

Brief for House of Commons of Canada Standing Committee on Health

A disruptive public health technology threatened by excessive regulation

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What are they? E-cigarettes generally consist of a battery, a heating coil and a liquid containing nicotine. Drawing on the e-cigarette triggers a pressure sensitive switch that activates the battery to heat the coil, which vaporises the liquid. This is then inhaled and the nicotine absorbed into the blood via mouth, throat and lungs. The liquids contain nicotine, water, a 'diluent' such as propylene glycol or glycerol, and a flavouring, such as tobacco, mint, vanilla or fruit. There are now hundreds of flavours and these are an intrinsic part of the appeal. The devices and the liquids can be sold as integrated units or separately. Some look like cigarettes (1st generation 'cig-a-likes' in the jargon), some look like pens (2nd generation 'Ego' type), and the larger ones with tanks can look very distinctively different (3rd generation 'tanks' or 'mods'). The products have emerged only recently due to advances in batteries, which can now provide sufficient power and battery life in a small unit.

Public health case. In 2013, 19.3% of Canadians aged 12 and older, roughly 5.7 million people, smoked either daily or occasionally. Worldwide about 1.3 billion people smoke and this is rising, with population and income growth. The current annual premature death tolls attributed to smoking are 37,000 in Canada and six million world-wide. WHO estimates one billion premature deaths from smoking in the 21st Century on current trends. The public health proposition is that: (1) e-cigarettes can substitute for cigarette use in the market for recreational nicotine; (2) provide a satisfactory alternative to smoking; (3) in doing so, dramatically reduce risks to health, likely by 95-100% among those who switch; (4) the risks of harmful unintended consequences are low and so far unsupported by evidence. The alternative public health approach is to insist that smokers quit smoking and nicotine altogether. But this strategy simply does not work for many smokers because they cannot or do not want to quit smoking. The public health case for e-cigarettes involves a major disruption of the continuing market for tobacco: global tobacco sales are variously estimated at \$700-800 billion (Bloomberg), mainly cigarettes, whereas sales of vapour products are no more than \$5 billion in 2014 (Euromonitor) – there is scope for a major structural change in the market for recreational nicotine that could make substantial inroads into the billion deaths projected by WHO.

The benefits to the smoker. From the smoker's perspective, e-cigarettes create a new value proposition. They offer many of the experiences of smoking (a nicotine hit, something to hold and gesture with, sensory experience etc) with few of the harms (long term risk much lower, less social disapproval, minimal odour nuisance) and at a lower cost. Prior to the emergence of e-cigarettes, the alternatives were broadly cast as 'quit or die' – this new value proposition fits between the two.

Harm arising from vaping. No-one claims vaping is entirely benign. Nor does it need to be to make very large inroads into the risks of disease if people switch from smoking. Studies of liquids and vapour chemistry reveal traces of contaminants and thermal breakdown products that are potentially harmful, but at levels generally two orders of magnitude lower than in cigarette smoke and unlikely to pose a material threat. Critics of e-cigarettes routinely cite studies suggesting

presence of harmful substances, but risk is determined by exposure, not merely by the presence of a hazardous substance – which are present in just about everything we consume at low levels. The most comprehensive literature review so far concluded¹:

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. ... Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.

Do e-cigarettes help people to quit smoking?The most comprehensive study so far of ‘real world’ use of e-cigarettes showed²

People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies such as patches or gum

Survey data commissioned by Action on Smoking and Health in the UK³ also supports a good news story about people quitting smoking –perhaps as many as 700,000 in Britain (about 7% of smokers):

ASH estimates that there are currently 2.1 million adults in Great Britain using electronic cigarettes, Of these, approximately 700,000 are ex-smokers while 1.3 million continue to use tobacco alongside their electronic cigarette use. Electronic cigarette use amongst never smokers remains negligible

What is the potential?One Wall Street analyst projects that vapour use will surpass smoking (in the US) within a decade (by which she means 2023)⁴ Much will depend on whether regulation encourages or suppresses innovation – and her forecast is contingent on an effective pro-innovation regulatory framework. Other analysts are less bullish, but all see great potential.

What are critics concerned about?Most opponents of e-cigarettes are slowly giving up the argument that ‘we don’t know what’s in them’ or concerns about the safety of the products themselves. They are instead concentrating on ‘population’ arguments. This is the idea that though vaping is very much less hazardous than smoking, at population level it could be *more dangerous* because it causes changes in the way people smoke, for example:

- It could be a ‘gateway’ to smoking for adolescents;
- It might divert people from quitting smoking because they don’t feel under so much social pressure if they can avoid smoking restrictions by vaping;
- By visible displays of smoking-like behaviour it might ‘renormalise’ smoking.

¹ Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health* 2014;**14**:18. doi:10.1186/1471-2458-14-18[[Link](#)]

² Brown J, Beard E, Kotz D, Michie S, and West R (2014) Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. *Addiction*109: doi: [10.1111/add.12623](#).

³ ASH (UK) Use of electronic cigarettes in Britain, July 2014 [[link](#)]

⁴ Cited in The Economist, Kodak moment, 23 September 2013. [[link](#)]

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There is no basis to believe any of these effects are real rather than tactical campaign arguments. The UK's foremost experts in smoking cessation who manage the surveillance of the market in nicotine products concluded⁵:

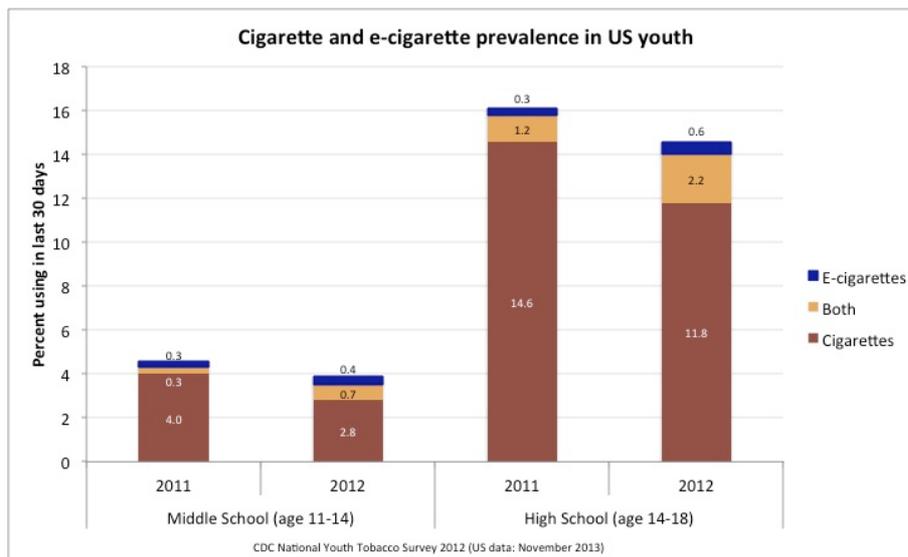
Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or 'renormalizing' smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking

The more plausible hypothesis is that e-cigarettes will function as an alternative to smoking; a gateway exit from smoking, and will normalise safer alternatives to smoking. The critics who use these population arguments to not have convincing explanations for how they would work in practice.

Gateway effects. Many activists and some public officials have pointed to rising e-cigarette use among adolescents and suggested they pose a 'gateway' risk: that they will lead somehow lead to more smoking. For example in 2013, much media coverage was created in the United States over National Youth Tobacco Survey Data showing a rise in e-cigarette use⁶.

This raises concern that there may be young people for whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes.

In fact the data show do not support a gateway effect, and a rise in use among adolescents would be expected to mirror the rise in use among adults. In reality, US teenage smoking prevalence fell sharply as e-cigarette use increased and e-cigarette use was concentrated among existing smokers⁷. Similar effects were found in France⁸. The relevant data are shown in the chart below.



⁵ West R. Brown J, Beard E. *Trends in electronic cigarette use in England*. Smoking Tool Kit Study. 13 June 2014 [\[link\]](#)

⁶ CDC E-cigarette use more than doubles among U.S. middle and high school students from 2011-2012, 5 September 2013 [\[link\]](#)

⁷ CDC MMWR Tobacco Product Use Among Middle and High School Students — United States, 2011 and 2012, 15 November 2013. [\[link\]](#)

⁸ Survey reported in English on *Le blog de Jacques LeHouezec*, 16 May 2014. [\[link\]](#)

Establishing gateway effects. To establish a gateway effect is in practice difficult. It is necessary to show that a period of e-cigarette use is the *reason* why someone develops a consolidated smoking habit. It is not sufficient to show rising e-cigarette use coincided with rising smoking⁹ – there could be independent reasons for these trends, or a common factor driving them. Nor is sufficient to show that a person used e-cigarettes first and then took up smoking – in the absence of e-cigarettes they may have simply started to smoke. It is also possible that e-cigarette use in adolescents is protective – preventing or diverting the onset of a consolidated cigarette smoking habit. Some care is required in drawing causal conclusions from observational data on e-cigarette use.

The case of snus – a cautionary tale. Many of the same ‘population’ arguments were made on a precautionary basis in the case to ban ‘oral tobacco’ in 1992 throughout the EU, even though it is 95-100% less hazardous than smoking. On accession, Sweden was granted an exemption from the ban. In fact, this product is the reason why Sweden has by far the lowest rate of smoking in the EU: 13% Swedish adults vs 28% EU average¹⁰. Snus has three main effects in Sweden and Norway: it is used to quit smoking; it is used to substitute for smoking; it diverts young people from onset of smoking.

Fear of the tobacco industry. A further source of critics’ concern is the possible negative role of the tobacco industry. In practice it is hard to see what this could be: the industry’s long-standing business model is threatened by e-cigarettes. To survive the disruption they will need to enter the market and produce high quality attractive alternatives to smoking or risk losing share in the recreational nicotine market to other tobacco or non-tobacco e-cigarette companies. It is more likely that they will become important drivers of a wholesale switch from smoking to vaping. Paradoxically, the danger from tobacco companies may arise from excessively burdensome regulation, eliminating competition from more agile or innovative competitors, leaving them with an oligopoly protected by regulatory barriers to entry.

To summarise: a market based public health phenomenon. The electronic cigarette has emerged through the interplay between consumers and innovative suppliers, with no public sector involvement or endorsement, no call on the taxpayer or health system resources, and minimal regulation. Yet this product is already providing very substantial health benefits. It has empowered smokers to take control of their risks and has greatly enhanced the welfare of hundreds of thousands of UK citizens. It has challenged the tobacco industry, but also interests in the public sector and civil society who have played no role – or a hostile role – in its rise.

Regulatory issues

The primary risk to these otherwise highly positive developments is poor and excessive regulation. At the heart of the regulatory challenge there is a ‘double negative’: being tough on e-cigarettes is being tough on the competitive alternative to cigarettes. There is a danger that loss-averse regulators will place excessive focus on the residual risks associated with vapour products, but in doing so render them less effective and appealing as alternatives to smoking and thereby increase total health risks through the unintended consequence of continuing smoking.

⁹ Goniewicz ML, Gawron M, Nadolska J, Balwicki L, Sobczak A. Rise in Electronic Cigarette Use Among Adolescents in Poland. *J Adolesc Heal* 2014; 55: 713–5.

¹⁰ European Commission, [Special Eurobarometer 385](#), Attitudes of European Citizens to Tobacco, March 2012

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Risks of unintended consequences. The following table illustrates how it is possible for regulatory measures to have unintended harmful consequences:

Policy proposal	Unintended consequence
Ban e-cigarette use in public places	Diminishes value proposition of e-cigarettes to users and 'denormalises' a much less risky option, diminishes the appeal of vaping relative to smoking, May promote relapse in existing vapers if they join smokers outside. Likely to lead to more smoking.
Restrictions on advertising, promotion and sponsorship	Reduces capacity of e-cigarette brands to compete with cigarettes, and diminishes means to communicate value proposition to smokers. May reduce means to communicate innovation or build trusted brands. May turn ads into bland public information notices. Some restrictions are undoubtedly justified, but the negative effects should always be considered.
Product design	There are numerous subtle trade-offs in product design. For example, the perfectly safe product that no-one wants to buy may be <i>worse</i> for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions, slow innovation and drive good products and firms out of the market through 'regulatory barriers' to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies. Regulation can adversely reshape the market.
Ban flavours	All e-cigarettes and liquids are flavoured with something – and this forms a key part of the appeal. Many former smokers report switching to non-tobacco flavours as a way of moving permanently away from smoking. There is significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, development of DIY and black market flavours – which may be more dangerous
Ban flavours that appeal to kids	It is a common mistake in public health to believe that adolescents are attracted to things that adults regard as child-like, such candy-flavours. Adolescent experimentation is often about emulating adults or rejecting childhood. A ban on flavouring may have impacts on adults, but adolescents may simply switch to a different flavour – like tobacco.
Impede product alteration to use of other drugs	This might require 'closed systems' to be made mandatory (as proposed by tobacco company RJ Reynolds with this justification, but probably for anti-competitive reasons). But this has the effect of removing the 'open system' 2 nd and 3 rd generation products from the market. Many vapers report these are more effective alternatives to smoking. Note vaping may be a safer way to take other drugs than smoking – so there may be a harm reduction benefit to drug users.
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. They may obscure much more important messages about relative risk compared to smoking – information that is not provided in official communications.
Sales to minors	There is near universal support for this. However it is worth noting that NRT is made available to people over 12 years in some jurisdictions – because young smokers also need to quit. It should not be assumed that 'harm reduction' should start at 18.
Prohibit health claims unless regulatory approval	Denies smokers real world truthful information about relative risk and may cause more smoking. It is uncontroversial that e-cigarettes are safer than smoking – the debate is over where in the range 95-100% less risky. Erects high and unnecessary regulatory barrier to truthful communication.
Regulate as a medicine	E-cigarettes are not medicines – in common sense or in law. Using ill-fitting or excessive regulation designed for a different purpose would be simply limit the development of competitive alternatives to cigarettes. The costs, burdens and restrictions of medicines regulation are excessive and serve little useful purpose (for example, 'consistent dosing' is important for medicines, but not for products where the user controls the dose) ¹¹ .
Regulate as a tobacco product	Most tobacco regulation is designed to prevent, suppress and control tobacco use. With e-cigarettes the public health imperative is best served by these products growing and innovating to capture market share from cigarettes – many of the tools of tobacco control applied to e-cigarettes are therefore harm-inducing and protective of cigarette sales.

¹¹ Bates C, Stimson S Costs and consequences of regulating e-cigarettes as medicines, 20 September 2013 [\[link\]](#)

The risk of user countermeasures to overcome poor regulation. Health Canada's approach to e-cigarettes has been to classify them as medicines without appropriate marketing authorisations and therefore deemed their sale to be unlawful. This approach has basically failed and fallen into disrepute. Canadian smokers are accessing e-cigarettes and e-liquids with ease, and despite overriding the regulatory regime, *this is a good for public health in Canada*. It is an example of a wider problem arising from excessive regulation: users will revolt and legitimately subvert regulation that they perceive to be harmful to their health or welfare. It is better to avoid the development of unregulated black or grey markets and home producing by having proportionate regulation.

Appropriate regulation. The optimum regulation regime would strike between subtle balances between protecting users, non-users, bystanders and limiting the risks of harmful unintended consequences. A good regulatory regime may cover of the following elements, and it may develop over time. This list is illustrative, and not intended to be complete:

Liquids

- Requirement for pharmaceutical grade nicotine and diluents in liquids
- Requirement for flavours to be at least food grade
- A ban on ingredients known to be carcinogenic, mutagenic, repro-toxic or respiratory sensitisers. That could be implemented a general duty or a negative-list
- Purity standards or thresholds for contaminants in liquids
- Products should be as described – contain the stated content of nicotine and flavours
- Child resistant containers – this may adopt ISO8317 for example
- Use-by date

Devices

- Electrical safety specification
- Heat safety specification
- Materials used in devices should be approved for use with food
- Possible operating thresholds for devices, eg. for maximum temperature

Testing

- A testing regime should support the regulatory objectives and regulatory decisions

Marketing

- Claims must be true, not misleading and supported by evidence
- Claims that present products as medicines should be subject to medicine regulation
- Proportionate warnings related to toxicity and addictiveness
- Restrictions on themes and media attractive to under-25s
- Restrictions sales to under-18s
- Age-verification for sales – on internet or in shops

Companies

- Registered address and 'responsible person' identified
- Quality management standard in place, eg. ISO9000
- Markings and the means to recall products

Setting the regulatory agenda. The current Canadian regime creates significant opportunity costs. It treats e-cigarettes as unlicensed medicines, creating a hypothetical *de facto* prohibition. However, it is widely ignored in practice, and therefore is failing to impose meaningful regulation on the products that are on sale and used by Canadians. By being highly restrictive in the name of health, safety and responsibility the current regime is, *in practice*, irresponsible and harmful to health and safety. It would be much better to get to work on the 'enabling' regulatory framework sketched out above than to continue in denial with a system that is not serving anyone well, driving legitimate businesses into a legal twilight and holding back the development of a promising alternative to smoking.

About the author

Clive Bates runs Counterfactual, a public interest consulting and advocacy organisation focussed on a broad approach to sustainability, policy-making for the long term and good governance. He was formerly a senior civil servant and Director of Action on Smoking and Health (London) as well as a founder of the NGO Framework Convention Alliance, set up to support the development of the WHO Framework Convention on Tobacco Control. He has been a long-term advocate of tobacco harm reduction¹²¹³¹⁴, a critic of the public health establishment approach to harm reduction¹⁵ and wrote about the policy challenge of products like e-cigarettes well before they were invented¹⁶.

Disclaimer. Views expressed in this brief do not necessarily reflect the views of former employers or affiliates. Clive Bates has no competing interests with respect to tobacco, pharmaceutical, e-cigarette industries

¹² Bates C, Fagerström K, Jarvis MJ, *et al.* European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health. *Tob Control* 2003;**12**:360–7. [doi:10.1136/tc.12.4.360](https://doi.org/10.1136/tc.12.4.360)

¹³ McNeill A, Foulds J, Bates C. Regulation of nicotine replacement therapies (NRT): a critique of current practice. *Addiction* 2001;**96**:1757–68. [doi:10.1080/09652140120089508](https://doi.org/10.1080/09652140120089508)

¹⁴ Bates C. Taking the nicotine out of cigarettes--why it is a bad idea. *Bull World Health Organ* 2000;**78**:944. [[link](#)]

¹⁵ Bates C. Flaw in WHO Framework Convention on Tobacco Control: letter identified wrong problem with the framework convention. *BMJ* 2004;**328**:1320. [doi:10.1136/bmj.328.7451.1320](https://doi.org/10.1136/bmj.328.7451.1320)

¹⁶ Bates C. What is the future for the tobacco industry? *Tob Control* 2000;**9**:237–8. [doi:10.1136/tc.9.2.237](https://doi.org/10.1136/tc.9.2.237)