House of Commons Select Committee on Science and Technology
Health, regulatory and financial implications of e-cigarettes

Submission by Clive Bates, London, United Kingdom

8 December 2017

Table of contents

Executive summary

- I am a former Director of Action on Smoking and Health UK, a former senior civil servant and currently run a small consultancy. I have no competing interests.
- I am pleased to provide this evidence to assist the Committee's work. This submission follows the format of the questions set in the terms of reference for the inquiry[1].

On health

- E-cigarettes function as consumer products and alternatives to smoking. Their positive impact for public health arises from their attractiveness as alternatives to smoking.
- E-cigarettes do not involve the combustion of tobacco leaf and inhalation of thousands of toxic products of combustion. They are, beyond reasonable doubt, far less harmful than smoking.
- Based on what is known, a working estimate endorsed by UK experts is that e-cigarettes are at least 95% lower risk than smoking, and may be substantially lower than that. At present there is no established serious or material risk to health.
- The experience from the United Kingdom and United States has been highly positive. In both cases, smoking has fallen rapidly among both adults and youth as vaping has risen, consistent with vaping products being used to quit smoking and displace cigarettes in the marketplace.
- There is no evidence of gateway effects or 'renormalisation' of smoking. As we would expect, vaping normalises vaping and functions as an anti-smoking technology.

On regulation

- There are many regulatory options available, but the primary concern should be with the unintended consequences of overzealous regulation. This can have the effect of protecting the cigarette trade and sustaining smoking by degrading the appeal of the lower-risk alternative.
- Most of the regulatory approaches tried by governments so far have been excessively risk-averse concentrating on micro-managing negligible personal risks rather than exploiting opportunities to reduce smoking and create major net health gains.
- The best regulatory approach will be to provide a light-touch framework of standards and only deviate from a market-based approach where there is a clear consumer benefit. This will minimise the risk of unintended consequences. No additional tax on these products is justified.
- Brexit is likely to have a net negative effect as UK is promising regulatory alignment with the EU but will lose its influence in setting the regulatory agenda.

On finances

- The regulatory regime imposed through the Tobacco Products Directive is onerous and its measures either have no value and only burdens or are actively counter-productive.
- Because the major effects of e-cigarettes are to reduce smoking, these products are likely to be strongly beneficial for the NHS, and for overall social welfare.

[1] House of Commons Science and Technology Committee, Inquiry into E-cigarettes. 25 October 2017 [link]

PART I: ON HEALTH

1 The impact on human health of e-cigarettes

1.1 What e-cigarettes are used for

The Royal College of Physicians summarises the role played by e-cigarettes in its extensive 2016 report on e-cigarettes for tobacco harm reduction[2]:

> *E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.*

Reasons for using e-cigarettes show harm-reduction motivation. A survey published by UK Office for National Statistics[3] give the following reasons for e-cigarette use:

Main reason for using e-cigarettes Great Britain, 2016	**Percentage e-cigarette users age 16 and over**
Perception that they are less harmful than cigarettes	26.6
Can be used indoors	4.4
Cheaper than tobacco products	8.1
Novelty	3.3
Aid to stop smoking	46.6
Range of different flavours available	5.1
Other reasons	5.9

Figure 1: main reasons for using e-cigarettes

The dominant stated purpose is reducing harm to health (26.6%) through quitting smoking (46.6%) and cutting the economic burden of smoking (8.1%) – meaning over 80% of the reasons given suggest a harm-reduction motivation. This is positive and should be encouraged.

1.2 Why vaping should be understood to pose lower risk to health than smoking

It is impossible to know with certainty what the ultimate health impact of products like e-cigarettes will eventually be – we cannot travel fifty years forward in time to observe what has still to happen. There are likely to be some negative effects with long term use, but these are likely to be greatly offset by reduced risks from smoking.

Of course, this limitation applies to anything new and we routinely make judgements in the face of unavoidable uncertainty rather than allowing uncertainty to provoke paralysis in the face of innovation. To make progress we generally make assessments of risk, not wait for final certainty. While it is impossible to know everything about the health effects of vaping relative to smoking, this

---

2 Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [link]

3 Office for National Statistics (UK). E-cigarette use in Great Britain. 2016, 15 June 2017. Table 3a Main reason for using e-cigarettes [link]

does not mean we know nothing. The case that e-cigarettes and personal vaporisers are much less hazardous than cigarette smoking rests on three main pillars, drawing on what is already known:

1. **The physical and chemical processes are very different**. E-cigarettes use electrical heating to create a nicotine-bearing aerosol from an inert liquid at temperatures of 100-250°C with little chemical change at normal operating temperatures. In contrast, cigarette smoke is created by combustion of tobacco leaf at 600-900°C with partial or complete combustion reactions creating thousands of new and hazardous chemicals in the form of smoke particles and toxic gases. It is these products of combustion that do most of harm to smokers[4]. We would not expect e-cigarettes and cigarettes to have remotely similar risks based on these physical and chemical differences. It is also likely that the much simpler chemistry of e-cigarette aerosol will be much easier to modify than cigarette smoke should an unforeseen problem emerge – for example by modifying ingredients, controlling temperature or changing the base diluent liquid.
2. **The respective toxic properties of cigarettes and e-cigarettes**. It is possible to run many different toxicology tests on the chemical properties of e-cigarette vapour and cigarette smoke. A range of review articles has summarised the literature and found that most toxic agents in cigarette smoke are not present and detectable levels or are present at levels that are one to three orders of magnitude lower. The literature makes a compelling case that the toxic effects of vaping would be much lower[5] [6] [7] [8] [9].
3. **Effects on the human body**. There is evidence that chronic conditions improve when smokers switch to vaping, for example in the case of asthma[10], breathing problems[11] and lung function[12]. It is possible to compare salivary or urine biomarkers to assess bodily exposure to hazardous agents. Again, the findings are very encouraging[13].

   The e-cigarette–only and NRT-only users had significantly lower metabolite levels for TSNAs (including the carcinogenic metabolite 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol

---

4 U.S.DHSS. How Tobacco Smoke Causes Disease The Biology and Behavioral Basis for Smoking-Attributable Disease A Report of the Surgeon General. Public Health. U.S. Dept. of Health and Human Services, Public Health Service, Office of the Surgeon General; 2010. 792 p. [link]

5 Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Therapeutic Advances in Drug Safety* 2014;**5**:67–86. [Link]

6 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. [Link]

7 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* [Internet]. 2014 Aug 31 [link]

8 Margham J, McAdam K, Forster M, Liu C, Wright C, Mariner D, et al. Chemical Composition of Aerosol from an E-Cigarette: A Quantitative Comparison with Cigarette Smoke. *Chem Res Toxicol*. American Chemical Society; 2016 Oct17;29(10):1662–78. [link]

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

10 Polosa R, Morjaria J, Caponnetto P, Caruso M, Strano S, Battaglia E, et al. Effect of smoking abstinence and reduction in asthmatic smokers switching to electronic cigarettes: Evidence for harm reversal. Int J Environ Res Public Health. Switzerland; 2014 May;11(5):4965–77. [link]

11 Campagna D, Cibella F, Caponnetto P, Amaradio MD, Caruso M, Morjaria JB, et al. Changes in breathomics from a 1-year randomized smoking cessation trial of electronic cigarettes. Eur J Clin Invest. 2016 Jun 20; [link]

12 Polosa R. Electronic cigarette use and harm reversal: emerging evidence in the lung. *BMC Med*.; 2015;13(1):54. [link]

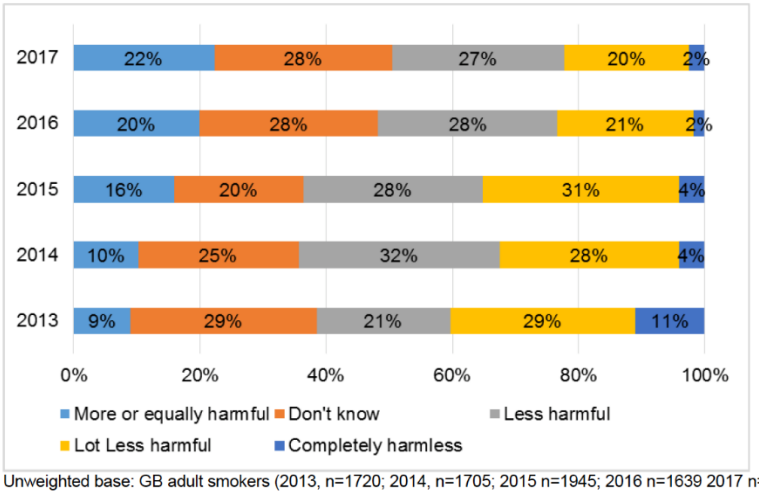
13 Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users. *Ann Intern Med.* 2017 Feb 7;24:442–8. [link]

[NNAL]) and VOCs (including metabolites of the toxins acrolein; acrylamide; acrylonitrile; 1,3-butadiene; and ethylene oxide) than combustible cigarette–only, dual combustible cigarette–e-cigarette, or dual combustible cigarette–NRT users. The e-cigarette–only users had significantly lower NNAL levels than all other groups.

1.3 The claim that e-cigarette use is likely to be at least 95% lower risk than smoking

Figures for relative risk of smoking and vaping have been developed by the expert community in the United Kingdom. It is important to understand the origin and purpose of these estimates as these have often been misrepresented by anti-vaping activists.

Perceptions of harm are dramatically misaligned with reality. Despite overwhelming evidence that e-cigarettes are likely beyond any reasonable doubt to be much less hazardous than smoking, health and medical organisations in the UK have been concerned that many smokers believe that e-cigarettes are no less risky than smoking. Furthermore, the gulf between public perception and reality is widening even though evidence that e-cigarettes are much less risky has been accumulating – see figure below on British smokers' perceptions of the comparative risks of smoking and vaping[14].



Unweighted base: GB adult smokers (2013, n=1720; 2014, n=1705; 2015 n=1945; 2016 n=1639 2017 n=1569)

Figure 2: Smokers' perceptions of harm from e-cigarettes

Only 20% of smokers accurately believe that e-cigarettes are a lot less harmful than cigarettes, the number believing they are harmless is negligible, but half of all smokers believe they are the same or more risky or don't know.

The importance of an anchor for risk perception. The misunderstanding of relative risk is a serious deterrent to trying a safer alternative and a reason to continue smoking. It is in the light of these misperceptions that leading public health and medical organisations in the UK have tried to provide clear direction to smokers, practitioners and policy makers to help them make properly informed decisions respectively about product choices, professional practice and policy.

In its August 2015 expert evidence review, Public Health England provided a working guideline[15]

[14] ASH (UK) / YouGov. Use of e-cigarettes among adults in Great Britain 2017. 8 May 2017. Figure 9 [link]

[15] Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [link] Public Health England. E-cigarettes: an evidence update 19 August 2015. [link]

> *..the current best estimate is that e-cigarettes are around 95% less harmful than smoking*

Public Health England's experts followed this up with an explanation of the reasoning behind this[16], that showed it was a conservative and cautious estimate with a significant safety margin.

> *the constituents of cigarette smoke that harm health – including carcinogens – are either absent in e-cigarette vapour or, if present, they are mostly at levels much below 5% of smoking doses (mostly below 1% and far below safety limits for occupational exposure)*

The Royal College of Physicians (London) had similar concerns. It also provided a carefully worded statement designed to anchor risk perceptions in a more realistic range in its April 2016 report[17]:

> *Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.*

The wording of the RCP statement carefully acknowledges uncertainty while giving a cautious estimate and a steer to users that the products are likely to be considerably safer, but should not be assumed safe. This is the statement that I recommend people use to discuss risks with friends or family members who smoke.

Statements of this nature are not intended to provide pinpoint accuracy, and they are carefully qualified to avoid suggesting they do. However, they are serious public health interventions designed to help the public and non-specialists make informed decisions with potential life or death consequences, drawing on the insights and specialist knowledge of experts. The alternative is fear and confusion, driven by media and alarmist commentators.

1.4 Why is there confusion? Common errors in reporting health effects of e-cigarettes

There is a considerable volume of misinformed and misleading commentary about the health effects of e-cigarettes and their impact on public health. In some frustration, the editor of the journal *Addiction* set out some of the typical errors found in literature and commentary in an editorial for a virtual edition of the journal devoted to e-cigarettes[18]:

> ***Failure to quantify*:** e.g., statement that e-cigarette vapour contains toxins so creating the impression that they are dangerous as cigarettes, without indicating that the concentrations are typically orders of magnitude less than tobacco smoke.
>
> ***Failure to account for confounding and reverse causality*:** e.g., arguing that use of e-cigarettes reduces chances of stopping because in cross-sectional surveys the prevalence of e-cigarette use is higher in smokers than in recent ex-smokers.

[16] McNeill A, Hajek P. Underpinning evidence for the estimate that e-cigarette use is around 95% safer than smoking: authors' note, 28 August 2015 [link]

[17] Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016. Section 5.5 page 87. [link]

[18] West R, Electronic cigarettes: getting the science right and communicating it accurately, *Addiction*, virtual edition on e-cigarettes, December 2014. [link]

***Selective reporting*:** e.g., focusing on studies that appear to show harmful effects while ignoring those that do not.

***Misrepresentation of outcome measures*:** e.g., claiming that e-cigarette use is prevalent among youth by using data on the proportion who have ever tried and creating the misleading impression that they are all current e-cigarette users.

***Double standards in what is accepted as evidence*:** e.g., uncritically accepting conclusions from observational studies with major limitations when these claim that electronic cigarettes are causing harm, but discounting similar or better controlled studies when these appear to show the opposite.

***Discrediting the source*:** e.g., arguing that researchers who have received financial support from e-cigarette manufacturers (and even companies that do not manufacture e-cigarettes) are necessarily biased and their results untrustworthy, and presenting themselves as having no conflicts of interest when their professional and moral stance represents a substantial vested interest.

Figure 3: Getting the science right and communicating it accurately

A more comprehensive guide to common errors in the science and scientific reporting of e-cigarettes and personal vaporisers is available, *The critics' guide to bad vaping science*[19] with a one-page summary at Appendix 1.

2 Benefits and risks of e-cigarettes as a 'stop smoking' tool

2.1 The rise of e-cigarettes has coincided with a sharp decline in smoking in Britain

The British prevalence data[20] suggest that many are successfully adopting this approach. In 2016, there were 8.2 million smokers and 2.8 million vapers, of which 1.5 million were ex-smokers. Over the period that vaping has risen sharply, we have seen sharp falls in adult smoking. The number of vapers who are ex-smokers (1.5m) now exceeds the number who are also current smokers (1.1m) and the vaping population, the population grew by 1.0 million or 1,380 per day from 2014 and 2016.

Proportion of whom are current vapers	Current smoker	Ex-smoker	Never-smoked	Adult population
2014	10.6%	6.8%	0.2%	3.7%
2015	14.4%	7.7%	0.2%	4.5%
2016	13.7%	12.1%	0.6%	5.5%
Number of vapers (thousand persons)				
2014	1,029	745	48	1,821
2015	1,299	908	59	2,267
2016	1,123	1,524	181	2,828

Figure 4: The recent rise of vaping in Britain

[19] Bates CD. The critic's guide to bad vaping science, Counterfactual, December 2016 [link]

[20] Office for National Statistics (UK). E-cigarette use in Great Britain. 2016, 2015, 2014 15 June 2017. Table 2a E-cigarette use, by sex and cigarette smoking status [link]

Over this short period, the number of smokers in the adult population has fallen by 1.5m from 9.7m to 8.2m, while the number of ex-smokers has increased by 1.7m from 10.9m to 12.6m

Population by smoking status	Current smokers	Ex-smokers	Never-smoked	Adult population
2014	9,689	10,910	29,168	49,767
2015	9,021	11,797	29,744	50,562
2016	8,198	12,594	30,190	50,982

Figure 5: The recent decline of smoking in Britain

2.2 Change in UK compared to Australia

Although Australia has generally been regarded as leader in tobacco control, its crown may be slipping.

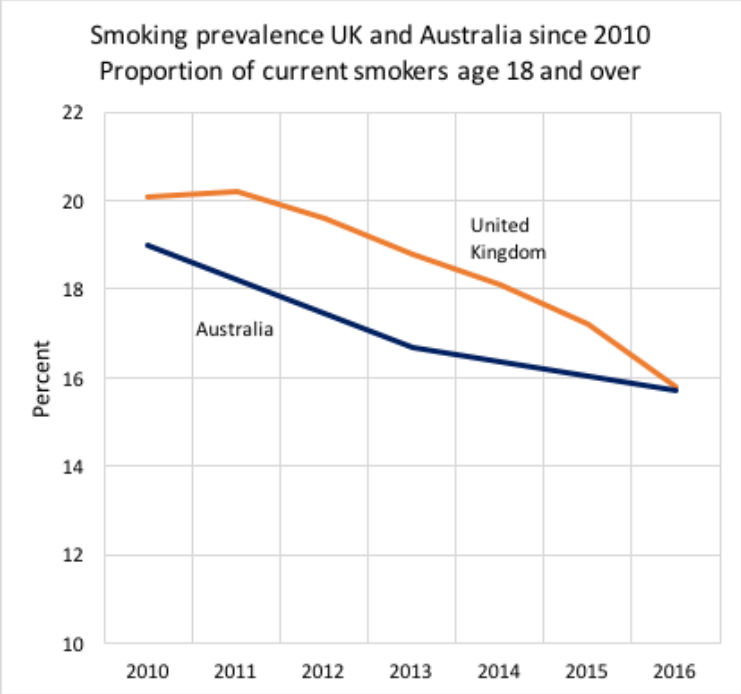


Figure 6: Decline of smoking in Australia and the United Kingdom

The rate of decline in the UK since 2013 has been three times as great as in Australia (UK average -1.0 percentage points per year compared to -0.33). This is despite Australia's aggressive tobacco control policies, including plain packaging (December 2012) and four 12.5% tax increases in December 2013 and September 2014, 2015 and 2016, amounting to 60% in total[21]. Average UK cigarette prices rose by 18% from 2013 to 2016. Plain packaging was introduced in December 2016.

2.3 A similar effect has been seen in the United States – for adults *and* youth

Though the e-cigarette usage data are not as readily accessible in the United States, there has also been a rapid decline in smoking coinciding with the rise of vaping. Adult smoking prevalence fell

[21] Australian Government, Department of Health: Plain packaging of tobacco products [link]; Tobacco taxation [link]

from 19.4% in 2010 to 15.1% in 2015[22]. An analysis of the data suggests there were 8.3 million vapers by 2015 of which 2.5 million were former smokers[23].

2.4 Findings from the scientific literature: impact of e-cigarettes on quitting smoking

A summary of key insights from the scientific literature into the role e-cigarettes have played in reducing smoking is presented at Appendix 2.

2.5 The testimonies of vapers are an important part of the evidence

The testimonies of vapers are sometimes dismissed as 'anecdotes' by anti-vaping activists, but there are good scientific reasons for considering such qualitative accounts within the overall assessment of evidence. There are thousands of personal testimonies that show that the vaping works well *for at least some people*. Vapers in Australia[24], the United Kingdom[25] and the United States[26] provide often moving and inspiring testimony of their experience in using e-cigarettes to quit smoking and legislators are recommended to view these to provide context and a citizen perspective.
More systematic surveys also suggest that vapers believe they have quit smoking through vaping. Analysis of European Union survey data found[27]:

> *An estimated 6.1 and 9.2 million EU citizens had quit and reduced smoking with the help of e-cigarettes, respectively.*

An online survey of users found[28].

> *The results of this worldwide survey of dedicated users indicate that ECs are mostly used to avoid the harm associated with smoking. They can be effective even in highly-dependent smokers and are used as long-term substitutes for smoking.*

---

22 National Center for Health Statistics, National Health Interview Survey [link], Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2016.[data] Accessed June 2017. The prevalence figure (15.8%) for 2016 is not comparable due to a change in sampling methodology.

23 CDC, National Health Interview Survey, 2015 Data Release [link], Analysis by Rodu B. How Many Americans Vape? CDC Data Show Fewer Vapers & Smokers in 2015, Tobacco Truth 17 July 2016 [link]

24 AussieVapers forum, Your story.

25 Counterfactual. UK vaping testimonies.. [link]

26 Consumer Advocates for Smoke-free Alternatives Association (CASAA), E-cigarette user testimonials. [link]

27 Farsalinos KE, Poulas K, Voudris V, Le Houezec J. Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. *Addiction*. 2016 Jun 24; [link]

28 Farsalinos KE, Romagna G, Tsiapras D, Kyrzopoulos S, Voudris V. Characteristics, perceived side effects and benefits of electronic cigarette use: A worldwide survey of more than 19,000 consumers. *Int J Environ Res Public Health*. 2014 Apr 22;11(4):4356–73. [link]

3 Uptake of e-cigarettes among young people and 're-normalising' smoking

3.1 Data from the United Kingdom

There is very little evidence to suggest any cause for concern. Summarising data from a five UK surveys, Bauld et al conclude[29].

> *In summary, surveys across the UK show a consistent pattern: most e-cigarette experimentation does not turn into regular use, and levels of regular use in young people who have never smoked remain very low.*

3.2 Data from the United States

Over the period in which vaping has risen rapidly in the United States, there have been very rapid declines in adolescent smoking. These observations are reassuring and shown in Appendix 3.

Much of adolescent e-cigarette use is experimental and occasional and poses minimal risk. The National Youth Tobacco Survey for 2014 showed that 74 percent of high school students who were using e-cigarettes used them on less than ten days in the month preceding the survey, 45 percent on only 1-2 days, with less than 10 percent being daily users[30]. Furthermore, the more regular e-cigarette use is strongly concentrated in smokers[31]. As Warner[32] puts it:

> *Non-smoking high school students are highly unlikely to use e-cigarettes; among those who do, most used them only on 1–2 of the past 30 days.*

The problem with the headline prevalence figures for adolescent e-cigarette use based on use in the last 30 days, is that they conceal and merge very different behaviours: regular use and experimentation.

A further complication is that many adolescents vapers report mostly using e-cigarettes *without* nicotine and therefore without the key dependence-forming agent. The Monitoring the Future Survey found that only 20 percent of 12th graders reported using e-cigarettes with nicotine[33].

3.3 The population effect of vaping

As should be expected by default, it does seem that people use safer products to reduce their risks, not to increase them. Adult smokers are quite capable of being rational guardians of their own

---

29 Bauld L, MacKintosh A, Eastwood B, Ford A, Moore G, Dockrell M, et al. Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute; 2017 Aug 29;14(9):973. [link]

30 Neff LJ, Arrazola RA, Caraballo RS, *et al.* Frequency of Tobacco Use Among Middle and High School Students--United States, 2014. *MMWR Morb Mortal Wkly Rep* 2015;**64**:1061–5 Table 35. [link]

31 Villanti AC, Pearson JL, Glasser AM, Johnson AL, Collins LK, Niaura RS, et al. Frequency of youth e-cigarette and tobacco use patterns in the U.S.: Measurement precision is critical to inform public health. *Nicotine Tob Res*. December 2016 [link]

32 Warner KE. Frequency of E-Cigarette Use and Cigarette Smoking by American Students in 2014. Am J Prev Med. 2016 Aug;51(2):179–84. [link]

33 Miech R, Patrick ME, et al. What are kids vaping? Results from a national survey of US adolescents. *Tob Control*; 2016 [link].

welfare and it should be assumed that they will seek out satisfactory ways of using nicotine that are less harmful, less stigmatised and less expensive unless there is evidence to the contrary.

The Royal College of Physicians reviewed and summarised the evidence as follows[34], finding no evidence that negative population effects were dominating beneficial effects.

> *There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking.*
>
> *To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.*

3.4 Findings from the scientific literature: impact of e-cigarettes on uptake of smoking

A summary of key insights from the scientific literature into whether e-cigarettes have played a role in the uptake of smoking is presented at Appendix 4.

3.5 Why is there confusion? Common errors in interpreting behavioural studies

The Committee may receive submissions citing studies that purport to show that e-cigarettes do not work, show gateway effects or that much safer products somehow cause people to smoke more. There is no sign of this happening in the respective trends in smoking and vaping described above. If vaping is causing more smoking, where are all the new smokers?

When subjected to careful examination, such studies do not bear out the claims of activists. The following types of error are evident throughout the literature:

- *Confusion over association and causation.* Several studies find that vapers are more likely to smoke and smoke more, and some make the inappropriate step of assuming the vaping is causing the smoking. It is more likely that inclination to vape and inclination to smoke are both driven by the same *independent* risk factors (parental smoking, peer group, culture, educational attainment, mental health issues, etc).
- *Selection bias*. In some observational studies, the people using vaping products may be an unusual subset of the population or smoker population. For example, they may have tried everything else and be more dependent. Some studies focus only on those who have failed to quit or have called help lines – again making them a specific atypical subset.
- *Reverse causation.* Smoking may be common among vapers because smokers are trying to use vaping to quit. The smoking causes the vaping.
- *The missing counterfactual*. The question 'what would have happened in the absence of vaping' is the most useful question for interrogating studies that purport to show vaping have a causal

[34] Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016. Key recommendations [link]

effect on smoking. Often the answer is that people found to be smoking after vaping would have smoked anyway.

- *Poor definitions*. Studies claiming find gateway effects usually fail to define terms like 'gateway effect' with any rigour and sometimes not at all. This prompted Public Health England's expert review to conclude[35]

  > *The gateway theory is ill defined and we suggest its use be abandoned until it is clear how it can be tested in this field.*

[35] McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [link]

PART II: ON REGULATION

4 Overview: the poor quality of e-cigarette regulation

4.1 All regulatory approaches adopted so far are sub-optimal

Regulations relating to e-cigarettes have generally take several forms:

- *Consumer protection legislation* (e.g. United States, European Union pre-2016). This approach draws on the body of legislation that applies to all consumer products. For example, in the European Union at least sixteen directives apply to e-cigarettes and personal vaporisers by default[36]. This approach is better than all others adopted so far, but is unlikely to be optimum – some level of specialised regulation will provide meaningful extra protection to consumers.
- *Standards and notification system* (e.g. European Union post 2016). This EU directive has been extensively criticised for its arbitrary standards, bureaucratic burdens for which no clear purpose exists, and excessive restrictions on advertising and trade[37] [38].
- *Product by product authorisation* (e.g. United States FDA deeming rule). The FDA's approach has attracted considerable criticism[39] and legal action[40] for both its costs and burdens, and for the opaque nature of the authorisation process which makes the process highly risky for all but the largest manufacturers, the tobacco companies..
- *De facto prohibition via regulating e-cigarettes as medicines* (e.g. Australia and Canada – and favoured by the UK government in 2013). Medical regulation has in fact functioned as a prohibition. Manufacturers are not making therapeutic products and they do not fit the definition of a medicine. The medicine framework is inappropriate for these products[41] and has functioned as a to a *de facto* prohibition. T
- *Outright prohibition of manufacturing, import and sale* (e.g. in the Persian Gulf states). This strategy appears to have the tacit approval of the WHO, but WHO has been subject to intense expert criticism for the quality of both its interpretation of evidence and the policy conclusions it

---

[36] For example, the following European Union Directives apply: General Product Safety 2001/95/EC; Technical Standardisation 1025/2012; Classification, Labelling and Packaging CLP 1272/2008; REACH 1907/2006; Low Voltage 2006/95/EC; Electro-Magnetic 2004/108/EC; RoHS 2011/65/EU; WEEE 2012/19/EU; Batteries 2006/66/EC; Weights and measures 76/211/EEC 2007/45/EC; Sale of goods 99/44/EC; Distance Selling 97/7/EC; Electronic Commerce 2000/31/EC; Misleading Advertising 2006/114/EC; Unfair Commercial Practices 2005/29/EC; Protection of Personal Data 95/46/EC

[37] Bates CD. What is wrong with the Tobacco Products Directive for vapour products? Counterfactual. 22 May 2015 [link]

[38] Snowdon CJ. E-cigarettes and Article 20 of the Tobacco Products Directive. European Policy Information Center (EPICENTER), September 2015. [link]

[39] Bates CD. Lehrer E. Sweanor DT. Reshaping American Tobacco Policy: Eight federal strategies to fight smoking and ignite a public health revolution, February 2017 [link][PDF] Bates CD. Rethinking nicotine: implications for U.S. federal tobacco policy – A discussion paper. June 2017 [link][PDF]

[40] Nicopure Labs et al vs Food and Drug Administration et al, Motion for Summary Judgement, 8 July 2016 [link] Brief of *amici curiae* of Clive Bates and other in support of plaintiffs' motion for summary judgement, 5 August 2016 [link]

[41] Bates CD, Stimson G. Costs and benefits of medicines regulation for e-cigarettes, Nicotine Science and Policy, 20 September 2013 [link]

has drawn as a result[42]. It is also possible that such prohibitions (and by implication *de facto* prohibitions) are unlawful under WTO agreements[43] [44].

Arguably, the most successful approach to date has been to rely on *no additional regulation* other than the consumer protection regulation that applies by default. This has been the situation in the United Kingdom and the United States until mid-2016, the period over which there has been most rapid growth in e-cigarette use combined with rapid falls in adult and youth smoking. It is quite possible that all government intervention so far has been negative for health.

4.2 The problem of unintended consequences

Intended consequences. The purpose of regulation of these products should be to mitigate a risk (e.g. of exposure to contaminants or battery fires) or to realise an opportunity (e.g. to standardise rules to promote competition and encourage people to switch to lower risk products). Much of the problem with EU regulation stems from inadequate specification of risks, with over-reaction to negligible risks. In the case of the European Union Tobacco Products Directive it is impossible to find credible justifications for most of the provisions applied to e-cigarettes once these are understood to be functioning as low-risk alternatives to smoking. Regulation was defined with e-cigarettes understood to be a threat, with little interest in the opportunity.

Unintended consequences. The much greater concern is that regulation, especially that imposed by the Tobacco Products Directive, will result in harmful unintended consequences. The Royal College of Physicians drew attention to the dangers[45]:

> *A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.*
>
> *However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187)*

The important point is that well-intentioned but ill-conceived regulation of e-cigarettes can do harm to human health by weakening alternatives to smoking or driving smokers away. A more complete guide to potential unintended consequences is set out at Appendix 5

Belatedly, the UK government has acknowledged the potential for unintended consequences associated with the EU Tobacco Products Directive provisions that relate to e-cigarettes[46] but by

---

42 Britton, J, McNeill, A, Bauld L, Bogdanovica I Commentary on WHO report on Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems, UK Centre for Alcohol and Tobacco Studies, 26 October 2016 [link][PDF]

43 Foltea M, Markitanova A. The "Likeness" of New and Conventional Tobacco Products in the WTO. In: Society of International Economic Law (SIEL), 2016. [link]

44 Bates CD. Lehrer E. Sweanor DT. Reshaping American Tobacco Policy: Eight federal strategies to fight smoking and ignite a public health revolution, February 2017, Proposal 8: Challenge vapor and smokeless prohibitions under WTO rules [link][PDF]

45 Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [link]

46 Department of Health, MHRA (UK), Tobacco Products Directive, Impact Assessment,18 April 2016. [link]

then, the directive had already been European law for two years and the provisions binding on the UK.

> *117. [...] There may also be potential negative health implications if the restrictions on advertising reduce the number of consumers switching from tobacco products to e-cigarettes. [...]*
>
> *207. There is a risk that due to the potential price increase and reduction of choice of e-cigarettes, people will choose to switch back to smoking, thus harming their health. This possibility is considered in the sensitivity analysis.*
>
> *208. There is a risk that a black market will develop with potentially harmful e-cigarette products, due to consumers no longer having the same degree of choice in the legal market*

Given these effects are likely to emerge in reality then it is possible that the Directive is already doing harm.

5 Regulatory variation and Brexit

5.1 Regulatory variation

The Tobacco Products is intended to be a harmonising directive but one of its major weaknesses is that it allows significant variation at member state level and, in the name of 'free movement of goods' it allows members states to ban some forms of commerce – for example internet or cross-border sales. The variations between jurisdictions are less important than the common core of regulation that must be applied in all EU jurisdictions. Legislators should focus greatest attention on this core.

5.2 Brexit

The impact of Brexit will depend on the terms of the final status trade agreement and transitional arrangements. In my view, the following scenario is likely:

- For economic and political reasons, the UK will either remain in the EU Single Market or remain in full regulatory alignment with the European Union *acquis*, which amounts to the same thing. This is the direction of travel that is clear in the recent interim statement on the Withdrawal Agreement[47].
- The likelihood is that UK will continue to comply with EU single market legislation (including tobacco product regulation) as it would as if it was a member of the European Economic Area and outside the European Union.
- The UK will have minimal influence of the Review under Article 28 of the TPD that will complete no later than May 2021. This will shape the next phase of EU regulation in this field.

[47] UK Government and European Commission. Joint report on progress during phase 1 of negotiations under Article 50 TEU on the UK's orderly withdrawal from the EU, 8 December 2017. [link]

- The UK will be required to comply with future iterations of the European Union directives related to tobacco products, but will have no say.
- The positive attitude of UK authorities will be lost to the negotiations, and it is likely more prescriptive and restrictive attitudes present in some other member states and the Commission will shape future directives to be more restrictive and more susceptible to unintended consequences.
- Vapers and firms who hope the Brexit will free the from pointless, expensive and damaging EU regulation of e-cigarettes will be disappointed.

6 The effectiveness of regulation on the advertising and marketing of e-cigarettes

6.1 No case for bans on e-cigarette advertising

The starting point for responding to this question is to be clear on what the policy is supposed to achieve – effective at doing what? Advertising of cigarettes is largely banned in the EU because smoking kills 700,000 EU citizens annually, and advertising is thought to increase the appeal of this product and therefore potentially mean more people smoke, smoke more, smoke for longer or don't quit as soon as they might.

These justifications for bans or restrictions on cigarette advertising cannot simply be applied to e-cigarette advertising. As alternatives to smoking, e-cigarettes function as a form of stop-smoking technology. Advertising for e-cigarettes is a form of anti-smoking advertising. A ban on e-cigarette advertising might therefore be harmful.

6.2 The UK approach to e-cigarette advertising

The correct approach to e-cigarette advertising was that adopted by the UK Committee on Advertising Practice (CAP) in 2014. The starting point is that conventional "legal, honest, decent, truthful" standards should apply, as they do to all advertising. That is in itself a significant protection. The CAP also produced useful guidelines on e-cigarette advertising that provide a reasonable balance of interest between protection of minors and promotion of new low-risk products to smokers. The framework is somewhat similar to the controls on alcohol advertising[48] controlling aspects of content and placement, but not imposing outright bans. CAP has recently consulted on allowing certain health claims to be permitted – a highly positive development.

If the regulation of e-cigarette advertising had purely been a UK matter, then it is likely we would have a workable and proportionate system. Unfortunately, through the Tobacco Products Directive the EU all forms of advertising capable of crossing a border are banned outright[49].

[48] Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [link]; UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [link]

[49] EU Tobacco Products Directive, 14/40/EU Article 20(5) [link]

7 The impact of the Tobacco and Related Products Regulations

I would like to provide two example of particularly ill-conceived regulation arising from the EU Tobacco Products Directive.

7.1 Warnings, risk communication and health claims

The aim should be to provide users with the basis for making an informed choice – reflecting both risks and benefits. Consumer information should not be misused to achieve a particular behavioural outcome – for example exaggerating risks to deter use. Warnings should refer to known risks – aiming to be both truthful and correctly understood: some truthful statements can be highly misleading, for example "this product is not a safe alternative to smoking"[50]. Some understanding of the possible perverse effects of warnings is essential. For example in the UK, European Union regulation requires a warning label on e-cigarettes and e-liquids that emphasises addiction. However, UK survey data[51] suggests the most important reason for smokers not switching to e-cigarettes is fear of substituting one addiction for another.

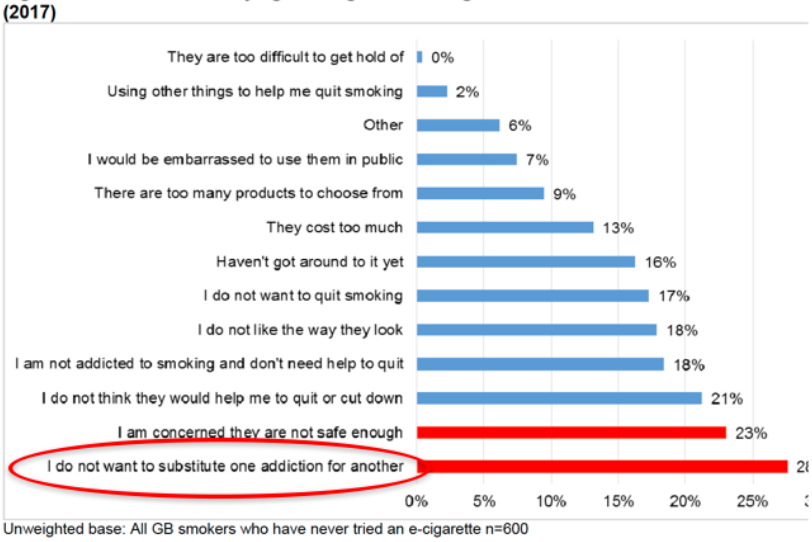
European Union warning	Reasons why British smokers do not try e-cigarettes
This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers	**Figure 7: Reasons for not trying an e-cigarette among smokers who never have (2017)**  Unweighted base: All GB smokers who have never tried an e-cigarette n=600

Table 1: Impact of warnings on attitudes to vaping

The second most common concern is belief that the products are not safe enough. Again this suggests that great care is required in mandating health warnings on e-cigarettes to ensure the much lower risk relative to smoking is properly understood. In defining risk communications, regulators and legislators should to consider three elements:

- The information that must be placed on the pack – this should not unduly frighten users or create a disproportionate impression of risk.
- The claims a manufacturer can make and in what circumstances – manufacturers should be free

[50] Kozlowski LT, Sweanor DS. Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines. Int J Drug Policy. Elsevier [link]

[51] Action on Smoking and Health, Fact sheet: ASH Fact Sheet on the use of electronic cigarettes among adults in Great Britain [link]

to make statements that are true and not misleading, but therapeutic claims should require evidence and an approval regime.

- The information the authorities provide for consumers. Governments or their agencies should take on the role of informing consumers with unbiased evidence-based information that can be readily understood. The regulator wold mandate true statements approved for use by e-cigarette manufacturers. For example, the following statements might be approved for use:

> *No inhaled nicotine product is completely safe, but use of this product is likely to be much less harmful than smoking*

The combination of these three elements should aim to provide the consumer with an accurate picture of risks, relative risk compared to smoking and a sense of the opportunities as well as risks.

7.2 Limiting nicotine concentrations

In the European Union Tobacco Products Directive Article 20(3)b[52], the maximum permissible nicotine concentration for e-liquids was set at 2% or 20mg/ml. This has no basis in science or risk management and attracted criticism from the scientific expert community[53] ad appears to be based on misunderstanding of the risk posed by liquid nicotine solution[54] and how we normally deal with type of risk – by warning, use of child-resistant containers and providing on what to do if expose.

There are essentially six reasons not to cap the strength at 20mg/ml.

1. The limit achieves absolutely nothing, so there are no benefits of the threshold to offset against risks. There is a well-established three-pronged approach to managing potentially hazardous substances in the home (bleach, medicines etc): use child resistant packaging; place a warning on the packaging; explain what to do if exposed.
2. Some vapers use products that have higher concentrations than 20mg/ml, and removing this option may risk relapse to smoking – but for no benefit. In Britain, six percent of vapers use liquids above 20mg/ml[55]. While this may not sound much, it equates to 170,000 users in the UK.
3. Though a small number continue to use higher strength liquids, many vapers use higher strength liquids during a transition from smoking to vaping and while they learn the techniques of vaping. Thus high strength liquids form a temporary bridge from smoking to vaping. Any measure of current use therefore understate the importance of higher strength liquids in the process of switching. One study found that 20 percent of vaper had started on products higher than 20mg/ml[56]

---

52 European Union Tobacco Products Directive, 2014/40/EU Article 20 [link]

53 Etter JF et al, Scientific Errors in the Tobacco Products Directive A letter sent by scientists to the European Union, E-cigarette Research. (Letter from 15 experts to European Commission) 16 January 2014 [link]

54 Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Arch Toxicol* 2014;**88**:5–7. doi:10.1007/s00204-013-1127-0 [link]

55 Action on Smoking and Health, Fact sheet: Use of electronic cigarettes (vapourisers) among adults in Great Britain, May 2017 [link]

56 Farsalinos KE, Romagna G, Tsiapras D, et al. Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette

4. Higher strength liquids may be more important to more highly dependent smokers, and therefore provide benefits to those at greater risk of smoking related disease. One of the most important concerns in designing a regulation is the approach to those who continue to smoke. Smokers frequently report that vaping is unsatisfying[57]:

   > *However, since most current smokers who have tried ENDS reject them as a satisfying alternative to regular cigarettes, the potential of ENDS becoming a disruptive technology replacing regular cigarettes remains uncertain. ENDS need to improve as a satisfying alternative or the attractiveness and appeal of the regular cigarette must be degraded to increase the potential of ENDS replacing regular cigarettes.*

   Limiting nicotine strength adds to this problem rather than addressing it.

5. Limiting higher strength liquids may be a barrier to innovation and prevent the development of new products that are more convenient to use, less intrusive, create fewer emissions, provide stronger competition to cigarettes or better suited to starters.

6. Limiting strength makes no sense from a health perspective. Vapers and smokers generally 'titrate' nicotine to achieve a desired level of consumption or exposure. Weaker liquids will mean inhaling a larger volume of aerolised liquid. To the extent there are toxins in the liquids, then weaker liquids will mean *higher* exposures – though still very low compared to cigarettes.

A much better approach would be to have no limit at all up to the level at which nicotine falls under poisons legislation. Nicotine is exempted from the Poisons Act 1972 in concentrations below 7.5% (75mg/ml or 75mg/g)[58].

8 The safety of e-cigarette devices, and any safety regulation requirements

8.1 E-cigarettes are comparatively safe

Though there are have been a number of highly publicised incidents with e-cigarettes, the overall profile is much safer than risk from smoking[59], which causes extensive harm to people and damage to property through fires started by smoking materials[60].

However, there are ways to improve the safety of e-cigarette products, principally through use of technical standards. This approach has either been ignored in the Tobacco Products Directive, or the standards set have been pointless or prone to unintended consequences.

Use: A Worldwide Survey of More than 19,000 Consumers. Int J Environ Res Public Health 2014;**11**:4356–73. [link]

57 Pechacek TF, Nayak P, Gregory KR, et al. The Potential That Electronic Nicotine Delivery Systems Can be a Disruptive Technology: Results From a National Survey. *Nicotine Tob Res* Published Online First: 3 May 2016. [link]

58 The UK exemption from poisons regulation for nicotine liquids under 7.5% concentration is implemented in The Poison Rules 1982, SI 82/218 Schedule 4 [link]

59 London Fire Brigade: 255 times more likely to have a fire caused by tobacco than vaping Brigade says, 20 August 2017 [link]

60 John R. Hall, The smoking material fire problem, National Fire Protection Service (US) , July 2013 [link]

8.2 A standards-based regime would be better than current EU regulation

It is possible to set standards to limit any thermal, mechanical, chemical or electrical risks. The constituents of the liquid should match the description, and any warnings needed should be specified.. This could set quality standards for liquids, specifying maximum levels of contaminants define a list of proscribed ingredients, and define the information that should be supplied in the packaging – for example, the strength of nicotine, information on how to respond if swallowed etc.

Standards in practice. The most highly evolved standards to date have been developed by the French national standards body AFNOR for devices and liquids, and related testing measures[61]. There have been e-cigarettes standards initiatives in the UK[62] and now the EU standardization body (CEN) is developing an e-cigarettes standard[63]. The American E-liquid Manufacturing Standards Association (AEMSA) has developed an industry standard for e-liquids and related manufacturing processes[64] and several respected American businesses have adopted this. There are many relevant electrical standards.[65] There are ISO standards for child-resistant packaging[66].

[61] AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [link], XP D90-300-2 Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 [link] March 2015, XP D90-300-3 Part 3: Emissions testing requirements and methods, July 2016 [link]

[62] BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products - Manufacture, importation, testing and labelling - Guide [link] July 2015

[63] European Centre for Standardisation, CEN/TC 437 - Electronic cigarettes and e-liquids [link]

[64] AEMSA E-liquid manufacturing standard Version 2.3.2 - March 8, 2017 – accessed 17 May 2013 [link]

[65] International Electrotechnical Commission (IEC) standards. For example: IEC 60335-1 2010 (safety of appliances) [link]; IEC 60335-2-29:2016 (safety of battery chargers) [link]; IEC 62133-1&2:2017 (safety of portable batteries) [Part 1: Nickel][Part 2: Lithium]; IEC 61558-1:2005 (safety of AC adaptors) [link]; IEC 61000 series (electromagnetic compatibility) [link]

[66] ISO 8317:2015 Child-resistant packaging -- Requirements and testing procedures for reclosable packages [link] and related standards, 55.020 - Packaging and distribution of goods in general [link]

PART III: ON FINANCE

9 The economic impact of the UK's e-cigarette industry

I have no data on the impact on the industry, but my concern is that the small to medium enterprises that have led the disruption of the tobacco market will be stressed by the following:

- Regulatory compliance costs
- Opportunity costs arising from excessive focus on bureaucratic burdens at the expense of consumer facing innovation
- Competition from tobacco companies that can cross-subsidise their e-cigarette business
- Competition from the black market and cross border internet trade
- Uncertainty about future regulation and costs of regulatory risk

10 The public finances implications of e-cigarettes,

10.1 The direct impact of e-cigarettes

The known health effects directly associated with e-cigarettes are trivial and there is no reason to believe they would adversely affect NHS costs. In fact, for NHS evaluation purposes, they should be more realistically treated as stop-smoking technologies rather than just a lower risk version of smoking. The effect on the NHS is likely to be highly positive. One US study showed a very significant health care cost benefit arising from uptake of e-cigarettes[67]

10.2 The economic value of quitting smoking via e-cigarettes is very high

In its Impact Assessment for the Tobacco Products Directive, the Department of Health estimates the average discounted value for the benefit of quitting smoking to £72,000 per successful quit arising from longer life[68]. The same assessment estimated loss of tobacco duty and net loss of VAT associated with quitting smoking at a present value of £11,000[69]. Note: these figures are not directly comparable. The value of longer life is a real welfare benefit but the lost excise is a *transfer* within the economy – the value lost by the Treasury is a gain to the quitter, which can be spent on other goods and services. However, they do give some basis for judging the costs and benefits to the public sector.

10.3 Tax revenue lost to quitting should be raised from other sources

For the sake of comparison, this tax loss could be thought of as a form of public spending (i.e. a drain on the public finances but with a benefit to society). If that were the case, then it implies an

---

67 Moody JS. Heartland Institute, E-cigarettes poised to save Medicaid billions, State Budget Solutions, March 2015 [link]

68 Department of Health (England). Impact Assessment for Tobacco Products Directive (TPD), April 2016 – paragraph 76 and Annex A. On average, each additional non-smoker will gain 1.2 life years (discounted). Each life-year gained is valued at £60,000 based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes. [link]

69 Department of Health (England). Impact Assessment for Tobacco Products Directive (TPD), April 2016. Annex A page 72. [link]

extremely high benefit-cost ratio of 6.5 (72,000/11,000). In public sector value for money assessment would be considered "very high value for money" compared to other forms of public investment[70].

What this means is that quitting smoking should be the policy priority even if the tobacco duty revenues are lost. It follows that a loss of tobacco revenue should not simply be addressed by taxing whatever is causing the quitting (that is likely to be the worst source of replacement revenue if it reduces quitting). It should be made up in one of two ways:

- By reducing spending on projects or programmes that have lower value for money. Almost everything else the government does has a benefit -cost ratio below 6.5. For example, the High Speed Train 2 project (HS2) has a b/c ratio of only 1.8[71] - based on optimistic forecasts.
- By raising *other* taxes in a less damaging way that does not reduce the number of those quitting by switching to smoke-free nicotine products. There is no reason to seek out the most similar-looking tax base, any replacement should come from the next least distorting tax base.

[70] Department of Transport (UK), Value for Money Assessments, accessed 11 October 2016. [link] "Very high value for money" is defined as a benefit-cost ratio greater than 4.

[71] The UK government's estimated benefit-cost ratio for phase one of the High Speed 2 (HS2) rail project is 1.7. See: High Speed 2 Outline Business Case, para 1.8 [link].

Appendix 1: The critic's guide to bad vaping science

1 Toxic chemicals have been identified in e-cigarette vapor or e-liquids

1.1 Did they show potentially harmful *exposure* not just the *presence* of a chemical? "The dose makes the poison".
1.2 How risky is the exposure compared to smoking?
1.3 How risky is the exposure compared to other risks such as those accepted under occupational health limits?
1.4 Were measurements made in realistic human operating conditions or in extreme or unrealistic conditions?
1.5 Are inappropriate proxies being used for risk – for example effects that are also seen with coffee or exercise?
1.6 Are flawed analogies being used – for example assuming all ultrafine particles are equally toxic?

2 Adverse health effects from e-cigarettes are reported

2.1 Was vaping the real cause?
2.2 Was the person suffering from adverse impacts of beings a smoker before using e-cigarettes?
2.3 Is the study just observing the effect of nicotine on the body (though no serious disease is caused by nicotine)?
2.4 Is there evidence of actual harm or is it just a *change* in the body or brain?
2.5 Is it based on a cell culture study are the limitations recognized and was exposure realistic proxy for human use?
2.6 Is it based on an animal study and are the limitations recognized?

3 Claims second-hand vapor is toxic and indoor vaping should be banned

3.1 Are vapor exposures to bystanders potentially harmful given they pose little risk to direct users?
3.2 Is the difference between risk or harm and nuisance or personal preference recognized?
3.3 Have false choices been proposed? e.g. between a ban and *laissez faire.*

4 Nicotine damages the adolescent brain

4.1 What is the specific nature of the detriment to human health?
4.2 Where is the evidence for the brain damage from nicotine in the longstanding human population of smokers?
4.3 How does this compare to damage from alcohol, cannabis or caffeine?

5 More children using e-cigarettes and gateway effects

5.1 Did they characterize use properly? For example, 'ever use' of an e-cigarette is a marker of experimentation.
5.2 Could the rising use of e-cigarettes be a good thing if it is displacing smoking?
5.3 High level of smoking associated with vaping – but is this due to independent common factors (confounding)?
5.4 Have they defined a gateway effect?
5.5 Are they assuming prior behaviour caused the later behaviour?

6 E-cigarettes keep people smoking and reduce quit rates

6.1 Has vaping been wrongly conceptualized as though it is a medical intervention?
6.2 Has the importance of product's consumer appeal been recognized?
6.3 Was "dual use" described as problematic – any cutting down is beneficial and may be part of a longer transition?
6.4 Did they claim there are no benefits to cutting down?
6.5 Have the limitation of randomized controlled trials been acknowledged?.

7 Flavours and e-cigarette marketing aimed at children

7.1 Do they assume it is just obvious that childish names appeal to kids?
7.2 Why would adolescents try to emphasize their childishness?
7.3 Have *preferences* for particular flavours been misrepresented as a *cause* of vaping?
7.4 Could it be a benefit that some flavours are attractive to adolescents if it means they don't smoke?
7.5 Is an e-cig advertising in effect an anti-smoking ad?

8 Citing uncertainty and appeal to the 'precautionary approach'

8.1 Have they understood what is known and recognized the physical processes in vaping are different to smoking?
8.2 Are they asking the impossible? E.g., by saying we will only know the risks when we have 40 years of data?
8.3 Do they realize that 'precautionary approach' can do be harmful if it blocks access to beneficial technology?

9 Tobacco industry involvement implies inevitable harm

9.1 Is the malign influence of tobacco companies assumed or demonstrated?
9.2 Is there over-reliance on decades old industry statements, documents or behaviours?
9.3 Is there a proper understanding of how the nicotine and tobacco market works?
9.4 Are the authors concerned about the right things? For example, are they fighting ill-health or capitalism?

10 Policy recommendations in a scientific paper

10.1 Do policy recommendations go beyond what their research justifies?
10.2 Have policy-making disciplines been followed – options generation, impact assessment, consultation etc.?
10.3 Are the authors' policy positions revealing their biases and priors?
10.4 Have unintended consequences been ignored? Many e-cigarette policy proposals could lead to more smoking.

Figure 7: Overview of the questioning approach to interrogating vaping science

Appendix 2: Do e-cigarettes help smokers quit cigarettes?

An overview of academic papers addressing the role of e-cigarettes in helping smokers to quit.

Population studies

Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. Bmj. 2017;358:j3262. [link]

> ***Conclusion*** *The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions.*

Beard E, West R, Michie S, Brown J. Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends. BMJ. 2016;354354:4645–4645. [link]

> ***Conclusion*** *Changes in prevalence of e-cigarette use in England have been positively associated with the success rates of quit attempts.*

Farsalinos KE, Poulas K, Voudris V, Le Houezec J. Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. Addiction. 2016;111(11):2032-40 [link]

> *Self-reports from a representative sample of 27,460 EU citizens*
>
> *Extrapolating to the whole EU population, an* ***estimated 6.1 million Europeans have quit smoking*** *with the use of e-cigarettes, while a further 9.2 million have reduced their smoking consumption'*

Action on Smoking and Health UK. Use of electronic cigarettes (vapourisers) among adults in Great Britain. Fact sheet. May 2017 [link]

> *An estimated 2.9 million adults in Great Britain currently use e-cigarettes (vape). For the first time there are more ex-smokers (1.5 million) who use e-cigarettes than currents smokers (1.3 million)'*
>
> *The main reason given by ex-smokers who are currently vaping is to help them stop smoking while for current smokers the main reason is to reduce the amount they smoke'*

Zhuang YL, Cummins SE, J YS, Zhu SH. Long-term e-cigarette use and smoking cessation: a longitudinal study with US population. Tob Control. 2016;25(Suppl 1):i90-i5 [link]

> *'Among those making a quit attempt, use of e-cigarettes as a cessation aid surpassed that of FDA-approved pharmacotherapy'.*
>
> *'Long-term vapers (over 2 years) had a four times higher odds of quitting for 3 months than short-term users and non-users. (OR 4.1 CI 1.6 to 13.9))'*

Longitudinal studies

Giovenco DP, Delnevo CD. Prevalence of population smoking cessation by electronic cigarette use status in a national sample of recent smokers. Addict Behav. Pergamon; 2018 Jan 1;76:129–34. [link]

- *Over half of daily e-cig users in the sample quit smoking in the last 5 years.*
- *Daily e-cig users were 3 times more likely to be quit than never e-cig users.*
- *Some day e-cig users were least likely to be quit.*
- *Some smokers may have quit or are preventing relapse with frequent e-cig use*

Biener L, Hargraves JL. A longitudinal study of electronic cigarette use among a population-based sample of adult smokers: association with smoking cessation and motivation to quit. Nicotine Tob Res. 2015;17(2):127-33 [link]

> *Daily use of electronic cigarettes for at least 1 month is strongly associated with quitting smoking at follow-up' 'intensive users of e-cigarettes were 6 times more likely than non-users/triers to report that they quit smoking (OR: 6.07, 95% CI = 1.11, 33.2)*

Hitchman SC, Brose LS, Brown J, Robson D, McNeill A. Associations Between E-Cigarette Type, Frequency of Use, and Quitting Smoking: Findings From a Longitudinal Online Panel Survey in Great Britain. Nicotine Tob Res. 2015;17(10):1187-94 [link]

> *Online longitudinal survey of 1643 current users: daily tank users were more likely to have quit*

Mantey DS, Cooper MR, Loukas A, Perry CL. E-cigarette Use and Cigarette Smoking Cessation among Texas College Students. Am J Health Behav 2017 [link]

> *Use of e-cigarettes for cigarette smoking cessation was associated with increased odds of cigarette smoking cessation at 6- and 12-month follow-ups*

Cross sectional studies

Brown J, Beard E, Kotz D, Michie S, West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Addiction. 2014 Sep 1;109(9):1531–40. [link]

> ***Conclusions.*** *Among smokers who have attempted to stop without professional support, those who use e-cigarettes are more likely to report continued abstinence than those who used a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.*
>
> *The adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over-the-counter'*

Randomised controlled trials

Hartmann-Boyce J,McRobbie H, Bullen C, Begh R, Stead LF,Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010216.. [link]

> ***Conclusions**. There is evidence from two trials that ECs help smokers to stop smoking in the long term compared with placebo ECs. However, the small number of trials, low event rates and wide confidence intervals around the estimates mean that our confidence in the result is rated 'low' by GRADE standards.*

Reviews

Royal College of Physicians (London) *Nicotine without smoke. Tobacco Harm Reduction*. 2016 [link]

> *E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.*

Public Health England. E-cigarettes - an evidence update. August 2015 [link]

> *Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. More research is needed in this area'*

Clearing the Air Evidence: A systematic review on the harms and benefits of e-cigarettes and vapour devices Review Monograph, Uni Victoria, Canada - 18 Jan 2017 [link]

> *Overall, there is encouraging evidence that vapour devices can be at least as effective as other nicotine replacements as aids to help tobacco smokers quit.*

United Kingdom Centre for Tobacco and Alcohol Studies. Commentary on WHO report on electronic nicotine delivery systems [etc.]. 2016 [link]

> *'Taking the totality of evidence including controlled trials, observational studies, changes in population smoking and ENDS use, the experience of nicotine replacement therapy, and widely reported user experience, there is confidence that ENDS are helping many smokers to quit smoking and not having negative effects'*

Glasser A. M., Collins L., Pearson J. L., Abudayyeh H., Niaura R. S., Abrams D. B. et al. Overview of electronic nicotine delivery systems: a systematic review. Am J Prev Med 2017; 52: e33–66. [link]

> *RCTs and population-based studies with more-precise exposure measures show that ENDS are at least as effective as NRT in helping some smokers to quit or reduce their smoking and may reach more smokers at scale than NRT'*

UK data

Towards a Smokefree Generation. A Tobacco Control Plan for England. 2017-2022. Dept Health UK July 2017 [link]

> *In 2016 it was estimated that 2 million consumers in England had used these products and completely stopped smoking and a further 470,000 were using them as an aid to stop smoking'.*

Appendix 3: Trends in youth tobacco and nicotine use in the United States

The two charts that follow are annotated to show salient features of the most recent data on youth smoking in the United States. The first chart is from the National Youth Tobacco Survey, published June 2017[72].

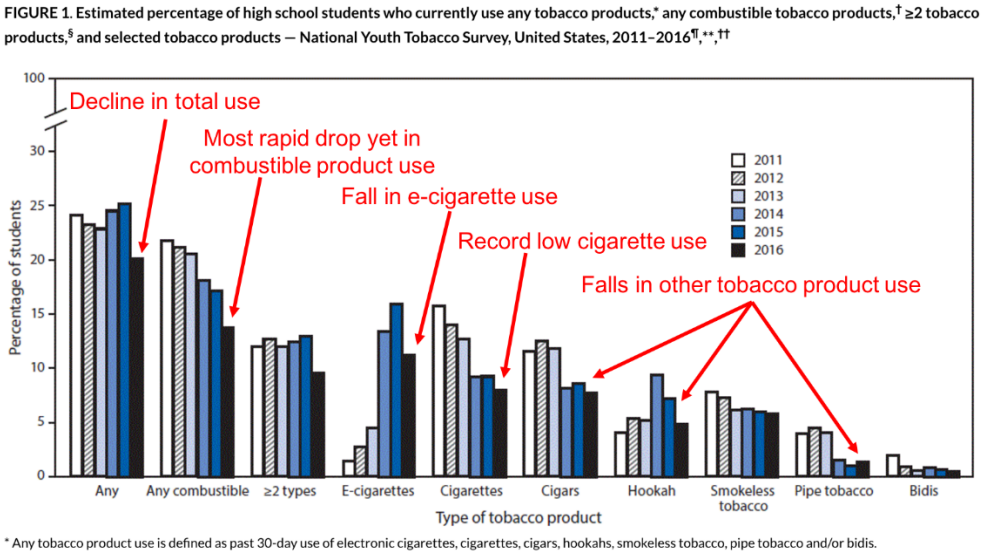


Figure 8: changes in patterns of youth nicotine use United States 2011-16

The second is from the 2016 University of Michigan Monitoring the Future survey, which has a time series dating back to 1975 for 12th grade smoking[73].

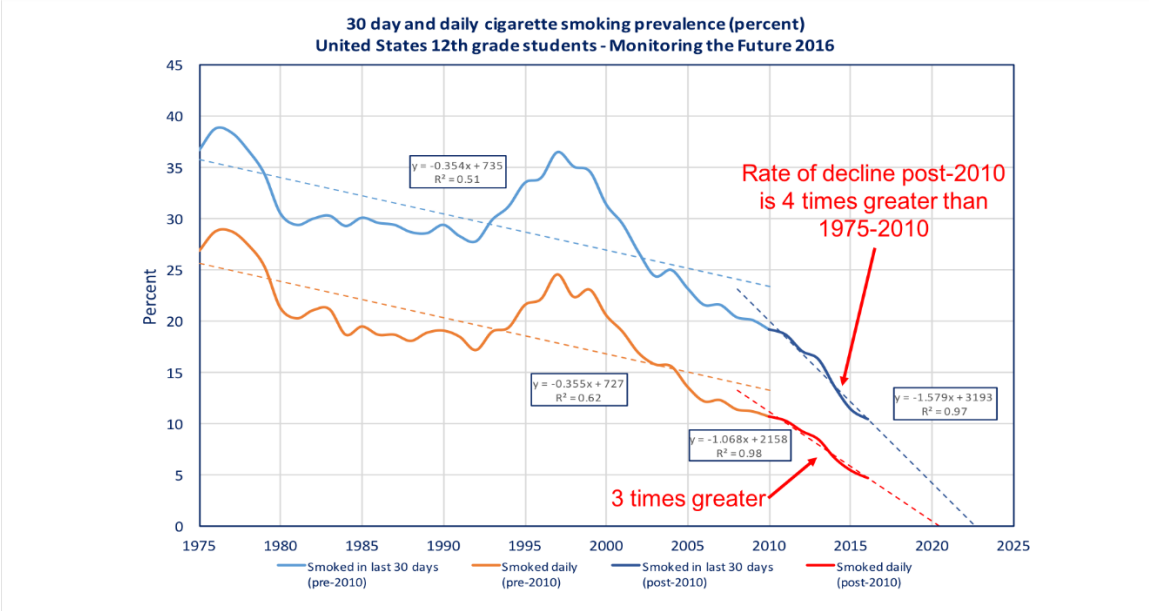


Figure 9: Accelerating decline in 12th grade smoking United States post-2010

[72] Jamal A, Gentzke A, Hu SS, Cullen KA, Apelberg BJ, Homa DM, et al. Tobacco Use Among Middle and High School Students - United States, 2011-2016. *MMWR Morb Mortal Wkly Rep*. 2017 Jun 16;66(23):597–603. [link]

[73] Miech RA, Johnston LD, O'Malley PM, Bachman JG, Schulenberg JE. Monitoring the Future national survey results on drug use, 1975-2016: Data tables. Table 2 - Trends in Prevalence of Use of Cigarettes. University of Michigan; Ann Arbor: 2016. [Tables][Dataset].

Appendix 4: Do e-cigarettes lead to uptake of cigarette smoking?

An overview of academic papers addressing the role of e-cigarettes in causing smoking uptake.

Adolescents and 'gateway' effects

Bauld L. Young People's Use of E-Cigarettes across the United Kingdom Findings from Five Surveys 2015–2017. IJERPH 2017 [link]

- *Of 11-16 year olds in the UK (n>60,000) 'only 3% or less report using them at least weekly, most of whom are regular smokers, with **less than 0.5%** of never smokers reporting weekly e-cigarette use'*
- *Professor Linda Bauld: 'Our analysis of the latest surveys from all parts of the United Kingdom, involving thousands of teenagers shows clearly that for those teens who don't smoke, e-cig experimentation is simply not translating into regular use'*

Polosa R. A critique of the U.S. SG's conclusions regarding e-cig use among youth and young adults in US. Harm Red J 2017 [link]

> *Multiple years of nationally representative surveys indicate the majority of e-cigarette use among US youth is either infrequent or experimental, and negligible among never-smoking youth' In the two large national studies, regular e-cigarette use by never smokers was <0.1% (NYTS 2015) and 0.7% (MTF 2014)*

Kozlowski LT, Warner KE. Adolescents and e-cigarettes: Objects of concern may appear larger than they are. *Drug Alcohol Depend.* 2017 May;174(1 May 2017):209–14. [link][PDF]

> *The data from large national cross-sectional studies provide no evidence that kids' use of e-cigarettes is increasing smoking. If anything, those data suggest the opposite.*
>
> *We conclude, currently, that youth use of e-cigarettes is unlikely to increase the ranks of future cigarette smokers.'*

Clearing the Air: a systematic review on the harms and benefits of e-cigarettes and vapour devices. University of Victoria, Centre for Addictions Research BC, Canada. January 2017 [link]

Comprehensive review of 1,622 journal articles concluding that:

> *There is no evidence of any gateway effect whereby youth who experiment with vapour devices are, as a result, more likely to take up tobacco use.*

Etter JF. Gateway effects and electronic cigarettes. Addiction 2017 [link]

> *The gateway hypothesis cannot currently be either accepted or confidently refuted because the evidence for it is scarce and inconclusive.*
>
> *In fact, it is more plausible that vaping uptake is largely explained because smoking causes people who are already dependent upon nicotine to look for less dangerous, more socially acceptable and cheaper ways to obtain nicotine*

ASH Youth Survey 2017 GB (prepublication)

> *Regular use of e-cigarettes (at least weekly) was reported by **0.1% of never-smokers***

Ever use of e-cigarettes was reported by 4% of never-smokers

Glasser AM Overview of Electronic Nicotine Delivery Systems. Am J Prev Med 2017. [link]

Systematic review of 687 articles by The Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative

ENDS uptake trends have coincided with significant reductions in smoking prevalence to record lows among youth and adults.'

Monitoring the Future Survey, National Institute of Drug Abuse 2016

Miech RA, Johnston LD, O'Malley PM, Bachman JG, Schulenberg JE. Monitoring the Future national survey results on drug use, 1975-2016: Data tables. Table 2 - Trends in Prevalence of Use of Cigarettes in Grades 8, 10, and 12. University of Michigan; Ann Arbor: 2016. [Tables][Dataset]. Chart created by Clive Bates [on-line]

Selya AS. Evaluating the mutual pathways among electronic cigarette use, conventional smoking and nicotine dependence. Addiction 2017 [link]

Longitudinal study over 4 years of young adults 19-23y (n=1,007)

- *E-cigarettes did not predict later smoking or later nicotine dependence*
- *the current study calls into question the concerns that e-cigarettes pose a risk for later conventional smoking*
- *Increased initiation with e-cigarettes may be replacing, rather than adding to, initiation with conventional cigarettes*

Adults

Farsalinos K et al. Prevalence and correlates of current daily use of electronic cigarettes in the European Union: analysis of the 2014 Eurobarometer survey. Intern Emerg Med 2017 [link]

Eurobarometer survey of 27 460 Europeans from 28 countries

*'Minimal current daily (**0.08%,** 95% CI 0.03–0.12%) and current daily nicotine-containing EC use **(0.04%**, 95% CI 0.01–0.08%) was observed among never smokers'.*

Eichler M. The Use of E-Cigarettes. A Population-Based Cross-Sectional Survey of 4002 Individuals in 2016. Dtsch Arztebl Int. 2016 [link]

*In Germany, only **0.1%** of adult never smokers used e-cigarettes at the time of the survey.*

Delnevo CD. Patterns of Electronic Cigarette Use Among Adults in the United States. Nicotine Tob Res 2015 [link]

Results:** Current e-cigarette use is extremely low among never cigarette smokers **(0.4%)

***Conclusions:** Extremely low e-cigarette use among never-smokers and longer term former smokers suggest that e-cigarettes neither promote widespread initiation nor relapse among adults.*

Schoenborn CA. Electronic Cigarette Use Among Adults: United States, 2014. NCHS Data Brief, US DHHS no 217, Oct 2015 [link]

> ***0.4%*** *of adults who had never smoked cigarettes used e-cigarettes*

Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. Bmj. 2017;358:j3262. [link]

> Current population survey-Tobacco Use 2014-2015 (US national survey 18y+)

> *'Only **0.3%** of never smokers currently used e-cigarettes at the time of survey (fig 3)*

West R, Brown J. Trends in smoking and e-cig use in England. Smoking Toolkit Study. 30/9/17 [link]

> *Current e-cigarette use by adult never-smokers is **0.3%.** negligible (fig 3)*

Office for National Statistics. E-cigarette use in England 2016 [link]

> ***0.7%*** *of never smokers were self-reported current e-cigarette users (Table 2b)*

Action on Smoking and Health UK. Use of electronic cigarettes (vapourisers) among adults in Great Britain. Fact sheet. May 2017 [link]

> ***0.3%*** *of adult never smokers in Great Britain were current e-cigarette users in 2017*

Gateway effects - methods problems

Phillips C V. Gateway Effects: Why the Cited Evidence Does Not Support Their Existence for Low-Risk Tobacco Products (and What Evidence Would). *Int J Environ Res Public Health* 2015;12:5439–64. [link]

> *It is often claimed that low-risk drugs still create harm because of "gateway effects", in which they cause the use of a high-risk alternative. Such claims are popular among opponents of tobacco harm reduction, claiming that low-risk tobacco products (e.g., e-cigarettes, smokeless tobacco) cause people to start smoking, sometimes backed by empirical studies that ostensibly support the claim. However, these studies consistently ignore the obvious alternative causal pathways, particularly that observed associations might represent causation in the opposite direction (smoking causes people to seek low-risk alternatives) or confounding (the same individual characteristics increase the chance of using any tobacco product).*

Gartner CE. E-cigarettes and youth smoking: be alert but not alarmed. *Tob Control*; 2017 Sep 8;tobaccocontrol-2017-054002. [link]

Fears that an increase in vaping will lead to an increase in smoking among young people via a 'gateway' effect have been used to support greater regulation of vaping products or to advocate for continued prohibition of vaping products containing nicotine in countries that do not allow their sale, possession or use by adults. Are these reasonable responses to these research findings?

Several things should be considered in the interpretation of these studies.

1. *A proportion of the young people who try vaping and then smoking would have also tried smoking without trying vaping due to a common liability to experiment with substance use.*
2. *It is plausible that vaping may increase the likelihood of experimenting with smoking through increased familiarity with a behaviour that resembles smoking and/or curiosity about how the two experiences compare. But it is unknown how many of those who might try smoking who would not have done so without trying vaping first will then go on to become regular smokers.*
3. *The baseline waves of these longitudinal studies were conducted in locations and at times when there were no age restrictions on sales of vaping products. In such a regulatory context, it is not surprising that young people may have tried the product with less restrictions first. This pattern may change as 18+ age restrictions are adopted in more jurisdictions.*
4. *The absolute number of young people regularly vaping or smoking remains low and appears to be decreasing.*

McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [link] Section 4 *Gateway* page 37

Since EC were introduced to the market, smoking prevalence among adults and youth has declined. Hence there is no evidence to date that EC are renormalising smoking, instead it's possible that their presence has contributed to further declines in smoking, or denormalisation of smoking. The gateway theory is ill defined and we suggest its use be abandoned until it is clear how it can be tested in this field. Whilst never smokers are experimenting with EC, the vast majority of youth who regularly use EC are smokers. Regular EC use in youth is rare.

Appendix 5: Plausible unintended consequences of regulation

Policy	Plausible unintended consequence
High compliance costs or barriers to entry	A loss of product diversity means consumers are unable to personalise the vaping experience or find products that they enjoy and find it less satisfactory, so continue to smoke or relapse.
Restrictions on liquid strength	Smokers are unable to sustain a satisfactory nicotine experience during the first stages of switching or while they are learning to vape, so relapse to smoking or give up on vaping. May drive users to black market and/or home mixing with high strength liquids
Limits on container and tank size	The experience of vaping becomes more inconvenient and so less attractive. More filling operations are required and the likelihood of running out of liquid is increased.
Ban e-cigarette use in public places	Diminishes value proposition of e-cigarettes to users and 'denormalises' vaping, a much less risky option, and so diminishes the appeal of vaping relative to smoking, May promote relapse in existing vapers if they cannot maintain adequate nicotine levels or if they join smokers outside.
Restrictions on advertising, promotion and sponsorship	Reduces the ability of e-cigarette brands to compete with cigarettes (the market incumbent) and diminishes means to communicate the value proposition to smokers. May reduce means to communicate innovation or build trusted brands. If subjected to excessive control products may become dull and sterile, diminishing appeal.
Bans on online sales	Because vaping options are highly diverse, user density still quite low, and technological evolution rapid, the internet-based business model is important to provide the greatest choice and convenience to users. If users are forced to purchase from 'bricks and mortar' outlets but do not have a specialist shop nearby they are likely to see their options limited and vaping relatively less attractive
Policy compliance burdens and other costs - leading to black markets	Black markets develop in response to restrictive or costly regulation or taxation. Black markets can to some extent compensate for poorly designed policy and they are likely to emerge as the TPD is implemented. However, they also cause harms through trade, transit and handling of high strength liquids, product quality, poor labelling, inferior packaging. They may exacerbate risks the policy is designed to mitigate.
Product design restrictions and requirements – testing and paperwork	There are numerous subtle trade-offs in product design between safety and appeal and cost. For example, the perfectly safe product that no-one wants to buy may be worse 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 and reduce the pace of innovation.

Policy	Plausible unintended consequence
Bans on 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 a significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and development of DIY and black market flavours – which may be more dangerous.
Bans on refillable systems	This idea has been proposed by tobacco companies for commercial and anti-competitive reasons. It means removing the 'open system' 2nd and 3rd generation products that increasingly dominate the market. Many vapers report these are more effective alternatives to smoking. Any (minor) risks of poisoning, dermal contact, DIY mixing etc have to be set against the likely black market response, and the substantial benefits arising from personalisation and huge extension to the diversity of products available.
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. This has always been the case with smokeless tobacco – warnings do not adequately communicate relative risk and, therefore, understate smoking risks or the advantage of switching. They may obscure much more important messages about relative risk compared to smoking that is not provided in official communications.
Ban sales to under-18s	There is near universal support for this policy. But US studies found that in areas where e-cigarette sales to under-18s had been banned the decline in smoking was slower than in areas where it was not banned. 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 or relative risks claims	This 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. This erects high and unnecessary regulatory barrier to truthful communication - and therefore obscures the most important consumer benefit from consumers. The authorities could address this by providing authoritative advice on relative risk - for example of the type provided by Public Health England or the Royal College of Physicians, which could be used in communication with consumers.
Raise taxes on e-cigarettes	This reduces the financial incentive to switch from smoking to vaping unless the tax on smoking is also increased. But these taxes if raised too far will tip users into other forms of unintended behaviour – accessing the black market, switching to rolling tobacco, or create cottage industries producing e-liquids in garages. It may also favour smoking cessation medications that are less effective on average, such as NRT (which in the UK actually receives an unjustified VAT discount)

About the author

Clive Bates is director of Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy and public health that he founded in 2013. He has had a diverse career in the public, private and non-profit sectors. After securing a degree in engineering from Cambridge University, he worked in information technology for IBM before moving on to work as an energy specialist with several environmental non-profits. From 1997 to 2003, he was the United Kingdom's director of Action on Smoking and Health, campaigning to reduce the harms caused by tobacco. In 2003, he joined Prime Minister Tony Blair's Strategy Unit as a civil servant and worked in several roles in the public sector in the United Kingdom and for the United Nations in Sudan.

This report was written as part of Counterfactual's advocacy program without additional funding. Clive Bates and Counterfactual have no competing interests with respect to e-cigarette, tobacco or pharmaceutical industries.