upper-package placement has been required for cigarette warning labels for a quarter of a century (since 1994).

Graphic health warnings for vaping product packages should be developed. The considerable knowledge and evidence about the efficacy of graphic health warning messages when compared to text only messages on cigarette packages in real world circumstances can be immediately applied to the development of vaping package warnings. There is additional experimental evidence to support graphic health warning messages for vaping products.<sup>79 80</sup> Korea requires a graphic health warning on vaping product packages, as shown in Figure 6 below.



**Figure 3. Warning obscured in stores where product display is allowed**



**Figure 2. Korean graphic health warning on vaping product packaging**

79 Brewer, NT et al. Op cit.

80 Andrews, JC et al. Op cit.