American Vaping Association
www.vaping.info

TESTIMONY OF GREGORY CONLEY

CONNECTICUT JOINT PUBLIC HEALTH COMMITTEE

MARCH 11, 2015

Chairpersons Gerratana and Ritter and distinguished members of the Joint Public Health Committee:

I am writing in regard to Proposed HBs No. 5449, 6283 and 6290 on behalf of the American Vaping Association (AVA), a nonprofit organization that advocates for small- and medium-sized businesses in the vapor product and electronic cigarette markets. The AVA urges you to reject any regulation that would make vapor products less accessible, affordable, or attractive to Connecticut adult smokers.

These bills pose a grave threat to small businesses in Connecticut that are creating jobs, paying taxes, occupying what may otherwise be empty storefronts, and offering an effective smoke-free alternative to Connecticut's 435,000-plus adult smokers. There is no evidence-based justification that supports imposing the broad range of proposals found in these proposed bills.

When considering any legislation that would impact the ability of adult smokers to use vapor products, policymakers should consider the words of Mitch Zeller, the Deputy Director of the FDA Center for Tobacco Products. "If we could get all of those people [who smoke] to completely switch all of their cigarettes to noncombustible cigarettes [i.e., vapor products], it would be good for public health," said Zeller when speaking before a U.S. Senate committee last year. Discouraging the use of vapor products by adult smokers is not sound policy.

Thousands of smokers in Connecticut will make a quit attempt this year. Regrettably, among those using traditional – and often state-subsidized – therapies like the nicotine patch or gum, approximately 93-97% will be smoking again within one year. Every month, more studies emerge showing that vapor products are far less hazardous than smoking and effective at helping smokers kick the habit. Indeed, two recent government-funded surveys have found that vapor products are now the most used product by smokers looking to quit in Minnesota and Oklahoma. The same is almost undoubtedly true in Connecticut.

If these bills are enacted, jobs and public health in Connecticut will suffer. More smokers will continue to smoke and those smokers who do try vapor products will be more inclined to purchase them online or out-of-state.

I look forward to answering any questions you may have about vapor products at Wednesday's committee hearing. We have also attached a comprehensive guide, "E-cigarettes, vaping, and public health: A summary for policy-makers," that we hope you will find helpful in weighing this important public health issue.

Sincerely,

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E-cigarettes, vaping and public health

A summary for policy-makers

Adapted from the work of Clive Bates, the former head of the U.K.'s largest anti-smoking organization, Action on Smoking & Health

February 2015

Version 3

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1 Background

1.1 What are e-cigarettes?

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

Types of e-cigarette or vaping equipment

1.2 How have e-cigarettes come about?

The products have emerged only recently (since 2007) thanks to advances in battery technology, which can now provide sufficient power to vaporise an adequate flow of liquid and sufficient battery life to make devices practical. This has been the key enabling development – partly a spin-off from mobile phone technology. E-cigarettes first emerged in China, which is still the largest manufacturer by far, with increasingly sophisticated plant and designs.

1.3 How much are e-cigarettes used?

A survey conducted for Action on Smoking and Health estimated that there were 2.1 million adults in Great Britain using electronic cigarettes in March 2014. Of these, approximately 700,000 were ex-smokers while 1.3 million continued to use tobacco alongside their electronic cigarette use. Electronic cigarette use amongst never-smokers was negligible[1]. For the US, CDC gives frequent use at 1.9% of adults and any e-cigarette use at 4.2% of adults[2], equating to around 4.6 and 10.1 million users respectively. A synthesis of 10 country surveys[3] identified widespread use in many countries, including substantial use in those such as Australia where the products are, in practice, banned. According to this survey 7% of Australian smokers and former smokers were current users of e-

1 ASH, Fact sheet: Use of electronic cigarettes in Great Britain, October 2014 [link]

2 CDC, Tobacco Product Use Among Adults — United States, 2012–2013 [link]

3 Gravely S, Fong GT, Cummings KM, et al. Awareness, Trial, and Current Use of Electronic Cigarettes in 10 Countries: Findings from the ITC Project. Int J Environ Res Public Health 2014; 11: 11691–704. [link]

cigarettes in 2013. This is likely to be a significant contributor to declines in smoking in Australia.

2 The public health case – tobacco harm reduction

2.1 Challenging the burden of smoking

Approximately 19% of U.S. adults, roughly 42 million people, smoke. Worldwide about 1 billion people smoke daily, about 6 trillion cigarettes are consumed annually (about 3 per adult person per day) and these numbers are *still rising*[4]. The current annual premature death tolls attributed to smoking are 400,000-plus in the U.S. and six million world-wide. WHO estimates smoking caused 100 million deaths in the 20th century. If current trends continue, it may cause one billion deaths in the 21st century[5]. The public health value of e-cigarettes could reduce this toll of death and disease by hundreds of millions if the promise is fulfilled.

The public health proposition is that:

(1) E-cigarettes provide a satisfactory alternative to smoking (nicotine, sensory and ritual aspects) and will displace cigarette use in the consumer market for recreational nicotine.

(2) E-cigarettes dramatically reduce risks to health, likely by 95-100%, among those who switch with negligible impacts on bystanders, at lower cost, and with lower social stigma. The vast majority of harm in smoking comes from tar and hot gases – products of combustion, rather than nicotine. These are almost entirely absent in e-cigarette vapour.

(3) E-cigarettes are a market-based public health phenomenon that 'meets people where they are'. The public health benefit does not rely on public spending, coercion, prohibition, punitive taxes, fear, stigma or treating smokers as though they are ill.

(4) The risks of harmful unintended consequences, like gateways to smoking, are low, remain hypothetical and are so far unsupported by <u>any</u> evidence.

The alternative public health approach is to insist that smokers quit smoking and nicotine altogether, sometimes offering a variety of pharmaceutical aids and behavioural support. But this strategy simply does not work for many people because they cannot or do not want to quit smoking, or don't think the benefits justify the losses and efforts required. The public health case for e-cigarettes involves a major technological disruption of the continuing market for recreational nicotine. Global tobacco sales are variously estimated at $700-800 billion (Bloomberg), mainly cigarettes, whereas sales of vapour products are no more than $5 billion in 2014 (Euromonitor). There is scope for a major structural change in the market for recreational nicotine that could make substantial inroads into the billion deaths projected by WHO.

2.2 Benefits of vaping to a smoker

From the smoker's perspective, e-cigarettes create a new 'value proposition'. They offer many of the experiences of smoking (a nicotine hit, something to hold and gesture with, sensory experience etc) with few of the harms (long term risk is much lower, less social disapproval, minimal odour nuisance) and at a lower cost, with beneficial knock-on effects to the family budget – which can be especially

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[4] Ng M, Freeman MK, Fleming TD, et al. Smoking prevalence and cigarette consumption in 187 countries, 1980-2012. *JAMA* 2014; **311**: 183–92 [link]. See full analysis at Counterfactual: *Are we in the endgame for smoking?* Jan 2015 [link]

[5] WHO Factsheet *Tobacco*, May 2014 [link]

important in poor families. Prior to the emergence of e-cigarettes, the alternatives were broadly cast as 'quit or die' – this new value proposition fits between the two. It is likely to be successful, because it requires less effort to reduce the harm – i.e. it does not require complete nicotine cessation. **Expert views suggest a health risk of at least 95% or 20 times lower than smoking**.

In advice to a UK parliamentary hearing, leading UK smoking cessation experts; Professor Robert West of University College London, Professor Peter Hajek of Queen Mary University of London, Profesor Ann McNeill, of Kings College London, Dr Jamie Brown of University College London and Deborah Arnott, the Director of Action on Smoking and Health, put the relative risk in perspective[6]

> *From analysis of the constituents of e-cigarette vapour, e-cigarette use from popular brands can be expected to be at least 20 times safer (and probably considerably more so) than smoking tobacco cigarettes in terms of long-term health risks*

Professor John Britton, Chair of the Royal College of Physicians Tobacco Group and Director of the UK Centre for Centre for Tobacco and Alcohol Studies, and his colleague Ilze Bogdanovica give a similar if unquantified message in an assessment for the government agency Public Health England[7]:

> *Overall however the hazards associated with use of products [e-cigarettes] currently on the market is likely to be extremely low, and certainly much lower than smoking.*

Robert West & Jamie Brown, in an editorial for the British Journal of General Practice[8], point out that we know enough to make reasonable judgements about e-cigarette risk relative to smoking.

> *Some reviews have bizarrely concluded that we do not know whether e-cigarette use is safer than smoking, **i**gnoring the fact that the vapour contains nothing like the concentrations of carcinogens and toxins as cigarette smoke. In fact, toxin concentrations are almost all well below 1/20th that of cigarette smoke.*

Professor Peter Hajek, reinforces the 95% reduction in risk, in an interview for News-Medical[9]

> *Electronic cigarettes are estimated to be at least 95% safer than cigarettes and they appeal to smokers who cannot or do not want to stop smoking, but who want to reduce the risks smoking poses to their health.*

2.3 Do e-cigarettes help people to quit smoking?

An assessment of the trials undertaken at the end of 2014 for the Cochrane Library concludes[10]

> *Combined results from two studies, involving over 600 people, showed that using an EC containing nicotine increased the chances of stopping smoking long-term compared to using an EC without nicotine. Using an EC with nicotine also helped more smokers reduce the amount they smoked by at least half compared to using an EC without nicotine.*

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6 West R et al Briefing: Electronic cigarettes what we know so far. Presented to UK All-Party Parliamentary Group on Pharmacy: 10th June 2014 [link]

7 Britton J, Bogdanovica I. Electronic cigarettes: A report commissioned by Public Health England. May 2014 [link]

8 West R, Brown J. Electronic cigarettes: fact and faction. Br J Gen Pract 2014; 64: 442–3.[link]

9 News-Medical, Electronic cigarettes and smoking cessation: an interview with Professor Peter Hajek, 5 Feb 2015 [link]

10 McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD010216. [link]

The most comprehensive study so far of 'real world' use of e-cigarettes showed[11]

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

Survey data commissioned by Action on Smoking and Health in the UK[12] also supports a good news story about people quitting smoking. 700,000 vapers are ex-smokers in Britain (~7% of smokers):

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

2.4 What is the potential?

The report by Britton and Bogdanovica for government agency Public Health England concluded[13].

> *Smoking kills, and millions of smokers alive today will die prematurely from their smoking unless they quit. This burden falls predominantly on the most disadvantaged in society. Preventing this death and disability requires measures that help as many of today's smokers to quit as possible. The option of switching to electronic cigarettes as an alternative and much safer source of nicotine, as a personal lifestyle choice rather than medical service, has enormous potential to reach smokers currently refractory to existing approaches. The emergence of electronic cigarettes and the likely arrival of more effective nicotine-containing devices currently in development provides a radical alternative to tobacco, and evidence to date suggests that smokers are willing to use these products in substantial numbers.*
>
> *Electronic cigarettes, and other nicotine devices, therefore offer vast potential health benefits, but maximising those benefits while minimising harms and risks to society requires appropriate regulation, careful monitoring, and risk management. However the opportunity to harness this potential into public health policy, complementing existing comprehensive tobacco control policies, should not be missed.*

It is not only public health experts. One Wall Street analyst, Bonnie Herzog of Wells Fargo Securities, projects that vapour use will surpass smoking (in the US) within a decade (by which she means 2023)[14]. Much will depend on whether regulation encourages or suppresses innovation – and her forecast is contingent on an effective pro-innovation regulatory framework. In March 2014 she said:

> *Bottom line: if regulations don't stifle innovation, we continue to believe e-vapor consumption could surpass combustible cig consumption in the next decade, driving total profit pool growth and generating a roughly 7% CAGR.*

If vaping came close to overtaking cigarette use, it would be one of the most remarkable disruptive

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

[12] ASH (UK) Fact sheet: Use of electronic cigarettes in Britain, July 2014 [link]

[13] Britton J, Bogdanovica I. Electronic cigarettes: A report commissioned by Public Health England. May 2014 [link]

[14] Cited in *The Economist*, Kodak moment, 23 September 2013. [link]

public health technologies of modern times.

3 What are critics concerned about?

Opponents of e-cigarettes focus on two main arguments: risks to users and bystanders arising from exposure to vapour, population risks arising from changes in smoking or nicotine-using behaviour caused by e-cigarettes.

3.1 Risks arising from exposure to vapour

No one should claim that vaping is entirely benign. It may prove to be, but that cannot be established without many years of data. However, vaping does not need to be *harmless* or *completely safe* to make deep inroads into the risks of disease if people switch from smoking.

Studies of liquids and vapour chemistry reveal traces of contaminants and thermal breakdown products that are potentially harmful, but at levels generally two orders of magnitude lower than in cigarette smoke and unlikely to pose a material threat. Critics of e-cigarettes routinely cite studies suggesting presence of harmful substances, but risk is determined by *exposure*, not merely by the presence of a hazardous substance – which are present in just about everything we consume at low levels. The most comprehensive literature review so far concluded[15]:

> *Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. … Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.*

Some commentators draw attention to the following to make the case that e-cigarettes are harmful.

3.1.1 Nicotine

The active drug in tobacco is not the primary cause of harm in smoking and would not be in vaping. It has been understood for four decades that: "*people smoke for the nicotine but die from the tar*"[16]. Nicotine is not a cause of cancer, cardiovascular disease or the respiratory conditions that dominate the ill health from smoking[17]. Pure nicotine is not completely benign, but it is widely sold in medicinal form and does not cause any serious illness[18]. The US Surgeon General has made a detailed assessment of nicotine risks[19], and though it is possible to measure many effects on the body, these are trivial compared to smoking: for health, it is *always* better to vape than to smoke.

3.1.2 Nicotine poisoning

There have been a small number of incidents of people or pets swallowing nicotine liquids and some have tried to characterise this risk by reference to the number of calls to poison centres. However,

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

[16] Russell MJ. Low-tar medium nicotine cigarettes: a new approach to safer smoking. BMJ 1976;1:1430–3. [link]

[17] In England in 2013, smoking caused 79,700 deaths of which 37,200 were from cancer, 24,300 respiratory diseases, 17,300 circulatory diseases, 900 digestive diseases. Health and Social Care Information Centre, Statistics on Smoking in England, October 2014 [link]. No deaths have been attributed to pure nicotine use.

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

[19] US. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress*. A Report of the Surgeon General. 2014. P.116 [link]

recent analysis shows nicotine toxicity is perhaps 20 times lower than widely assumed[20]. Although calls to US poisons centres are rising in line with growth and public awareness of e-cigarettes and liquids, they represent a tiny fraction of the calls arising from medicines, cosmetics, domestic cleaning products etc[21] [22]. There is a simple protective measure available: to insist on child resistant packaging, for which there is a federal standard[23]. [**CHANGE CITE]**

3.1.3 Ultrafine particles

Some have claimed that the aerosol droplets in e-cigarette vapour have a similar effect on the body as the particles in tobacco smoke or diesel exhaust[24]. This makes little sense as the chemistry of the vapour particle is completely different, and it is the toxicity of the particles that causes damage with tobacco smoke and environmental pollution – the entire argument is baseless[25].

3.1.4 Formaldehyde

A news story originating in Japan suggested that e-cigarette vapour could contain up to ten times as much formaldehyde as conventional cigarette smoke. This was in fact an anomalous single unpublished and unverifiable result, almost certainly arising from the device running hot and dry. Looking more carefully at the published results, the overall picture showed formaldehyde levels 6-50 times *lower* than for cigarettes[26]. The mistake was repeated in a letter in the New England Journal of Medicine[27] claiming that formaldehyde-related cancer risks from e-cigarettes were 5-15 times higher than for cigarettes, but the experiment made the elementary error of running the vaporiser in 'dry puff' conditions that no human user would ever be exposed to[28]. *Under normal operating conditions, no formaldehyde was detected*. Cigarettes contain thousands of chemicals not present in e-cigarettes and formaldehyde is widely present in the environment.

3.1.5 Carcinogens and toxicants

Carcinogens are found almost everywhere. For example writing in 1998, one of the leaders in the field said[29]: "*Over 1000 chemicals have been described in coffee: 27 have been tested and 19 are rodent carcinogens. Plants that we eat contain thousands of natural pesticides, which protect plants from insects and other predators: 64 have been tested and 35 are rodent carcinogens".* The question is whether any carcinogens cause exposures at levels and via pathways that pose a material

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[20] Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. Arch Toxicol 2014; 88: 5–7. [link]

[21] 2013 Annual Report of the American Association of Poison Control Centers ' National Poison Data System (NPDS). Calls for e-cigarettes and nicotine liquids were 1,543 in 2013 and 3,957 in 2014, respectively just 0.06% and 0.15% of the total exposure calls. Table 17A shows calls for analgesics (298,633), cosmetics (199,838), cleaning substances (196,183) etc. [link]

[22] Full discussion of the evidence at Bates C. Keep calm it's only poison, The Counterfactual. 17 November 2014 [link]

[23] Poison Prevention Packaging Act, Title 16 CFR parts 1700 through 1702. [link]

[24] See for example, WHO paper for FCTC COP-6, Electronic nicotine Delivery Systems, 1 September 2014. Para 15-16 [link]

[25] Full discussion of the evidence at Bates C. Scientific sleight of hand: constructing concern about 'particulates' from e-cigarettes, The Counterfactual. 17 November 2014 [link]

[26] Farsalinos K. Electronic cigarette aerosol contains 6 times LESS formaldehyde than tobacco cigarette smoke. 27 November 2014. [Link]

[27] Jensen RP, Luo W, Pankow JF, Strongin RM, Peyton DH. Hidden formaldehyde in e-cigarette aerosols. N Engl J Med 2015; 372: 392–4. [link]

[28] See full detailed critique at Counterfactual, Spreading fear and confusion with misleading formaldehyde studies, 21 January 2015, with links to detailed assessments [link].

[29] Ames BN, Gold LS. The prevention of cancer. Drug Metab Rev 1998; 30: 201–23.[link]

risk. Where toxicants are found in e-cigarette vapour, they are found at much lower levels than tobacco smoke. The largest study on toxicants in vapour[30] concluded: *"The levels of the toxicants were 9-450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product".* Many of the more important toxins in cigarette smoke are simply not present at all in measurable quantities in vapour. The data on toxicity and carcinogenicity are consistent with the claim that vaping is *at least* 95% safer than smoking.

3.1.6 Heavy metals

Traces of metals can be found in some e-cigarette vapour, but at very low levels that do not pose a material risk – equivalent to or lower than levels found and permitted in medicines[31]: "*an average user would be exposed to 4–40 times lower amounts for most metals than the maximum daily dose allowance from impurities in medicinal products*". Some regulations covering the materials used in device construction would reduce this still further.

3.1.7 Lung irritation

A February 2015 study exposed mice to e-cigarette vapour and concluded it demonstrates "*that e-cig exposure elicits impaired pulmonary anti-microbial defences*" (in mice)[32]. In fact, the study greatly over-interpreted the applicability of a mouse study to humans[33], failed to measure impacts for tobacco smoke for comparative purposes and failed to note that free radical exposure was *150 times lower* than is typically found for smoking[34].

3.2 Risks to the population

As it becomes clearer that e-cigarettes offer smokers a 95-100% reduction in risk, the critics of e-cigarettes have moved their focus onto 'population' arguments. This is the idea that though vaping is very much less hazardous than smoking for an *individual*, at *population* level it could be more dangerous because it somehow causes changes in the way people smoke. For example:

- Visible displays of smoking-like behaviour or marketing might 'renormalise' smoking.
- Vaping may divert people from quitting smoking because they don't feel discomfort of temporary withdrawal or under so much social pressure.
- It could be a 'gateway' to smoking for adolescents, and 'kiddie flavours' may be used to lure children into nicotine addiction and ultimately on to smoking.

There is no basis to believe any of these effects are real rather than tactical campaign arguments.

3.2.1 Renormalising smoking

The UK's foremost experts in smoking cessation who also manage the surveillance of the market in

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[30] Goniewicz M., Knysak J., Gawron M., Kosmider L., Sobczak A., Kurek J., et al. . (2013) Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control 2014 Mar;23(2):133-9 [abstract][paper from March 2015]

[31] Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf* 2014;**5**:67–86. [link]

[32] Sussan TE, Gajghate S, Thimmulappa RK, et al. Exposure to electronic cigarettes impairs pulmonary anti-bacterial and anti-viral defenses in a mouse model. PLoS One 2015; [link]

[33] Explained by Mike Siegel, *New Study Reports Adverse Effects of E-Cigarette Aerosol on Mouse Respiratory Epithelial Cells*, The Rest of the Story, 5 February 2015. [link]

[34] Farsalinos K. A new study in mice provides no information for smokers but verifies e-cigarettes are less harmful, E-cigarette Research. 5 February 2015 [link]

nicotine products in England concluded[35]:

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

The more plausible and obvious hypothesis is that e-cigarettes will function as an alternative to smoking; a gateway exit from smoking, and will normalise safer alternatives to smoking.

Marketing that looks like cigarette marketing. There have been some objections that some e-cigarette advertising looks like cigarette advertising[36]. In fact it is not surprising or undesirable that some advertising looks this way: the advertisers are appealing to smokers to switch smoking behaviour to an alternative to smoking that very much les harmful. If the similar branding adds to the effectiveness of the appeal to smokers, then it is contributing to better health. Note that the use of tobacco brands in e-cigarette marketing ("brand stretching") is illegal in the United States [**check], so there will never be a "Marlboro" or "Camel" e-cigarette product. In order to encourage smokers to switch, we must keep advertising of products that are *rivals to cigarettes* legal.**

3.2.2 Reduced quitting

Where this has been studied properly and the results interpreted correctly, there is no sign of e-cigarettes reducing quitting, and nor would a neutral observer expect one[37]. The most thorough survey in the world, the Smoking Toolkit Survey for England[38], concluded in January 2015, that: *Rates of quitting smoking are higher than in previous years. E-cigarettes may have helped approximately 20,000 smokers to stop last year who would not have stopped otherwise*.

3.2.3 Gateway effects

Many activists and some public officials have pointed to rising e-cigarette use among adolescents and suggested they pose a 'gateway' risk: that they will lead to more smoking. *There is no evidence supporting this hypothesis anywhere*. In fact e-cigarettes appeal primarily to existing smokers and the 'value proposition' they offer is strongest among existing smokers with mounting concern about the health and other costs. This expectation is confirmed by data. For example, the UK Office for National Statistics states[39]:

> *E-cigarettes are used almost exclusively by smokers and ex-smokers. Almost none of those who had never smoked cigarettes were e-cigarette users.*

However, this has not stopped wild misinterpretations of data. For example in 2013, much media coverage was created in the United States over National Youth Tobacco Survey Data showing a rise in e-cigarette use[40]. According to a top public health official:

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

36 See for example: Campaign for Tobacco Free Kids, 7 Ways E-Cigarette Companies Are Copying Big Tobacco's Playbook [link] and de Andrade M & Hastings G, The marketing of e-cigarettes: a UK snapshot, BMJ Blog 6 April 2013 [link]

37 Letter to WHO Director General Margaret Chan: *The importance of dispassionate presentation and interpretation of evidence*. 26 June 2104. A letter from 50 scientists addresses some of these claims in more detail [link]

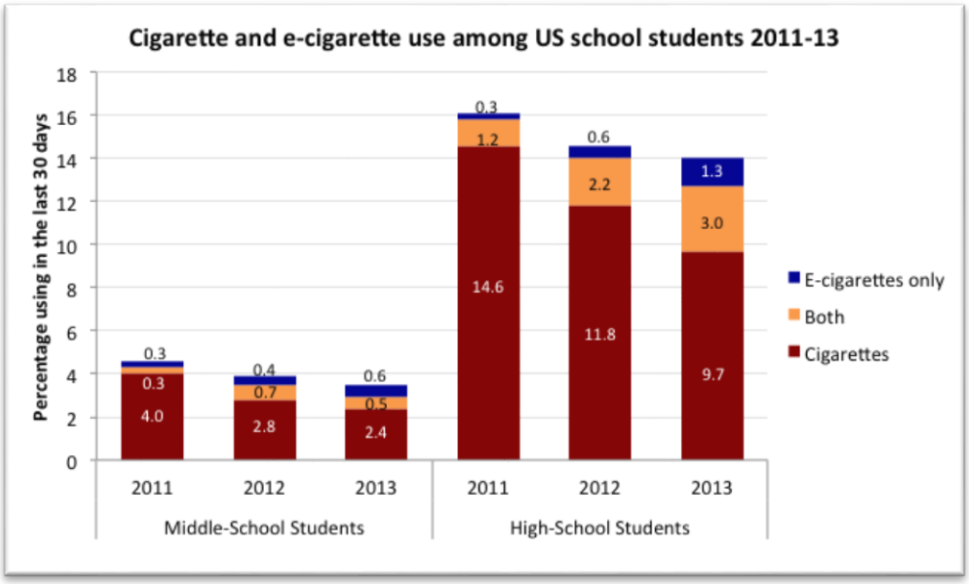
38 West R. Brown J, Beard E. *Trends in electronic cigarette use in England.* Smoking Tool Kit Study. 15 January 2015 [link]

39 ONS, Opinions and Lifestyle Survey, Adult Smoking Habits in Great Britain, 2013, 25 November 2014 [link]

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

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

In fact the data do not support a gateway effect and a rise in e-cigarette use among adolescents would be expected to mirror the rise in use among adults. In reality, US teenage smoking prevalence fell sharply as e-cigarette use increased and e-cigarette use was highly concentrated among existing smokers[41]. The relevant CDC data are shown in the chart below:



Source: raw data from CDC National Youth Tobacco Surveys (NYTS). Data analysis and graphic by Brad Rodu

Similar effects were found in France[42] and confirmed for the United States in the Monitoring the Future survey, which showed a rise in e-cigarette use, but also found record low rates and record annual declines for "daily" and "past 30 day" cigarette smoking by teens from 2013 to 2014[43]. In essence we are seeing e-cigarette use rise in line with growth in adults, but cigarette smoking falling sharply. These are reasons to be positive, not to conclude that e-cigarettes a problem.

3.2.4 Understanding and defining gateway effects

It is difficult to find a proponent of the gateway effect who can rigorously define what they mean and how they would measure it. To establish a gateway effect is in practice difficult. It is necessary to show that a period of e-cigarette use is the *reason* why someone develops a consolidated smoking habit. It is not sufficient to show rising e-cigarette use coincided with rising smoking[44] – there could be independent reasons for these trends, or a common factor driving them. Nor is it sufficient to show that a person used e-cigarettes first and then took up smoking – in the absence of e-cigarettes they may have simply started to smoke anyway. It is also possible that e-cigarette use in

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41 CDC MMWR Tobacco Product Use Among Middle and High School Students — United States, 2011 and 2012, 15 November 2013. [link] Higher resolution graphic [link]

42 Survey reported in English on *Le blog de Jacques LeHouezec*, 16 May 2014. [link]

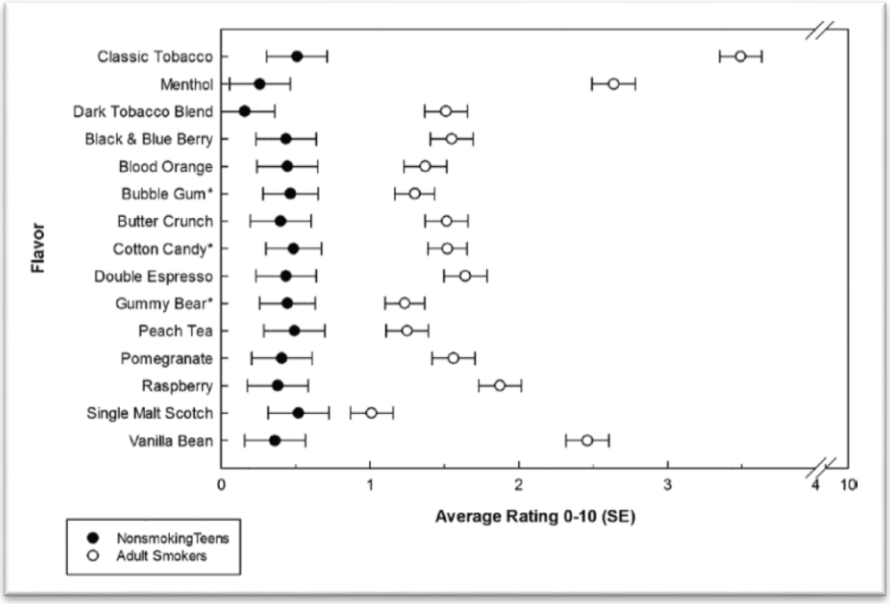
43 L. D., O'Malley, P. M., Miech, R.A., Bachman, J. G., & Schulenberg, J. E. (2015). Monitoring the Future national results on adolescent drug use: Overview of key findings, 2014. Ann Arbor, Mich.: Institute for Social Research, the University of Michigan [link]

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

adolescents is *protective* – preventing or diverting the onset of a consolidated cigarette smoking habit. Some care is required in drawing causal conclusions from observational data on e-cigarette use but *every claim* for detecting a gateway effect fails to address these issues.

3.2.5 Kiddie flavours to appeal to children

It is often asserted, as if it is obvious, that flavours with childish characteristics will appeal to adolescents. There is no evidence for this, just assertion, and it is actually counter-intuitive: most adolescents are imitating adult behaviour, not reinforcing their status as children. The one study that has looked at the preferences of young people for e-cigarette flavours found extremely low interest. Teenagers were asked to rate their interest on a scale of 0-10 in using e-cigarettes and were offered a list of flavours. They reported minimal interest (average =0.41 out of 10), much less than adult smokers (1.73 out of 10) and interest did not vary much across flavours[45]. To the extent that any preferences were revealed among teens, 'Single Malt Scotch" and 'Classic Tobacco' were top.



Other studies confirm that adults are attracted to supposedly juvenile flavours like cherry crush, or fruit loop. For example a survey of users of the world's largest user forum found fruit to be the most popular flavour category[46]. A similar survey of over 4,519 users found 44% used tobacco, 32% menthol/mint, 61% sweet, 15% nuts, 69% fruit, 37% drink, and 22% other[47]. Non-users should understand that flavours are an important aspect of vaping and integral to the experience. They are also part of a migration away from tobacco. Initial switchers tend to favour tobacco flavours but gradually move on to non-tobacco flavours often as part of a permanent switch from smoking.

3.3 Seeing through controversy

Many points are made against e-cigarettes but they almost all suffer from flaws and can mislead users about risks. Professor Robert West detailed six typical flaws (or 'tactics' if you believe this is

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45 Shiffman S, Sembower MA, Pillitteri JL, Gerlach KK, Gitchell JG. The impact of flavor descriptors on nonsmoking teens' and adult smokers' interest in electronic cigarettes. Nicotine Tob Res 2015; published online Jan 7 [link][release].

46 E-cigarette forum, Survey of users. *Big survey 2014 - initial findings eliquid* , 17 July 2014. [link]

47 Farsalinos KE, Romagna G, Tsiapras D, Kyrzopoulos S, Spyrou A, Voudris V. Impact of flavour variability on electronic cigarette use experience: an internet survey. Int J Environ Res Public Health 2013; 10: 7272–82.[link]

deliberate) in an editorial in the journal *Addiction*[48].

> It is worth highlighting the ways in which science is being misused so that readers can be better placed to evaluate the messages.
>
> *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.

3.4 The case of snus – a cautionary tale

Many of the same 'population' arguments were made on a precautionary basis in the case to ban 'oral tobacco' in 1992 throughout the EU, even though it is 95-100% less hazardous than smoking. On accession, Sweden was granted an exemption from the ban. In fact, this product is the reason why Sweden has by far the lowest rate of smoking in the EU: 13% Swedish adults vs 28% EU average[49]. Snus has three main effects in Sweden and Norway: it is used to quit smoking; it is used to substitute for smoking; it diverts young people from onset of smoking. It provides a compelling 'proof of concept' for tobacco harm reduction, and a warning about perverse impacts of regulation. It also showed that tobacco control activists were prepared to mount a campaign against a product that was achieved real reductions in disease and premature death.

3.5 Concern about the tobacco industry

A further source of critics' concern is the possible negative role of the tobacco industry, which is unsurprising given the history. In practice, and in the present, it is hard to see what this could be *if the e-cigarette industry remains competitive*. The tobacco industry's long-standing cigarette-based business model is threatened by e-cigarettes. To survive the disruption they will need to enter the market (as they are doing) and produce high quality attractive alternatives to smoking or risk losing share in the recreational nicotine market to other tobacco or non-tobacco e-cigarette companies. It is more likely that they will become important drivers of a wholesale switch from smoking to vaping through the mechanism of market-based competition. The real danger from tobacco companies arises from excessively burdensome regulation, eliminating competition from more agile or

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

[49] European Commission, Special Eurobarometer 385, Attitudes of European Citizens to Tobacco, March 2012

innovative competitors, leaving them with an oligopoly protected by regulatory barriers to entry, and endorsed paradoxically by health organisations. Unfortunately many public heath establishment organisations and individuals are doing their utmost to cause this to happen, though not always realising that protection of tobacco companies from competition will be the effect, if not their aim[50].

3.6 Disruptive technology also challenges public health

E-cigarettes have empowered smokers to take control of their risks and have greatly enhanced the welfare of hundreds of thousands of UK citizens. It has challenged the tobacco industry, but it has also challenged interests in the public sector and civil society who have played no role – or a hostile role – in its rise. For many smokers and vapers, the hostility of the public health establishment to vaping or tobacco harm reduction is highly perplexing. Here are several possible explanations:

- **Not invented here**: the products and harm reduction benefits have emerged through free play of producers and consumers in a lightly regulated market. No one in public health has given their approval or been asked for it, no public spending is required and public health organisations have no controlling influence.
- **Hostility to the private sector:** culturally, the public health establishment is inclined to paternalism, and state-based or not-for-profit interventions. It instinctively distrusts the private sector and capitalism, and is ill at ease with the idea of consumers as empowered agents.
- **Countercultural:** the toolkit of tobacco control is replete with coercive measures: restrictions penalties, (regressive) taxes, fear based campaigns, medicalisation of smoking and so on. Harm reduction approaches are non-judgemental, 'meet people where they are' and allow them to judge their own interests and preferences.
- **Undeclared motives:** some in tobacco control have a 'non-smokers' rights' orientation, rather than 'population health' orientation, and these have different implicit objectives. As with any issue that involves a recreational drug, there are prohibitionist instincts at work, there may be affronted authority figures ('doctor knows best') and those with concerns about bodily purity[51].
- **Conflicts of interest:** public health academia, science, and advocacy is beset by ideological biases, prior positions to defend, funders' interests to respect, charities' declared policy positions, pharmaceutical funding, and highly prone to insularity and group-think.
- **Tobacco industry focus:** many activists and academics have defined their fight as with the tobacco industry and assume what is harmful to them is beneficial to health. This leads to lazy and muddled thinking in the area of tobacco harm reduction.

Not all individuals or organisations involved exhibit all or any or these characteristics, but they are drawn out here to emphasise that it is not safe to assume that anyone with a public health profession or remit to protect health is actually acting rationally in the interests of health.

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[50] See David Sweanor, *Big Tobacco's Little Helpers*, The Counterfactual, 27 January 2015. [link] and Clive Bates, *Turning the tables on public health: let's talk about the risks they create*, 3 July 2014 [link]

[51] See for example discussion by Alderman J, Dollar KM, Kozlowski LT. Commentary: Understanding the origins of anger, contempt, and disgust in public health policy disputes: applying moral psychology to harm reduction debates. J Public Health Policy 2010; 31: 1–16. [link]

4 Regulatory issues

4.1 Poor regulation is the primary risk to public health

The primary risk to the otherwise highly positive developments with e-cigarettes is poor and excessive regulation**.** At the heart of the regulatory challenge there is a 'double negative': being tough on e-cigarettes is being tough on the competitive alternative to cigarettes. There is a danger that loss-averse regulators and officials will place excessive focus on the residual risks associated with vapour products, but in doing so render them less effective and appealing as alternatives to smoking. In doing so, they will increase *total health ri*sks through the unintended consequence of additional continuing smoking. <u>All regulatory proposals advanced so far suffer from this weakness</u>.

4.2 Unintended consequences of regulation will dominate

The following table illustrates how it is possible for regulatory measures to have unintended harmful consequences – protecting the cigarette trade and leading to more smoking than there otherwise would be. These effects are likely to far outweigh the intended consequences of most regulatory proposals under development today.

Regulatory idea	Likely unintended consequence
Ban e-cigarette use in public places	Diminishes value proposition of e-cigarettes to users and 'denormalises' vaping, a much less risky option, diminishes the appeal of vaping relative to smoking, May promote relapse in existing vapers if they join smokers outside. Likely to lead to more smoking.
Restrictions on advertising, promotion and sponsorship	Reduces ability of e-cigarette brands to compete with cigarettes, and diminishes means to communicate value proposition to smokers. May reduce means to communicate innovation or build trusted brands. May turn ads into bland public information notices. Some restrictions are undoubtedly justified and a balance should be struck, but excessive restriction will protect the cigarette trade.
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.
Ban flavours	All e-cigarettes and liquids are flavoured with something – and this forms a key part of the appeal. Many former smokers report switching to non-tobacco flavours as a way of moving permanently away from smoking. There is significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and development of DIY and black market flavours – which may be more dangerous.
Ban flavours that appeal to kids	It is a common mistake in public health to believe that adolescents are attracted to things that adults regard as child-like, such candy-flavours. Adolescent experimentation is often about emulating adults or rejecting childhood. A ban on flavouring may have impacts on adults, but adolescents may simply switch to a different flavour – like tobacco.
Ban open systems because they may be used for other drugs	This might require 'closed systems' to be made mandatory (as proposed by tobacco company RJ Reynolds with this justification, but probably for anti-competitive reasons). But this has the effect of removing the 'open system' 2nd and 3rd generation products from the market. Many vapers report these are more effective alternatives to smoking. Note vaping may be a safer way to take other drugs than smoking – so there may be a harm reduction benefit to drug users.
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. 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.

Regulatory idea	Likely unintended consequence
Ban sales to minors	There is near universal support for this. However it is worth noting that NRT is made available to people over 12 years in some jurisdictions – because young smokers also need to quit. It should not be assumed that 'harm reduction' should start at 18.
Prohibit health claims unless regulatory approval	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 claim-making should be tested in the same way any consumer claim must be truthful and proportionate – not to the standard required for medicines.
Regulate as a medicine	E-cigarettes are not medicines – in common sense or in law. Using ill-fitting or excessive regulation designed for a different purpose would simply limit the development of competitive alternatives to cigarettes. The costs, burdens and restrictions of medicines regulation are excessive and serve little useful purpose (for example, 'consistent dosing' is important for medicines, but not for products where the user controls the dose).
Regulate as a tobacco product	Most tobacco regulation is designed to prevent, supress and control tobacco use. With e-cigarettes the public health imperative is best served by these products growing and innovating to capture market share from cigarettes – many of the tools of tobacco control applied to e-cigarettes are therefore harm-inducing and protective of cigarette sales.

4.2.1 The risk of user countermeasures to overcome poor regulation

Regulators do not have a free hand. If regulation is excessive, or removes products from the market that users want, then users will revolt and legitimately subvert regulation that they perceive to be harmful to their health or welfare. It is better to avoid the development of unregulated black or grey markets and home producing by having proportionate regulation.

4.3 The current approach of key regulators is arbitrary and disproportionate

It is not possible to review all regulatory developments, especially in relation to marketing, age restrictions and banning vaping in public places. This section comments on the main initiatives with respect to regulating the product itself.

4.3.1 UK approach

The UK's preferred approach was originally to regulate vapour products as medicines.[52] This onerous regime applies costs, burdens and restrictions that would dramatically contract the range of products and number of suppliers, whilst acting as a barrier to innovation[53] and unlawfully forcing a non-medical consumer product into a medical definition and regulatory regime[54]. After this approach was rejected in the European Union, the UK has adopted the EU 'twin track' approach (see below). The UK government generally has a positive outlook towards tobacco harm reduction, but as long ago as 2009, its policy-makers incorrectly assumed such developments would come through pharmaceutical innovation. It has taken several years to adjust to a different reality – a process that is not yet complete. The separate jurisdictions on England, Scotland and Wales have adopted different stances on vaping in public and other policies.

4.3.2 European Union approach

The EU's favoured approach is "twin track": to regulate using measures designed for tobacco

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[52] MHRA, Press Release: 13 June 2013, UK moves towards safe and effective electronic cigarettes and other nicotine-containing products [link]. See overview page: Nicotine Containing Products [link].

[53] Bates C, Stimson S, Costs and consequences of regulating e-cigarettes as medicines, 20 September 2013 [link]

[54] Bates C, Are e-cigarettes medicines? Counterfactual March 2013. [link]

products or to allow medicine licensing. After the proposal of the Commission and Council to regulate e-cigarettes as medicines was thrown out by the European Parliament on 8 October 2013, a new directive was hastily contrived entirely behind closed doors, without any consultation and with minimal supporting analysis or scrutiny. The resulting directive (2012/40/EC – Article 20)[55] has numerous flaws of arbitrary and unscientific policy and poor policy-making process, and is likely to be found in breach of key treaty principles.

- **A ban on almost all advertising sponsorship and promotion.** The anti-competitive ban protects the incumbents from a disruptive challenger and is unjustified in a directive with a single market legal base, and disproportionate relative to tobacco. Most tobacco advertising is banned in the EU, but tobacco kills 700,000 per year. In contrast, vaping is likely to reduce premature deaths.
- **Limiting the strength of nicotine liquids to 20mg/ml.** Approximately 25-30% of consumers use liquids stronger than this. They may be more important for more heavily dependent smokers and those just switching. The threshold is arbitrary and pointless.
- **Limiting liquid container sizes.** We manage hazardous liquids (like bleach) by having packaging and labelling standards not by limiting the containers to tiny and inconvenient sizes.
- **Requiring large warnings.** The directive requires cigarette-like warnings that contain misleading and off-putting information covering 30% of the pack. The warnings are not proportionate.
- **Numerous technical measures** that would fail a reasonable risk-benefit assessment.
- **A continuing ban on snus –** despite it being the reason, beyond doubt, for the best tobacco-related health outcomes in Europe in Sweden, snus will remain banned throughout the rest of the EU. It is unscientific, unethical and probably unlawful to ban this product.

Legal challenge. A UK-based vendor, Totally Wicked, has challenged article 20 of the directive via the English Courts and a case will likely be heard in Court of Justice of the EU in 2016[56]. The directive has entered into force and its provisions apply in stages from 2016/17.

4.3.3 United States approach

Following a legal challenge to its designation of e-cigarettes as medicines in 2010[57], the currently favoured approach of US Food and Drug Administration is to treat e-cigarettes as tobacco products on the basis that the pure nicotine used is originally extracted from tobacco. In April 2014, the FDA announced its intention to apply tobacco legislation to e-cigarettes[58] (the so-called 'deeming regulation'). This means the provisions of the Family Smoking Prevention and Tobacco Control Act will apply. This legislation was designed with the primary purpose of slowing innovation and creating burdens for the cigarette manufacturers, and it is wholly excessive and inappropriate to use this to regulate a disruptive low risk entrant to the cigarette market. It will mean almost all products are removed from the market and only the mass commodity products market by the largest

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[55] Directive 2014/40/EU 'Tobacco Products Directive' [link]

[56] See more details at: *Totally Wicked legal challenge to the Tobacco Products Directive e-cigarette measures*, Counterfactual, November 2014 [link]

[57] U.S. Court of Appeals for the D.C. Circuit, in Sottera, Inc. v. Food & Drug Administration, 627 F.3d 891 2010 [link]

[58] United States Food and Drug Administration. FDA proposes to extend its tobacco authority to additional tobacco products, including e-cigarettes (press release with links) 24 April 2014 [link]. Also see SFATA (industry) [link] and CASSA (consumer) [link] resources

companies will meet approval[59].

4.3.4 Australia and Canada and other countries with *de facto* bans

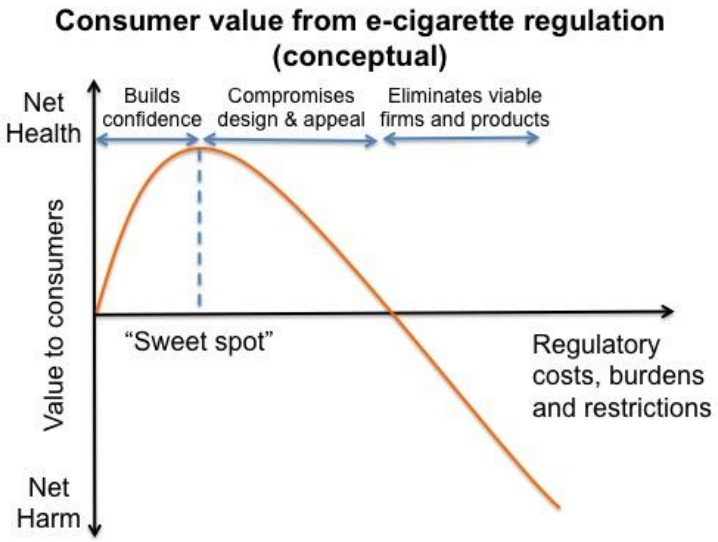
By defining these products as poisons or medicines, several jurisdictions have created an ostensible ban on e-cigarettes. As with all popular recreational drugs prohibition has led to a creative black market, which is likely to be reducing smoking and be beneficial to health. The force of the law has been used to ensure that cigarettes are widely available, while e-cigarettes are disadvantaged – a highly perverse approach to public health. It creates the appearance of toughness on the part of the regulator, but in practice it irresponsibly promotes an illegal and unregulated supply chain.

4.3.5 The World Health Organisation

WHO has taken on an activist advocacy role and strayed into misrepresentation and miscommunication of the science and policy issues[60]. The WHO's favoured approach is to classify these products as both medicines and tobacco and to apply the restrictive measure of the WHO's tobacco treaty (the Framework Convention on Tobacco Control)[61]. The WHO would also like to include these products in UN targets to reduce tobacco consumption by 30% by 2025[62] – making it impossible to achieve this target by denying the most likely way of meeting it. Fifty-three of the world's top experts wrote to WHO in May 2014 to implore it to take a more constructive approach[63].

4.4 A better approach to regulation

The aim should be to achieve a 'sweet spot' of regulatory intervention that builds confidence among consumers and removes cowboys and rogue products from the market, but does not impose costs, burdens and restrictions that crush the smaller players, radically change the products available and obstruct innovation. This relationship is illustrated conceptually in the graphic below.



The optimum regulatory regime would strike a subtle balance between protecting users, non-users,

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59 See CASAA assessment in: Fourth Call to Action for FDA Proposed Regulations Streamlined Version, 26 July 2014 [link]

60 Bates C, WHO position on ENDS: A critique of the use of science and communication of risk, Oct 2014 [context][report]

61 See WHO position paper on ENDS, FCTC/COP/6/10 Rev.1 September 2014 [link] and Decision FCTC/COP6(9) from the Conference of the Parties to the FCFC, October 2014. [link]

62 See Clive Bates review of WHO documents: WHO plans e-cigarette offensive, 17 April 2014 [link]

63 Letter to Dr Margaret Chan, Director General WHO, Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control 26 May 2014 [context][letter]

bystanders and limiting the risks of harmful unintended consequences.

About the original author

Clive Bates runs Counterfactual, a public interest consulting and advocacy organisation focussed on a broad approach to sustainability, policy-making for the long term and good governance. He was formerly a senior civil servant and Director of Action on Smoking and Health (London) as well as a founder of the NGO Framework Convention Alliance, set up to support the development of the WHO Framework Convention on Tobacco Control. He has been a long-term advocate of tobacco harm reduction[64] [65] [66], a critic of the public health establishment approach to harm reduction[67] and wrote about the policy challenge of products like e-cigarettes well before they were invented[68].

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

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

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

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

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