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in regard to Bill 44, An Act to bolster tobacco
control

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I. INTRODUCTION

1. This submission by Nicoventures Holdings Limited (“Nicoventures”) (the “submission”) has been prepared for the Committee on Health and Social Services of the Quebec National Assembly (the “Committee”) in relation to the special consultation the Committee has convened to consider **Bill 44, An Act to bolster tobacco control**, tabled by the Minister for Rehabilitation, Youth Protection and Public Health (“the Bill”).
2. The following comments address certain key issues related to vaping products¹.
3. Section 2 of the Bill proposes to include vaping products in the definition of tobacco pursuant to Section 1 of the Tobacco Act. The proposed amendment would result in vaping products being regulated as tobacco products, except for the ban on flavours, from which these products would be exempted. In this submission, Nicoventures offers its position on the proposed Bill and wishes to highlight the scientific evidence, regulatory policy analyses and rationale in favour of allowing consumers access to vaping products without the same restrictions as those that apply to tobacco products.

A. GENERAL COMMENTS ON HOW E-CIGARETTES SHOULD BE REGULATED

4. Smokers across the world are increasingly switching from conventional cigarettes to electronic cigarettes (e-cigarettes or e-cigs). In countries such as the USA, UK, Poland, Germany, France, Italy and Russia, it is estimated that there are over a million smokers, each who have chosen to partially or completely switch away from tobacco smoking to ‘vaping’ e-cigarettes, thus reducing overall tobacco consumption at an individual as well as population level.
5. There are those in positions of authority who have responded to the e-cigarette phenomenon with caution, based on concerns such as absolute safety, gateway into smoking, (especially youth) and renormalisation of smoking. There is growing consensus among many in public health that e-cigarettes are generally significantly less risky than conventional cigarettes and that a switch to e-cigarettes by smokers has the potential to lead to an unprecedented public health success in terms of tobacco control and harm reduction.
6. According to the head of the UK Royal College of Physicians’ tobacco advisory group, Professor John Britton, *“The potential benefits of electronic cigarettes lie in their role as a reduced-hazard competitor for cigarettes.”*²

¹ Throughout this submission, the terms “vaping products” refer to electronic nicotine and non-nicotine delivery systems (“ENDS”, also commonly referred to as e-cigarettes or “EC”), including e-liquids.

² Electronic Cigarettes: A report commissioned by Public Health England, John Britton and Ilze Bogdanovica, May 2014. Link: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf

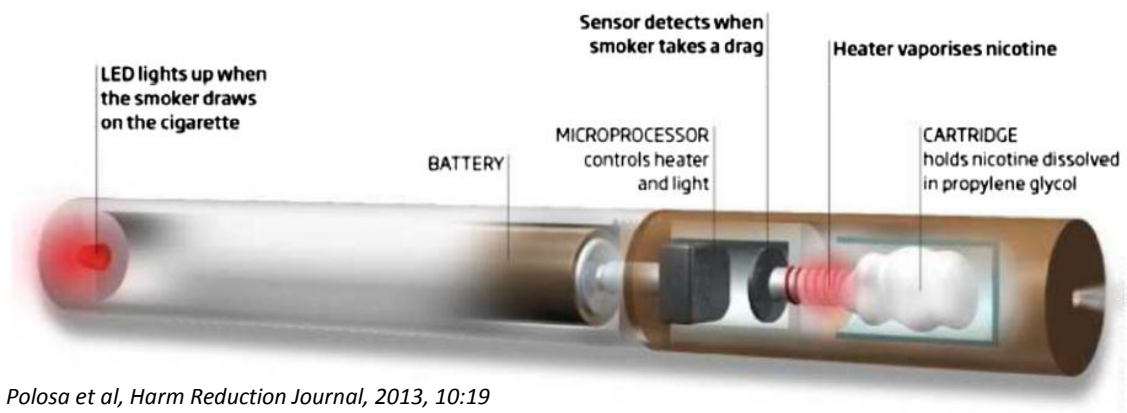
7. Given such potential, it is critical that e-cigarettes are regulated in a way that enables responsible growth. Specifically, we believe that the most appropriate regulatory framework is one that puts product quality and consumer safety first and, at the same time, allows for swift innovation and distribution and marketing freedoms.
8. As such, we should seek national standards, for example through the Standards Council of Canada, based on a federal regulatory framework that would be established prior to the development and implementation of provincial regulations. This would ensure a coherent approach to regulating this new category. It would further ensure that the nature, properties and risk profile of vaping products as well as the fundamental differences between tobacco products and vaping products are taken into account.
9. We do not believe it makes sense for e-cigarettes to be regulated in the same way as tobacco products as they contain no tobacco and are significantly safer than cigarettes. In this respect, legislating vaping products as tobacco products is misguided. It is contrary to the available evidence, which shows that vaping products provide significant potential public health benefits as part of a harm reduction strategy.

II. BACKGROUND AND RELEVANT EVIDENCE

A. WHAT IS AN E-CIGARETTE?

10. E-cigarettes recreate the experience of smoking and deliver a controlled dose of nicotine without the toxicity of smoking tobacco. They are generally used by adult smokers who want to reduce, replace, or stop smoking.
11. E-cigarettes typically consist of a battery, a heating coil and a liquid. These liquids generally contain nicotine, water, a "diluent" such as propylene glycol and/or glycerol, and sometimes flavourings. They do not contain tobacco. The liquid is pulled into the coil by a wicking mechanism. Drawing on the e-cigarette or pressing a switch activates the battery to heat the coil, which vaporises the liquid. This vapour is then inhaled by the e-cigarette user. As there is no tobacco or combustion, the user inhales vapour, not smoke, and no tobacco "tar" is produced – the vapour does not contain the toxic components created in tobacco combustion. E-cigarettes and the liquids can be sold as integrated units or with liquids sold separately (either disposable or refillable cartridges).

Figure 1: What is an e-cigarette?



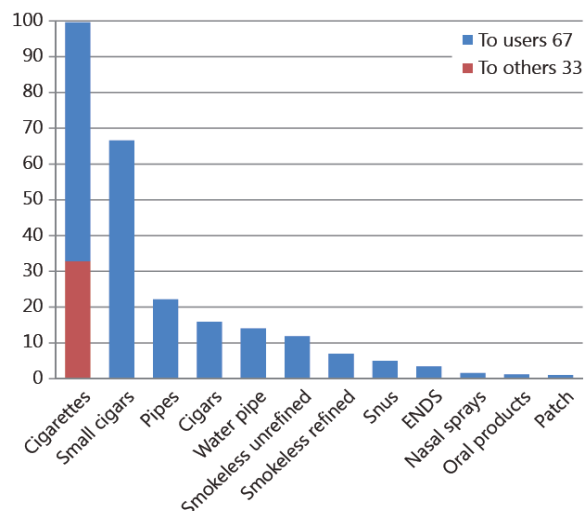
Source: Polosa et al, *Harm Reduction Journal*, 2013, 10:19

12. The following elements are common to all e-cigarettes:
 - An e-liquid formulation usually containing a mixture of nicotine, glycerol, propylene glycol, water and flavours;
 - Offer comfort to smokers due to the close proximity to the hand-to-mouth ritual;
 - Generate a 'vapour' on puffing, mimicking the sensation of smoking in the throat and the way in which nicotine is delivered.
13. Nicoventures believes electronic nicotine delivery systems (ENDS), such as e-cigarettes, should be regulated, legal, and widely available for sale in Canada.

B. ENDS: A SAFER PRODUCT

14. Smokers across the world are increasingly switching from conventional cigarettes to ENDS. In many countries, including Canada, it is estimated that there are now millions of smokers who have chosen to partially or completely switch from smoking tobacco to ‘vaping’ ENDS, thus reducing overall tobacco consumption at an individual as well as population level. In fact, Action on Smoking and Health in the UK (ASH) estimates that 2.6 million adults in Great Britain are using e-cigarettes and that of these, 1.1 million have completely abandoned tobacco³. Regular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible.⁴
15. The real potential benefits of ENDS lie in their role as a much safer replacement to cigarettes. They do contain nicotine, but are free from tobacco and from the ill effects of toxic elements and carcinogens that emanate from burning tobacco. ENDS provide adult smokers wanting to reduce, replace or stop smoking a quality alternative solution.
16. There is growing consensus among many in public health that ENDS are generally significantly safer than conventional cigarettes and that a switch to ENDS by smokers has the potential to lead to an unprecedented public health success in terms of tobacco control and harm reduction thus saving lives. In a recently published paper by the UK based *Independent Scientific Committee on Drugs*, Professor Nutt and a group of world experts from the fields of public health policy, nicotine science and medicine, ranked different nicotine and tobacco products on the basis of their relative harms to users and the wider society. This study attributed a relative harm score of 99.6 out of a 100 for conventional cigarettes, while giving a score of 4 out of a 100 for their electronic counterparts (referred to as “ENDS” in the study). Medically licensed nicotine replacement therapies got a score of 2 out of a 100⁵.

Figure 2: Nicotine and tobacco products ranked on the basis of their relative harms



³ Action on Health and Smoking UK 2015. *Use of electronic cigarettes (vapourisers) among adults in Great Britain*. Available at http://www.ash.org.uk/files/documents/ASH_891.pdf

⁴ *Id.*

⁵ Nutt et al, Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. *Eur Addict Res* 2014; 20:218–225, at 224, Fig 3 at 223.

17. As Health Canada has indicated, there is potential for some ENDS to be an effective substitute and cessation product for some smokers. Research is evolving in this area and regulations are needed to establish standardized means of ensuring quality control and to help prevent ENDS from undermining tobacco control efforts to reduce smoking.

C. WHAT IS "TOBACCO HARM REDUCTION"?

18. Harm reduction is a well-established public health concept which seeks pragmatic ways to minimise the health impact of an inherently risky activity or behaviour, without seeking to stop it entirely. Examples include the use of seat belts and airbags in cars to reduce the risks of injury or death from road traffic accidents.
19. Tobacco harm reduction means the continued use of less risky alternatives to cigarettes without quitting nicotine usage altogether. The US Institute of Medicine, which is supportive of this view, has defined it as "...minimising harms and decreasing total morbidity and mortality without completely eliminating tobacco and nicotine use".⁶
20. A recent report commissioned by the UK Department of Health's executive agency, Public Health England, has described tobacco harm reduction as: *"The options for harm reduction in tobacco control include cutting down on smoking, use of modified cigarettes, smokeless tobacco products, nicotine replacement therapies, and more recently electronic cigarettes"*.⁷
21. The fact that use of vaping products is almost entirely limited to current or former smokers shows that this product category can play a pivotal role in the reduction of tobacco consumption and thus yield very considerable public health benefits. It is therefore unsurprising that there is increasing consensus in the scientific literature that vaping products are unlikely to present significant health risks to users.

D. NICOTINE'S ROLE IN TOBACCO HARM REDUCTION

22. Nicotine is the addictive component of tobacco smoke, but unlike some other constituents of tobacco smoke, it is not carcinogenic and according to the UK Royal College of Physicians, 'medicinal nicotine is a very safe drug'. The UK Medicines and Healthcare products Regulatory Agency ("MHRA") assessed the health effects of nicotine and stated "there is a large body of evidence that medicinal nicotine (in current licensed forms) is not a significant risk factor for cardiovascular events, and does not cause cancer or respiratory disease". The UK National Institute for Health and Care Excellence concludes similarly: "Most health problems are caused by other components in tobacco smoke, not by the nicotine".

⁶ Clearing the Smoke – Assessing the Science Base for Tobacco Harm Reduction, Institute of Medicine (2001).

⁷ Electronic Cigarettes: A report commissioned by Public Health England, John Britton and Ilze Bogdanovica, May 2014. Link: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf

E. E-CIGARETTES' ROLE IN REDUCING SMOKING INCIDENCE

23. Use of e-cigarettes by smokers to quit

Action on Smoking and Health (ASH), the UK anti-smoking charity, has conducted numerous surveys in the past 5 years tracking e-cigarette use in the UK. The 2015 survey report states:

"ASH estimates that there are currently 2.6 million adults in Great Britain using electronic cigarettes. Of these, approximately 1.1 million are ex-smokers while 1.4 million continue to use tobacco alongside their electronic cigarette use. Regular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible."

*"Among current vapers, the principal reasons given by ex-smokers are "to help me stop smoking entirely" (61%) and "to help me keep off tobacco" (53%)."*⁸

24. Reducing Smoking Incidence

Although too small to capture any treatment advantage, a recent clinical trial in New Zealand suggested effectiveness and safety of e-cigarettes comparable to licensed nicotine replacement patches and led them to conclude:

*"Our findings point to potential for e-cigarettes in regard to cessation effectiveness beyond that noted in the present study. Furthermore, because they have far greater reach and higher acceptability (as shown by the present study) among smokers than NRT, and seem to have no greater risk of adverse effects, e-cigarettes also have potential for improving population health."*⁹

25. Another great example is one not of a regular sample but a whole country...

*"The Swedish experience with smokeless 'snus' (oral snuff) is proof-of-concept that disease risk can be massively reduced through use of a different delivery system. The very rapidly growing global demand for electronic cigarettes (e-cigarettes) reinforces this message with what appears to be a far more acceptable product for many smokers, and even the presence of long-term users of nicotine replacement therapy (who use the products for well over a decade), shows the viability of vastly less hazardous alternatives to obtaining nicotine via smoking cigarettes."*¹⁰

⁸ Action on Health and Smoking UK 2015. *Use of electronic cigarettes (vapourisers) among adults in Great Britain*. Available at http://www.ash.org.uk/files/documents/ASH_891.pdf

⁹ Bullen et al. (2013) *Electronic cigarettes for smoking cessation: A randomised clinical trial*. *Lancet* 382; 1629-1637

¹⁰ Dr Derek Yach, ex-Cabinet Director of the WHO and Professor David Swenor, *South African Medical Journal*, November 2013

F. RELATIVE RISK PROFILE

26. Why might e-cigarettes be considered to reduce risk? The quality of content and function of e-cigarettes varies, but in general terms:

- Do not contain tobacco;
- Do not involve combustion of tobacco that leads to the formation of the thousands of toxicants and carcinogens in cigarette smoke ;
- Nicotine is delivered in an aerosol of glycerol or propylene glycol, rather than in cigarette smoke.

27. A systematic review of published e-cigarette vapour composition studies conducted in 2014 concluded:

“Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces.

However, the aerosol generated during vaping as a whole (contaminants plus declared ingredients) creates personal exposures that would justify surveillance of health among exposed persons in conjunction with investigation of means to keep any adverse health effects as low as reasonably achievable. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.”¹¹

28. According to Cancer Research UK “...While nicotine is addictive, and not entirely harmless, e-cigarettes do not contain the extensive cocktail of cancer-causing chemicals found in tobacco. While the long term health consequences of e-cigarette use are uncertain, they are almost certainly far safer than tobacco cigarettes.”

29. A review on e-cigarettes commissioned by Public Health England, published in August 2015¹² concludes:

- e-cigarettes contribute to falling smoking rates among adults and young people. The current best estimate is that e-cigarettes are around 95% less harmful than smoking;
- the highest successful quit rates are now seen among smokers who use an e-cigarette;
- nearly half the population (44.8%) don’t realise e-cigarettes are much less harmful than smoking;

¹¹ Burstyn, I 2014 “Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks.” *BMC Public Health* 14:18 Igor Burstyn.

¹² [E-cigarettes: an evidence update](#) McNeill A, Brose LS, Calder R, Hitchman SC, Hajek P, McRobbie H. Aug 2015

- there is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers;
- 2.6 million adults using e-cigarettes in Great Britain are current or ex-smokers, most of whom are using the devices to help them quit smoking or to prevent them going back to cigarette;
- when used as intended, e-cigarettes pose no risk of nicotine poisoning to users.

30. Although the relative lower risk of e-cigarettes as a category vis-à-vis traditional cigarettes can only be definitively confirmed when more data become available regarding composition of the e-liquids in the marketplace and the resultant vapour, and the effects of longer term use, the emerging trends are promising.

G. RESPONSE TO PUBLIC HEALTH CONCERNS REGARDING E-CIGARETTES

31. Public health concerns have been raised, mainly regarding the following elements:

1. Health concerns regarding e-cigarettes' ingredients and emissions
2. Use of Flavours
3. Gateway
4. Dual Use
5. Normalisation
6. Addiction
7. Public Place Vaping
8. Are people using e-cigarettes to cut down and/or quit?

1. Health concerns regarding e-cigarettes' ingredients and emissions

32. Some in public health have expressed concerns that e-cigarettes present health risks to users from the formation of formaldehyde during vaporization as well as to non-users, due to the exposure to nicotine and other toxicants from passive exposure to e-cigarette vapour. It should be noted that low levels of carcinogens are found almost everywhere in the environment and the air that we breathe and the food that we eat. It is not merely the presence of trace amounts of carcinogens, but whether these carcinogens cause exposures at levels and via pathways that pose material risk. The largest study to date on toxicants in e-cigarette vapour concluded: "The levels of the toxicants were 9-450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference [pharmaceutical nicotine] product"¹³. Overall, there is good evidence that the toxicant yield of e-cigarettes is low, because e-cigarettes do not involve combustion of tobacco that leads to the formation of the many toxicants and carcinogens at levels found in cigarette smoke. Instead, e-cigarettes deliver nicotine in an aerosol or vapour of glycerol, rather than in smoke.

¹³ Goniewicz M, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, et al. (2013) Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tob Control* 2014 Mar; 23(2):133-9.

33. **Formaldehyde:** It has been reported that formaldehyde is present in the vapour from e-cigarettes, but where found this is at levels 6-50 times lower than found in conventional cigarette smoke¹⁴. The only study that is cited regarding health effects is a single (non-peer reviewed) letter to the editor of the New England Journal of Medicine suggesting that high levels of certain formaldehyde-releasing agents could be formed during vaporisation of e-liquid¹⁵. The results reported in this letter have not been verified, duplicated or validated. In fact, this letter and its conclusions have subsequently been called into serious question. One commentator, for example, noted that the experimental conditions employed for the e-cigarette analysis described in the letter bear no resemblance to how people actually use e-cigarettes¹⁶. Another recent study directly refuted the findings of the letter, leading to the conclusion that far lower and minimal amounts of aldehydes are released in the e-cigarette aerosol at normal vaping conditions¹⁷.
34. **Propylene glycol:** Some assert that propylene glycol (present in many e-liquids) is a known irritant when inhaled and hence poses a risk to users and non-users. However, it has been reported that "[t]he results of extensive studies on animals, reviewed elsewhere, suggest that PG [propylene glycol] should be safe for inhalation in humans, although in children, chronic exposure to PG in indoor air may exacerbate or induce rhinitis, asthma, eczema and allergic symptoms. Acute and chronic respiratory effects, including reduced lung function, were reported in people chronically exposed to theatre fogs containing PG"¹⁸. The authors' concluded that "PG and glycerol inhalation is likely to pose a low risk, although their long-term effects as well as the effects of long-term inhalation of EC flavourings and additives need to be studied"¹⁹.
35. A systematic review of e-cigarette vapour composition published in 2014 concluded that: "Current state of knowledge about chemistry of liquids and aerosols associated with e-cigarettes indicates that there is no evidence that vaping produces inhalable exposures to *contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces"²⁰.
36. A recent review of available research on content and safety of e-cigarettes, and their potential harm or benefit, concluded that the e-liquids and aerosols tested contain toxicants in

¹⁴ Farsalinos K. E-Cigarette Research Blog, 27 November 2014, available at <http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2014/188-frm-jp>.

¹⁵ Jensen, R P, et al. Hidden Formaldehyde in E-Cigarette Aerosols, N. Engl J Med 2015; 372:392-392 (January 22, 2015) (see Proposal, ¶ 7).

¹⁶ Nitzkin JL, Farsalinos K, Siegel M. More on hidden formaldehyde in e-cigarette aerosols. N Engl J Med. 2015 Apr 16; 372(16):1575. doi: 10.1056/NEJMc1502242#SA1.

¹⁷ Farsalinos KE, Voudris V, Poulas K. E-cigarettes generate high levels of aldehydes only in 'dry puff' conditions. Addiction. 2015 May 20. doi:10.1111/add.12942.

¹⁸ Hajek, P, Etter, JF, Benowitz, N, Eissenberg, T, and McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Addiction, 109(11), 1801-1810, at 3.

¹⁹ Id.

²⁰ Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. Igor Burstyn. BMC Public Health (2014).

concentrations far lower than that of tobacco smoke, and also contain negligible concentrations of carcinogens. In terms of the potential for e-cigarettes to cause excess morbidity and mortality, the authors stated: "[H]ealth effects of long-term EC [e-cigarette] use are currently not known and a degree of risk may yet emerge. However, based on the data available regarding the toxicant content of EC liquid and aerosol, long-term use of EC, compared to smoking, is likely to be much less, if at all, harmful to users or bystanders. This is because unlike cigarettes, EC do not deliver combustion generated toxicants that are linked to cancer, chronic lung disease and cardiovascular disease (CVD)"²¹.

37. Another review of published e-cigarette vapour composition studies conducted in 2014 found that the "[c]urrent state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to *contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. . . . Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern"²².
38. The current situation on e-cigarette safety and risk profile is well summarised by Professor Britton and Dr. Bogdanovica in the Public Health England commissioned report on e-cigarettes: *"Overall however the hazards associated with use of products currently in the market is likely to be extremely low, and certainly much lower than smoking. They could be reduced further still by applying appropriate product standards."*
39. Nicoventures reiterates the points made above showing that vaping products do not expose users to any significant level of toxicants. Given the extremely low level of exposure to users, risk to bystanders is likely to be entirely insignificant. Indeed, a wide range of authorities have concluded that second hand vapour from vaping products poses negligible risks to the health of others.

2. Use of flavours

40. There are some in public health who are concerned about the potential unintended consequences of flavoured e-cigarettes in recruiting non-smokers, and particularly those underage into vaping and eventually smoking. These concerns are not substantiated by current evidence. Our proposed approach to flavoured e-cigarettes regulation is based on insights from population level consumer behaviour and on sound principles of toxicological risk assessment.
41. Evidence produced by a variety of organisations including ASH and the American Cancer Society (ACS) clearly shows that flavours do not entice non-smokers to use e-cigarettes. Researchers from

²¹ Hajek, P, Etter, JF, Benowitz, N, Eissenberg, T, and McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*, 109(11), 1801-1810, at 6.

²² Burstyn, I. (2014). *Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks*. *BMC public health*, 14(1), at 1. See also Nutt et al, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*. *Eur Addict Res* 2014;20:218–225 (attributing a relative harm score of 100 % for conventional cigarettes, while giving a score of 4% for electronic cigarettes (also known as "Electronic Nicotine Delivery Systems")).

the ACS found that flavours did not increase the attractiveness of e-cigarettes to teenagers. Rather, 'Even after controlling for other statistically significant correlates, the odds of a smoker being willing to try an e-cigarette were 10 times those of a non-smoker.' Tobacco cigarettes are the gateway to tobacco smoking, not e-cigarettes.

42. With reference to Action on Smoking and Health's (ASH) research, Deborah Arnott, Chief Executive of ASH, stated: "There is no evidence from our research that e-cigarettes are acting as a gateway into smoking." The research showed that regular use of e-cigarettes amongst children and young people is rare and is confined almost entirely to those who currently smoke or have previously smoked.
43. The ex-director of UK anti-smoking charity ASH-UK, Clive Bates has stated that "Non-users should understand that flavours are an important aspect of vaping and integral to the experience. They are also part of a migration away from tobacco. Initial switchers tend to favour tobacco flavours but gradually move on to non-tobacco flavours often as part of a permanent switch from smoking".
44. The EU TPD position on e-cigarette flavours is that: "It could be useful for Member States to consider the placing on the market of flavoured products. In doing so, they should be mindful of the potential attractiveness of such products for young people and non-smokers".
45. We recognise that this causes concern for some EU Member State policy makers who worry that certain flavours may be particularly appealing to young people and that eventually e-cigarettes use could act as a 'gateway' for young people starting to smoke traditional cigarettes. However, as cited above, current research at a population level in the UK (which has an estimated 2.1 million e-cigarette users) assures that these concerns are unfounded.
46. Our own approach to flavour risk assessment is to systematically evaluate flavours as a part of our product stewardship approach²³. We have presented and published this science in conferences and in a peer reviewed publication. We have also shared this with the wider industry, scientific and regulatory community so as to raise the quality and safety of e-cigarettes worldwide. This approach is now also part of the British Standards Institution's PAS 54115 on e-cigarette quality and safety.
47. In conclusion flavours are an integrated part of the appeal of e-cigarettes to smokers to encourage trial and switching out of smoking. Use of flavours in e-cigarettes should be allowed as long as they are not specifically targeted towards the underage and have been risk-assessed toxicologically.

²³ An approach to ingredient screening and toxicological risk assessment of flavours in e-liquids, Regulatory Toxicology and Pharmacology, July 2015, Costigan S and Meredith C,

3. Gateway

48. There is a concern among some in tobacco control that e-cigarettes are a "gateway" to eventual cigarette smoking, after e-cigarette users, and in particular youth, have become "addicted to nicotine through e-cigarettes". There is no meaningful data to support gateway concerns.
49. Instead, current evidence from the UK suggests this phenomenon is not occurring. Rather, the evidence shows that "[r]egular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible," and that "[r]egular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked"²⁴. Nationally representative survey data from the UK anti-smoking organisation ASH show that even having tried e-cigarettes is rare among children, particularly those under the age of 15²⁵.
50. Similarly, a recent review of the available research concluded that *"although there have been claims that EC [e-cigarette] is acting as a 'gateway' to smoking in young people, the evidence does not support this assertion. Regular use of e-cigarettes by non-smokers is rare and no migration from e-cigarettes to smoking has been documented (let alone whether this occurred in individuals not predisposed to smoking in the first place). The advent of EC has been accompanied by a decrease rather than increase in smoking uptake by children."*²⁶
51. At present, there is no indication that e-cigarettes are acting as a gateway into smoking; however this needs to be continuously monitored in the future.
52. Based on a review of the current evidence base on e-cigarettes, Prof. Britton and Dr. Bogdanovica state in a report commissioned by Public Health England (an executive agency of the Department of Health):

"Experimentation with electronic cigarettes among non-smoking children in the UK is currently rare, and only about 1% of 16 to 18-year-old never smokers have experimented to electronic cigarettes and few if any progress to sustained use. Furthermore, experimentation with electronic cigarettes should be considered in the context of current levels of experimentation with tobacco cigarettes, which in Great Britain currently generates a prevalence of smoking of 15% among 16 to 19-year olds, and 29% in 20 to 24-year olds."

"Experimentation with electronic cigarettes is most likely to occur predominantly in the same group that currently experiment with tobacco, as indeed is suggested by recent US

²⁴ ASH UK Fact Sheet May 2015, Use of electronic cigarettes (vapourisers) among adults in Great Britain; see also ASH UK Fact Sheet May 2015, Use of electronic cigarettes among children in Great Britain).

²⁵ ASH UK survey conducted by YouGov. ASH Briefing, November 2014, available at www.ash.org.uk.

²⁶ See Hajek 2014, citing US Center for Disease Control and Prevention. National Youth Tobacco Survey (NYTS). Smoking and Tobacco Use. 2012.

data. It is therefore relatively unlikely that availability and use of electronic cigarettes causes or will cause significant additional numbers of young people to become smokers than do at present.”²⁷

53. In conclusion, concerns about a “gateway” effect are entirely unfounded and contradicted by the available evidence.

²⁷ *Electronic Cigarettes: A report commissioned by Public Health England, May 2014*
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf

4. Dual Use

54. The International Tobacco Control Policy Evaluation Project, an international tobacco control project, found in its 4-country survey: *“Consistent with previous research, the majority of survey participants indicated that they used ENDS (e-cigarettes) to reduce the harm of traditional cigarettes or to help them quit traditional cigarettes.”*²⁸
55. *“The use of e-cigarette is largely confined to smokers and ex-smokers. Around 170,000 people (in the UK) may have replaced smoking (entirely) with e-cigarette use.”*²⁹ (May 2013)
56. In a study from Poland, cigarette consumption/day fell significantly following e-cig use. In the study, 50% of respondents reported >20 cig/day before starting e-cig use. Following e-cig use, only 2% of respondents reported >20 cig/day use³⁰
57. Experience in NRT suggests that those who use NRT whilst still smoking are more likely to make a quit attempt and ultimately have higher cessation rates³¹ – this may also be seen to operate with e-cigarettes.
58. Based on a review of the current evidence base on e-cigarettes, Prof Britton and Dr. Bogdanovica state in a report commissioned by Public Health England:

*“It has been suggested that there is a risk of sustained dual use among smokers who might otherwise have quit smoking completely, representing missed opportunities to achieve complete cessation. This concern clearly applies equally to NRT (nicotine replacement therapy products), which is licensed for what is in effect dual use and recommended on the grounds that dual use is likely to increase quit attempts. The concern is therefore inconsistent; if dual use is good as a pathway to quitting, that surely applies to dual use involving either NRT or electronic cigarettes.”*³²

²⁸ Adkison et al, American Journal of Preventive Medicine, 2013 ENDS International Tobacco Control Four-Country Survey

²⁹ Dockrell et al, Nicotine and Tobacco Research Journal May 2013, E-cigarettes: Prevalence and Attitudes in Great Britain

³⁰ Prof Jean-Francois Etter presentation referencing the findings from Goniewicz et al, Drug Alc Review, 2013. Prof Jean-Francois Etter, ‘E-cigarettes: The Vapor This Time’, 3rd October 2013 <http://www.trdrp.org/docs/Etter%20e-cig%20vapor%20this%20time%20slides%202013.pdf> (accessed on 20th February 2014)

³¹ Fagerstrom et al, Aiding reduction of smoking with nicotine replacement medications: hope for the recalcitrant smoker? Tob Control 1997; 6: 311–16

³² Electronic Cigarettes: A report commissioned by Public Health England, May 2014

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/E-cigarettes_report.pdf

5. Normalisation

59. The ASH-UK adult smoker survey:

“While we found evidence supporting the view that e-cigarette use may be a bridge to quitting, we found negligible evidence of e-cigarette use among those who had never smoked.”

60. They also make an observation:

“The failure to support and educate smokers on the effective use, risks, and benefits of e-cigarettes may represent a lost opportunity for public health”³³

61. From 11 surveys³⁴ in representative samples of the general population (UK, USA, New Zealand, Canada, Poland, Switzerland, and Czech):

- Ever use in never smokers: Range: 0.1 to 3.8%; Median: 0.5%
- Use in past 30 days, in never smokers: 0% to 2.2%; median 0.3%

62. Responsible advertising and appropriate targeting will be important in both avoiding accusation of a renormalisation agenda, and potentially maintaining this positive evidence.

63. Based on a review of the current evidence base on e-cigarettes, Prof. Britton and Dr. Bogdanovica dismiss any hazard of “re-normalisation” by state in a report commissioned by Public Health England (an executive agency of the UK Department of Health):

“Some argue that use of electronic cigarettes, which to a degree resembles cigarette smoking, in places where smoking is currently prohibited might re-normalize smoking and undermine tobacco control efforts. However, although similar in appearance, even cigalike products are easily distinguishable, both in appearance and smell, from tobacco cigarettes. Therefore, use of electronic cigarettes in smoke free places is more likely to lead to normalisation of nicotine devices than to smoking, and hence potential benefit as a support to existing well smoke-free policies.”³⁵

64. Concerns about “re-normalisation” are equally unfounded and contradicted by the available evidence.

³³ Dockrell et al, Nicotine and Tobacco Research Journal May 2013, E-cigarettes: Prevalence and Attitudes in Great Britain

³⁴ Summarised in Prof Jean-Francois Etter’s presentation: ‘E-cigarettes: The Vapor This Time’, 3rd October 2013
<http://www.trdrp.org/docs/Etter%20e-cig%20vapor%20this%20time%20slides%202013.pdf> (accessed on 20th February 2014)

³⁵ Electronic Cigarettes: A report commissioned by Public Health England, May 2014
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf

6. Addiction

65. An addiction is compulsive use in spite of adverse consequences for the user's health, family and social life.
66. E-cigarettes are increasingly regarded as significantly less risky than conventional cigarettes³⁶, and habitual use of e-cigarettes for nicotine consumption will not have the same individual and societal implications as nicotine addiction from conventional cigarettes.
67. Summaries of published studies³⁷ of vapers indicated:
 - E-cigarettes were perceived by users as less addictive than cigarettes.
 - Time (minutes) between waking up and time to first use was longer for e-cigs than for cigarettes.
 - Only 18% felt they craved e-cigarettes as much as tobacco

7. Public Place Vaping

68. First, e-cigarettes should not be subject to tobacco control regulations (i.e. not subject to smoke-free areas) as they do not present the same characteristics (vaping products do not contain tobacco, their use does not involve combustion and they do not generate smoke when used) as tobacco products. For this reason alone, the inclusion of vaping products in the definition of tobacco products is unwarranted.
69. This is particularly important. Those using e-cigarettes should not be forced into the same environment/space as smoking – a habit they have distanced themselves from or are trying to replace or quit.
70. E-cigarettes emit a smoke-like vapour and consequently some people mistakenly believe that e-cigarettes' vapour has the same risk profile as that of second hand cigarette smoke. Policymakers and lay people might therefore make ill-informed choices in terms of imposing the same public place restrictions on vaping as applied to cigarette smoking.

³⁶ Clive Bates has stated that "The growth of e-cigarettes has astonishing potential to erode the market for cigarettes and to meet the demand for nicotine with products that are likely to be two orders of magnitude (99%) less dangerous." Clive Bates, ex-director of ASH-UK, www.clivebates.com/documents/tpdecigarettes.docx (accessed on 20th February 2014)

³⁷ Prof Jean-Francois Etter's presentation: 'E-cigarettes: The Vapor This Time', 3rd October 2013 <http://www.trdrp.org/docs/Etter%20e-cig%20vapor%20this%20time%20slides%202013.pdf> (accessed on 20th February 2014).

71. Some concerns have been expressed in many ways on the potential impact of electronic cigarettes' vapour on users and bystanders. The main concerns expressed:

- Expose bystanders to harmful chemicals that might be contained in the vapour
- Undermine smoking bans by
 - a) "renormalizing smoking"
 - b) facilitating tobacco initiation by acting as a gateway into smoking
 - c) making smoking bans hard to enforce
- Sustain addiction by facilitating dual use and discouraging quit attempts

72. In addition to being different on the account of essential product characteristics, the risk profile of vaping products is fundamentally different from that of tobacco products. Based on scientific evidence on the contents of the e-cigarette vapour in a systematic review of the existing literature on vapour chemistry and toxicological reports on vapour constituents, Prof Igor Burstyn concludes that:

*"...Comparisons to the most universally recognized workplace exposure standards, Threshold Limit Values (TLVs), were conducted under "worst case" assumptions about both chemical content of aerosol and liquids as well as behaviour of vapers. The calculations reveal that there was no evidence of potential for exposures of e-cigarette users to contaminants that are associated with risk to health at a level that would warrant attention if it were an involuntary workplace exposures by approaching half of TLV... **Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.**"³⁸*

73. Studies have also been done on vaping in enclosed spaces. Findings are variable, but conclusions are relatively consistent³⁹:

- The content of inhaled vapour is in comparison to that of a cigarette, of much lower potential toxicity, with concentrations of major toxicants 9 to 450 times less (Goniewicz et al 2013).
- A study using machine vaping demonstrated VOCs (Volatile Organic Compounds) and polyaromatic hydrocarbons (PAHs) largely below limits of detection (McAuley et al 2012).
- Particle emissions and nicotine concentrations in ambient air are an order of magnitude lower than from cigarettes (McAuley et al 2012, Czogola et al 2013).

³⁸ *Peering through the mist: What does the chemistry of contaminants in electronic cigarettes tell us about health risks? Dr Igor Burstyn, Drexel University, PA, USA. Aug 2013*

³⁹ *Goniewicz ML. et al. (2013) Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tobacco Control 23(3)*

McAuley TR. et al. 2012. Comparison of the effects of e-cigarette vapour and cigarette smoke on indoor air quality. Inhalation Toxicology 24(12) pp. 850-857

Czogola J. et al. (2013) Secondhand Exposure to Vapors From Electronic Cigarettes. Nicotine and Tobacco Research `

- Where stated, overall toxicological analysis of results and impact on air quality showed no expected health impact from compounds identified (McAuley et al 2012).

74. ASH UK has made its position clear on why smoke free legislation should not be extended to public place vaping:

"In the UK smoke free legislation exists to protect the public from the demonstrable harms of second hand smoke. ASH does not consider it appropriate for electronic cigarettes to be subject to this legislation, but that it should be for organisations to determine on a voluntary basis how these products should be used on their premises".⁴⁰

8. Are people using e-cigarettes to cut down and/or quit?

75. There is emerging evidence from around the world regarding growing use of e-cigarettes by smokers as a substitute for conventional cigarettes. This evidence is based on population level surveys of representative samples (e.g. ASH UK surveys, Professor Robert West's Smoking Toolkit Study data) and randomised controlled clinical trials using e-cigarettes for smoking cessation (e.g. Dr. Bullen's clinical trial in New Zealand, Prof. Polosa's ECLAT study in Italy). Large sample-sized surveys from e-cigarette forums (e.g., a worldwide survey of over 19,000 e-cigarette users published by Dr. Farsalinos) also confirm that e-cigarettes are indeed proving effective as a substitute for conventional tobacco cigarettes.

a) Randomised controlled clinical trials

76. There are already two published randomised controlled clinical trials that suggest that e-cigarettes may prove efficacious as a smoking cessation aid.

77. Dr. Chris Bullen's e-cigarette clinical trial in New Zealand: A team at the University of Auckland, New Zealand, led by smoking cessation expert Dr. Chris Bullen, conducted a clinical trial comparing e-cigarettes with nicotine patches in 657 people. The results published in the Lancet, a very prestigious medical journal, showed 7.3% using e-cigarettes had quit after six months compared with 5.8% using patches. Also, after six months, 57% of e-cigarette users had halved the number of cigarettes smoked each day compared with 41% in those using patches.

78. Professor Riccardo Polosa's ECLAT trial in Italy: In a prospective 12-month randomised, controlled trial that evaluated smoking reduction/abstinence in 300 smokers not intending to quit smoking, Prof Polosa found that the use of e-cigarettes, with or without nicotine, decreased cigarette consumption and elicited enduring tobacco abstinence without causing significant side effects. In this study, smoking reduction was documented in 22.3% and 10.3% at week-12 and week-52 respectively. Complete abstinence from tobacco smoking was documented in 10.7% and 8.7% at week-12 and week-52 respectively.

⁴⁰ Electronic cigarettes (also known as vapourisers) ASH Briefing June 2014
http://www.ash.org.uk/files/documents/ASH_715.pdf

79. The findings from published clinical trials of e-cigarettes are summarised in the Cochrane Review⁴¹ led by Prof Peter Hajek: "Combined results from two studies... showed that using[e-cigarette] containing nicotine increased the chances of stopping smoking long-term compared to using an [e-cigarette] without nicotine. Using an [e-cigarette] with nicotine also helped more smokers reduce the amount they smoked by at least half compared to using an [e-cigarette] without nicotine...This study showed that people who used [e-cigarettes] were more likely to cut down the amount they smoked by at least half than people using a patch. The other studies were of lower quality, but they supported these findings. There was no evidence that using [e-cigarettes] at the same time as using regular cigarettes made people less likely to quit smoking" .
- b) Worldwide survey of e-cigarette users
80. Dr. Farsalinos' team conducted an online questionnaire in 10 languages and had a total of 19,441 participants from around the world. This was the first such globally comprehensive survey of e-cigarette users, and confirmed findings from national surveys and randomised controlled clinical trials. The key finding from this survey was that over 15,000 vapers (80%) of the respondents had quit smoking altogether using e-cigarettes. One key finding was the improvement in the quality of life of the smokers who had quit using e-cigarettes, and e-cigarettes helped these former smokers remain smoke free. These findings give a compelling insight into the real-world safety and effectiveness of e-cigarettes as a smoking substitute.
81. Some of the abovementioned studies and survey findings are based on older products, and as the quality and performance of e-cigarettes keep on improving in newer generations of products, it is expected that their effectiveness as a cigarette substitute will improve even further.

⁴¹ McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. *Cochrane Database of Systematic Reviews* 2014, Issue 12. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub2.

H. GROWING PUBLIC HEALTH SUPPORT

83. If the Quebec Government wishes to furthermore reduce the smoking rate, consideration ought to be given to a recent letter on e-cigarettes that was addressed to the World Health Organisation.
84. Aligning with global public health sentiment, more than fifty leading public health experts, including five Canadians – Dr. Gaston Ostiguy, Dr. Martin Juneau and Professors David Sweanor, Tim Stockwell and André Castonguay (Prof. Emeritus) –, wrote to the Director-General of the World Health Organisation in support of tobacco harm reduction products such as vaping products. The letter articulates the benefits of e-cigarettes stating that: *“Tobacco harm reduction allows people to control the risk associated with taking nicotine and to reduce it down to very low or negligible levels”*⁴² *“[...] these products could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives.”*⁴³ Importantly, these experts urged the WHO to resist the urge to control and suppress vaping products as tobacco products, arguing instead for regulation that is “fit for purpose.”
85. Echoing this view is a significant recent review by Prof. Peter Hajek et al; *“EC (electronic cigarette) reduce urges to smoke and there is preliminary evidence that EC use facilitates both quitting and reduction in cigarette consumption in smokers interested in quitting smoking. In England, which has the most detailed data on EC and cigarette use, the growth in EC use has been accompanied by an increase in smoking cessation rates, a continued reduction in prevalence and no increase in smoking uptake”*.⁴⁴
86. Further recent research from Belgium demonstrates the real world effectiveness of e-cigarettes in a population of smokers who are not motivated to quit tobacco.⁴⁵ The study’s conclusion was that e-cigarette use resulted in *“remarkable reductions in or (biologically confirmed) complete abstinence from tobacco smoking in almost half of the participants [44%] who had no intention to quit smoking.”* Support for e-cigarette use can also be found in the tobacco control community.
87. Groups such as Action on Smoking and Health (ASHUK) recently stated that:

“...the harm from smoking is caused primarily through the toxins produced by the burning of tobacco. By contrast, non-burnt pure nicotine products, although addictive, are considerably less

⁴² Letter to WHO Director from 53 Specialists in nicotine science and public health policy, 26th May 2014. Link: <http://nicotinepolicy.net/documents/letters/MargaretChan.pdf>

⁴³ Id.

⁴⁴ Hajek P, Etter J-F, Benowitz N, Eissenberg T, McRobbie H. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*. 2014;31 July. doi:10.1111/add.12659.

⁴⁵ Adriaens K, Van Gucht D, Declerck P, Baeyens F. Effectiveness of the Electronic Cigarette: An Eight-Week Flemish Study with Six-Month Follow-up on Smoking Reduction, Craving and Experienced Benefits and Complaints. *International Journal of Environmental Research and Public Health*. 2014; 11(11):11220-11248

harmful. Electronic cigarettes consequently represent a safer alternative to cigarettes for smokers who are unable or unwilling to stop using nicotine.”⁴⁶

Concerns about e-cigarettes have been addressed

88. Nicoventures notes that some commentators have voiced concerns about e-cigarette use. Accordingly, Nicoventures encourages the Health Protection Service to consider the real world evidence that addresses these concerns:

- British Government Office of National Statistics data⁴⁷ show that e-cigarettes are not acting as a ‘gateway’ to smoking. There, e-cigarette use by non-smokers is 0.14% of the population.⁴⁸
- ASHUK evidence indicates that use by those under the age of 18 is ‘rare’.⁴⁹
- ASHUK in a review of public place vaping states that *“In relation to electronic cigarettes the current evidence would not support legislation to prohibit their use in workplaces on the basis of the harm caused by their second-hand vapour”*.⁵⁰

89. Further evidence refuting concerns about e-cigarettes can be found in several extensive independent reviews published during 2014 for the English Department of Health and in the journal ‘Addiction’.^{51 52 53}

⁴⁶ Action on Smoking and Health UK, “Electronic Cigarettes”, March 2014,
http://www.ash.org.uk/files/documents/ASH_715.pdf

⁴⁷ http://www.ons.gov.uk/ons/dcp171778_386291.pdf

⁴⁸ *Ibid.*

⁴⁹ http://www.ash.org.uk/files/documents/ASH_891.pdf

⁵⁰ http://www.ash.org.uk/files/documents/ASH_900.pdf

⁵¹ Hajek P, Etter J-F, Benowitz N, Eissenberg T, McRobbie H. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*. 2014;31 July. doi:10.1111/add.12659.

⁵² www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf

⁵³ *Ibid*

I. A GROWING MARKET

90. Given the embryonic nature of the category in Canada, market data is limited. However, one thing is clear; the category is established and growing very quickly and vaping products are being used increasingly. The 2013 Canadian Tobacco, Alcohol and Drugs Survey (CTADS) found that 2.5 millions of Canadians of 15 and older have tried vaping products, while 521,000 reported past 30 day use.⁵⁴
91. Canada's e-cigarette trends are generally echoing what was seen in more mature e-cigarette markets like Great Britain and the US; there is definitely significant demand from Canadians for these products.
92. Despite the fact that no ENDS have been approved for sale by Health Canada at this time and that e-cigarettes with nicotine are illegal for sale in Canada due to a lack of enforcement, the e-cigarette market is consistently growing. Awareness and usage of e-cigarettes in Canada is growing in a similar pattern to Great Britain, the USA and Australia.

Australia market

93. Australian tobacco control expert Prof. Ron Borland compared the British and Australian experiences of smokers and former smokers. His research shows that use of e-cigarettes among Australian respondents increased from 0.6% in 2010 to 6.6% by 2013.⁵⁵

UK market

94. In the UK, use increased from 4.5% to 18.8% in the same period.⁵⁶
Action on Smoking and Health (ASH) estimated there were 1.3 million current users of e-cigarettes in Britain. This number is almost entirely made-up of current and ex-smokers; with as many as 400,000 people having replaced smoking with e-cigarette use.⁵⁷

USA market

95. The USA accounts for a majority of global e-cigarette sales, with 58 per cent.⁵⁸ Morgan Stanley tobacco analyst David Adelman estimated that e-cigarettes would take the place of around 1.5 billion cigarettes in the US in 2013, up from around 600 million in 2012.⁵⁹

⁵⁴ Canadian Tobacco, Alcohol and Drugs Survey (CTADS), Summary of Results for 2013. Available at: <http://healthycanadians.gc.ca/science-research-sciences-recherches/data-donnees/ctads-ectad/summary-sommaire-2013-eng.php>

⁵⁵ Yong HH, Borland R, Balmford J, et al. Trends in e-cigarette awareness, trial, and use under the different regulatory environments of Australia and the UK. *Nicotine Tob Res*. 2014.

⁵⁶ Ibid.

⁵⁷ Action on smoking and health, 2014, ASH Briefing: Electronic Cigarettes. Report. Available at: http://ash.org.uk/files/documents/ASH_715.pdf

⁵⁸ Azer et al., April 2013, "Disruptive Innovation: Ten things to stop and think about". Citigroup. http://www.academia.edu/4943184/Citi_DISRUPTIVE_INNOVATION_Ten_Things_to_Stop_and_Think_About

⁵⁹ Ro S., April 2013, *Chart of the day: E-Cigarettes Are A Small, But Rapidly Growing Problem For Big Tobacco*. Article. <http://www.businessinsider.com.au/chart-e-cigarette-growth-2013-4>

III. LEGISLATING E-CIGARETTES

96. Taking note of this growing demand for e-cigarettes in Canada, and concerned that the e-cigarettes that smokers buy as a safer alternative to tobacco products, or to help them quit or reduce smoking do not meet any prescribed and appropriate quality standards, Nicoventures strongly recommends to the Quebec Government that it demands prompt federal action in the area of product regulation for e-cigarettes. In addition, recognizing the unique nature of e-cigarettes, Nicoventures supports the Government's desire to introduce a legislative framework.

97. However, we believe that Bill 44 is premature and that its proposal to regulate ENDS as combustible cigarettes is misguided. The proposed legislation of vaping products as tobacco products is also premature given that it does not take into account the ongoing debate at the federal level. In fact, working in cooperation with the Canadian Government towards developing a new comprehensive regulatory framework for vaping products would better serve the interests of public health. These products are not tobacco products and offer a unique opportunity to reduce the burden of smoking-related diseases.

A. A PROGRESSIVE APPROACH TO E-CIGARETTES EXISTS IN SIMILAR JURISDICTIONS

98. In adopting efficient and effective approaches for making these products available to smokers while maintaining consumer safety, the British Government was at the forefront of developing e-cigarette regulation.^{60 61} In November 2014 the British Standards Institute published a publicly available specification for the manufacture, importation, testing, and labelling of vaping products, including e-cigarettes, e-shisha and directly-related products⁶² and in October 2014 the British Advertising Standards Authority published rules on the advertising of electronic cigarettes.⁶³

99. The British Government believes that by regulating e-cigarettes, it will ensure that *"high-quality products can be made available to help support smokers to cut down their smoking and to quit"*.⁶⁴ Accordingly, e-cigarettes are the most common quitting aid used by smokers in that country.⁶⁵

⁶⁰ <http://www.bbc.com/news/health-22870301>

⁶¹ <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Productspecificinformationandadvice%E2%80%93M%E2%80%93T/NicotineContainingProducts/index.htm>

⁶² <http://drafts.bsigroup.com/Home/Details/53856>

⁶³ <http://www.cap.org.uk/News-reports/Media-Centre/2014/New-ecig-ad-rules.aspx>

⁶⁴ Ibid.

⁶⁵ West, R. Electronic cigarettes in England: latest trends. Smoking Toolkit Study. 8 April 2014.

B. PRINCIPLES FOR A CANADIAN REGULATORY FRAMEWORK

1. Our preferred regulatory future

100. Products manufactured by Nicoventures are not yet available in Canada. For us to enter a market, governments need to establish a legal and regulatory framework that establishes a safe environment for adult smokers to transition away from harmful tobacco products.
101. In referencing the British experience, and that from other countries such as Germany,⁶⁶ at a top-line, a model regulatory framework would contain the following elements:
- Sale of e-cigarettes should be restricted to adults only.
 - E-cigarettes should meet mandated national quality standards and be child resistant
 - E-cigarettes should not be subject to tobacco control regulations (i.e. not subject to smoke-free areas)⁶⁷
 - E-cigarettes should be at least as freely available as tobacco products and nicotine replacement therapies such as patches and gums
 - E-cigarettes should be cheaper to purchase than tobacco products⁶⁸
 - Subject to appropriate restrictions, e-cigarettes should be allowed to be advertised

2. Principles for a regulatory framework

102. More precisely, set out below are the principles on which we believe the regulatory framework for e-cigarettes should be based:

1. Ban sales to minors

103. Most electronic nicotine delivery systems (ENDS) contain nicotine, and addictive substance. Given this fact, ENDS should not be sold to minors. The only exception that could be considered is a situation where under a supervised treatment against tobacco use a physician could prescribe medical or natural product classified e-cigarettes.

2. Product Standards

104. Proper national product standards need to be introduced to reassure smokers and regulators that the products on the market meet appropriate criteria with regards to quality and safety. The standard should include provisions related to e-liquid content, aerosol content, product stability, content labelling, device safety and child resistance. We are working with National standards bodies (e.g. the UK BSI, France' AFNOR, European CEN) technical committees to set and raise the product quality and safety standards across the industry.

⁶⁶ <http://ecigintelligence.com/untangling-case-law-a-special-report-overview-of-the-german-e-cigarette-sector/>

⁶⁷ This is particularly important those using e-cigarettes should not be forced into the same environment as smoking – a habit they have distanced themselves from.

⁶⁸ <http://www.rcplondon.ac.uk/press-releases/rcp-comment-regulation-nicotine-containing-products>

3. Appropriate marketing freedoms

105. With the growing acceptance among public health professionals of the potential of nicotine containing products to aid smoking reduction and cessation or to be a safer alternative to tobacco products, we believe that it makes sense to permit broad freedoms for marketing to adult smokers and users of other nicotine products. Informing adult smokers of the various products and options available is key to transitioning a larger amount of smokers to a safer alternative. However given that they contain an addictive substance we also believe that appropriate restrictions on marketing to children should be part of the regulatory regime.

4. Availability of a wide range of flavours

106. An important quality that appeals to adult smokers wanting to transition away from tobacco is a product that has flavours they like. In fact, consumer tests show that an important number of smokers don't find the taste of tobacco ENDS appealing preferring other flavours. Thus the market across the world has adapted to adult smokers by offering a variety of flavours including sweet, candy or fruit. These flavours should be made available.

5. Distribution freedoms

107. In order for ENDS to fulfil their true potential as a safer replacement to cigarettes, they have to be widely available in all the retail channels where smokers today buy their cigarettes, as well as on the Internet.

6. Innovation Freedoms

108. The category is still relatively young and product improvement and innovation will further enhance functionality and quality over time. Consequently, there should be regulatory oversight by a competent national body which provides comfort that the product standards are being complied with, but does not impede swift and flexible innovation.

7. Taxes

109. ENDS are not tobacco products and are significantly less risky alternatives to smoking tobacco. We believe that if tax is to be applied, it should be a specific tax levied on the quantity of e-liquid sold (i.e. not on the device or the number of puffs per device); it should be commensurate with the lower risk profile of e-cigarettes vis-à-vis conventional cigarettes; and it should be simple to collect and not stifle the innovation of e-cigarettes.

C. QUEBEC'S BILL 44 – SPECIFIC COMMENTS

110. Introduction of Bill 44 at this time is premature. We believe national standards should be developed based on a federal regulatory framework established prior to the development and implementation of provincial regulations. However, should the Quebec Legislation decide to move forward, we would like to offer hereafter specific comments on the proposed Bill.

1. Standalone regulatory regime

111. We would like to reiterate that ENDS or electronic-cigarettes are not tobacco products. They should be dealt with in separate, specific, standalone regulatory regime.
112. We do not think it makes sense for e-cigarettes to be regulated in the same way as tobacco products as they contain no tobacco and are substantially less risky than cigarettes. Currently, various regulators are considering whether e-cigarettes should be treated as medicines or as general consumer products. However, we do not think that the existing strict medicines regimes in many countries or current consumer product regulations are appropriate without modifications which take into account the specifics of this new category.
113. Different e-cigarettes in the market have varying risk profiles. Expecting e-cigarettes to be totally risk-free may perhaps be unrealistic; however, the key point is whether these products are significantly less risky than traditional cigarettes. Our product stewardship work before market launch and our proposed product safety and quality standards for the industry and regulators are expected to address and mitigate these risks. Manufacturers should be required to make reasonable efforts to minimise the probability of causing harm to the users and those around them, through product design, labelling and marketplace practices.
114. Specifically we want to see a regulatory regime that puts product quality and consumer safety first whilst at the same time allowing for swift innovation, and for distribution and appropriate marketing freedoms which will promote the growth of the category.

2. Selling or supplying to persons under 18

115. We fully agree that ENDS should not be sold to minors.

3. Display and promotion

116. As ENDS are a new product category and that Quebec should be seeking to greatly reduce health risks and promote harm reduction to current tobacco users, communications to consumers of tobacco products is essential.

- We suggest no advertising or promotion to minors.
- We ask that information, promotion and display of ENDS products at points of sales should be allowed, and even encouraged, to adult tobacco users in order to invite them to switch to ENDS.
- We request that ENDS products not be hidden at points of sale, but be placed in plain sight.

4. Availability /Sales

117. ENDS should be available anywhere tobacco products are currently offered and beyond.

- In some jurisdictions, ENDS products have been recognized by national health departments as harm reduction tools. As non-tobacco products, it would be appropriate to have them widely available, including in pharmacies and other points where other nicotine-containing products are sold.

5. Signs in retail stores

118. As ENDS are a new product category and that Quebec should be seeking to greatly reduce health risks and promote harm reduction to current tobacco users, communications to consumers of tobacco products is essential.

- We suggest allowing reasonable signage freedoms in stores, in order to better inform consumers.

6. Packaging

119. Laws and regulations on packaging should be left to the Canadian government to regulate. A consistent regulatory regime should exist throughout the country, not a patchwork of different provincial regulations.

7. Flavoured electronic cigarettes

120. Most tobacco users don't particularly enjoy the taste of tobacco ENDS. Although this article is not yet applicable to electronic cigarettes, we insist on the fact that a wide variety of flavours should be and remain in the offering.

- We suggest that the spectrum of flavours remains as wide as possible to increase acceptability with adult consumers.

8. Prohibition / Public place vaping

121. Studies show that ENDS are not only a much safer alternative to tobacco products, but that secondary vapour is to a greater degree even less harmful than secondary smoke. Hence, we believe a smoke free legislation should not be extended to public place vaping.

IV. CONCLUSION

122. The proposed legislation of vaping products as tobacco products overlooks the fundamental nature of vaping products. It fails to take into account the fact that because vaping products do not contain tobacco, do not involve combustion of tobacco, and do not generate smoke, they likely present minimal health risks to users and non-users alike.
123. The observation that the Bill does not take into account the evidence of what vaping products are and what role they can play in public health stresses the need to review and rely that much more on the available current evidence, most of which helped develop legislative frameworks in other parts of the world.
124. From the outset, and for the reasons set out in the preceding sections, Nicoventures believes that the proposal to include vaping products in the definition of tobacco products should be abandoned.
125. While we support the Quebec government's desire to introduce a regulatory framework for e-cigarettes, we believe that Bill 44 is premature and its proposal to regulate ENDS as combustible cigarettes is misguided. Nicoventures' view is that if appropriately regulated, e-cigarettes can have a positive impact for smokers wishing to quit, reduce smoking or use a safer alternative to tobacco products.
126. We encourage federal and provincial Governments to work together in order to have a regulatory regime that can assure a predictable and interesting market for industry and a safe environment for adult smokers to transition away from harmful tobacco products.
127. We believe that by manufacturing ENDS that respect the highest product standards (e.g. using pharmaceutical grade nicotine), by checking and testing the quality of vapour for every e-liquid crafted, every blend of flavour and every device manufactured, we can help support individuals in their desire to use a safer alternative to tobacco products.
128. As such, we reiterate the importance to seek national standards based on a federal regulatory framework that would be established prior to the development and implementation of provincial regulations. In the meantime, we invite Quebec to request that the federal government enforces the existing directives to prevent the illegal sale of ENDS.
129. We appreciate the opportunity to have been able to submit these arguments and hope we have addressed the concerns and helped inform regulators in their process to develop an appropriate regulatory framework that reflects the harm reduction potential of ENDS. Nicoventures would be very happy to provide any further details or information that the Committee might require.

V. BACKGROUND ON NICOVENTURES

130. Nicoventures⁶⁹ is engaged in the development and sale of innovative and high-quality e-cigarette products that meet relevant regulatory requirements. Its efforts are exclusively aimed at bringing quality nicotine products to adult smokers. The Nicoventures team has extensive pharmaceutical experience of nicotine replacement therapy (NRT) coupled with an understanding of smoking behaviour, which we believe will be of immeasurable value in providing consumers with products that they want to use and that are substantially safer alternatives in comparison with their usual cigarettes.
131. Nicoventures currently manufactures e-cigarettes and e-liquids that contain pharmaceutical grade nicotine, water, propylene glycol and/or glycerol and flavours. It currently sells e-cigarette products under the "VYPE" brand (specifically, the VYPE "eStick" e-cigarette and the "ePen" vapour pen). VYPE products at present are sold only in the United Kingdom.
132. Products manufactured by Nicoventures are not yet available in Canada.

⁶⁹ Nicoventures is a wholly owned subsidiary of British American Tobacco, which is managed separately from BAT's tobacco business.