

Standing Committee on Health, Aged Care and Sport
Inquiry into the Use and Marketing of Electronic Cigarettes and Personal
Vaporisers in Australia

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Executive summary	2
1 The use and marketing of e-cigarettes and personal vaporisers to assist people to quit smoking... 3	
1.1 Positioning of e-cigarettes are a consumer alternative to cigarettes	3
1.2 The rise of e-cigarettes has coincided with a sharp decline in smoking in Britain.....	4
1.3 A similar effect has been seen in the United States – for adults <i>and</i> youth.....	4
1.4 Rapidly declining UK smoking prevalence reaches parity with Australia.....	5
1.5 The testimonies of vapers place the burden of proof on those favouring prohibition	5
1.6 The challenge of assessing the population impact of vaping products.....	6
1.7 Common misunderstandings about studies on vaping ‘effectiveness’	7
1.8 Conclusion: insights from UK and US experience relevant to legislators in Australia.....	8
2 The health impacts of the use of E-cigarettes and personal vaporisers.....	9
2.1 Why vaping should be understood to pose lower risk to health than smoking	9
2.2 E-cigarette use is likely to be at least 95% lower risk than smoking	10
2.3 So-called “dual use” of e-cigarettes and cigarettes	11
2.4 Common errors in reporting health effects of e-cigarettes and personal vaporisers.....	13
3 International approaches to regulating the use of e-cigarettes and personal vaporisers	14
3.1 Regulatory approaches adopted so far and their weaknesses	14
3.2 The key challenge in regulatory practice: unintended consequences	15
4 The appropriate regulatory framework for E-cigarettes and personal vaporisers in Australia	17
4.1 The nicotine rescheduling proposal put to the Therapeutic Goods Administration.....	17
4.2 Regulatory options for Australia	18
4.3 Product standards for liquids and devices	18
4.4 Corporate responsibility and quality control	18
4.5 Controls on e-cigarette and personal vaporiser marketing	19
4.6 Warnings, risk communication and health claims	19
4.7 Point of sale and retail restrictions	21
4.8 Use of e-cigarettes in public places – applying the ‘harm principle’	21
4.9 Taxation – an appropriate fiscal regime.....	23
4.10 Official guidance to healthcare professionals	23
5 Any other related matter	25
5.1 Broaden the scope to other low-risk alternatives to smoking	25
Appendix 1: Trends in youth tobacco and nicotine use in the United States.....	26
Appendix 2: The critic’s guide to bad vaping science	27
Appendix 3: Plausible unintended consequences of regulation	28
About the author	30

Response by Clive Bates, London UK

Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia

Executive summary

- I am pleased to provide this evidence to assist the Committee's important work. This submission follows the format of the five questions set in the terms of reference for the inquiry¹.
- E-cigarettes and personal vaporisers function as consumer products and alternatives to smoking. Their positive impact for public health arises from their attractiveness as alternatives to smoking. These products are not medicines and not poisons in the way they used by consumers and medicines and poison regulation are inappropriate and ill-fitting regulatory frameworks.
- 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.
- Declines in smoking in the UK have proceeded at three times the rate of Australia since 2013, despite Australia's punitive tobacco policy. The United Kingdom now has achieved parity in adult smoking prevalence with Australia on a like-for-like basis – the first time since records began.
- E-cigarettes and personal vapourisers do not involve the combustion of tobacco leaf and inhalation of thousands of toxic products of combustion. They are, beyond any reasonable doubt, much less harmful than smoking. Though we cannot have decades of data, nor are we entirely ignorant. 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.
- There is no scientific, ethical or compassionate case for Australia's *de facto* ban on e-cigarettes and personal vaporisers. There is no credible case to justify why Australians exposed to the health risks, stigma and punitive cost of smoking should be denied options widely available, welcomed by consumers and successful elsewhere. The burden of proof remains with the prohibitionists.
- 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.
- The proposal made to amend the Poison Schedule should have been accepted by the TGA – it makes no sense on to permit the most dangerous forms of nicotine ("tobacco prepared and packed for smoking") and to impose a *de facto* ban all the lower-risk alternatives.
- 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.
- The prohibition on other low-risk tobacco and nicotine products, for example smokeless tobacco and heated tobacco products, should also be lifted to widen the options for smokers to quit.

¹ Parliament of Australia, House of Representatives. Standing Committee on Health, Aged Care and Sport, Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia, referred 25 May 2017 [[link](#)]

Response by Clive Bates, London UK

1 The use and marketing of e-cigarettes and personal vaporisers to assist people to quit smoking

1.1 Positioning of e-cigarettes are a consumer alternative to cigarettes

E-cigarettes are used as alternatives to smoking, as recreational nicotine products for which their appeal relative to smoking is a crucial factor in their success. An apt comparison would be with diet soda – diet soda is rarely described as an anti-obesity treatment or a medication, but more often as a different way of enjoying soda with fewer calories that may have an effect on obesity and appeals to those who are fitness and weight-conscious. The Royal College of Physicians recognises equivalent positioning in its extensive 2016 report on e-cigarettes for tobacco harm reduction²:

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 Statistics³ 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.

In the tobacco and nicotine field, e-cigarettes and personal vaporisers function more like a product like ‘snus’ than a smoking cessation medication. Snus is a form of smokeless tobacco (and certainly not a medicine) that has largely displaced smoking in Sweden (smoking prevalence has fallen to 7.0%⁴) and this represents a ‘proof-of-concept’ for achieving deep cuts in smoking through the availability of low-risk alternative nicotine products with significant benefits to population health⁵.

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 [\[link\]](#)

⁴ European Commission. Eurobarometer Special Survey 458: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2017. Fieldwork March 2017. Published May 2017 [\[link\]](#) [\[PDF\]](#)

⁵ Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. *Int J Environ Res Public Health*. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). [\[link\]](#)

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

The British prevalence data⁶ 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 2: The recent rise of vaping in Britain

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 3: The recent decline of smoking in Britain

1.3 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 from 19.4% in 2010 to 15.1% in 2015⁷. An analysis of the data suggests there were 8.3 million vapers by 2015 of which 2.5 million were former smokers⁸.

Although much has been made of the risk to adolescents posed by the rise of vaping in the United States, the true picture is of rapidly declining adolescent smoking coinciding with rising vaping among young people. There is no sign of a “gateway effect” and the trends are consistent with vaping displacing smoking among adolescents. See [Appendix 1](#) for more data and graphics.

⁶ 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 [\[link\]](#)
⁷ 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.
⁸ 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 [\[link\]](#)

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1.4 Rapidly declining UK smoking prevalence reaches parity with Australia

The UK trend has meant that the decline in smoking prevalence in the UK has been faster than in Australia and, on an equivalent basis (current adult smokers age 18 and over), the UK has now reached parity with Australia, which has had lower smoking rates than the UK since records began. Comparing smoking prevalence on a like for like basis in UK⁹ and Australia¹⁰.

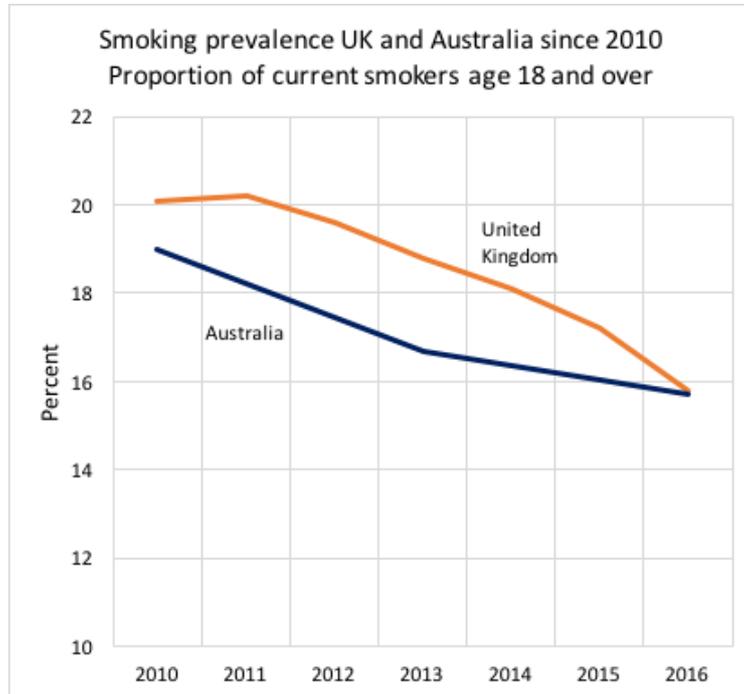


Figure 4: Decline of smoking in Australia and the United Kingdom

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 total¹¹. Average UK cigarette prices rose by 18% from 2013 to 2016. Plain packaging was introduced in December 2016.

1.5 The testimonies of vapers place the burden of proof on those favouring prohibition

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 Australia¹², the United Kingdom¹³ and the United States¹⁴ 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.

⁹ Office for National Statistics (UK). Smoking habits in the UK and its constituent countries, 2016. 15 June 2017 [\[link\]](#)

¹⁰ Australian Institute of Health and Welfare, National Drug Strategy Household Survey, 2016. Datasets [\[link\]](#)

¹¹ Australian Government, Department of Health: Plain packaging of tobacco products [\[link\]](#); Tobacco taxation [\[link\]](#)

¹² AussieVapers forum, Your story.

¹³ Counterfactual. UK vaping testimonies.. [\[link\]](#)

¹⁴ Consumer Advocates for Smoke-free Alternatives Association (CASAA), E-cigarette user testimonials. [\[link\]](#)

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More systematic surveys also suggest that vapers believe they have quit smoking through vaping. Analysis of European Union survey data found¹⁵:

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 found¹⁶.

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.

Why testimonies matter. The reason that such testimonies are important to Australia's legislators is that it is the policy of the government to try to purposefully deny these highly positive experiences to Australians. That begs the question: why and on what basis? The evidence of highly positive experiences demands that some commensurately negative effect is found to justify the *de facto* prohibition built in to Australia's regulatory regime. But no such negative case exists to justify overriding the rights and options of those who wish to use these products.

1.6 The challenge of assessing the population impact of vaping products

Critics have stressed the small number of randomised controlled trials available to provide supporting evidence of e-cigarette effectiveness, arguing that evidence is weak. In reality the impact of e-cigarettes and personal vapourisers is inherently difficult to study. The main reason is that these products do not work like medical drugs in which a pharmacologically active substance changes the body irrespective of what the user does or what is going on in their surroundings. The introduction and diffusion of a new technology functions as a perturbation of a complex behavioural eco-system and many changes happen simultaneously.

In contrast to a typical drug, the impact of vapour products on smoking behaviour is not determined solely by the product itself, but by a wide range of influences on behaviour that are independent of the product. These include the influence of news and commentary on risk perceptions, taxation and pricing, ease of access and availability of retail or internet sales, vaping policies in public or work places, peer support (e.g. through social media or vape shops) and the strengths of brands. Vapers will typically progress from a simple device to a more complicated 'tank' system and may change the strength and volume of liquid consumed over time. In the real world, there is a 'learning curve' to master as a vaping novice learns how to use the product to replace the experience of smoking. If learning takes too long, then they may relapse to smoking. This complexity does not lend itself to randomised controlled trials (RCTs), the common approach for evaluating medicines, because it is impossible and unrealistic to control for all these variables.

¹⁵ 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; [\[link\]](#)

¹⁶ 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. [\[link\]](#)

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Just as diet soda makers do not make claims about obesity, vaping manufacturers rarely make therapeutic claims for vaping products so there is no obligation on them to run expensive trials to prove claims that they do not make.

There is already some evidence that vaping products differ in effectiveness according to the regulatory regime of the country in which they are used. Yong et al (2017)¹⁷ found that vaping was less effective in Australia and Canada than in the UK and United States – not because of the products, but the policy-induced barriers to using them effectively.

1.7 Common misunderstandings about studies on vaping ‘effectiveness’

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 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 conclude¹⁸

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.

¹⁷ Yong H-H, Hitchman SC, Cummings KM, Borland R, Gravely SML, McNeill A, et al. Does the Regulatory Environment for E-Cigarettes Influence the Effectiveness of E-Cigarettes for Smoking Cessation?: Longitudinal Findings From the ITC Four Country Survey. *Nicotine Tob Res*; 2017 Apr 5;25(e1):e1–2. [\[link\]](#)

¹⁸ McNeill A, Brose LS, Calder R, et al. E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [\[link\]](#)

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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 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 follows¹⁹, 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.

1.8 Conclusion: insights from UK and US experience relevant to legislators in Australia

The United Kingdom and United States have both experienced very substantial and positive movement in smoking behaviour during the rise in popularity of vaping and many users say they are using these products to reduce harm and quit smoking. The data is consistent with vaping causing the rapid decline in smoking and this would be a common sense interpretation of the trends and testimonies of vapers. However, this type of data cannot *formally prove* that vaping is *causing* the decline in smoking and we should acknowledge that it is inherently difficult to make this assessment.

But the data do suggest two significant conclusions for Australian legislators:

1. Nothing is going wrong and much appears to be going very well in the UK and United States where e-cigarettes and personal vaporisers have been widely available and regulated as consumer products (until 2016). Both adult and youth smoking rates have been falling rapidly. Despite exhaustive efforts to identify problems with vaping, the reality is highly positive.
2. It is hard to see how the government could justify *preventing* Australian citizens having access to e-cigarettes and personal vaporisers products given much lower individual risk (see [next section](#)) and the positive experience of these products in the UK and US. The burden of proof should rest with those insisting that a much safer alternative to smoking should be banned while leaving cigarettes freely available. The supporters of the *status quo* in Australia are proposing a to maintain a prohibition on a much safer product than the market leader. This is a bizarre approach – why protect the cigarette trade and deny smokers the safer alternative? It is up to them to justify it by providing evidence showing material net harms are likely, which they cannot. The supporters of prohibition need to assume some responsibility for the potential for increased smoking if their preferred policy is to deny access to the lower risk products, something they appear unwilling to do.

¹⁹ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016. Key recommendations [\[link\]](#)

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2 The health impacts of the use of E-cigarettes and personal vaporisers

2.1 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 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 smokers²⁰. 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^{21 22 23 24 25}.

²⁰ 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. [\[link\]](#)

²¹ 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. [\[Link\]](#)

²² 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. [\[Link\]](#)

²³ 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 [\[link\]](#)

²⁴ 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. [\[link\]](#)

²⁵ 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. [\[link\]](#)

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3. **Effects on the human body.** There is evidence that chronic conditions improve when smokers switch to vaping, for example in the case of asthma²⁶, breathing problems²⁷ and lung function²⁸. It is possible to compare salivary or urine biomarkers to assess bodily exposure to hazardous agents. Again, the findings are very encouraging²⁹.

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

2.2 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 vaping³⁰.

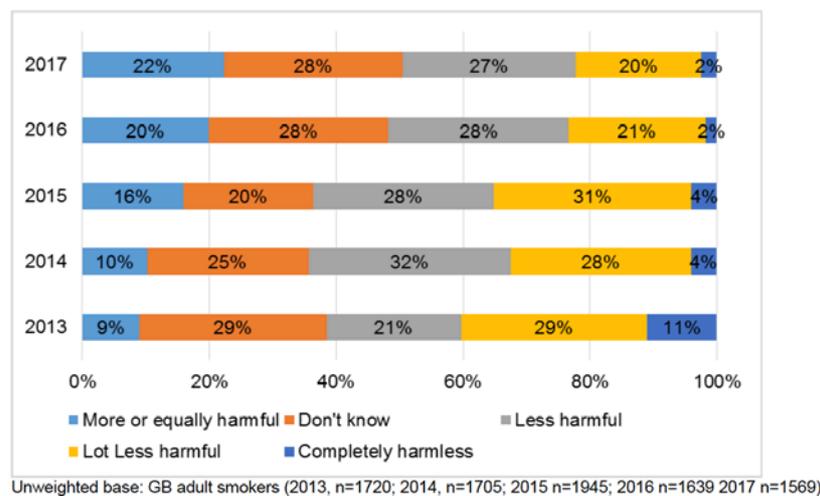


Figure 5:Smokers’ perceptions of harm from e-cigarettes

²⁶ 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. [\[link\]](#)

²⁷ 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; [\[link\]](#)

²⁸ Polosa R. Electronic cigarette use and harm reversal: emerging evidence in the lung. *BMC Med*.; 2015;13(1):54. [\[link\]](#)

²⁹ 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. [\[link\]](#)

³⁰ ASH (UK) / YouGov. Use of e-cigarettes among adults in Great Britain 2017. 8 May 2017. Figure 9 [\[link\]](#)

Response by Clive Bates, London UK

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 guideline³¹

..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 this³², 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 report³³:

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.

2.3 So-called “dual use” of e-cigarettes and cigarettes

Anti-vaping activists have made much of the fact that some vapers also smoke, at least if a snapshot is taken at any point in time. They have claimed that this “dual use” provides no benefits to health and even that it is a deliberate ploy by tobacco companies to keep people both smoking and vaping.

³¹ 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. [\[link\]](#)

³² McNeill A, Hajek P. Underpinning evidence for the estimate that e-cigarette use is around 95% safer than smoking: authors' note, 28 August 2015 [\[link\]](#)

³³ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016. Section 5.5 page 87. [\[link\]](#)

Response by Clive Bates, London UK

This is a case of a misunderstanding of the pathways that people follow from smoking to not smoking combined with a naivety about how competitive markets work.

Consider the following observations about dual use:

- It is argued that studies of cutting down show no health benefits. However, cutting down with an alternative nicotine source is different to cutting down without. This is because consumers are generally seeking a desired dose of nicotine and adjust their smoking behaviour accordingly. It is possible to cut down number of cigarettes and not actually reduce *exposure* because of a compensatory effect of smoking more intensively. Such an effect is less likely if there is an alternative nicotine source. It is impossible to transfer conclusions from the studies without alternative nicotine to situations where there is, for example from e-cigarettes.
- There are many smoking-related diseases, such as cancer, for which a linear exposure-risk relationship is understood. Cutting down with alternative nicotine should reduce these risks if it reduces the nicotine taken in from cigarettes, and by implication the exposure to smoke.
- Dual use can be many different things – ranging from nearly always vaping and occasional smoking to the opposite. These are *completely* different behaviours and it is obvious that cutting down from smoking a pack a day to two cigarettes a week will make a significant difference to health – though the user would still be considered a ‘dual-user’. The behaviour referred to as ‘dual use’ needs to be disaggregated by frequency of use.
- Vapers who continue to smoke may be undergoing a longer-term transition from smoking to non-smoking – the system is ‘dynamic’ and users may be moving through different stages of use that are not evident in a snapshot survey. There is some evidence that dual users have an increased likelihood of going on to quit³⁴ and cutting down is an stated purpose for some NRT products in some jurisdictions, with a view to making quitting easier³⁵.
- Almost everyone who quits smoking *by any method* carries on smoking for months or years while they do it – this is because success rates are so low with all established methods including NRT, prescription drugs, behavioural support and ‘cold turkey’. People will quit and relapse back to smoking multiple times before they finally quit, if they ever do.
- Unless a product was 100% immediately successful, and nothing is, then some sort of dual use or continued smoking is inevitable – so an artificial and unrealistic expectation has been fabricated to imply some kind of inadequacy in these products – a straw man – given it applies equally to everything else done in tobacco control.
- Tobacco companies do not have control over consumers preferences in a competitive market and they cannot sell unsatisfying products to consumers even if they wanted to, and there is no evidence they do want to. They would simply lose out to competitors with superior products.

³⁴ Manzoli L, Flacco ME, Ferrante M, Vecchia CL, Siliquini R, Ricciardi W, et al. *Cohort study of electronic cigarette use: effectiveness and safety at 24 months*. Tobacco Control. 2016 [\[link\]](#)

³⁵ For example, NiQuitin Patient Information leaflet [\[link\]](#). [product can be used to] “cut down on smoking, perhaps before you go on to stop completely (*reducing to quit* or just *reducing*). Reducing the number of cigarettes smoked can increase the chances that you will go on to quit completely.”

Response by Clive Bates, London UK

2.4 Common errors in reporting health effects of e-cigarettes and personal vaporisers

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-cigarettes³⁶:

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.

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 6: 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 critic's guide to bad vaping science*³⁷. The overview of this guide's approach to interrogating scientific claims is reproduced at [Appendix 2](#).

Some of the debate in Australia about tobacco policy and alternative strategies like tobacco harm reduction has descended to lamentable standards of scientific literacy and risk communication³⁸. We hope the committee will find these guides useful in assessing the evidence presented to the inquiry by both sides of what has become a needlessly acrimonious debate.

³⁶ West R, Electronic cigarettes: getting the science right and communicating it accurately, *Addiction*, virtual edition on e-cigarettes, December 2014. [\[link\]](#)

³⁷ Bates CD. The critic's guide to bad vaping science, Counterfactual, December 2016 [\[link\]](#)

³⁸ For an example of this style of argument see Professor Simon Chapman in the Sydney Morning Herald, *Keep TGA control of e-cigarettes or risk repeating the smoking health disaster*, 20 June 2017 [\[link\]](#). My line-by-line response: Bates CD. *A critical review of an Australian anti-vaping polemic*, Counterfactual, 21 June 2017 [\[link\]](#)

Response by Clive Bates, London UK

3 International approaches to regulating the use of e-cigarettes and personal vaporisers

3.1 Regulatory approaches adopted so far and their weaknesses

Regulatory approaches adopted. The Institute for Global Tobacco Control at Johns Hopkins Bloomberg School of Public Health maintains a rolling scan of e-cigarette policies³⁹ and publishes snapshots from time to time⁴⁰. At the time of writing the scan covered the following:

There are 79 countries that have national/federal laws regulating e-cigarettes including laws related to the sale (including minimum age), advertisement, promotion, sponsorship, packaging (child safety packaging, health warning labeling and trademark), product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavors), reporting/notification, taxation, use (vape-free) and classification of e-cigarettes

Regulatory approaches adopted so far have been subject to criticisms. Regulations relating to the product itself 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 default⁴¹. 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^{42 43}.
- *Product by product authorisation* (e.g. United States FDA deeming rule). The FDA's approach has attracted considerable criticism⁴⁴ and legal action⁴⁵ 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..

³⁹ Institute for Global Tobacco Control. Country Laws Regulating E-cigarettes: A Policy Scan. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. June 5, 2017. Accessed 1 July 2017 [\[link\]](#)

⁴⁰ Kennedy RD, Awopegba A, De León E, Cohen JE. Global approaches to regulating electronic cigarettes. *Tob Control*. 2017 Jul;26(4):440–5. [\[link\]](#):

⁴¹ 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](#)

⁴² Bates CD. What is wrong with the Tobacco Products Directive for vapour products? Counterfactual. 22 May 2015 [\[link\]](#)

⁴³ Snowdon CJ. E-cigarettes and Article 20 of the Tobacco Products Directive. European Policy Information Center (EPICENTER), September 2015. [\[link\]](#)

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 [\[link\]](#)[\[PDF\]](#) Bates CD. Rethinking nicotine: implications for U.S. federal tobacco policy – A discussion paper. June 2017 [\[link\]](#)[\[PDF\]](#)

⁴⁵ 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 [\[link\]](#)

Response by Clive Bates, London UK

- *De facto prohibition via regulating e-cigarettes as medicines* (e.g. Australia and Canada). 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 products⁴⁶ and has functioned as a *de facto* prohibition.
- *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 has drawn as a result⁴⁷. It is also possible that such prohibitions (and by implication *de facto* prohibitions) are unlawful under WTO agreements^{48 49}.

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.

Regulatory purpose often unclear. 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 international approaches to regulation stems from inadequate specification of risks, with over-reaction to negligible or theoretical risks, combined with indifference to the opportunities.

3.2 The key challenge in regulatory practice: unintended consequences

The main problem with all the regulatory schemes developed so far is insufficient sensitivity to unintended consequences of regulation. The Royal College of Physicians explains how regulation could implicitly support continued smoking and protect cigarette sales if it comprised key attributes of e-cigarette use⁵⁰:

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.

⁴⁶ Bates CD, Stimson G. Costs and benefits of medicines regulation for e-cigarettes, *Nicotine Science and Policy*, 20 September 2013 [\[link\]](#)

⁴⁷ 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 [\[link\]](#)[\[PDF\]](#)

⁴⁸ Foltea M, Markitanova A. The “Likeness” of New and Conventional Tobacco Products in the WTO. In: *Society of International Economic Law (SIEL)*, 2016. [\[link\]](#)

⁴⁹ 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 [\[link\]](#)[\[PDF\]](#)

⁵⁰ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016. Section 12.10 page 187 [\[link\]](#)

Response by Clive Bates, London UK

The failure to assess unintended consequences. A pre-requisite for “Getting this balance right”, to quote the RCP, is an understanding that there is a balance to be struck in the first place. Yet there is scant evidence that regulators anywhere have recognised the possibility that regulation will make matters worse than having no regulation, and internalised this insight into their decision-making.

Given the very high risks associated with smoking and the low risks associated with vaping, it requires only small unintended consequences of the type mentioned by the RCP to swamp any intended benefits claimed for regulation itself. None of the main regulatory schemes proposed so far (including EU Tobacco Products Directive, US FDA deeming rule, Australia’s TGA and all the policy advice provided by WHO), have made any attempt to recognise or assess these unintended consequences. It follows therefore that none have a rational case that their measures are justified or optimal.

Belatedly, the UK government has acknowledged the potential for unintended consequences associated with the EU Tobacco Products Directive provisions that relate to e-cigarettes⁵¹ but by 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

It is important that recognition of unintended consequences *precedes* regulatory intervention and is incorporated into the deliberations of regulators and informed by consumers as a regulator framework is defined.

A more complete account of plausible unintended consequences is provided at [Appendix 3](#).

⁵¹ Department of Health, MHRA (UK), Tobacco Products Directive, Impact Assessment, 18 April 2016. [\[link\]](#)

Response by Clive Bates, London UK

4 The appropriate regulatory framework for E-cigarettes and personal vaporisers in Australia

4.1 The nicotine rescheduling proposal put to the Therapeutic Goods Administration

The most important regulatory intervention for Australia is to reschedule nicotine e-liquids so that they are no longer classified as poisons. A proposal was made to the Therapeutic Goods Administration (TGA) to amend Australia's Poisons Schedule to reschedule nicotine-based e-liquids up to 3.6% nicotine, with a range of additional safeguards. This would have extended the exemption granted to "tobacco prepared and packed for smoking" (i.e. cigarettes) to much safer alternatives.

Schedule 7 - Proposed amendment

NICOTINE **except:**

- a. when included in Schedule 6 [an exception for nicotine used to treat animals];
- b. in preparations for human therapeutic use; or
- c. in tobacco prepared and packed for smoking; **or**
- d. in preparations for use as a substitute for tobacco when packed and labelled:**
 - i. for use in an electronic nicotine delivery system (ENDS)**
 - ii. nicotine concentration up to 3.6%**
 - iii. maximum nicotine per container: 900 mg**
 - iv. in a child resistant container**
 - v. labelled with the concentration of nicotine and other ingredients**
 - vi. labelled with the statement 'Keep out of reach of children'**
 - vii. labelled with the statement 'Not to be sold to a person under the age of 18 years'.**

The TGA examined then rejected this proposal outright⁵² despite extensive expert evidence provided to justify it⁵³. While it is possible that TGA could have made a case for the refusal, its reasoning was wholly inadequate. Following publication of its interim decision⁵⁴, an expert group provided a detailed critique of the TGA's reasoning⁵⁵ and others provided similar analysis. I do not believe the arguments put to the TGA and its committees were assessed through an appropriate public health lens, in which smoking is properly recognised as the underlying problem and the needs and rights of Australia's 2.8 million smokers were given due emphasis. This proposal was a perfectly good proposal for a first step in reregulating e-cigarettes in Australia and should not have been rejected.

⁵² Therapeutic Goods Administration (Australia), Joint Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS #14) Final decisions on matters referred to an expert advisory committee: 2.1 Nicotine. 23 March 2017 [\[link\]](#)

⁵³ Submission by forty international and Australian experts. Proposed Amendments to the Poisons Standard. Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine. 31 August 2016 [\[link\]](#)

⁵⁴ Therapeutic Goods Administration (Australia), Joint Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS #14) Interim decisions on matters referred to an expert advisory committee: 2.1 Nicotine. 2 February 2017 [\[link\]](#)

⁵⁵ Submission by twenty-one international and Australian experts. Proposed Amendments to the Poisons Standard Further comments on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine – critique of the delegates' interim decision. 16 February 2016. [\[link\]](#)

Response by Clive Bates, London UK

4.2 Regulatory options for Australia

Because of the possible unintended consequences of intervention, the 'do nothing' option should figure prominently in any regulatory impact assessment. In this case 'do nothing' would mean applying the rules that already apply to consumer products, advertising, fair trading practices, etc. However, the sections below briefly discuss seven aspects of regulatory intervention

- Product standards for liquids and devices
- Corporate responsibility and quality control
- Controls on e-cigarette and personal vaporiser marketing
- Warnings, risk communication, and health claims
- Use in public places
- Taxation
- Advice to health care professionals and the public

4.3 Product standards for liquids and devices

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 measures⁵⁶. There have been e-cigarettes standards initiatives in the UK⁵⁷ and now the EU standardization body (CEN) is developing an e-cigarettes standard⁵⁸. The American E-liquid Manufacturing Standards Association (AEMSA) has developed an industry standard for e-liquids and related manufacturing processes⁵⁹ and several respected American businesses have adopted this. There are many relevant electrical standards.⁶⁰ There are ISO standards for child-resistant packaging⁶¹.

4.4 Corporate responsibility and quality control

It is important that the companies engaged this business are responsible, identifiable and have good quality control procedures in place. These include:

⁵⁶ 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 [\[link\]](#)

⁵⁷ 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

⁵⁸ European Centre for Standardisation, CEN/TC 437 - Electronic cigarettes and e-liquids [\[link\]](#)

⁵⁹ AEMSA E-liquid manufacturing standard Version 2.3.2 - March 8, 2017 – accessed 17 May 2013 [\[link\]](#)

⁶⁰ 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) [\[link\]](#)

⁶¹ 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 [\[link\]](#)

Response by Clive Bates, London UK

- **Identification.** Registered address, contact information and ‘responsible person’ identified.
- **Quality control.** Manufacturers should meet a quality management standard, for example, ISO9000:2015⁶²

4.5 Controls on e-cigarette and personal vaporiser marketing

While it may be tempting to ban e-cigarette advertising by simply extending the prohibition of tobacco advertising⁶³, this would be disproportionate and counter-productive. Firstly, it would lack a rationale: cigarette smoking is extremely harmful and this provides the basis for banning its advertising, but no serious risks with vaping have so far been established. Secondly, a ban would have the undesirable effect of preventing companies from encouraging smokers to switch protecting the incumbent cigarette trade from competition. Thirdly, it would make it harder to communicate innovation, including innovation in health and safety, ease of use and experience relative to smoking. In doing so it could slow the steady displacement of smoking by vaping. Finally it would prevent the building of trusted brands and so lower customer confidence and the return to investment in high quality products.

It is appropriate to think of e-cigarette advertising as ‘anti-smoking’ – it is generally negative about smoking and encourages quitting - but to provide some protections that limit the appeal to children. Such a system would be based on Australia’s normal controls guaranteeing advertising is legal, honest, decent and truthful⁶⁴ with some additional restrictions that control themes, timing and placement of advertising to prevent appeal to children or irresponsible marketing of e-cigarettes.

The UK Committee on Advertising Practice produced useful guidelines on advertising provide a reasonable balance of interest between protection of minors and promotion of new low-risk products to smokers, somewhat similar to the controls on alcohol advertising⁶⁵. In Australia, the approach used to regulate the advertising of alcohol would provide a reasonable starting place (though e-cigarettes are likely to be much less harmful overall than alcohol)⁶⁶.

4.6 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”⁶⁷. 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.

⁶² International Organization for Standardization. ISO 9000:2015 Quality Management, 23 September 2015 [\[link\]](#) ISO 9001:2015 for Small Enterprises - What to do? [\[link\]](#)

⁶³ Tobacco is advertising in banned in Australia, Tobacco Advertising Prohibition Act 1992 [\[link\]](#)

⁶⁴ Australian Competition and Consumer Commission, under the Competition and Consumer Act 2010 [\[link\]](#)

⁶⁵ 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 [\[link\]](#)

⁶⁶ The Alcohol Beverages Advertising Code Scheme (Australia) [\[link\]](#), ABAC Responsible Alcohol Marketing Code [\[link\]](#)

⁶⁷ 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 [\[link\]](#)

Response by Clive Bates, London UK

However, UK survey data⁶⁸ suggests the most important reason for smokers not switching to e-cigarettes is fear of substituting one addiction for another.

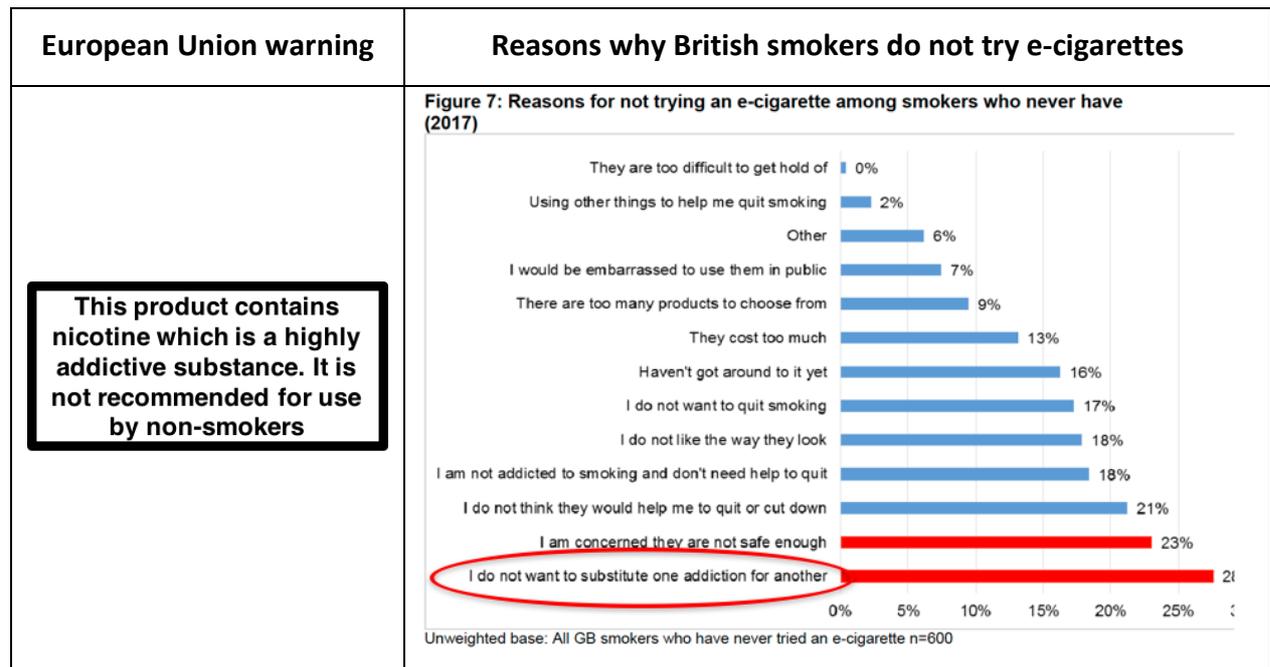


Table 1: Impact of warnings on attitudes to vaping

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 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 would 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.

⁶⁸ Action on Smoking and Health, Fact sheet: ASH Fact Sheet on the use of electronic cigarettes among adults in Great Britain [\[link\]](#)

Response by Clive Bates, London UK

4.7 Point of sale and retail restrictions

There are a number of possible controls on sales of e-cigarettes applied at the point of sale.

- **Age restrictions.** Almost everyone involved favours restricting e-cigarette sales to people age 18 and over. However, even this is open to question on public health grounds. There are already studies^{69 70} from the United States suggesting *smoking has increased* among teenagers where age restrictions have been placed on sales of e-cigarettes. This may be considered part of the 'license to operate'.
- **Retail accessibility.** E-cigarettes should be at least as easily available as cigarettes. Proposals to sell only in pharmacies, for example, should be rejected. There is no case for banning display or point of sale advertising. In fact, there is a strong case to encourage switching in the store where cigarettes are on sale. Specialist vape stores combine a wide range of products with coaching and advice on selection and use of products, creating what amounts to a smoking cessation service offering.
- **Internet sales.** Sales over the Internet are integral to the e-cigarette business model and are especially important for the more experienced users or those remote from vape towns capable of supporting a vape store. This is because the density of customers is lower, the diversity of stock much greater, and the rate of innovation much higher. Each of these favours large concentrations of stock rather than stock held in convenience stores serving small customer populations.

4.8 Use of e-cigarettes in public places – applying the 'harm principle'

E-cigarettes release emissions into the atmosphere, which can affect air quality indoors. Should this be permitted? There are essentially two approaches to this:

1. A government or regulator determines that e-cigarettes cannot be used in certain public (often privately owned) places – often applying a broad prohibition or imposing the same bans on use that apply to smoking.
2. The owners or managers of each place decide whether to allow e-cigarettes use or not – taking account of the type of place, their clients and their commercial interests. This does not imply a 'right to vape', but leaves the decision to a property owner or manager.

Generally, governments should support option one only where there a material risk to bystanders has been established and the government has a proper justification to override the preferences of owners or managers. This type of state action requires a justification – and this is usually found in the 'harm principle' first articulated by John Stuart Mill⁷¹

That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.

⁶⁹ Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [[pubmed](#)]

⁷⁰ Pesko MF, Hughes JM, Faisal FS. The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use. *Prev Med (Baltim)*, February 2016 [[pubmed](#)]

⁷¹ Mill JS. On Liberty, 1859. [[link](#)]

Response by Clive Bates, London UK

Applying this principle, there is no case for banning vaping by law or a blanket prohibition – the case for banning smoking by law rests on material harm to others, and the evidence suggests that e-cigarettes cause is no material risk to bystanders. In his detailed review of the toxicity evidence, Igor Burstyn concluded that risks to active vapers were well below thresholds used to set workplace exposure standards and concluded that for passive vaping⁷²:

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

It is true that not everyone wishes to be exposed to someone else’s exhaled vapour. The issue is thus one of nuisance and etiquette, not a matter in which legislators should intervene to override the preferences of owners or managers of public spaces to protect bystanders or workers, for whom vaping represents a minor occupational exposure.

There are many places, times, events, and circumstances where vaping may be reasonable or commercially valuable and should not be ruled out by a blanket ban and that a centrally directed prohibition would be clumsy and inappropriate. The figure below gives examples of reasonable vaping policies that owners or managers of space may adopt given the choice.

Real world examples of options for vapour policy set by owners and managers
<ol style="list-style-type: none"> 1. A bar wants to have a vape night every Thursday 2. A bar wants to dedicate one room where vaping is permitted 3. In a town with three bars, one decides it will cater for vapers, two decide they will not allow vaping 4. A bar manager decides on balance that his vaping customers prefer it and his other clientele are not that bothered – he’d do better allowing it 5. A hotel wants to allow vaping in its rooms and in its bar, but not in its restaurant, spa, and lobby 6. An office workplace decides to allow vaping breaks near the coffee machine to save on wasted smoking break time and encourage smokers to quit by switching 7. A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter instead of going out in the cold 8. A vape shop is trying to help people switch from smoking and wants to demo products in the shop 9. A shelter for homeless people allows vaping to make its clients feel more welcome 10. A supermarket does not allow vaping, but a bookshop keen to attract browsers does

Table 2: Examples of options for vaping policies

The purpose of a blanket ban would be to prevent managers and owners making these nuanced and reasonable decisions (as above) using broad provisions and the force of law. In the absence of harm, the appropriate policy is to allow owners and operators to decide their policy and make informed judgements, including the welfare value to vapers and smokers and make clear whether vaping is permitted or not. The role of the government should be limited to providing guidance to assist in making such decisions, an approach that has been adopted in England^{73 74}.

⁷² 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 [\[link\]](#)

⁷³ See ASH structured questions: Will you permit or prohibit e-cigarette use on your premises? 2014 [\[link\]](#)

⁷⁴ Public Health England, Use of e-cigarettes in public places and workplaces, 6 July 2016 [\[link\]](#)

Response by Clive Bates, London UK

4.9 Taxation – an appropriate fiscal regime

There are strong practical and principled reasons not to tax e-cigarettes at all, above normal sales taxes⁷⁵. If it is accepted they are assisting with smoking cessation, then economically they should be treated as if they create societal benefits commensurate with smoking cessation. Smoking cessation tends to attract *public spending* rather than taxation through campaigns or the healthcare system. However, in practice governments are likely to approach taxation of e-cigarettes products with four contending objectives in mind: raising revenue; public health impact; cost of administration; potential for black market. In making these trade-offs, the following considerations should apply:

1. **Comparison with smoking – societal harm.** Experts in tobacco taxation argue that tax should reflect risks, and therefore that e-cigarettes should be taxed at a significantly lower rate than cigarettes⁷⁶. This will provide a fiscal incentive to switch. Vapour product use is likely to have at least a 95% lower risk than smoking. If tax was set proportionate to risk as some proportional deterrent, then the tax yield for e-cigarettes would be so low it would not be worth the cost of collecting. The only way to make a tax viable is to tax vaping *disproportionately* to risk. This means applying a disproportionately large deterrent to e-cigarette use.
2. **Comparison with NRT – therapeutic value.** E-cigarettes in fact produce a *net health benefit* by reducing smoking – their risk is on average *negative*. From an economic and tax perspective, e-cigarettes should be viewed more like over-the-counter medicines. Some jurisdictions apply a reduced sales tax to NRT⁷⁷ - a tax subsidy. In the UK, NRT attracts a sales tax (VAT) of 5% compared to the 20% standard rate.
3. **Replacing lost cigarette tax revenue.** The argument that because tax-take is falling from cigarettes as people switch, then excise duty should be applied to e-cigarettes is appealing but does not have an economic rationale, even if superficially appealing. Tax should be raised from the least distorting and most efficient tax base available, or from cuts in inefficient public spending: there is no reason why cigarette excise losses should be recovered from taxes on e-cigarettes, but could be raised from, say, a carbon tax or aggregates tax, or offset by cutting inefficient public spending.
4. **Comparison with consumer goods.** E-cigarettes carry relevant sales taxes. What rationale is there for taking more than the standard level of tax from these products, given they do little harm and probably more good than most consumer products?

4.10 Official guidance to healthcare professionals

There is now recognition among tobacco control professionals and public sector practitioners that e-cigarettes can be used constructively to reduce harm. For example, in Britain the National Centre for Smoking Cessation and Training and Public Health England, the government's public health agency, has developed evidence-based guidance for health professionals. It provides a clear and measured

⁷⁵ New Nicotine Alliance. Revision of the Tobacco Excise Directive (EU), Implications for low-risk nicotine products, December 2016 [[link](#)][[full report - PDF](#)]

⁷⁶ Chaloupka FJ, Swenor D, Warner KE. Differential Taxes for Differential Risks--Toward Reduced Harm from Nicotine-Yielding Products. *New England Journal of Medicine* 2015;373:594–7. [[link](#)]

⁷⁷ In the UK, NRT sold OTC is subject to a reduced 5% rate of Value Added Tax

Response by Clive Bates, London UK

assessment of the state of science and best practice. This guidance could be valuable to any country wishing to exploit the opportunities and minimise the risks⁷⁸.

The following table is a summary of the official guidance given to UK health professionals by the NCSCST and Public Health England.

<p><i>Recommendations for practice</i></p> <ol style="list-style-type: none"><i>1. Be open to e-cigarette use in people keen to try them; especially in those who have tried and failed to stop smoking using licensed stop smoking medicines.</i><i>2. Provide advice on e-cigarettes that includes:</i><ul style="list-style-type: none"><i>• E-cigarettes provide nicotine in a form that is much safer than smoking.</i><i>• Some people find e-cigarettes helpful for quitting, cutting down their nicotine intake and/or managing temporary abstinence.</i><i>• There is a wide range of e-cigarettes and people may need to try various types, flavours and nicotine dosages before they find a product that they like.</i><i>• E-cigarette use is not like smoking and people may need to experiment and learn to use them effectively (e.g. longer ‘drags’ may be required and a number of short puffs may be needed initially to activate the vaporiser and improve nicotine delivery). They may also need to recognise when atomisers need replacing.</i><i>• People previously using e-cigarettes while smoking (e.g. to reduce the number of cigarettes that they smoke) may need to consider changing devices and/or nicotine concentrations when making a quit attempt.</i><i>• Although some health risks from e-cigarette use may yet emerge, these are likely, at worst, to be a small fraction of the risks of smoking. This is because e-cigarette vapour does not contain the products of combustion (burning) that cause lung and heart disease, and cancer.</i>

Figure 7: Guidance on e-cigarettes to health and smoking cessation professionals in England

This is a balanced and open-minded approach, and reflects an emerging consensus on how to exploit the opportunities of e-cigarettes while containing any risks. The guidance is notable for a number of balanced statements about vaping that successfully blend scientific evidence and empathy for smokers’ and their efforts to use vaping to protect their health⁷⁹. It is a model that could be adopted in Australia.

⁷⁸ McRobbie H. McEwen A. E-cigarette briefing (Version 2). National Centre for Smoking Cessation and Training, Public Health England. London, February 2016 [\[link\]](#)

⁷⁹ Bates C. Blending evidence and empathy – a new guide to e-cigarettes, Counterfactual, February 2016 [\[link\]](#)

Response by Clive Bates, London UK

5 Any other related matter

5.1 Broaden the scope to other low-risk alternatives to smoking

Any reconsideration of policy in this area should extend to all tobacco / nicotine products that are prohibited by virtue of poison scheduling. Schedule 7 allow for recreational nicotine only in a form that is “prepared and packed for smoking”. This prohibits several important low-risk product categories that fall outside the definition of “prepared and packed for smoking” and also the focus of this inquiry in “electronic cigarettes and personal vaporisers”. These products are other forms of tobacco or nicotine that do not involve combustion – smokeless tobacco, the newly emerging heated tobacco products and consumer nicotine products. A segmentation is illustrated below.



Figure 8: alternative low-risk nicotine products

All of these products share one important characteristic – they provide nicotine *without the combustion of tobacco*. As a result, they offer much lower levels of toxicity and health risk. The second characteristic they share is that all are prohibited in Australia even though cigarettes are permitted, *and they are banned precisely because they are not for smoking*.

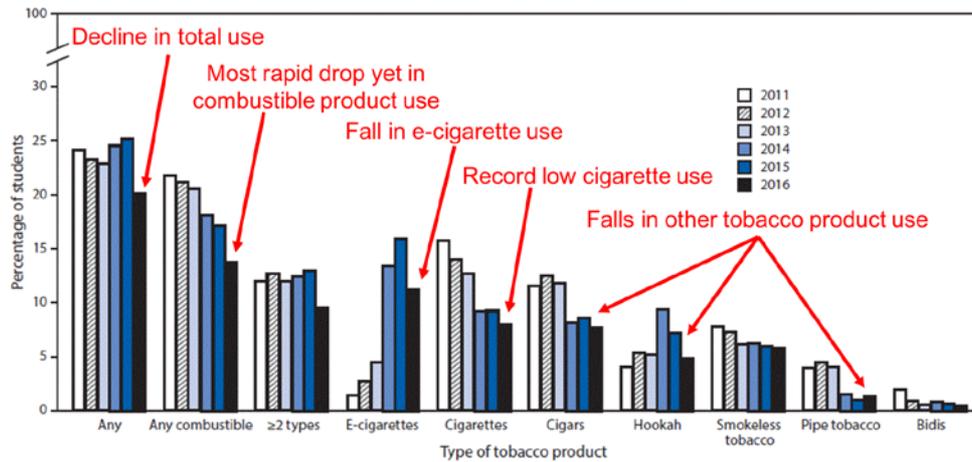
The idea of allowing the availability of such products is to increase the options available to Australians to stop smoking. For example, it is possible that heated tobacco products can mimic the sensation of smoking more closely than e-cigarettes, so there may be a prospect of attracting more committed smokers to a greatly reduced risk product. Different people may want different products at different times of day and at different points in a transition from smoking to not smoking. Given the risks are one to three orders of magnitude lower than smoking, there is no reason for the government to actively prevent people accessing these alternatives. Many of the approaches suggested for regulation of e-cigarette would work well if adapted for these products.

Response by Clive Bates, London UK

Appendix 1: 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 2017⁸⁰.

FIGURE 1. Estimated percentage of high school students who currently use any tobacco products,* any combustible tobacco products,[†] ≥2 tobacco products,[‡] and selected tobacco products – National Youth Tobacco Survey, United States, 2011–2016^{§,¶,||}



* Any tobacco product use is defined as past 30-day use of electronic cigarettes, cigarettes, cigars, hookahs, smokeless tobacco, pipe tobacco and/or bidis.

Figure 9: 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 smoking⁸¹.

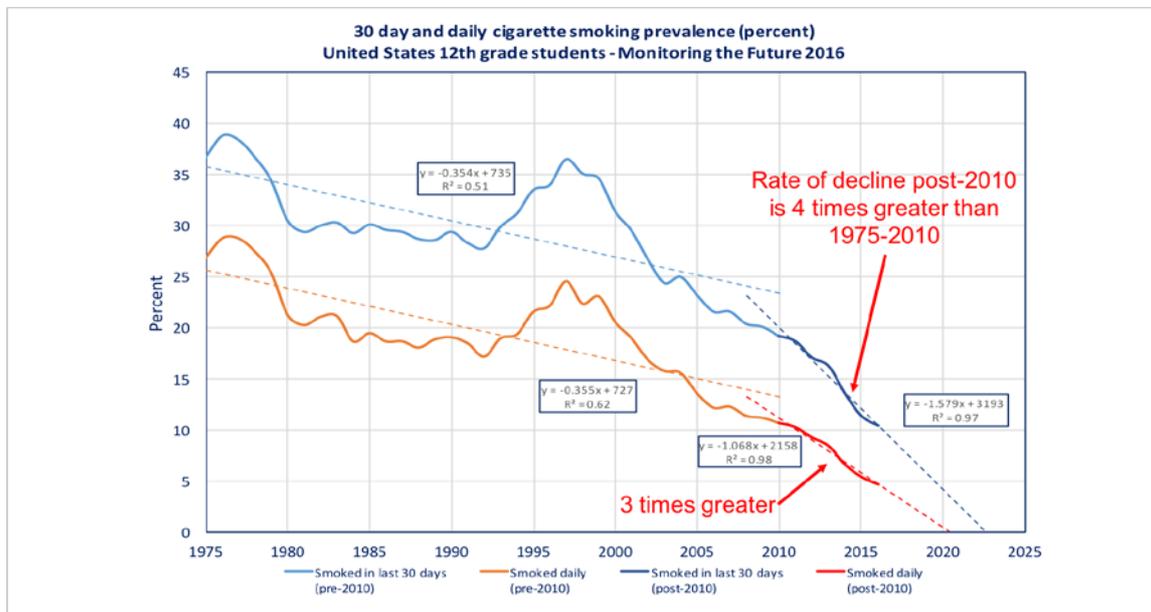


Figure 10: Accelerating decline in 12th grade smoking United States post-2010

⁸⁰ 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](#)]

⁸¹ 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](#)].

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Appendix 2: 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 being 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 11: Overview of the questioning approach to interrogating vaping science

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Appendix 3: 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.

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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’ 2 nd and 3 rd 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)

Response by Clive Bates, London UK

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.

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