

# Response to proposed Vaping Products Labelling and Packaging Regulations.

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## Introduction

Physicians for a Smoke-Free Canada respectfully submits that the proposed regulations for vaping products labelling and packaging which were published in the Canada Gazette on June 22 are inadequate to provide Canadian consumers with the information they are entitled to receive when using these product or the protection they require from the marketing of products that carry exceptional risk.

We acknowledge that the primary responsibility for reducing the harms associated with vaping products lies with the manufacturers, and that the duties of these companies are not diminished as a result of the adoption of the federal *Tobacco and Vaping Products Act* (TVPA). Parliament has nonetheless provided the department with the authority and responsibility to develop regulations to intervene where the companies' voluntary actions are insufficient. The department's duties are framed by the purpose of the TVPA and the Minister's responsibilities under the *Department of Health Act*.

Although the proposed regulation covers a number of important aspects, our comments in this brief are focused on two:

- A. The mandatory health warnings to be carried on product packages
- B. The concentration of nicotine permitted to be sold for use in vaping devices.

## A. Comments on proposed health warning messages for vaping product packages

### Health Canada has properly identified the need for regulatory measures to protect young people, non-users and vulnerable populations.

The RIAS to the proposed regulation outlines the objectives and goals for the proposed regulatory approach. The first objectives identified is the intention of reducing nicotine use and addiction among young people. The RIAS also includes references to the health risks of vaping and the need to implement regulatory measures to reduce these risks. The following assessments and objectives identified in the RIAS can serve as the standard against which the proposed warnings can be assessed:

*The first objective of the proposal is to use the authorities set out in the TVPA to help protect young persons and non-users of tobacco from exposure to, and dependence on, nicotine and to help prevent vaping product use from leading to the use of tobacco products. ...*

*The proposed nicotine concentration statement and the health warnings are intended to enhance awareness of the health hazards posed by using vaping products and to prevent the public from being deceived or misled with respect to these health hazards.*

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<sup>1</sup> Canada Gazette, Part I, Volume 153, Number 25: Vaping Products Labelling and Packaging Regulations

*Vaping products are harmful, particularly to the health of youth and non-users of tobacco products.*

*Canada's Tobacco Strategy aims to protect the health of the people of Canada, especially young people, from the dangers of tobacco use, including by helping the people of Canada quit smoking or reduce the harms of nicotine addiction.*

*Most vaping products contain nicotine, which is highly addictive. Children and youth are especially susceptible to the risk of dependence.*

*Youth experimentation with and uptake of vaping could lead to tobacco use. Over a dozen studies show that among never-smoking youth, vaping significantly increases the risk of tobacco initiation.*

*Vaping products are also particularly harmful to youth and non-smokers because while they are less harmful than cigarettes, they emit chemicals during use that could negatively affect the health of youth and non-smokers. The long-term health effects of vaping products are still unknown, and there is limited research on the effects of second-hand vapour.*

## **Other legal and health authorities have set standards for warnings on 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.

The World Health Organization recommends that e-cigarettes carry warnings about addiction as well as about other health risks. The RIAS correctly identifies this as follows:

*Among other things, the [WHO] report recommends that Parties that have not banned the importation, sale, and distribution of Electronic Nicotine Delivery Systems (ENDS) / Electronic Non-Nicotine Delivery Systems consider the following options to minimize health risks to users and non-users:*

- *Regulate appropriate labelling of devices and vaping substances;*
- *Require health warnings about potential health risks deriving from their use. Health warnings **may additionally inform** the public about the addictive nature of nicotine in ENDS...*

*(emphasis added)*

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>2</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.*

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

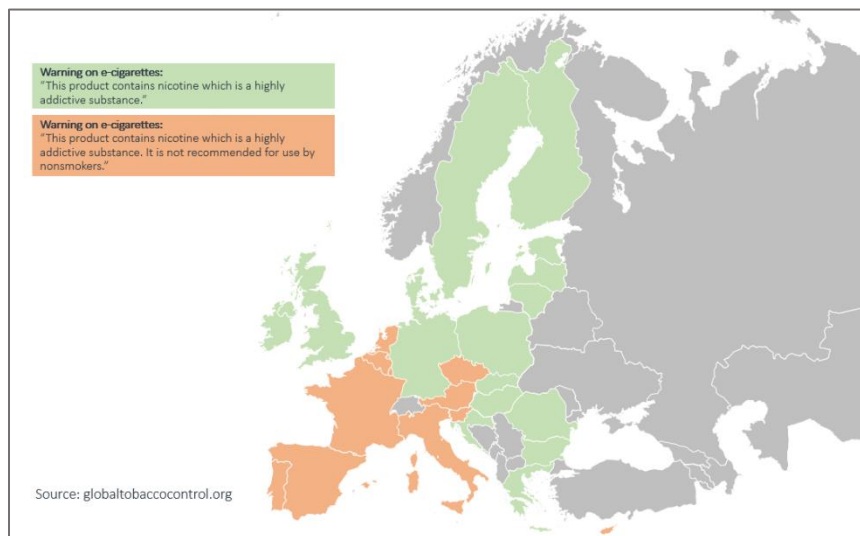
In April 2019, the Canadian Council of Chief Medical Officers of Health, expressed concerns that vaping may “lead to a resurgence in smoking or create new public health problems.”<sup>3</sup>

Some U.S. state public health authorities have recently issued public warnings about potential risks of lung disease from vaping.<sup>4</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>5</sup> While the RIAS identifies the EU requirement for an addictiveness warning similar to the one it proposes for Canada, it fails to mention the decision of health authorities in some EU countries to require additional warnings. Iceland and Israel have recently required health warning labels and have both elected to identify health risks beyond addiction.<sup>6 7 8</sup> A list of EU member states which have opted to caution non-smokers against using vaping products is shown in Figure 1.

Notably, these authorities point to the need for consumers to be provided with information on **potential** health risks, and not only those for which there is absolute certainty.

**Figure 1: Map of e-cigarette warnings required by EU member states**



3 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>

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

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

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

7 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>

8 Government of Israel. Restriction of advertising and marketing of tobacco products law, 2019. (Translation).

<https://www.tobaccocontrollaws.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>9</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>10</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>11</sup> <sup>12</sup> E-cigarette aerosol induces adverse changes to blood platelets, including activation, aggregation and adhesion.<sup>13</sup> <sup>14</sup> These and other adverse biological changes lead to an increased risk of heart disease and stroke from e-cigarettes. <sup>15</sup> <sup>16</sup> <sup>17</sup> <sup>18</sup> <sup>19</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.

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- 9 National Academies of Sciences, Engineering and Medicine . Public Health Consequences of e-Cigarettes. Washington, DC: The National Academies Press; 2018.
  - 10 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.
  - 11 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.
  - 12 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.
  - 13 Glantz S, Bareham D. E-cigarettes: use, effects on smoking, risks, and policy implications. *Annu Rev Public Health.* 2018; 39: p. 215-235
  - 14 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.
  - 15 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.
  - 16 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).
  - 17 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.
  - 18 Middlekauff H. Cardiovascular impact of electronic cigarette use. *Trends in Cardiovascular Medicine.* <https://doi.org/10.1016/j.tcm.2019.04.006>. 2019.
  - 19 Osei AD, et al. Association Between E-Cigarette Use and Cardiovascular Disease Among Never and Current Combustible-Cigarette Smokers. *Am J Med.* 2019.

- **Lung diseases**

E-cigarette vapour damages the epithelial cells that line airways, thereby interfering with their normal healthy functioning.<sup>20 21 22 23</sup> E-cigarette vapour also causes a number of other physiological changes that compromise the normal, healthy functioning of airways and lungs.<sup>24,25 26</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 diseases.<sup>27 28 29</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>30</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>31</sup> It has also been observed that e-

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- 20 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.
- 21 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.
- 22 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.
- 23 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.
- 24 Glantz S, et al, op cit.
- 25 Bhatta D, et al., op cit.
- 26 Jabba, S et al., op cit.
- 27 Perez M, Atuegwu E, Oncken C, Mortensen E. E-cigarette use is associated with emphysema, chronic bronchitis and COPD. In *American Thoracic Society International Conference Abstract #A6245/402*; 2018; San Diego.
- 28 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.
- 29 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.
- 30 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.
- 31 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.

cigarettes deregulate genes associated with cancer.<sup>32</sup> E-cigarettes deliver large amounts of nicotine. While not a carcinogen itself, nicotine speeds growth of cancerous tumours.<sup>33</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>34</sup>

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

A great many studies over many years have shown in research settings that various preparations of low-dose nicotine, together with the drugs varenicline and bupropion increase the rate of successful smoking cessation. However, when these approved therapeutic drugs move from research settings to the real world their effectiveness declines dramatically. Among heavy smokers, the NRT three-month success rates was 9%, compared with 15% among those who quit unassisted.<sup>35</sup> So it is with e-cigarettes. 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>36</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>37</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>38</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

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- 32 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.
- 33 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.
- 34 Pankow, JF. Benzene formation in electronic cigarettes. *PlosOne* 2017.
- 35 Pierce J, Cummins S, White M, Humphrey A, Messer K. Quitlines and nicotine replacement for smoking cessation: Do we need to change policy? *Annual Review of Public Health.* 2012; 33: p. 341-356.
- 36 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.
- 37 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.
- 38 Hajek, P. op cit.

become cigarette smokers. One recent well-done study found youth who started on e-cigarettes were four times more likely to go on to become cigarette smokers.<sup>39</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>40</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>41 42 43</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>44 45 46 47</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>48</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>49</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.*

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- 39 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.
- 40 Olfson 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.
- 41 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.
- 42 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.
- 43 McKelvey K, Balocci M, Halpern-Felsher B. Adolescents’ and young adults’ use and perceptions of pod-based electronic cigarettes. *JAMA Network Open* doi:10.1001/jamanetworkopen.2018.3535. 2018 Oct 19; 1(6): p. e183535.
- 44 Brewer, NT et al. Impact of e-cigarette health warnings on motivation to vape and smoke. *Tobacco Control*. July 2019.
- 45 Sontag, J et al. US young adults’ perceived effectiveness of draft pictorial e-cigarette warning labels. *Tob Control*. 2019 Jun 5.
- 46 Andrews. JC et al. Effects of E-Cigarette Health Warnings and Modified Risk Ad Claims on Adolescent E-Cigarette Craving and Susceptibility. *Nicotine Tob Res*. 2019 May
- 47 Wackowski, OA, et al. Considerations and Future Research Directions for E-Cigarette Warnings-Findings from Expert Interviews. *Int J Environ Res Public Health*. 2017.
- 48 U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General
- 49 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)

- *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>50</sup>

### **Canadian Health Authority conclusions about health risks to young persons.**

Health Canada has acknowledged these risks on its web-site:

*Children and youth are especially susceptible to the harmful effects of nicotine, including addiction. They may become dependent on nicotine with lower levels of exposure than adults.*

*Nicotine:*

- *can affect memory and concentration*
- *is known to alter teen brain development*

*Exposure to nicotine during adolescence may cause*

- *reduced impulse control*
- *cognitive and behavioural problems*

*Vaping may predispose youth to addiction to nicotine and possibly other drugs*

A letter from the Minister of Health to retailer associations in 2019 noted that:<sup>51</sup>

*Nicotine is highly addictive and can have harmful impacts on the brain, affecting memory and concentration in everyone and brain development in youth and young adults. Early exposure to nicotine in adolescence may also increase the severity of future dependence to nicotine and tobacco. We need to protect our young people from the risks and harms associated with vaping nicotine.*

In a background document to support inspection of sales-to-youth measures, Health Canada acknowledged the particular risks to young people, including the impact of youth vaping on future cigarette use:

*There is clear evidence that nicotine exposure during adolescence adversely affects cognitive function and development. Nicotine is a potent and powerfully addictive substance, particularly for youth. Vaping products containing nicotine could potentially lead to addiction, the subsequent use of tobacco products, and the renormalization of smoking behaviours.<sup>52</sup>*

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<sup>50</sup> 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

51 Health Canada. Ministers Letter to Retail Associations Concerning Youth Vaping. <https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/risks/ministers-letter-retail-associations-youth-vaping.html>

52 Statement of Work. Retailers’ Behaviour Toward Youth Access-to-Electronic Cigarettes and Promotion at Retail and Online. [https://buyandsell.gc.ca/cds/public/2018/09/19/4a74b94b748ddaa08f02e0151b4184be/rfp\\_1000202494\\_sept\\_17\\_2018\\_en\\_final.pdf](https://buyandsell.gc.ca/cds/public/2018/09/19/4a74b94b748ddaa08f02e0151b4184be/rfp_1000202494_sept_17_2018_en_final.pdf)



- **Risks particular to pregnancy**

Although Health Canada initially proposed a warning regarding the use of nicotine during pregnancy,<sup>53</sup> a warning specific to this potential health risk has been rejected. The following reason is provided in the RIAS:

*The statement “Use of nicotine during pregnancy may harm the fetus” is not included in the current proposal due to feedback received from scientific experts that there were limitations in the current scientific knowledge to support its inclusion for vaping products at this time.*

Regulatory decisions should be made on open and transparently published science, not private consultations. By citing anonymous scientific advice, the department is creating an unnecessary vulnerability for regulatory policy making. Given the history of exploitation of scientists by tobacco companies, and the spirit of FCTC article 5.3, the department should not base its decisions on unpublished data or confidential advice.

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>54</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>55</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>56</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

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53 Health Canada. Proposals for the Regulation of vaping products. August 2017. <https://www.canada.ca/en/health-canada/programs/consultation-regulation-vaping-products/proposals-regulate-vaping-products.html>

54 National Academy of Sciences, Engineering and Medicine. Public Health Consequences of E-cigarettes.

55 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.

56 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.

strategy to reduce smoking puts this population at great risk.”<sup>57</sup> There are several recent published scientific research papers which caution against the use of electronic cigarettes by pregnant women.<sup>58 59 60 61 62 63 64</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>65</sup>

### **Significant health risks are not addressed by the proposed package warning regulation**

For reasons not made clear in the RIAS, Health Canada focused the development of warning messages on vaping products to a singular warning on addiction. The Public Opinion research cited, for example, tested only three warning options:<sup>66</sup>

*Option 1: “CAUTION: NICOTINE IS HIGHLY ADDICTIVE – HEALTH CANADA” (OPTION 1)*

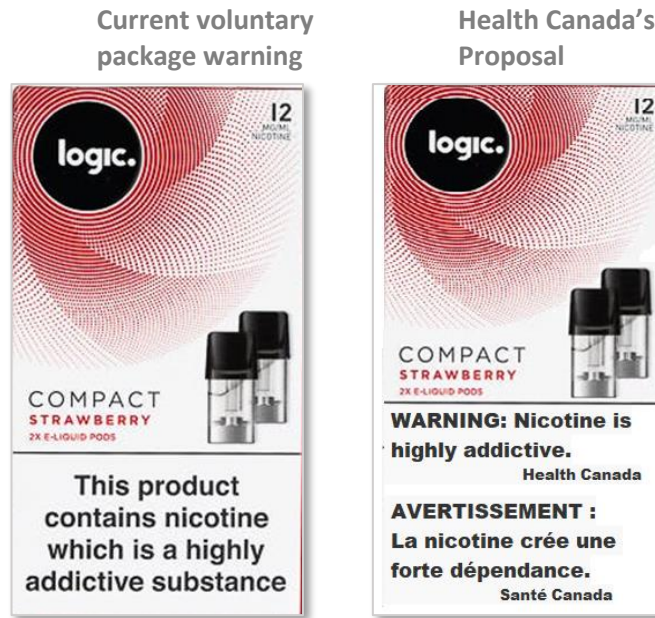
*Option 2: “THIS PRODUCT CONTAINS NICOTINE WHICH IS A HIGHLY ADDICTIVE SUBSTANCE – HEALTH CANADA”*

*Option 3: “WARNING: THIS PRODUCT CONTAINS NICOTINE. NICOTINE IS AN ADDICTIVE SUBSTANCE – HEALTH CANADA”*

The proposed regulation would require a single bilingual warning - WARNING: Nicotine is highly addictive. AVERTISSEMENT : La nicotine crée une forte dépendance. As shown in Figure 2, this warning will not significantly increase the information currently available to consumers of vaping products.

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- 57 England, LJ. Nicotine and the Developing Human: A Neglected Element in the Electronic Cigarette Debate. *Am J Prev Med.* 2015
- 58 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.
- 59 Suter, MA Is there evidence for potential harm of electronic cigarette use in pregnancy? *Birth Defects Res A Clin Mot Teratol.* 2015
- 60 Beeza-Loya, S. et al. Perceptions about e-cigarette safety may lead to e-smoking during pregnancy. *Bull Menninger Clin.* 2015.
- 61 McCubbin, A. et al. Perceptions and use o electronic cigarettes in pregnancy.” *Health Education Research.* 2017.
- 62 Wittington, JR et al. The Use of Electronic Cigarettes in Prewgnancy: A Review of the Literature. *Obstet Gynecol Surv.* 2018.
- 63 Orzabal, M et al.. Impact of Electronic Cigarette Aerosols on Pregnancy and Early Development. *Curr Opin Toxicol.* 2019.
- 64 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.
- 65 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.
- 66 Corporate Research Associates Inc. Evaluation of Possible Labelling Elements for Vaping Products – Phase I and Phase II. 2018.

**Figure 2: Visualization of impact of Health Canada’s proposed package warning for vaping products.**



We applaud the adoption of a method to facilitate changes to the warning messages and the use of a ‘list of health warnings for vaping products,’ which would be incorporated by reference into the regulation. The usefulness of this approach is reduced, however, if the regulations do not anticipate multiple rotating warnings being required, as is done for cannabis or tobacco product.

It is worth noting that the proposed regulation would provide consumers with less information about health risks than is currently conveyed in the warning provided by manufacturers. BAT’s Canadian web-site for VYPE provides the following warning:

*Vype products may be harmful to health and contain nicotine which is addictive. VYPE PRODUCTS ARE NOT SUITABLE FOR USE BY: persons who are not adults; persons who are under the legal age to purchase vaping products; persons who are allergic/sensitive to nicotine; pregnant or breast-feeding women; persons who have been advised to avoid using tobacco or nicotine products for medical reasons; persons with reduced physical, sensory, mental capabilities or lack of experience/knowledge unless they are under supervision or have been given instructions concerning the use of the product by a person responsible for their safety; and persons with an unstable heart condition, severe hypertension or diabetes. Keep Vype products out of reach of children.<sup>67</sup>*

## **B. Comments on Maximum Nicotine Concentration**

**Health Canada’s reasons for restricting the concentration of nicotine in vaping liquids are too narrow.**

The proposed regulation will limit the concentration of nicotine permitted in vaping liquids to 66 mg/mL. This level is a lateral transfer from pre-existing product standards under the *Consumer Chemicals and Containers Regulations, 2001*.

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67 Govype.ca.

The maximum nicotine level proposed in the regulation is a result of the overly-narrow focus on toxicity by ingestion (and especially the risk of accidental poisoning in children). The department should instead develop maximum concentration levels which apply the more general understanding of toxicity as the extent to which a chemical substance can damage an organism. With respect to cigarettes, for example, toxicity is not assessed by the harmfulness of chemicals when ingested, but the harm when they are inhaled. The same should apply to vaping products

### **Acute poisoning is not the only reason that the concentration of nicotine in vaping products should be restricted.**

Other jurisdictions have sought to provide some measure of protection by setting maximum levels of nicotine in order to reduce the health consequences of inhalation. The European Union set a maximum nicotine concentration of 20 mg/mL, as Israel,<sup>68</sup> Iceland<sup>69</sup> and Korea<sup>70</sup> have recently done.

Researchers have raised concerns that higher-levels of nicotine in vaping products can increase the risk of addiction by non-smoking users.<sup>71</sup>

- Analysis of emissions from JUUL electronic cigarettes found that the liquid concentration was 69 mg/mL (higher than the stated 5% level).<sup>72</sup>
- Higher nicotine delivering e-cigarettes have become more popular with young people.<sup>73 74</sup>
- Young people are preferentially drawn to higher delivery nicotine vaping products.<sup>75</sup>
- Higher-delivery products using nicotine salts raise concerns about the potential for earlier and more significant nicotine addiction in teens.<sup>76</sup>
- Canadian research is helping establish that higher nicotine levels in vaping products are associated with greater levels of addiction.<sup>77</sup>

In the absence of restrictions on nicotine concentrations, manufacturers of nicotine products are incentivized to sell products which enhance the bioavailability of nicotine. The marketing of JUUL, with higher concentrations of protonated nicotine, launched a “nicotine arms race” and prompted researchers to call for a cap on the amount of nicotine permissible in e-cigarettes.<sup>78</sup>

*If the USA adopted this standard, it would almost certainly reduce the tendency of e-cigarettes to act as a gateway to youth nicotine addiction. However, it may also reduce their efficacy in cigarette smoking cessation. As high-nicotine versions may well prove more efficacious in transitioning*

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68 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>

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

70 The Korea Herald. E-cigarette maker Juul Labs seeks Korean market entry.

<http://www.koreaherald.com/view.php?ud=20190312000675>

71 Boykin, R et al. Evidence of Nicotine Dependence in Adolescents Who Use Juul and Similar Pod Devices. International Journal of Environmental Research and Public Health. 2019.

72 Talih, S. et al. Characteristics and toxicant emissions of JUUL electronic cigarettes. Tob Control, 2019.

73 Vogel, E. Adolescents' E-Cigarette Use: Increases in Frequency, Dependence, and Nicotine Exposure Over 12 Months. J. Adolescent Health.

74 Jenssen, B. What is new in electronic-cigarettes research? Curr Opin Pediatr. 2019.

75 Keamy-Minor, E et al. Young adult perceptions of JUUL and other pod electronic cigarette devices in California: a qualitative study. BMJ Open, 2019.

76 Goniewicz, ML et al. High exposure to nicotine among adolescents who use Juul and other vape pod systems ('pods'). Tobacco Control. 2018.

77 Personal communication with Robert Schwartz. Publications forthcoming.

78 Jackler, RJ. Nicotine arms race: JUUL and the high-nicotine product market. Tobacco Control, 2019.

*cigarette smokers to aerosol, one option would be to allow sale of high-nicotine e-liquids only by doctor's prescription.*

This 'nicotine arms race' has also been observed in Canada. A year ago, shortly after the nicotine market was legalized, British American Tobacco announced that it would be offering 3 types of vaping products. None of them contained more than 18 mg/ml of nicotine.<sup>79</sup> Subsequent to the introduction of JUUL in the Canadian market in late summer 2018, BAT launched a fourth product (ePod), which had higher nicotine levels using nicotine salts. It also increased the nicotine levels in its other pod-based device (ePen 3). The absence of protective regulations has resulted in BAT selling higher-nicotine products in Canada than in all markets other than the United States, as shown in Figure 3.

### **Health Canada should consider restricting the types of nicotine which can be sold for use in vaping devices.**

The marketing of vaping products which use nicotine salts has coincided with the rapidly expanding use of vaping products by young people.

The use of nicotine salts was patented by Juul (in the USA and Canada<sup>80</sup>) in 2014, an innovation which has raised concerns, in part because of the extensive imitation by other manufacturers.<sup>81</sup>

As BAT acknowledges (see Figure 4), vaping liquids made with nicotine salts have a greater and faster impact on nicotine blood delivery than do liquids which do not use this 'protonated' technology.<sup>82</sup>

Health Canada has the regulatory authority to set standards for the production of vaping products, to control the chemicals which are used in their production, and to demand that manufacturers submit information on their research and development activities related to vaping products and their emissions. (TVPA, s. 7.2 to 7.3, 7.8). The Department of Health Act also provides the Minister with the authority to set regulations and issue Interim Orders in cases where the Minister believes that immediate action is required to address health risks. The FDA used similar powers in April 2018 and May 2018, when it sent official requests for information to several manufacturers of products made with nicotine salts.<sup>83 84</sup>

Health Canada has not at this time identified the need to develop additional regulations to control the concentration, amount or type of nicotine that can be sold.<sup>85</sup> The current regulatory proposal gazetted in June 2018 can be amended to set maximum levels of protonated and maximum levels of unprotonated nicotine.

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79 Physicians for a Smoke-Free Canada. See Vype Go. June 2018.  
<http://smoke-free-canada.blogspot.com/2018/06/see-vype-go.html>

80 Canadian Intellectual Property Office. Patent 2909967  
<http://brevets-patents.ic.gc.ca/opic-cipo/cpd/eng/patent/2909967/summary.html>

81 J ackler, RK et al. op cit.

82 British American Tobacco. Investor Presentation. March 2018. Science Supporting Accelerated Delivery.

83 Letter from FDA to JUUL labs. April 24, 2018 <https://www.fda.gov/media/112339/download>

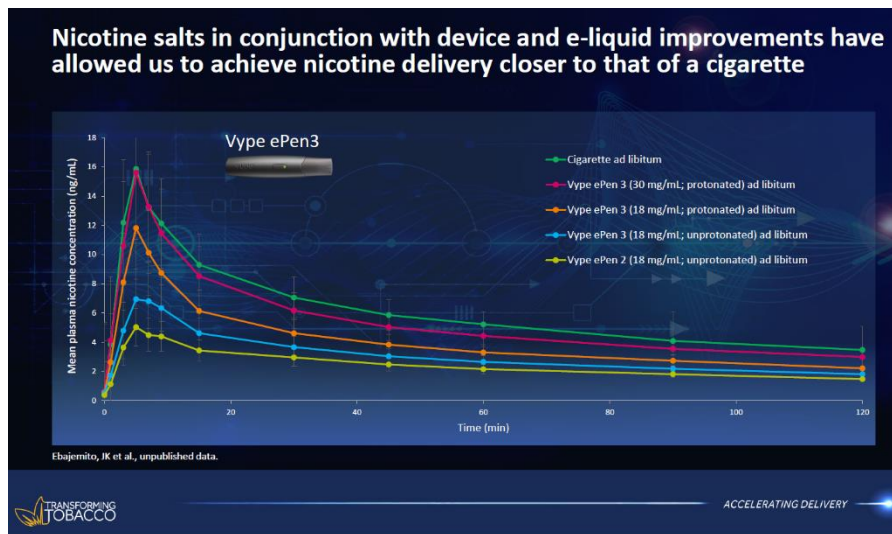
84 FDA News Release. FDA requires additional e-cigarette makers to provide critical information so the agency can better examine youth use and product appeal, amid continued concerns around youth access to products. May 2018.

85 Health Canada. Forward Regulatory Plan: 2019- to 2021

Figure 3: Nicotine levels of pod-systems sold by BAT.<sup>86</sup>



Figure 4: British American Tobacco Investor presentation on the effect of nicotine salts on speed and intensity of delivery.



86 Physicians for a Smoke-Free Canada. Cheaper. BAT marketing of Vype . A comparison of British American Tobacco’s marketing of the Vype e Pen 3 and Vype ePod in Canada and elsewhere, based on web-sites accessed July 3, 2019

## C. Recommendations

### 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:

- 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).

**Figure 5. Vaping product packages displayed at retail. Voluntary warning is obscured.**



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>87 88</sup>

Korea requires a graphic health warning on vaping product packages, as shown in Figure 6 below.

**Figure 6: Korean graphic health warning on vaping product packaging.**



- **Quit line information should be provided on vaping product packages.**  
The same logic that is applied to the mandatory display of Quit line information on cigarette packages should be applied to vaping product packages. Korea has adopted this approach, as seen in Figure 5. Quit line information does not need to be on the principal display panel.
- **Plain packaging of vaping products should be required.**  
Plain packaging has been shown to increase the effectiveness of health warnings on cigarettes. This same logic will apply to vaping product packages.
- **Regulatory flexibility which should be developed for vaping package warning regulations:**  
The proposed regulations are not sufficiently flexible to allow for expansion of warning messages to cover additional health risks. Although the approach of using a reference list of warnings is expected to greatly facilitate improvements to warnings, the proposed regulations do not currently anticipate multiple rotating warnings being required, as is done for cannabis or tobacco product. The regulation should be amended to allow for multiple and rotating warnings.

We recommend the following sequencing of these recommendations:

1. **Immediate:**  
CG2 of the proposed regulation should be implemented using the longer warning required by the EU, as now in use in France, Spain, Italy, etc. (**“This product contains nicotine which is a highly addictive**

87 Brewer, NT et al. Op cit.

88 Andrews, JC et al. Op cit.



substance. It is not recommended for use by non-smokers.”). Preferably, this warning would be strengthened to **“This product contains nicotine which is a highly addictive substance. It is not safe for use by non smokers.”** The regulation should require warnings to be at least 50% of the two principal display surfaces and to be at the top of the package. The regulation should be amended to allow for future changes, including rotating messages.

2. **Short term (18-24 months):**

Development of a new list of health warnings for vaping product packages should be given priority. This revised list should include graphic warnings on the health risks identified earlier. Quit line information should be required.

3. **Medium term (24 – 48 months):**

Plain packaging of vaping devices and other vaping products should be required.

A comparison of our recommendations with the current proposal and existing packaging is shown in Figure 7.

**2. Nicotine concentration and types**

We recommend that the regulation be amended at CG2 to set the maximum level of nicotine at 20 mg/mL.

We recommend that Health Canada review the impact of the marketing of nicotine salts on youth update of vaping, and consider restrictions on the sale of such products (i.e. additional restrictions on flavours, locations of purchase, prohibition or other.)

**Figure 7: Illustrations of recommendations**

**PSC Recommendation – Immediate term (A)**



**PSC Recommendation – Immediate term (B)**



**PSC Recommendation - Short term<sup>89</sup>**



89 Illustration taken from U.S. Centres for Disease Control. Op cit. “New Brain Print ad” [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/assets/OSH-2019-E-Cigarette-Print-Ad-508.pdf](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/assets/OSH-2019-E-Cigarette-Print-Ad-508.pdf)